

## Visit

### Screening 1

- Informed Consent
- Demographics
- Eligibility
- Medical History
- Vital Signs (Weight, Height and Temperature)
  - Version 1
  - Version 2
- Ophthalmic Examination

### Screening 2

- Vital Signs (Temperature)
  - Version 1
  - Version 2
- Auditory Verbal Learning Test
- Ophthalmic Examination

### Baseline

- Vital Signs (Weight and Temperature)
  - Version 1
  - Version 2
- Patient Health Questionnaire-9 (PHQ-9)
- Satisfaction With Life Survey (SWLS)
- Hamilton Depression Rating Scale - 17 (HAMD 17)
- Ophthalmic Examination

### Week 2

- Vital Signs Vital Signs (Weight and Temperature)
  - Version 1
  - Version 2
- Auditory Verbal Learning Test (AVL02)
- Ophthalmic Examination

### Week 4

- Vital Signs Vital Signs (Weight and Temperature)
  - Version 1
  - Version 2
- Auditory Verbal Learning Test (AVL02)
- Ophthalmic Examination

### Week 6

- Vital Signs Vital Signs (Weight and Temperature)
  - Version 1
  - Version 2

### Week 8

- Vital Signs Vital Signs (Weight and Temperature)
  - Version 1
  - Version 2
- Auditory Verbal Learning Test (AVL02)
- Ophthalmic Examination

### Week 12

- Vital Signs Vital Signs (Weight and Temperature)
  - Version 1
  - Version 2
- Patient Health Questionnaire-9 (PHQ-9)
- Satisfaction With Life Survey (SWLS)

Auditory Verbal Learning Test (AVL02)  
Ophthalmic Examination

**Week 16**

Vital Signs Vital Signs (Weight and Temperature)  
Version 1  
Version 2

Patient Health Questionnaire-9 (PHQ-9)  
Satisfaction With Life Survey (SWLS)  
Auditory Verbal Learning Test (AVL02)  
Ophthalmic Examination

**Week 20**

Vital Signs Vital Signs (Weight and Temperature)  
Version 1  
Version 2

Patient Health Questionnaire-9 (PHQ-9)  
Satisfaction With Life Survey (SWLS)  
Ophthalmic Examination

**Week 24**

Vital Signs Vital Signs (Weight and Temperature)  
Version 1  
Version 2

Patient Health Questionnaire-9 (PHQ-9)  
Satisfaction With Life Survey (SWLS)  
Auditory Verbal Learning Test (AVL02)  
Ophthalmic Examination

**Week 26**

Vital Signs Vital Signs (Weight and Temperature)  
Version 1  
Version 2

Ophthalmic Examination  
End of Treatment  
Patient Summary

**Early Discontinuation Retrieval**

Vital Signs (Temperature)  
Version 1  
Version 2  
Patient Health Questionnaire-9 (PHQ-9)  
Satisfaction With Life Survey (SWLS)  
Auditory Verbal Learning Test (AVL02)  
Hamilton Depression Rating Scale - 17 (HAMD 17)  
Ophthalmic Examination  
Patient Summary

**Running Records**

Exposure  
Electroencephalogram  
Adverse Events  
Injection Site Reactions  
Concomitant Medications  
Death Details

## Form

Adverse Events

[Running Records](#)

Auditory Verbal Learning Test (AVL02)

[Screening 2](#)

[Week 4](#)

[Week 8](#)

[Week 12](#)

[Week 16](#)

[Week 24](#)

[Early Discontinuation Retrieval](#)

Concomitant Medications

[Running Records](#)

Death

[Running Records](#)

Demographics

[Screening 1](#)

Electroencephalogram

[Running Records](#)

Eligibility

[Screening 1](#)

End of Treatment

[Week 26](#)

Exposure

[Running Record](#)

Hamilton Depression Rating Scale - 17 (HAM-D 17)

[Baseline](#)

[Early Discontinuation Retrieval](#)

Informed Consent

[Screening 1](#)

Injection Site Reactions

[Running Records](#)

Medical History

[Screening 1](#)

Ophthalmic Examination

[Screening 1](#)

[Screening 2](#)

[Baseline](#)

[Week 2](#)

