STATISTICAL ANALYSIS PLAN

STUDY NUMBER: SECOMBIT

A three arms prospective, randomized phase II study to evaluate the best sequential approach with combo immunotherapy (ipilimumab/nivolumab) and combo target therapy (LGX818/MEK162) in patients with metastatic melanoma and BRAF mutation.

Sequential Combo Immuno and Target therapy (SECOMBIT) study

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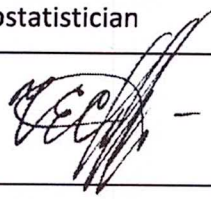
VERSION NUMBER AND DATE: Version 1.0, 15Oct2021

APPROVAL SIGNATURE PAGE

Study Biostatistician:	Name: Elizaveta Chefanova Title: Biostatistician		15 October 2021
			
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Reviewer:	Name: Diana Giannarelli Title: Senior Biostatistician		
			15 Oct 2021
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	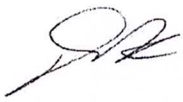		15 Oct 21
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Summary

1. LIST OF ABBREVIATIONS

AEs	Adverse Events
AESIs	Adverse Events of Special Interest
ALT	Alanine Transaminase (SGPT)
AST	Aspartate Transaminase (SGOT)
bid	Bis in die (twice daily)
BMI	Body Mass Index
BORR	Best Overall Response Rate
BRAF	B-raf murine sarcoma vioral oncogene homolog B1
BUN	Blood Urea Nitrogen
CI	Confidence Interval
CRP	C-reactive Protein
CT	Computed Tomography
DoR	Duration of Response
ECG	Electrocardiogram
EchO	Echocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
ENR	Enrolled Analysis Set
EORTC QLQ-C30	30-item European Organisation for Research and Treatment of Care quality of life questionnaire
EQ-5D	European Quality of Life 5-Dimensions
HGF	Hepatocyte Growth Factor
HRQoL	Health-related Quality of life
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
INR	International Normalized Ratio
ITT	Intent-To-Treat Analysis Set
Kg	Kilogram
LDH	Lactate dehydrogenase
LVEF	Left Ventricle Ejection Fraction
MedDRA	Medical Dictionary for Regulatory Activities
MDSCs	Myeloid-derived Suppressor Cells
MEK	Methyl Ethyl Ketone
mg	Milligram
ml	Millilitre
MRI	Magnetic Resonance Imaging
MUGA	Multiple Gated Acquisition Scan

od	Once Daily
ORR	Overall Response Rate
OS	Overall Survival
PD	Progression of Disease
PFS	Progression-Free Survival
p.o.	Per os (oral route)
PP	Per Protocol Analysis Set
PS	Performance Status
RECIST	Response Evaluation Criteria In Solid Tumors
SAE	Serious Adverse Events
SAF	Safety Analysis Set
SAP	Statistical Analysis Plan
sCD25	Soluble interleukin-2 receptor
SECOMBIT	Sequential Combo Immuno and target Therapy
SNP	Single nucleotide polymorphism
sHGF	Soluble Hepatocyte Growth Factor
sVEGF	Serum Vascular Growth factor
T3	Triiodotyroxine
T4	Tyroxine
TPFS	Total Progression-Free Survival
TSH	Thyroid Stimulating Hormone
VAS	Visual Analog Scale
VEGF	Vascular Endothelial Growth Factor
WBC	White blood cell
WPAI:GH	Work Productivity and Activity Impairment: General Health
DMC	Data Monitoring Committee
FPFV	First Patient First Visit
LPLV	Last Patient Last Visit
C	Celsius
cm	centimetre
m	metre
SOC	System Organ Class
WHO-DRL	WHO-drug reference list
ATC	Anatomical Therapeutic Chemical
SAS	Statistical Analysis System
SDF	Survival Distribution Function
PFSR	Progression Free Survival Rate
SD	Standard Deviation

SE	Standard Error
RS	Raw Score
PT	Preferred Term
LLN	Lower Limit Of Normal
ULN	Upper Limit Of Normal
SI	International System of Units
CS	Clinically Significant
NCS	Not Clinically Significant
Min	The lowest observation
Max	The highest observation
HIV	Human Immunodeficiency Virus
Ms	Millisecond
mmHg	Millimeters of mercury
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
bpm	beats per minute
ETDRS	Early Treatment Diabetic Retinopathy Study
OS	Left Eye
OD	Right Eye

2. INTRODUCTION

This document describes the statistical methods to be used during the analyses and reporting of study SECOMBIT. This SAP includes all details for the analysis and reporting (tables, listings and graph of the data collected as part of this protocol.

This Statistical Analysis Plan is based on the study protocol version Final 10.0, dated 03 May 2021.

3. STUDY OBJECTIVES

3.1. PRIMARY OBJECTIVE

The primary objective of this study is to define the best sequencing combination treatment in primary efficacy variable (Overall Survival, OS).

3.2. SECONDARY OBJECTIVES

The secondary objectives are to evaluate the effects of the three sequencing combination treatments on:

- Total Progression-Free Survival (PFS);
- 3 years PFS rate;
- Percentage of patients alive at 3 years;
- Best overall response rate (BORR);
- Duration of response (DoR);
- Toxicity of the investigational medicinal products (IMPs);
- Quality of life and general health status defined by:
    - Health-related quality of life (HRQoL), by means of the 30-item European Organisation for Research and Treatment of Care quality of life questionnaire (EORTC QLQ-C30);
    - General health status, by means of the European Quality of Life 5-Dimensions (EQ-5D) questionnaire;
    - Impairment of work productivity and activity, by means of the Work Productivity and Activity Impairment: General Health (WPAI:GH) questionnaire.

3.2.1. BIOLOGICAL MARKERS (BIOMARKERS STUDY)

The objective of the biomarker study is to focus on understanding mechanisms of action/resistance. In particular, the biomarker study:

- Will inform how to sequence targeted RAF/MEK agents with immunotherapy agents (i.e., ipilumumab and nivolumab) in melanoma;
- Will be hypothesis-generating only.

3.3. SAFETY OBJECTIVES

The safety of the sequencing combination treatments will be evaluated, in terms of:

- Toxicity of the IMPs;
- Adverse events (AEs) and serious adverse events (SAEs);
- Vital signs;
- Laboratory safety parameters.

4. STUDY DESIGN

4.1. DESCRIPTION OF THE STUDY

This is an open-label, prospective, randomized, Phase II design study.

4.2. SAMPLE SIZE

This study was designed as a phase II, randomized trial with no formal comparative test. The sample size was discussed for the primary endpoint Overall Survival (OS).

For each arm a single-stage design as described by A'Hern (A'Hern, 2001) was used.

A median PFS of about 10 months for the combo target therapy (LGX818/MEK162) was assumed (Mc Arthur et al, 2013) and a similar value for the combo immunotherapy (ipilimumab/nivolumab) derived from the aggregate clinical activity rate of 65% (Wolchock et al, 2013) which, using an exponential distribution for PFS, could broadly give a median PFS of about 9.5 months. OS seems to be strictly correlated with total PFS.

The null hypothesis was a median OS time of 15 months (i.e. percentage of surviving patient of 33% at 24 months). The alternative hypothesis was a median OS time of 23 months (i.e. percentage of surviving of 48% at 24 months).

Using an exact 5% one-sided significance test, at least 69 patients would have to be randomized in each treatment arm when the power of the study is 80%.

For each arm the strategy would be further investigated if at least 30 patients, alive at 24 months, were observed.

Taking into account a 10% drop-out rate, a total of 230 patients would be enrolled to ensure a minimum of 207 randomized patients.

4.3. DESCRIPTION OF TREATMENTS

The following IMPs will be used in the study:

- Arm A: Combo Target (LGX818 450 mg p.o. od + MEK162 45 mg p.o. bid) until PD; then Combo Immuno (nivolumab 1 mg/kg solution i.v.combined with ipilimumab 3 mg/kg solution i.v.every 3 weeks for 4 doses then nivolumab 3 mg/kg solution i.v.every 2 weeks) until PD.
- Arm B: Combo Immuno (nivolumab 1 mg/kg solution i.v.combined with ipilimumab 3 mg/kg solution i.v.every 3 weeks for 4 doses then nivolumab 3 mg/kg solution i.v.every 2 weeks) until PD; then Combo Target (LGX818 450 mg p.o. od + MEK162 45 mg p.o. bid) until PD.
- Arm C: Combo Target (LGX818 450 mg p.o. od + MEK162 45 mg p.o. bid) for 8 weeks followed by Combo Immuno (nivolumab 1 mg/kg solution i.v.combined with ipilimumab 3 mg/kg solution i.v.every 3 weeks for 4 doses then nivolumab 3 mg/kg solution i.v.every 2 weeks) until PD; then Combo Target (LGX818 450 mg p.o. od + MEK162 45 mg p.o. bid) until PD.

4.4. DESCRIPTION OF THE STUDY FLOW

The study will be conducted according to an open-label, prospective, randomized, phase II design.

Randomization will be stratified according to stage arranged in the 3 following strata:

- IIIb/c – M1a – M1b;
- M1c with normal LDH (≤ 2ULN);

- M1c with elevated LDH (> 2 ULN).

All screening/baseline assessments as outlined in Tables 1 of the protocol (arm A), 2 (arm B) and 3 (arm C) of the Study Protocol must be performed within 28 days prior to the first administration of study drugs on Day 1. Results of tests or examinations performed as standard of care before obtaining informed consent and within the 28 days prior to commencing study drugs may be used. All assessments during the study must be performed within a window +/-3 days of the day indicated on the schedule of assessment, except for tumor evaluations for which a window of +/- 7 days will apply and for Combo Immuno visits for which a window of +/- 2 days will apply.

Eligibility for the study will be determined by the Investigator from the mandatory screening/baseline assessments performed during screening and according to the study inclusion/exclusion criteria.

First dosing of study drugs will be determined by the patient's eligibility and the laboratory assessments done on Day 1 prior to dosing.

Hematology and biochemistry assessments do not need to be repeated on Day 1 if performed within 7 days; if it is necessary to repeat these blood tests, the results must be known before the patient receives treatments to ensure inclusion/exclusion criteria related to these tests are met. Test for HIV infection is mandatory at screening.

Subject Re-enrollment: This study permits the re-enrollment of patients that was not randomized within 28 from ICF signature, after obtaining agreement from the medical monitor prior to re-enrolling a subject. If authorized to re-enrollment, the patient must be re-consented and the same subject-code can be used.

Subjects will be assessed for response by computed tomography (CT) or Magnetic Resonance Imaging (MRI). All measurable and non-measurable lesions must be documented at screening (within 28 days prior to randomization) and re-assessed at each subsequent tumor evaluation (every 8 weeks (+/- 1 week) for the first year, every 12 weeks (+/- 1 week) while the patient is on study). Tumor assessments with CT or MRI scans of the brain, chest, abdomen, and pelvis will be performed until disease progression after the second combo treatment per RECIST v1.1.

For patients who discontinue study treatment for reason other than investigator–determined disease progression, tumor assessments should continue to be performed as scheduled.

Patients will continue to be on study and can be switched to the subsequent therapy after PD as per protocol in both arm A and B.

In case of an interruption of the treatment in arm C, reason other than investigator–determined disease progression, during the first 8 weeks (2 cycles of therapy), patient can continue the study treatment with combo immuno, as scheduled.

For patients with palpable/superficial lesions, clinical disease assessments by physical examination should be performed at baseline and throughout study treatment as clinically indicated. Color photographs with ruler/calipers will be taken at baseline and at all subsequent tumor assessment time points.

The National Cancer Institute Common Toxicity Criteria for Adverse Events (NCI CTC-AE) Version 4.03 will be used to evaluate the clinical safety of the treatment in this study. Patients will be assessed for AEs at each clinical visit and as necessary throughout the study.

Biomarker study

A correlative biological study will be performed for the evaluation of biomarkers on the biological sample savailable (paraffin-embedded tissue, frozen tissue, blood, serum, etc.). Approximately 80-90 patients will take part in the biomarkerstudy.

4.5. SCHEDULE OF EVENTS

Schedule of events can be found in Tables 1 of the protocol (arm A), 2 (arm B) and 3 (arm C) of the Section 1 of the study protocol.

4.6. CHANGES TO ANALYSIS FROM PROTOCOL

No changes are done in statistical analysis from those planned in the final study protocol.

In this document more details about the multivariate statistical analyses have been added: for Cox's Proportional Hazards regression model on Overall Survival, total Progression Free Survival and Duration of Response the list of potential predictors have been detailed (see paragraph *9.1*).

5. PLANNED ANALYSES

Only the Final Analysis will be performed for this study.

5.1. DATA MONITORING COMMITTEE (DMC)

In accordance with ICH E9 [1], Data Monitoring Committee is described in the protocol.

At least 1 database lock is planned for this study (final analysis), nonetheless, any additional DMC meetings can be conducted to assess safety and efficacy of the interventions during the clinical trial. All the necessary information will be further described in the relevant documents.

In any case, none of statistical tests will be applied to the data for DMC purposes.

5.2. INTERIM ANALYSIS

There will be no Interim Analysis for this study.

5.3. FINAL ANALYSIS

All final planned analyses identified in this SAP will be performed by SPARC Consulting, Milan on behalf of CRT after Sponsor Authorization of this Statistical Analysis Plan, Database Lock and Sponsor Authorization of Analysis Sets.

All summaries and listings will be performed using the SAS System version 9.4 or later under Windows 10 PRO operating system.

Continuous variables will be summarized by descriptive statistics (number of cases, mean, standard deviation, median, minimum, maximum, first and third quartile). Categorical variables will be summarized using counts of patients and percentages 95% confidence interval will be employed, unless otherwise specified.

6. MAJOR PROTOCOL DEVIATIONS

Major protocol deviations are protocol deviations that might significantly affect the completeness, accuracy, and/or reliability of the study data or that might significantly affect a subject's rights, safety, or well-being.

Major protocol deviations include:

- Any violations of Inclusion and/or Exclusion criteria;
- Incorrect dose of investigational product taken (Dose reduced/Dose delayed/Dose delayed and reduced) for more than 3 consecutive IMP cycles;
- Repeated or severe non-compliance to intake of investigational product (less than 80% or more than 120% of the prescribed dose of LGX818 and MEK162);
- Treatment with any other investigational agent at any time during the study;
- Randomized patient who received an incorrect treatment

The above major protocol deviations will be identified and confirmed prior to or at the Data Review Meeting at the latest and they will lead to the exclusion of a subject from the PP set.

Additional major protocol violations will be identified and documented following a data review meeting prior to database lock.

7. DEFINITION OF ANALYSIS SETS AND SUBGROUPS

Agreement and authorization of patients included/excluded from each analysis set will be performed on a case-by-case basis before the database lock.