[Week 8](#)

[Week 12](#)

[Week 16](#)

[Week 20](#)

[Week 24](#)

[Week 26](#)

[Early Discontinuation Retrieval](#)

Patient Health Questionnaire-9 (PHQ-9)

[Baseline](#)

[Week 12](#)

[Week 16](#)

[Week 20](#)

[Week 24](#)

Early Discontinuation Retrieval

Patient Summary

Week 26

Satisfaction With Life Survey (SWLS)

Baseline

Week 12

Week 16

Week 20

Week 24

Early Discontinuation Retrieval

Vital Signs (Temperature)

Screening 2

Version 1

Version 2

Early Discontinuation Retrieval

Version 1

Version 2

Vital Signs (Weight and Temperature)

Baseline

Version 1

Version 2

Week 2

Version 1

Version 2

Week 4

Version 1

Version 2

Week 6

Version 1

Version 2

Week 8

Version 1

Version 2

Week 12

Version 1

Version 2

Week 16

Version 1

Version 2

Week 20

Version 1

Version 2

Week 24

Version 1

Version 2

Week 26

Version 1

Version 2

Vital Signs (Weight, Height and Temperature)

Screening 1

Version 1

Version 2

**DS (Disposition)**

DSCAT = PROTOCOL MILESTONE

**INFORMED CONSENT**

DSTERM / DSDECOD  
= INFORMED CONSENT OBTAINED

Informed Consent Date

**DM (Demographics)**

DSSTDTC

RFICDTC

**DEMOGRAPHICS**

Birth Year

BRTHDTC

AGE

AGEU

Age

years

Sex

☐

Female

☐

Male

SEX

Race (Check all that apply)

☐

White

☐

Black or African American

RACE

☐

Asian

☐

Native Hawaiian or Other Pacific Islander

☐

American Indian or Alaskan Native

When multiple values are selected then RACE =  
MULTIPLE and individual responses are RACE1,  
RACE2, RACE3, etc. in SUPPDM

Ethnic

☐

Hispanic or Latino

ETHNIC

☐

Not Hispanic or Latino

## IE (Inclusion/Exclusion Criteria Not Met)

### ELIGIBILITY

Date

IEDTC

Met Criteria

☐ Yes

☐ No

[NOT SUBMITTED]

Criterion Type

IECAT

☐

Inclusion

IEORRES = N

☐

Exclusion

IEORRES = Y

Exception Criterion Identifier

IEATESTCD = "EXCL" or "INCL", depending on IECAT, concatenated with exception criterion identifier padded to 2 digits

MH (Medical History)

MEDICAL HISTORY

MHEVDTYPE = SYMPTOM ONSET

Alzheimer's Disease  
Symptom Start Date



MHSTDTC

## VS (Vital Signs)

### VITAL SIGNS

[NOT SUBMITTED]

Vital Signs Collected?

☐

Yes

☐

No

VSSTAT = NOT DONE  
when VSTESTCD = VSALL

Visit

VISIT

Date

VSDTC

VSTESTCD = WEIGHT Weight

VSORRES

pounds

VSORRESU

VSTESTCD = HEIGHT Height

VSORRES

inches

VSORRESU

VSTESTCD = TEMP Temperature

VSORRES

F

VSORRESU

VSPPOS

Pulse and Blood Pressure (Supine)

VSTESTCD = PULSE Pulse

VSORRES

bpm

VSORRESU

VSTESTCD = SYSBP Systolic

VSORRES

mmHg

VSORRESU

VSTESTCD = DIABP Diastolic

VSORRES

mmHg

VSORRESU



## VS (Vital Signs)

### VITAL SIGNS

[NOT SUBMITTED]

Vital Signs Collected?

☐

Yes

☐

No

VSSTAT = NOT DONE  
when VSTESTCD = VSALL

Visit

VISIT

Date

VSDTC

[VSTESTCD = WEIGHT] Weight

VSORRES

pounds

VSORRESU

[VSTESTCD = HEIGHT] Height

VSORRES

inches

VSORRESU

[VSTESTCD = TEMP] Temperature

VSORRES

F

VSORRESU

[VSREPNUM = 1]

[VSPOS]

1st Measurement (Supine)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

[VSREPNUM = 2]

[VSPOS]

2nd Measurement (Standing)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

[VSREPNUM = 3]

[VSPOS]

3rd Measurement (Standing)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

## VS (Vital Signs)

### VITAL SIGNS

[NOT SUBMITTED]

Vital Signs Collected?