The following analysis sets have been defined for this study:

Enrolled Analysis Set [ENR]

The all patients enrolled (ENR) set contains all patients who provided informed consent for this study.

Intent-to-Treat set [ITT]

The Intent-to-Treat (ITT) set will contain all randomized patients. Subjects in the ITT population will be analysed in the treatment group to which they were assigned by the randomization schedule, regardless of which study drug they receive.

The analysis of primary and secondary variables will be carried out in the ITT set.

Safety Analysis Set [SAF]

The Safety Analysis set (SAF) will contain all randomized subjects who received at least one dose of study medication. Subjects in the SAF will be analysed in the treatment group for the study drug they actually received.

The analysis of safety will be carried out in the safety population. If there is any doubt whether a subject was treated or not, they will be assumed treated for the purposes of analysis.

Per Protocol Analysis Set [PP]

The Per Protocol Analysis set (PP) will contain all randomized subjects who did not report any major protocol deviations (as detailed Paragraph 6).

The analysis on the primary variable (OS) will be repeated in the PP.

8. GENERAL CONSIDERATIONS

8.1. BASELINE

Baseline value is defined as the last available valid, non-missing observation for each subject before the first study treatment administration for each Treatment scheme. In this study Baseline 1, Baseline 2 and Baseline 3 visits will be accounted for depending on the context and on the analysis. The reference days for each baseline are described in Table 1.

Table 1 Reference days for Baseline

Arm	Treatment	Baseline	Reference Day
A	LGX818 + MEK 162	Baseline 1	Day 1 of TR1 [BAS 1]
	Nivolumab + Ipilimumab/ Nivolumab	Baseline 2 (one baseline for both treatments)	Day 1 of TR1 [BAS 2]
B	Nivolumab + Ipilimumab/ Nivolumab	Baseline 1 (one baseline for both treatments)	Day 1 of TR1 [BAS 1]
	LGX818 + MEK 162	Baseline 2	Day 1 of TR1 [BAS 2]
C	LGX818 + MEK 162	Baseline 1	Day 1 of TR1 [BAS 1]
	Nivolumab + Ipilimumab/ Nivolumab	Baseline 2 (one baseline for both treatments)	Day 1 of TR3 [BAS 2]
	LGX818 + MEK 162	Baseline 3	Day 1 of TR1 [BAS 3]

8.2. WINDOWING CONVENTIONS

All visit windows reported in the protocol will be applied to the analysis. The visit windows are described in more details for each assessment per Arm in Table 1 (Schedule of assessment) of the protocol [2]. Moreover, only values collected at scheduled study visits/time points will be presented in summary tables. However, additional exams may be scheduled as necessary to ensure the safety and well-being of subjects who experience AEs during the study. If a repeat assessment was performed, the result from the original assessment will be presented as the result at the specific visit/time point. All collected data will be included in the data listings. Additionally, unscheduled assessments will have the prefix “UNSCHEDULED” and will be sorted by the start date to its simpler recognizing.

8.3. STATISTICAL TESTS

No comparative tests between the three sequencing treatment arms will be performed and results will be presented as descriptive statistic.

8.4. COMMON CALCULATIONS

For quantitative measurements, change from baseline will be calculated with respect to the immediately previous baseline visit, i.e.:

- For values reported after Baseline 1 visit and before Baseline 2 visit, change from baseline will be calculated with respect to Baseline 1.
- For values reported after Baseline 2 visit (and before Baseline 3 visit, for Arm C), change from baseline will be calculated with respect to Baseline 2.
- For Arm C only, for values reported after Baseline 3, change from baseline will be calculated with respect to Baseline 3

The following formulas will be applied:

- Absolute: Value at Visit X – Baseline Value

- Relative: ((Value at Visit X – Baseline Value)/Baseline Value) *100

8.5. SOFTWARE VERSION

All statistical analyses will be performed using The SAS System version 9.4 or later under Windows 10 Pro operating system.

9. STATISTICAL CONSIDERATIONS

9.1. ADJUSTMENTS FOR COVARIATES AND FACTORS TO BE INCLUDED IN ANALYSES

The following adjustment for covariates is planned for this study.

The Cox's Proportional Hazards regression model on Overall Survival, Total Progression Free Survival and Duration of Response will include as covariates:

a) Treatment sequence assigned: Arm A, Arm B, Arm C;
b) Age (years): continuous variable;
c) Gender: Male and Female;
d) Melanoma Type: Cutaneous, Mucosal, Ocular;
e) Stage at current diagnosis: IIIa, IIIb, IIIc, IV – M1a, IV – M1b, IV – M1c;
f) Baseline LDH level: continuous variable;
g) ECOG PS at baseline: 0, ≥1;

9.2. MULTICENTER STUDIES

This study will be conducted by multiple investigators at multiple centers (approximately 30 sites in Italy and Europe) [2]. Prior to statistical analysis, data obtained at all sites will be combined into one data set.

Due to a large number of sites in this study and a small number of patients in this site, statistical tests by site will not be performed.

9.3. MISSING DATA

Any Missing data will not be imputed (including efficacy data).

9.4. MULTIPLE COMPARISONS/ MULTIPLICITY

Not applicable for this study.

9.5. ACTIVE-CONTROL STUDIES INTENDED TO SHOW NON-INFERIORITY OR EQUIVALENCE

Not applicable for this study.

9.6. EXAMINATION OF SUBGROUPS

No subgroup analyses will be performed for this study.

10. OUTPUT PRESENTATIONS

Appendix 1 shows conventions for presentation of data in outputs.

The templates provided with this SAP describe the presentations for this study and therefore the format and content of the summary tables, figures and listings to be provided by SPARC Consulting, Milan on behalf of CRT.

11. DISPOSITION AND WITHDRAWALS

All subjects who provide informed consent [ENR set] will be accounted for in this study.
The following summary tables and listings will be provided:

- A summary table of patients enrolled in the study by site per Arm (including non-randomized patients)
- A summary with the number and percentage of the screening failures and of the subjects who did not satisfy inclusion/exclusion criteria, together with a data listing containing screening failures and details of the non-satisfied criteria.
- A summary with the number and percentage of the subjects included in the analysis populations (ENR, ITT, SAF, PP) and of the reasons for exclusion from ITT, SAF and PP by treatment arm. A listing of reasons for exclusion from the analysis populations will be provided.
- A frequency table and a listing of major protocol deviations
- A frequency table and a listing of end of treatment data:
    - Completion of the trial (Yes, No)
    - Primary reason for withdrawal (Progression of disease, Death, withdrawn informed consent for the study and for FU, withdrawn informed consent for the study but NOT for FU, Subject no longer meets study criteria (after the first PD), Screening Failure, AE, Poor/Non-compliance with protocol requirements, Loss of follow-up, Administrative reason by Sponsor, Subject's decision, Other)

12. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographic data and other baseline characteristics will be presented for the ITT set by treatment arm.
No statistical testing will be carried out for demographic or other baseline characteristics.
The following demographic and other baseline characteristics will be reported for this study by means of default summary statistics and individual data listings:

- Demographic variables:
  - Age (years) – derived as specified in Paragraph 12.1
  - Gender at birth (Male, Female)
  - Race (White/Caucasian, Black/African American, Asian, American Indian or Alaska native, Native Hawaiian or Pacific Islander, Other)
  - Ethnic Origin (Hispanic/Latino, Not Hispanic/Latino, Mixed Ethnicity, Other)
- Vital Signs at screening:
  - Body weight (Kg)
  - Height (cm)
  - BMI (kg/m^2)
  - Systolic supine blood pressure (mmHg)
  - Diastolic supine blood pressure (mmHg)
  - Heart rate (bpm)
  - Body temperature (°C)
  - Respiratory rate (breaths/min)
- ECOG PS
  - 0 = Fully active, able to carry on all pre-disease performance without restriction,
  - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work,
  - 2 = Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours,
  - 3 = Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours,
  - 4 = Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair,
  - 5 = Dead.