☐

Yes

☐

No

VSSTAT = NOT DONE  
when VSTESTCD = VSALL

Visit

VISIT

Date

VSDTC

[VSTESTCD = TEMP]

Temperature

VSORRES

F

VSORRESU

[VSPOS]

1st Measurement (Supine)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

## VS (Vital Signs)

### VITAL SIGNS

[NOT SUBMITTED]

Vital Signs Collected?

☐

Yes

☐

No

VSSTAT = NOT DONE  
when VSTESTCD = VSALL

Visit

VISIT

Date

VSDTC

VSTESTCD = TEMP Temperature

VSORRES

F

VSORRESU

VSPPOS

VSREPNUM = 1

1st Measurement (Supine)

VSTESTCD = PULSE

Pulse

VSORRES

bpm

VSORRESU

VSTESTCD = SYSBP

Systolic

VSORRES

mmHg

VSORRESU

VSTESTCD = DIABP

Diastolic

VSORRES

mmHg

VSORRESU

VSPPOS

VSREPNUM = 2

2nd Measurement (Standing)

VSTESTCD = PULSE

Pulse

VSORRES

bpm

VSORRESU

VSTESTCD = SYSBP

Systolic

VSORRES

mmHg

VSORRESU

VSTESTCD = DIABP

Diastolic

VSORRES

mmHg

VSORRESU

VSPPOS

VSREPNUM = 3

3rd Measurement (Standing)

VSTESTCD = PULSE

Pulse

VSORRES

bpm

VSORRESU

VSTESTCD = SYSBP

Systolic

VSORRES

mmHg

VSORRESU

VSTESTCD = DIABP

Diastolic

VSORRES

mmHg

VSORRESU

## VS (Vital Signs)

### VITAL SIGNS

[NOT SUBMITTED]

Vital Signs Collected?

☐

Yes

☐

No

VSSTAT = NOT DONE  
when VSTESTCD = VSALL

Visit

VISIT

Date

VSDTC

VSTESTCD = WEIGHT Weight

VSORRES

pounds

VSORRESU

VSTESTCD = TEMP Temperature

VSORRES

F

VSORRESU

VSPPOS

Pulse and Blood Pressure (Supine)

VSTESTCD = PULSE

Pulse

VSORRES

bpm

VSORRESU

VSTESTCD = SYSBP

Systolic

VSORRES

mmHg

VSORRESU

VSTESTCD = DIABP

Diastolic

VSORRES

mmHg

VSORRESU

## VS (Vital Signs)

### VITAL SIGNS

[NOT SUBMITTED]

Vital Signs Collected?

☐

Yes

☐

No

VSSTAT = NOT DONE  
when VSTESTCD = VSALL

Visit

VISIT

Date

VSDTC

[VSTESTCD = WEIGHT] Weight

VSORRES

pounds

VSORRESU

[VSTESTCD = TEMP] Temperature

VSORRES

F

VSORRESU

[VSPOS]

[VSREPNUM = 1]

1st Measurement (Supine)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

[VSPOS]

[VSREPNUM = 2]

2nd Measurement (Standing)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

[VSPOS]

[VSREPNUM = 3]

3rd Measurement (Standing)

[VSTESTCD = PULSE]

Pulse

VSORRES

bpm

VSORRESU

[VSTESTCD = SYSBP]

Systolic

VSORRES

mmHg

VSORRESU

[VSTESTCD = DIABP]

Diastolic

VSORRES

mmHg

VSORRESU

## EC (Exposure as Collected)

### EXPOSURE

Did the subject take  
Zanomaline?