  Only numbers (from 0 to 5) will be reported in tables and listings.
- Disease History of Melanoma: Initial diagnosis
  - Melanoma Type (Cutaneous, Mucosal, Ocular, Unknown)
    - If mucosal, primary site of mucosal melanoma (Head and neck, Oesophagus, Stomach, Small Intestine, Colon, Rectum, Vagina, Bladder, Other)
    - If cutaneous, primary site of cutaneous melanoma (Head, Neck, Trunk, Legs, Arms, Buttocks, Other)
  - Melanoma subtype (Superficial spreading, Lentigo maligna, Nodular, Desmoplastic, Unknown, Other)
  - Time from first diagnosis of melanoma to study enrolment (months) – derived as specified in paragraph 12.1
  - Stage at initial diagnosis (0, I, Ia, Ib, Ic, II, IIa, IIb, IIc, III, IIIa, IIIb, IIIc, IV, Iva, IVb, IVc)

- Disease History of Melanoma: Current diagnosis
  - Stage at current diagnosis (IIIa, IIIb, IIIc, IV – M1a, IV – M1b, IV – M1c)
  - Recurrence/Relapse (Yes/No)
    - If yes, time from first recurrence/relapse (months) – derived as specified in paragraph 12.1
    - If yes, time from most recent recurrence/relapse (months) – derived as specified in paragraph 12.1
- Molecular status (local) mutant (Yes, No)

  If yes, type of mutation (Exon 15 V600E, Exon 15 V600K, Exon 15 V600D, Exon 15 V600R, Other)
- Childbearing potential status and pregnancy test:
  - Childbearing potential (Yes, No)
  - Post-menopausal (Yes, No)
  - Accepted to use an adequate contraception for the total study duration (Yes, No)
  - Serum pregnancy test (if applicable) done (Yes, No) and result (Positive, Negative).
- HIV test:
  - Performed (Yes, No, Not applicable)
  - Result (Negative, Positive)

12.1. DERIVATIONS

The following variables will be derived:

- Age (years) = integer [(Date of informed consent – "15/Jul/year of birth") / 365.25]
- Time from first diagnosis of melanoma to study enrolment (months) = [(Date of informed consent – date of first diagnosis of melanoma)/30.4]

  If Date of first diagnosis of melanoma is partial, the following conventions will be used:
  - If day is unknown, but month and year are known, use first day of the month;
  - If day and month are unknown, but year is known, use 01 January;
  - If day, month and year are unknown, leave it missing.
- Time from first recurrence/relapse to study enrolment (months) = [(Date of informed consent – date of first recurrence/relapse)/30.4]

  If Date of first recurrence/relapse is partial, the following conventions will be used:
  - If day is unknown, but month and year are known, use 15 as day;
  - If day and month are unknown, but year is known, use 01 July;
  - If day, month and year are unknown, leave it missing.
- Time from most recent recurrence/relapse to study enrolment (months) = [(Date of informed consent – date of most recent recurrence/relapse)/30.4]

  If Date of most recent recurrence/relapse is partial, the following conventions will be used:
  - If day is unknown, but month and year are known, use 15 as day;
  - If day and month are unknown, but year is known, use 01 July;
  - If day, month and year are unknown, leave it missing.

13. MEDICAL HISTORY

Medical history information will be presented for the ITT set.

Medical history verbatims will be coded using MedDRA dictionary version 20.0 or higher.

Medical conditions with "Ongoing" field not ticked in eCRF will be considered as previous diseases while those reported as "Ongoing" in eCRF will be considered as concomitant diseases.

Previous and concomitant diseases will be analyzed separately with frequency tables reporting the number of patients who exhibited at least one disease and showing diseases by primary System Organ Class and Preferred Term by treatment arm.

Line listings of previous and concomitant diseases will be produced for the ITT set.

14. PHYSICAL EXAMINATION

Physical examination information will be presented for the ITT set.

Physical examination verbatims will be derived from the eCRF "Physical Examination" form in the "If abnormal, specify" field and will be coded using MedDRA dictionary version 20.0 or higher.

Clinically significant and not clinically significant abnormalities will be analyzed separately with frequency tables reporting the number of patients who exhibited at least one abnormality and showing abnormalities by primary System Organ Class and Preferred Term by treatment arm.

A line listing of physical examinations and significant abnormalities will be produced for the ITT set.

15. SYSTEMIC ADJUVANT TREATMENTS

Systemic adjuvant treatments will be presented for the ITT set and coded using WHO-DRL dictionary version 2017 or higher.

Prior systemic treatments are those treatments with "Ongoing" field not ticked and which stopped prior to the first dose of study medication.

Concomitant systemic treatments are those reported as "Ongoing" in the "Prior systemic treatment" eCRF form.

Frequency tables of prior and concomitant systemic treatments by primary therapeutic subgroup (3rd level ATC level subgroup) and generic name will be presented by treatment arm.

Line listings of prior and concomitant systemic treatments will be produced.

16. PRIOR RADIATION TREATMENTS

Prior radiation treatments will be presented for the ITT set and coded using WHO-DRL dictionary version 2017 or higher.

A frequency table of prior radiation treatments by primary therapeutic subgroup (3rd level ATC level subgroup) and generic name will be presented by treatment arm.

A line listing will be produced for the ITT set.

17. PRIOR MELANOMA-RELATED SURGERY

Prior (melanoma-related) surgeries will be presented for the ITT set and coded using WHO-DRL dictionary version 2017 or higher.

A frequency table of prior surgeries by primary therapeutic subgroup (3rd level ATC level subgroup) and generic name will be presented by treatment arm.

A line listing will be produced for the ITT set.

18. MEDICATIONS

Medications will be presented for the ITT set and coded using WHO-DRL dictionary version 2017 or higher.

Prior medications are those which stopped prior to the first dose of study medication.

Concomitant medications are those which:

- Started prior to, on or after the first dose of study medication and started no later than date of last study dose,
- AND ended on or after the date of first dose of study medication or were ongoing at the date of last study dose.
- If the date of last study dose is unknown the medication will be considered as concomitant.

Also, see Table 9 for handling of partial dates for medications, in the case where it is not possible to define a medication as prior or concomitant, the medication will be classified by the worst case.

The following tables will be presented:

- A frequency tables of prior medications by primary therapeutic subgroup (3rd level ATC level subgroup) and generic name by treatment arm.
- A frequency tables of concomitant medications by primary therapeutic subgroup (3rd level ATC level subgroup) and generic name by treatment arm.

Data listings of prior and concomitant medications will be produced.

19. STUDY MEDICATION EXPOSURE AND COMPLIANCE

Exposure in days and compliance to oral IMPs (LGX818 and MEK162) will be presented for the SAF set.

The date of first study drug administration will be taken from the eCRF “LGX818 (450 mg p.o od)”, “MEK162 (45 mg p.o. bid)”, “Nivolumab 1 mg/kg solution IV”, “Ipilimumab 3 mg/kg solution IV” taking the “Start therapy date” which occurs first.

The date of last dose of study medication will be taken from the eCRF “End of Treatment” form (“Date when the investigational product was last taken”). If this date is missing, the date of last study medication will be taken from the eCRF “LGX818 (450 mg p.o od)”, “MEK162 (45 mg p.o. bid)”, “Nivolumab 1 mg/kg solution IV”, “Ipilimumab 3 mg/kg solution IV” taking the “End therapy date” which occurs last.

Temporarily interruptions and dose changes are not considered for overall duration of exposure.

Default summary statistics will be presented for overall duration of exposure and duration of exposure to each study drug by treatment arm (see specifications for derivations in Section 19.1). A line listing of duration of exposure will be produced.

Compliance to oral IMPs (LGX818 and MEK162) will be summarized with default statistics by treatment arm. A line listing will be produced.

19.1. DERIVATIONS

Overall duration of exposure [weeks]: [(date of last dose – date of first study drug administration + 1) / 7].

Duration of exposure to LGX818 [weeks]: sum over all cycles [(end therapy date – start therapy date + 1) / 7].

Duration of exposure to MEK162 [weeks]: sum over all cycles [(end therapy date – start therapy date + 1) / 7].

Duration of exposure to Nivolumab [weeks]: sum over all cycles [(end therapy date – start therapy date + 1) / 7]. For this calculation consider study periods with 1 mg/kg and 3 mg/kg IV infusion.

Duration of exposure to Ipilimumab [weeks]: sum over all cycles [(end therapy date – start therapy date + 1) / 7].

Compliance to LGX818 [%] = Total dose administered of LGX818 over all cycles / (Total daily dose to be administered as per protocol x duration of exposure to LGX818 [days]) x 100. Note that total daily dose to be administered as per protocol is 450 mg.

Compliance to MEK162 [%] = Total dose administered of MEK162 over all cycles / (Total daily dose to be administered as per protocol x duration of exposure to MEK162 [days]) x 100. Note that total daily dose to be administered as per protocol is 90 mg.

20. EFFICACY OUTCOMES

20.1. PRIMARY EFFICACY

20.1.1. PRIMARY EFFICACY VARIABLE & DERIVATION

OS is the primary endpoint of the study. OS will be calculated from the date of randomization until the date of death from any cause. Any patient not known to have died at the time of data analysis will be censored at the time of the last recorded date on which the patient was known to be alive.

OS (months) = [(Date of death or last contact – date of randomization + 1)/30.4]

20.1.2. ANALYSIS OF PRIMARY EFFICACY VARIABLE

The analysis will be performed in the ITT set and in the PP set.

The estimate of the survivor function using the Kaplan-Meier approach will be displayed graphically by treatment arm. Median time and the corresponding two-sided 95% confidence interval will be presented together with the estimates for the other quartiles (SAS procedure PROC LIFETEST) by treatment arm separately.

SAS-code for Kaplan-Meier approach[3]:

```
PROC LIFETEST DATA = <input dataset> PLOTS=SURVIVAL(ATRISK(OUTSIDE(0.15)))
  OUTSURV= <output dataset> CONFTYPE=LOGLOG;
```

```
 TIME <OS time in months>* <flag with censored data>(0)[1];
 STRATA <treatment group>;
RUN;

DATA <new dataset>;
 SET <output dataset>;
 UCL = ROUND(100*(1-SDF_UCL),.1);
 LCL = ROUND(100*(1-SDF_LCL),.1);
RUN;
```

A Cox's proportional hazard regression model will also be performed to assess the influence of some baseline covariates on OS. Covariates of interest are those reported in section 9.1. Hazard ratios estimates with their 95% confidence limits will be also presented (SAS procedure PROC PHREG).

SAS-code for Cox's proportional hazard regression model [4,5]:

```
PROC PHREG DATA = <adam.dataset>;
  CLASS <arm>(REF=FIRST) <gender>(REF=<'MALE'>) <melanoma type>(REF=FIRST) <stage of
diagnosis>(REF=FIRST) <ECOG PS>(REF=FIRST) / PARAM=REF;
  MODEL <duration of OS in months>*<censoring>(0) = <arm> <age> <gender> <melanoma type>
<stage of diagnosis> <LDH level> <ECOG PS> / TIES=EFRON RISKLIMITS;
RUN;
```

20.2. SECONDARY EFFICACY

The secondary analyses will be performed in the ITT set.

20.2.1. SECONDARY EFFICACY VARIABLES & DERIVATIONS

The secondary efficacy endpoints are:

a) Total PFS, calculated from the date of randomization until the date of the second progression (i.e., the progression to second treatment); any progression or death will be considered as an event if patient cannot complete treatment sequence.
   Any patient not known to have experienced progression or died at the time of data analysis will be censored at the time of the last recorded date on which the patient was known to be alive without disease progression.
   Total PFS (months) = [(Date of second progression or any progression/death or last contact – date of randomization +1)/30.4]
b) 3 years PFS rate (PFSR), calculated from the date of randomization until the date of progression or death from any cause. This rate estimates the proportion of patients who did not progress and were alive 3 years after randomization.
c) Percentage of patients alive at 2 and 3 years;
d) Best overall response rate (BORR), defined as the best response designation, as determined by the investigator, recorded between the date of randomization and the date of objectively documented progression per RECIST version 1.1 criteria;
e) Duration of response (DoR), calculated as the time from the date of first documented response (CR or PR) until the date of the first documented progression or death due to

[1] *where 0=censored; 1 = event.*

underlying cancer. If a patient with a CR or PR has no progression or death due to underlying cancer, the patient is censored at the date of last adequate tumor assessment;
DoR (months) = [(Date of first documented progression/death due to underlying cancer or date of last tumor assessment – date of first CR or PR +1)/30.4]

f) Health-related quality of life (HRQoL), by means of the 30-item European Organisation for Research and Treatment of Care quality of life questionnaire (EORTC QLQ-C30);
g) General health status, by means of the European Quality of Life 5-Dimensions (EQ-5D) questionnaire;
h) Impairment of work productivity and activity, by means of the Work Productivity and Activity Impairment: General Health (WPAI:GH) questionnaire.

20.2.2. Analysis of Secondary Efficacy Variables

The secondary efficacy analyses will be performed in ITT set.

The following statistical methods will be applied on the secondary efficacy endpoints:

a) Total PFS: The estimates of the survivor function using the Kaplan-Meier approach will be displayed graphically by treatment arm. Median time and the corresponding two-sided 95% confidence interval will be presented together with the estimates for the other quartiles (SAS procedure PROC LIFETEST) by treatment arm separately.
A Cox's proportional hazard regression model will also be performed to assess the influence of some baseline covariates on total PFS. Covariates of interest are those reported in Paragraph 9.1. Hazard ratios estimates with their 95% confidence limits will be also presented (SAS procedure PROC PHREG).
b) 3-years PFSR: The PFSR at 3 years will be estimated by the Kaplan-Meier method. The 95% confidence intervals for the PFSR will be estimated using Greenwood's estimate of the standard error (SE) and a linear transformation of the progression-free survival function.
c) Percentage of patients alive at 2 and 3 years will be reported using Wilson score intervals for each treatment arm.
d) BORR: Default summary statistics of the best overall response from the date of randomization to the date of objectively documented progression per RECIST version 1.1 criteria will be presented, by treatment arm.
For each treatment arm, the Overall Response Rate (ORR) will be calculated as the percentage of patients in the ITT set who have a CR or PR before any evidence of progression (as defined by RECIST).
A 95% confidence interval (CI) will be derived for the ORR using Wilson score intervals (CIs for a single proportion).
e) The estimates of the survivor function of DoR using the Kaplan-Meier approach will be displayed graphically by treatment arm. Median time and the corresponding two-sided 95% confidence interval will be presented together with the estimates for the other quartiles (SAS procedure PROC LIFETEST) by treatment arm separately.
A Cox's proportional hazard regression model will also be performed to assess the influence of some baseline covariates on DoR. Covariates of interest are those reported in Paragraph 9.1. Hazard ratios estimates with their 95% confidence limits will be also presented (SAS procedure PROC PHREG).
f) Default summary statistic of all scale scores of the EORTC QLQ-C30 and of the changes from baseline of each scale will be presented by treatment arm, according to the following scoring method.