☐ Yes ☐ No

ECOCUR

If No, Reason Not  
Administered

ECREASOC in SUPPEC

Date

ECSTDTC

ECENDTC

Lot Number

ECLOT

Dose

ECDOSE

5 mL

ECDOSU

# **QS (Questionnaires)**

QSCAT = PHQ-9

## **PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)**

QSEVLINT = -P2W

Over the last 2 weeks, how often have you been bothered by any of the following problems?  
(Use "✓" to indicate your answer)

Not at all      Several days      More than half the days      Nearly every day

QSORRES

QSTESTCD = PHQ0101

1. Little interest or pleasure in doing things

0      1      2      3

QSSTRESC / QSSTRESN

QSTESTCD = PHQ0102

2. Feeling down, depressed, or hopeless

0      1      2      3

QSTESTCD = PHQ0103

3. Trouble falling or staying asleep, or sleeping too much

0      1      2      3

QSTESTCD = PHQ0104

4. Feeling tired or having little energy

0      1      2      3

QSTESTCD = PHQ0105

5. Poor appetite or overeating

0      1      2      3

QSTESTCD = PHQ0106

6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down

0      1      2      3

QSTESTCD = PHQ0107

7. Trouble concentrating on things, such as reading the newspaper or watching television

0      1      2      3

QSTESTCD = PHQ0108

8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual

0      1      2      3

QSTESTCD = PHQ0109

9. Thoughts that you would be better off dead or of hurting yourself in some way

0      1      2      3

FOR OFFICE CODING 0 + + +

QSTESTCD = PHQ0111 =Total Score:

QSORRES

QSSTRESC / QSSTRESN

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

QSTESTCD = PHQ0110

Not difficult at all

Somewhat difficult

Very difficult

Extremely difficult

☐

☐

☐

☐

QSORRES

QSSTRESC

## QS (Questionnaires)

QSCAT = SWLS

Below are five statements that you may agree or disagree with. Using the 1 - 7 scale below, indicate your agreement with each item by placing the appropriate number on the line preceding that item. Please be open and honest in your responding.

QSSTRESC / QSSTRESN

QSORRES

- 7 Strongly agree
- 6 Agree
- 5 Slightly agree
- 4 Neither agree nor disagree
- 3 Slightly disagree
- 2 Disagree
- 1 Strongly disagree

\_\_\_ In most ways my life is close to my ideal. QSTESTCD = SWLS0101

\_\_\_ The conditions of my life are excellent. QSTESTCD = SWLS0102

\_\_\_ I am satisfied with my life. QSTESTCD = SWLS0103

\_\_\_ So far I have gotten the important things I want in life. QSTESTCD = SWLS0104

\_\_\_ If I could live my life over, I would change almost nothing. QSTESTCD = SWLS0105

- 31 - 35 Extremely satisfied
- 26 - 30 Satisfied
- 21 - 25 Slightly satisfied
- 20 Neutral
- 15 - 19 Slightly dissatisfied
- 10 - 14 Dissatisfied
- 5 - 9 Extremely dissatisfied



FTSCAT = FORM

--	--	--

 \_S\_ 

--	--	--	--

### Trial 1 Instruction:

### Trial 2-5 Instructions:

**List B Instructions:**

### Trial 6 Instructions:

FTREPNUM

Say, "Now tell me all the words you can remember from the first list, the list I repeated a number of times."

FTREPNUM:

List A	AFTER B-RECALL						List B	List B Recall
	1	2	3	4	5	6		
Drum						FTTESTCD = AVL0218	Desk	FTORRES
Curtain						FTTESTCD = AVL0219	Ranger	
Bell						FTTESTCD = AVL0220	Bird	
Coffee						FTTESTCD = AVL0221	Shoe	
School						FTTESTCD = AVL0222	Stove	
Parent						FTTESTCD = AVL0223	Mountain	
Moon						FTTESTCD = AVL0224	Glasses	
Garden						FTTESTCD = AVL0225	Towel	
Hat						FTTESTCD = AVL0226	Cloud	
Farmer						FTTESTCD = AVL0227	Boat	
Nose						FTTESTCD = AVL0228	Lamb	
Turkey						FTTESTCD = AVL0229	Gun	
Color						FTTESTCD = AVL0230	Pencil	
House						FTTESTCD = AVL0231	Church	
River						FTTESTCD = AVL0232	Fish	
Totals						FTTESTCD = AVL0233		
Intrusions						FTTESTCD = AVL0234		