For all the scales, the Raw Score (RS) is the mean of the component items:

$$RS = (I_1 + I_2 + \ldots + I_n)/n.$$

A linear transformation to standardise the Raw Scores is used, so that scores range from 0 to 100; a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms.

For Functional Scales, the transformation to be used is the following:

$$Score = \left\{1 - \frac{(RS - 1)}{range}\right\} \times 100$$

where range is the difference between the possible maximum and the minimum response to individual items.

For Symptoms scales/items and Global health status / QoL the transformation is the following:

$$Score = \left\{\frac{(RS - 1)}{range}\right\} \times 100$$

The component items and the range which define each scale score are reported in the following table.

Table 2 Component items and range for EORTC QLQ-C30 scoring

	Scale	Number of items	Item range	Item numbers
Global health status / QoL	QL2	2	6	29,30
Functional scales				
Physical functioning	PF2	5	3	1 to 5
Role functioning	RF2	2	3	6, 7
Emotional functioning	EF	4	3	21 to 24
Cognitive functioning	CF	2	3	20, 25
Social functioning	SF	2	3	26, 27
Symptom scales / items				
Fatigue	FA	3	3	10, 12, 18
Nausea and vomiting	NV	2	3	14, 15
Pain	PA	2	3	9, 19
Dyspnoea	DY	1	3	8
Insomnia	SL	1	3	11
Appetite loss	AP	1	3	13
Constipation	CO	1	3	16
Diarrhoea	DI	1	3	17
Financial difficulties	FI	1	3	28

g) The EQ-5D questionnaire consists of 5 5-levels items (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and of the EQ Visual Analogue Scale (EQ VAS). The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state (11111 indicates no problems, while 55555 indicates severe problems in all the 5 dimensions). Missing values can be coded as 9. Ambiguous values should be treated as missing values. Health states will be converted into a single index values by using the UK TTO value set. Default summary statistics and changes from baseline of the EQ-5D index will be presented by treatment arm.

h) The following percentages will be calculated for each patient at each of the foreseen administrations. Default summary statistics and changes from baseline of these 4 scores will be presented by treatment arm.
   - Percent work time missed due to health: Q2/(Q2+Q4) x 100;
   - Percent impairment while working due to health: Q5 x 10;

- Percent overall work impairment due to health: {Q2/(Q2+Q4) + [(1-(Q2/(Q2+Q4))) x (Q5/10)]} x 100
- Percent activity impairment due to health: Q6 x 10.

21. SAFETY OUTCOMES

All outputs for safety outcomes will be based on the Safety Analysis Set (SAF).

Safety and tolerability will be assessed in terms of AEs, laboratory data (haematology, blood chemistry, urinalysis), ECG data, vital signs (heart rate and blood pressure), BMI and weight, which will be collected for all patients.

21.1. ADVERSE EVENTS

All adverse events (AEs) reported on eCRF and experienced by the patient on or after the informed consent date will be considered in the analysis. Thus, there will not be derivation to Treatment-emerged Adverse Events (TEAE) and not TEAE.

Adverse event Investigator terms will be assigned to a Preferred Term (PT) and will be classified by primary System Organ Class (SOC) according to the Medical Dictionary for Regulatory Activities (MedDRA) thesaurus, version 20.0 or higher

Counts and percentages will be presented by primary System Organ Class (SOC) and Preferred Term (PT) as defined in MedDRA thesaurus, by treatment arm.

A patient having more than one AE with the same PT will be counted only once in the incidence calculation for that PT. Similarly, if a patient has more than one AE in the same SOC, the patient will be counted only once in the total number of patients with an AE for that SOC.

An AE will be defined “Related” if causality is “Certain”, “Probable” or “Possible”.

The following frequency distributions of adverse events will be provided by treatment arm:

- An overview of AEs including the number of patients with:
  - at least one AE,
  - at least one non-serious AE,
  - at least one AE related to Ipilimumab,
  - at least one AE related to Nivolumab,
  - at least one AE related to Combo Immuno Therapy,
  - at least one AE related to LGX818,
  - at least one AE related to MEK162,
  - at least one AE related to Combo Target Therapy,
  - at least one serious AE (SAE),
  - at least one SAE related to Ipilimumab,
  - at least one SAE related to Nivolumab,
  - at least one SAE related to Combo Immuno Therapy,
  - at least one SAE related to LGX818,
  - at least one SAE related to MEK162,
  - at least one SAE related to Combo Target Therapy,
  - at least one AE leading to hospitalization,
  - at least one AE leading to withdrawal from the study,

  - at least on AESI,

  and the number of AEs, non-serious AEs, SAEs, AEs related to Ipilimumab, AEs related to Nivolumab, AEs related to Combo Immuno Therapy, AEs related LGX818, AEs related to MEK162, AEs related to Combo Target Therapy, SAEs related to Ipilimumab, SAEs related to Nivolumab, SAEs related to Combo Immuno Therapy, SAEs related LGX818, SAEs related to MEK162, SAEs related to Combo Target Therapy, AEs leading to hospitalization, AEs leading to death, AEs leading to study withdrawal, AESIs;
- AEs presented by Primary SOC and PT;
- AEs related to Ipilimumab presented by Primary SOC and PT;
- AEs related to Nivolumab presented by Primary SOC and PT;
- AEs related to Combo Immuno Therapy presented by Primary SOC and PT;
- AEs related to LGX818 presented by Primary SOC and PT;
- AEs related to MEK162 presented by Primary SOC and PT;
- AEs related to Combo Target Therapy presented by Primary SOC and PT;
- Serious AEs presented by Primary SOC and PT;
- AEs leading to hospitalization presented by Primary SOC and PT;
- AEs leading to death presented by Primary SOC and PT;
- AEs leading to study withdrawal presented by Primary SOC and PT.
- AESIs presented by Primary SOC and PT

The following individual data listings will be produced:

- A listing of all AEs;
- A listing of AEs related to Ipilimumab;
- A listing of AEs related to Nivolumab;
- A listing of AEs related to Combo Immuno Therapy;
- A listing of AEs related to LGX818;
- A listing of AEs related to MEK162;
- A listing of AEs related to Combo Target Therapy;
- A listing of all SAEs;
- A listing of all AEs leading to death;
- A listing of AEs leading to hospitalization;
- A listing of AEs leading to study withdrawal;
- A listing of AESIs.

21.2. LABORATORY EVALUATIONS

Laboratory data will be analyzed on the SAF set.

Descriptive summaries of hematology, blood chemistry, coagulation, thyroid function, Cardiac Muscle Enzyme and endocrine panel will be provided for actual values and changes from baseline at each visit by treatment arm.

Default frequency tabulations will be also provided for urinalysis by treatment group for each visit.