FTTESTCD = AVL0201

FTTESTCD = AVL0202

FTTESTCD = AVL0203

FTTESTCD = AVL0204

FTTESTCD = AVL0205

FTTESTCD = AVL0206

FTTESTCD = AVL0207

FTTESTCD = AVL0208

FTTESTCD = AVL0209

FTTESTCD = AVL0210

FTTESTCD = AVL0211

FTTESTCD = AVL0212

FTTESTCD = AVL0213

FTTESTCD = AVL0214

FTTESTCD = AVL0215

FTTESTCD = AVL0216

FTTESTCD = AVL0217

FTORRES

**FT (Functional Tests)****Auditory Verbal Learning Test - 30 Minute Delay**  
Baseline Visit

Subject Number

--	--	--	--	--	--	--	--

\_S\_

DELAY DATE/TIME: \_\_-\_\_-\_\_ 

--	--	--	--

  
**FTDTC** (dd-mmm-yyyy) (24-hour clock)**30 Minute Delay Instructions:****FTELTM = PT30M**

Say, "Awhile ago I read a list of words to you several times, and you had to repeat back the words. Tell me the words from that list."

**IMPORTANT:** The words from the original list are NOT read again before recall is elicited on this trial

	List A (DO NOT READ)	30 MINUTE DELAY
<b>FTTESTCD = AVL0201</b>	Drum	<b>FTORRES</b>
<b>FTTESTCD = AVL0202</b>	Curtain	
<b>FTTESTCD = AVL0203</b>	Bell	
<b>FTTESTCD = AVL0204</b>	Coffee	
<b>FTTESTCD = AVL0205</b>	School	
<b>FTTESTCD = AVL0206</b>	Parent	
<b>FTTESTCD = AVL0207</b>	Moon	
<b>FTTESTCD = AVL0208</b>	Garden	
<b>FTTESTCD = AVL0209</b>	Hat	
<b>FTTESTCD = AVL0210</b>	Farmer	
<b>FTTESTCD = AVL0211</b>	Nose	
<b>FTTESTCD = AVL0212</b>	Turkey	
<b>FTTESTCD = AVL0213</b>	Color	
<b>FTTESTCD = AVL0214</b>	House	
<b>FTTESTCD = AVL0215</b>	River	
<b>FTTESTCD = AVL0216</b>	Totals	
<b>FTTESTCD = AVL0217</b>	Intrusions	

**FTREPNUM = 7****Recognition Instructions:**

Say, "Sometimes people can remember more of the words if they see them. Read all these words and circle the ones that you think were on that first list I read...the list I read 5 times to you."

# RS (Disease Response and Clin Classification)

RSCAT = HAMD 17

RSEVLINT = -P1W

## I DEPRESSED MOOD (sadness, hopeless, helpless, worthless)

- 0 ☐ Absent.  
1 ☐ These feeling states indicated only on questioning.  
2 ☐ These feeling states spontaneously reported verbally.  
3 ☐ Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.  
4 ☐ Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

## 2 FEELINGS OF GUILT

- 0 ☐ Absent.  
1 ☐ Self reproach, feels he/she has let people down.  
2 ☐ Ideas of guilt or rumination over past errors or sinful deeds.  
3 ☐ Present illness is a punishment. Delusions of guilt.  
4 ☐ Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

## 3 SUICIDE

- 0 ☐ Absent.  
1 ☐ Feels life is not worth living.  
2 ☐ Wishes he/she were dead or any thoughts of possible death to self.  
3 ☐ Ideas or gestures of suicide.  
4 ☐ Attempts at suicide (any serious attempt rate 4).

## 4 INSOMNIA: EARLY IN THE NIGHT

- 0 ☐ No difficulty falling asleep.  
1 ☐ Complains of occasional difficulty falling asleep, i.e. more than 1/2 hour.  
2 ☐ Complains of nightly difficulty falling asleep.

## 5 INSOMNIA: MIDDLE OF THE NIGHT

- 0 ☐ No difficulty.  
1 ☐ Patient complains of being restless and disturbed during the night.  
2 ☐ Waking during the night – any getting out of bed rates 2 (except for purposes of voiding).

## 6 INSOMNIA: EARLY HOURS OF THE MORNING

- 0 ☐ No difficulty.  
1 ☐ Waking in early hours of the morning but goes back to sleep.  
2 ☐ Unable to fall asleep again if he/she gets out of bed.

## 7 WORK AND ACTIVITIES

- 0 ☐ No difficulty.  
1 ☐ Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies.  
2 ☐ Loss of interest in activity, hobbies or work – either directly reported by the patient or indirect in listlessness, indecision and vacillation (feels he/she has to push self to work or activities).  
3 ☐ Decrease in actual time spent in activities or decrease in productivity. Rate 3 if the patient does not spend at least three hours a day in activities (job or hobbies) excluding routine chores.  
4 ☐ Stopped working because of present illness. Rate 4 if patient engages in no activities except routine chores, or if patient fails to perform routine chores unassisted.

## 8 RETARDATION (slowness of thought and speech, impaired ability to concentrate, decreased motor activity)

- 0 ☐ Normal speech and thought.  
1 ☐ Slight retardation during the interview.  
2 ☐ Obvious retardation during the interview.  
3 ☐ Interview difficult.  
4 ☐ Complete stupor.

## 9 AGITATION

- 0 ☐ None.  
1 ☐ Fidgetiness.  
2 ☐ Playing with hands, hair, etc.  
3 ☐ Moving about, can't sit still.  
4 ☐ Hand wringing, nail biting, hair-pulling, biting of lips.

## 10 ANXIETY PSYCHIC

- 0 ☐ No difficulty.  
1 ☐ Subjective tension and irritability.  
2 ☐ Worrying about minor matters.  
3 ☐ Apprehensive attitude apparent in face or speech.  
4 ☐ Fears expressed without questioning.

## 11 ANXIETY SOMATIC (physiological concomitants of anxiety) such as:

gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching  
cardio-vascular – palpitations, headaches  
respiratory – hyperventilation, sighing  
urinary frequency  
sweating

- 0 ☐ Absent.  
1 ☐ Mild.  
2 ☐ Moderate.  
3 ☐ Severe.  
4 ☐ Incapacitating.

## 12 SOMATIC SYMPTOMS GASTRO-INTESTINAL

- 0 ☐ None.  
1 ☐ Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.  
2 ☐ Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastro-intestinal symptoms.

## 13 GENERAL SOMATIC SYMPTOMS

- 0 ☐ None.  
1 ☐ Heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability.  
2 ☐ Any clear-cut symptom rates 2.

## 14 GENITAL SYMPTOMS (symptoms such as loss of libido, menstrual disturbances)

- 0 ☐ Absent.  
1 ☐ Mild.  
2 ☐ Severe.

## 15 HYPOCHONDRIASIS

- 0 ☐ Not present.  
1 ☐ Self-absorption (bodily).  
2 ☐ Preoccupation with health.  
3 ☐ Frequent complaints, requests for help, etc.  
4 ☐ Hypochondriacal delusions.

## 16 LOSS OF WEIGHT (RATE EITHER a OR b)

### a) According to the patient:

- 0 ☐ No weight loss.  
1 ☐ Probable weight loss associated present illness.  
2 ☐ Definite (according to patient) weight loss.  
3 ☐ Not assessed.

### b) According to weekly measurements:

- 0 ☐ Less than 1 lb weight loss in week.  
1 ☐ Greater than 1 lb weight loss within week.  
2 ☐ Greater than 2 lb weight loss in week.  
3 ☐ Not assessed.

## 17 INSIGHT

- 0 ☐ Acknowledges being depressed and ill.  
1 ☐ Acknowledges illness but attributes cause to bad mood, climate, overwork, virus, need for rest, etc.  
2 ☐ Denies being ill at all.