Line listings of laboratory data during the study will be provided.

Presentations for continuous variables will use SI Units: conversion will be provided using the International Laboratory Normal Ranges (SI Unit Conversion Guide, M. Laposata, NEJM, 1992).

To convert from the conventional unit to the SI unit, laboratory specific derivations will be used, multiply by the conversion factor.

Table 3- Hematology: conversion factors

Component	Conventional Unit	Conversion Factor	SI Unit
Hemoglobin	g/dL	10	g/L
Hematocrit	%	0.01	Proportion of 1.0
RBC Count	X 10^6/µl	1	X 10^{12}/L
WBC Count	X 10^3/µl	1	X 10^9/L
Neutrophils	X 10^3/µl	1	X 10^9/L
Lymphocytes	X 10^3/µl	1	X 10^9/L
Monocytes	X 10^3/µl	1	X 10^9/L
Eosinophils	X 10^3/µl	1	X 10^9/L
Basophils	X 10^3/µl	1	X 10^9/L
Platelets	X 10^3/µl	1	X 10^9/L

Table 4- Biochemistry: conversion factors

Component	Conventional Unit	Conversion Factor	SI Unit
Glucose	mg/dL	0.05551	mmol/L
Sodium	mEq/L	1	mmol/L
Potassium	mEq/L	1	mmol/L
	mg/dL	0.2558	
Calcium	mEq/L	0.5	mmol/L
	mg/dL	0.250	
Chloride	mEq/L	1	mmol/L
Bicarbonate	mEq/L	1	mmol/L
Magnesium	mg/dL	0.4114	mmol/L
Urea	mg/dL	0.167	mmol/L

BUN	mg/dL	0.357	mmol/L
Uric Acid	mg/dL	59.48	µmol/L
Albumin	g/dL	10	g/L
Creatinine	mg/dL	88.4	µmol/L
Creatinine Clearance	mL/min	0.01667	mL/s
Total Proteins	g/dL	0.01	g/L
Total Bilirubin	mg/dL	17.104	µmol/L
Indirect Bilirubin	mg/dL	17.104	µmol/L
Alkaline phosphatase	units/L	1	U/L
Alanine aminotransferase (ALT)	units/L	1	U/L
Aspartate aminotransferase (AST)	units/L	1	U/L
Gamma-GT	units/L	1	U/L
HDL Cholesterol	mg/dL	0.02586	mmol/L
LDL Cholesterol	mg/dL	0.02586	mmol/L
LDH	Units/L	1	U/L
	Units/L	0.01667	µkat/L
Amylase	Units/L	1	U/L
	Units/L	0.01667	µkat/L
Lipase	Units/L	1	U/L
	Units/L	0.01667	µkat/L

Table 5- Coagulation: conversion factors

Component	Conventional Unit	Conversion Factor	SI Unit
INR	Ratio	1	ratio

aPTT	Seconds	1	seconds
PTT	Seconds	1	seconds
Protrombin time	Seconds	1	seconds
Fibrinogen	g/dL	29.41	µmol/L
	mg/dL	0.01	g/L

Table 6 – Thyroid function test: conversion factors

Component	Conventional Unit	Conversion Factor	SI Unit
TSH	µU/mL	1	mU/L
Free T4	µg/dL	12.87	nmol/L
Free T3	ng/dL	0.01536	nmol/L

Table 7 – Cardiac Muscle Enzyme: conversion factors

Component	Conventional Unit	Conversion Factor	SI Unit
Creatine Kinase	µkat/L	59.988	U/L
	ng/dL	100	ng/mL
Troponin	ng/L	1000	
	µg/L	1	
Creatinin Kinase Isoenzyme	%	0.01	Fraction of 1.00
Myoglobin	ng/mL	17.513	nmol/L

Table 8 – Endocrine panel: conversion factors

Component	Conventional Unit	Conversion Factor	SI Unit
ACTH	pg/mL	0.2202	pmol/L
Total cortisol	µg/dL	27.59	nmol/L

The following parameters will be collected for urinalysis:

- Glucose (Neg, Trace, 1+, 2+, 3+, 4+)
- Protein (Neg, Trace, 1+, 2+, 3+, 4+)
- Blood (Neg, Trace, 1+, 2+, 3+, 4+)
- Bilirubin (Neg, Trace, 1+, 2+, 3+, 4+)
- Ketones (Neg, Trace, 1+, 2+, 3+, 4+)
- Leukocytes (Neg, Trace, 1+, 2+, 3+, 4+)
- UWBC/HPF (Not present, Present) and continuous value if present
- URBC/HPF (Not present, Present) and continuous value if present
- Casts/LPF (Not present, Present) and continuous value if present
- Bacteria (Not present, Present) and continuous value if present
- Other (Not present, Present) and continuous value if present

The following summaries will be provided for urinalysis data by treatment arm:

- Actual and change from baseline by visit for continuous values of UWBC/HPF, URBC/HPF, Casts/LPF, Bacteria and Other, if present;
- Frequency tables by visit for glucose, protein, blood, bilirubin, ketones, leukocytes, UWBC/HPF, URBC/HPF, Casts/LPF, Bacteria and Other.

21.3. CARDIOLOGICAL ASSESSMENTS

ECG and ECHO/MUGA parameters will be analysed on the SAF set.

Descriptive summaries of PR interval (ms), QT interval (ms), QRS interval (ms), QTcB interval (ms), cardiac axis (°), Ejection Fraction Value (%) will be provided for actual values and changes from baseline at each visit by treatment arm.

Default frequency tabulations will be also provided for ECG result (Normal, Abnormal) and interpretation of abnormal ECG (not clinically significant, clinically significant), type of LVEF scan (ECHO, MUGA) and ECHO/MUGA scan interpretation (Normal, Clinically insignificant abnormality, Clinically significant abnormality) by treatment arm.

Line listings of ECG and ECHO/MUGA parameters during the study will be provided.

21.4. VITAL SIGNS

Vital signs parameters will be analyzed on the SAF set.

Descriptive summaries of the following parameters will be provided for actual values and changes from baseline at each visit by treatment arm:

- Body weight (Kg)
- BMI (kg/m2)
- Systolic Blood Pressure (mmHg)
- Diastolic Blood Pressure (mmHg)
- Heart Rate (bpm)
- Body Temperature (°C)

- Respiratory rate (breaths/min)

A line listing of vital signs during the study will be provided.

22. ANALYSIS OF PHARMACOKINETIC DATA

Not applicable.

23. OTHER ASSESSMENTS

23.1. OPHTHALMOLOGICAL EXAMINATION

Ophthalmological examinations will be analyzed on the SAF set.

According to study protocol, this examination will be performed at each baseline visit (Baseline 1, Baseline 2 and Baseline 3 – for Arm C only).

Descriptive summaries of the following parameters will be provided for each visit by treatment arm:

- Ophthalmological examination performed (No, Yes, Not Applicable);
- Eye(s) assessed (Left Eye, Right Eye, Both);
- Visual Acuity assessed (No, Yes):
    - Total Visual Acuity Score (ETDRS) – Left Eye (OS),
    - Total Visual Acuity Score (ETDRS) – Right Eye (OD),
    - Total Visual Acuity snellens equivalent – Left Eye (OS),
    - Total Visual Acuity snellens equivalent – Right Eye (OD);
- Intraocular pressure assessed (No, Yes):
    - Intraocular pressure – Left eye (OS) (mmHg),
    - Intraocular pressure – Right eye (OD) (mmHg),
- Dilated fundoscopy performed (No, Yes):
    - Eye(s) assessed (Left eye, Right eye, Both),
    - For each eye, assessment (Normal, abnormal) of the following areas:
        - Viterous
        - Retina
        - Macula
        - Choroid
        - Optic nerve pallor
        - Other
- Slit lamp examination performed (No, Yes):
    - Eye(s) assessed (Left eye, Right eye, Both),
    - For each eye, assessment (Normal, Abnormal) of the following areas:
        - Lids/lashes
        - Cornea
        - Conjunctiva
        - Iris
        - Lens
        - Anterior chamber

    - Other
- Visual field testing performed (No, Yes) and Abnormalities (No, Yes);
- Optical coherence tomography performed (No, Yes) and abnormalities (No, Yes).