Total score:

RSORRES when RSTESTCD = HAMD110

RSORRES when RSTESTCD = HAMD111

RSORRES when RSTESTCD = HAMD112

RSORRES when RSTESTCD = HAMD113

RSORRES when RSTESTCD = HAMD114

RSORRES when RSTESTCD = HAMD115

RSORRES when RSTESTCD = HAMD116A

RSORRES when RSTESTCD = HAMD116B

RSORRES when RSTESTCD = HAMD117

RSORRES when RSTESTCD = HAMD118

RSORRES when RSTESTCD = HAMD101

RSORRES when RSTESTCD = HAMD102

RSORRES when RSTESTCD = HAMD103

RSORRES when RSTESTCD = HAMD104

RSORRES when RSTESTCD = HAMD105

RSORRES when RSTESTCD = HAMD106

RSORRES when RSTESTCD = HAMD107

RSORRES when RSTESTCD = HAMD108

RSORRES when RSTESTCD = HAMD109

## NV (Nervous System Findings)

### ELECTROENCEPHALOGRAPH

---

EEG Date

NVDTC

Interpretation

NVORRES when  
NVTESTCD = INTP

Clinically Significant

☐ Yes

☐ No

NVCLSIG in SUPPNV

## OE (Ophthalmic Examinations)

### OPHTHALMIC EXAMINATION

OEMETHOD = SLIT LAMP [NOT SUBMITTED]

Slit lamp examination performed? ☐ Yes ☐ No

Visit  VISIT

OESTAT = NOT DONE when  
OETESTCD = OEALL

Date    OEDTC

OELAT OEFOCID  
OELOC Eye ☐ Left (OS)  
☐ Right (OD)

Interpretation

☐ Normal OEORES when OETESTCD = INTP  
☐ Abnormal

Abnormalities:

Location  OELOC

Abnormality  OEORES when  
OETESTCD = ABDETAIL

Clinically significant? Check if Yes ☐

OECLSIG in SUPPOE

## AE (Adverse Events)

### ADVERSE EVENTS

Were any adverse events experienced?

☐ Yes ☒ No [NOT SUBMITTED]

If yes please provide details below.

AE Identifier

AELNKID

What is the adverse event term?

AETERM

Start Date

/ / AESTDTC

Severity

☐ Mild  
☒ Moderate AESEV  
☐ Severe

Relationship to Study Treatment

☐ Not Related  
☒ Unlikely Related AEREL  
☐ Possibly Related  
☐ Related

Serious

☐ Yes  
☒ No AESER

If Serious

Death	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESDTH
Life threatening	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESLIFE
Significant Disability	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESDISAB
Hospitalization	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESHOSP
Congenital Anomaly or Birth Defect	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESCONG
Cancer	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESCAN
Overdose	<input type="radio"/> Yes	<input checked="" type="radio"/> No	AESOD

Outcome

☐ Fatal  
☒ Not Recovered/Not Resolved AEOUT  
☐ Recovered/Resolved  
☐ Recovered/Resolved with Sequelae  
☐ Recovering/Resolving

Action Taken with Study Treatment

☐ Dose Increased  
☐ Dose Not Changed  
☒ Dose Reduced AEACN  
☐ Drug Interrupted  
☐ Drug Withdrawn

Ongoing

☐ Yes ☒ No If Yes then AEENRTPT = ONGOING

End Date

/ / AEENDTC

## AE (Adverse Events)

## FA (Findings About Events or Interventions)

### ADVERSE EVENTS

Did the subject have an injection site reaction?

☐ Yes  
☐ No

[NOT SUBMITTED]

If yes please provide details below.

RELREC when FALNKGRP = AELNKID

AE Identifier

AELNKID

FALNKGRP

Date

FADTC

What is the adverse event term?

INJECTION SITE REACTION

AETERM

Start Date

AESTDTC

Severity

☐ Mild  
☐ Moderate  
☐ Severe

AESEV

Relationship to Study Treatment

☐ Not Related  
☐ Unlikely Related  
☐ Possibly Related  
☐ Related

AEREL

Serious

☐ Yes  
☐

AESER

If Serious

Death  
Life threatening  
Significant Disability  
Hospitalization  
Congenital Anomaly or Birth Defect  
Cancer  
Overdose

☐ Yes  
☐ Yes  
☐ Yes  
☐ Yes  
☐ Yes  
☐ Yes  
☐ Yes

☐ No  
☐ No  
☐ No  
☐ No  
☐ No  
☐ No  
☐ No

AESDTH

AESLIFE

AESDISAB

AESHOSP

AESCONG

AESCAN

AESOD

Outcome

☐ Fatal  
☐ Not Recovered/Not Resolved  
☐ Recovered/Resolved  
☐ Recovered/Resolved with Sequelae  
☐ Recovering/Resolving

AEOUT

Action Taken with Study Treatment

☐ Dose Increased  
☐ Dose Not Changed  
☐ Dose Reduced  
☐ Drug Interrupted  
☐ Drug Withdrawn

AEACN

Ongoing

☐ Yes ☐ No

If Yes then AEENRTPT = ONGOING

End Date

AEENDTC

## FA (Findings About Events or Interventions)

### INJECTION SITE REACTIONS FACAT

FAOBJ

Did erythema occur?

FAORRES when  
FATESTCD = OCCUR

☐ No

☐ Yes

Severity:

☐ Mild

☐ Moderate

☐ Severe

FAORRES when  
FATESTCD = SEV

Did pain (including burning) occur?

☐ No

☐ Yes

Severity:

☐ Mild

☐ Moderate

☐ Severe

Did induration occur?

☐ No

☐ Yes

Severity:

☐ Mild

☐ Moderate

☐ Severe

Did pruritus occur?

☐ No

☐ Yes

Severity:

☐ Mild

☐ Moderate

☐ Severe

Did edema occur?

☐ No

☐ Yes

Severity:

☐ Mild

☐ Moderate

☐ Severe



CM (Concomitant and Prior Medications)

CONCOMITANT MEDICATIONS

[NOT SUBMITTED]

Were any medications taken? ☐ Yes ☐ No

Medication

Indication ☐ Primary Study Condition ☐ Prophylaxis or Non-Therapeutic Use

Dose

Dose Unit

Frequency

Route

Start Date  /  /

Ongoing ☐ Yes ☐ No

End Date  /  /

DD (Death Details)

DM (Demographics)

DEATH

Collection Date

DDDTC

Death Date

DTHDTC

What is the primary cause of death?

DDORRES when  
DDTESTCD = PRCDTH

If AE, specify AE Number

DDLNKID

RELREC when  
DDLNKID = AELNKID

## DS (Disposition)

DSCAT = DISPOSITION EVENT

DSSCAT = STUDY TREATMENT

### END OF TREATMENT

Disposition Event Date

DSSTDTC

What was the subject's treatment status?

- ☐ COMPLETED **DSTERM / DSDECOD**
- ☐ ADVERSE EVENT
- ☐ DEATH
- ☐ LACK OF EFFICACY
- ☐ LOST TO FOLLOW-UP
- ☐ PHYSICIAN DECISION
- ☐ PREGNANCY
- ☐ PROTOCOL VIOLATION
- ☐ STUDY TERMINATED BY SPONSOR
- ☐ WITHDRAWAL BY PARENT/GUARDIAN
- ☐ WITHDRAWAL BY SUBJECT
- ☐ OTHER

If the subject's status is Adverse Event, Death or Other

SPECIFY

**DSTERM**

If the subject's status is Adverse Event or Death

PRIMARY AE #

**DSL NKID**

RELREC when  
DSL NKID = AELNKID

## DS (Disposition)

DSCAT = DISPOSITION EVENT

DSSCAT = STUDY PARTICIPATION

### PATIENT SUMMARY

---

Disposition Event Date

DSSTDTC

What was the subject's status?

- ☐ COMPLETED DSTERM / DSDECOD
- ☐ ADVERSE EVENT
- ☐ DEATH
- ☐ LACK OF EFFICACY
- ☐ LOST TO FOLLOW-UP
- ☐ PHYSICIAN DECISION
- ☐ PREGNANCY
- ☐ PROTOCOL VIOLATION
- ☐ SCREEN FAILURE
- ☐ STUDY TERMINATED BY SPONSOR
- ☐ WITHDRAWAL BY PARENT/GUARDIAN
- ☐ WITHDRAWAL BY SUBJECT
- ☐ OTHER
- 

If the subject's status is Adverse Event, Death or Other

SPECIFY

DSTERM

---

If the subject's status is Adverse Event or Death

PRIMARY AE #

DSL NKID

RELREC when  
DSL NKID = AELNKID