A line listing of the ophthalmological examinations during the study will be provided.

23.2. DERMATOLOGICAL EXAMINATION

Dermatological examinations will be analyzed on the SAF set.

According to study protocol, this examination will be performed at each baseline visit and every 8 weeks.

Descriptive summaries of the following parameters will be provided for each visit by treatment arm:

- Dermatological examination performed (No, Yes);
- Result of the dermatological examination (Normal, Abnormal);
- If Results is Abnormal, Diagnosis (Squamous cell carcinoma, Keratoacanthomas, Other pathology findings)
- Evidence of severe or uncontrolled systemic disease or concurrent undesirable condition (No, Yes)

A line listing of dermatological examinations during the study will be provided.

23.3. PERFORMANCE STATUS

A frequency table and a line listing of ECOG PS during the study will be provided.

23.4. PREGNANCY TEST

A frequency table and a corresponding listing of pregnancy test result during the study will be provided. Pregnancy test is performed at baseline 1, then every 6 weeks during study treatment, at Follow up visit and at the long-term follow-up visit.

24. TABLE SHELLS AND SPECIFICATIONS

24.1. TABLE SPECIFICATIONS

Tables will be provided as defined by the table shells.

Similar tables based on different populations will have the same number, except for the last digit.

All output will be generated by SAS and exported into a RTF format and then convert to PDF format. All output will be in landscape orientation. Font size will be Courier New 8 pt.

The header containing the sponsor' name (Fondazione Melanoma (ONLUS)) and protocol number will appear on the top left corner of each page of the output. The page number, in the format of "Page x of y", will appear on the top right corner of the output, where y = last page of corresponding output.

Column headers in tables include the total possible numbers to be included in summaries for that table, designated as "(N=XX)".

The SAS program name, and the date and time of the creation of the output (run date) will appear on the bottom left corner as follows:

Source: [program name].sas, Run on ddmmyyyy

Table Format Specification:

Maximum and minimum values will be reported with the same number of decimal places as collected. Means and medians will be reported to one additional decimal place. Standard deviations and standard errors will be reported to two decimal places more than the collected data. Percentages will be reported with one decimal place.

Data in the tables are formatted as follows:

- Text fields in the body of the tables and listings will be left-justified.
- When no data are available for a table, an empty page with the title will be produced with suitable text. Example: THERE WERE NO SERIOUS ADVERSE EVENTS.

25. REFERENCES

1. ICH. Statistical Principles for Clinical Trials, Guideline E9 [Electronic resource]. 1998.
2. Nazionale I. et al. Clinical Study Protocol (SECOMBIT). 2021.
3. SAS. SAS/STAT ® 14.2 User's Guide The LIFETEST Procedure. 2016.
4. Yu LI, Cheng L. How to Compute Custom Hazard Ratio in SAS (V8 . 2 & V9 . 2) PHREG Procedure. P. 1–8.
5. SAS. User ' s 14.3 Guide The PHREG Procedure. 2017.

APPENDIX 1. PROGRAMMING CONVENTIONS FOR OUTPUTS

DATES & TIMES

Depending on data available, dates and times will take the form ddmmyyyy hh:mm.

SPELLING FORMAT

English US.

LISTINGS

All listings will be ordered by the following (unless otherwise indicated in the template):

- Treatment Arm
- Site ID
- Patient ID
- Visit
- Date (where applicable).

APPENDIX 2. **PARTIAL DATE CONVENTIONS**

Imputed dates will NOT be presented in the listings.

Table 9 Algorithm for Prior / Concomitant Medications

START DATE	STOP DATE	ACTION
Known	Known	If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= end of treatment, assign as concomitant If stop date >= study med start date and start date > end of treatment, assign as post study
	Partial	Impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= end of treatment, assign as concomitant If stop date >= study med start date and start date > end of treatment, assign as post treatment
	Missing	If stop date is missing could never be assumed a prior medication If start date <= end of treatment, assign as concomitant If start date > end of treatment, assign as post treatment
Partial	Known	Impute start date as earliest possible date (i.e. first day of month if day unknown or 1st January if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= end of treatment, assign as concomitant If stop date >= study med start date and start date > end of treatment, assign as post treatment
	Partial	Impute start date as earliest possible date (i.e. first day of month if day unknown or 1st January if day and month are unknown) and impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= end of treatment, assign as concomitant If stop date >= study med start date and start date > end of treatment, assign as post treatment
	Missing	Impute start date as earliest possible date (i.e. first day of month if day unknown or 1st January if day and month are unknown), then: If stop date is missing could never be assumed a prior medication If start date <= end of treatment, assign as concomitant If start date > end of treatment, assign as post treatment
Missing	Known	If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant Cannot be assigned as 'post treatment'
	Partial	Impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant Cannot be assigned as 'post treatment'
	Missing	Assign as concomitant

26. TABLES AND LISTINGS SHELLS

In the following pages tables and listings shells are presented.

TABLE 1. Patients enrolment by sites

POPULATION: ENR

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)	Not randomized (N = XX)
Number of Enrolled Patients					
Site 01	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Site 02	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
..					
Site nn	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: a) Percentages are calculated relative to the total number of patient by arm. enrolled.
b) FPFV: DDMONYYYY Patient XX.
c) LPLV: DDMONYYYY Patient YY.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 2. Summary of screening failures

POPULATION: ENR

	Statistic	N = XX
Number of total screening failures	n (%)	xx (xx.x%)
Number of patients who did not meet at least one inclusion criterion	n (%)	xx (xx.x%)
Number of patients who did not meet at least one exclusion criterion	n (%)	xx (xx.x%)
Number of patients who did not meet at least one inclusion and/or exclusion criterion	n (%)	xx (xx.x%)

Note: Percentages are calculated relative to the total number of patients in the ENR population.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 3. Summary of Major Protocol Deviations

POPULATION: ENR

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients with at least one major deviation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Type of Major Protocol Deviations				
XXXXXXXXXXXXXXX	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XXXXXXXXXXXXXXX	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XXXXXXXXXXXXXXX	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XXXXXXXXXXXXXXX	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: a) Percentages are calculated relative to the total number of patients in the ENR Population by treatment arm.
b) Patients may be counted in more than one major protocol deviation category

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 4. Summary of patients' disposition

POPULATION: ENR

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)	Not Randomized (N = XX)
Has the subject completed the trial?					
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Primary reason for withdrawal					
Progression of disease	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawn informed consent for the study and for FU	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawn informed consent for the study but NOT for FU	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject no longer meets study criteria (after the first PD)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Screening failure	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse event	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Poor/Non-compliance with protocol requirements	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow-up	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Administrative reason by Sponsor	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject's decision	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other					

Note:
Percentages are calculated relative to the total number of patients in the ENR population by arm.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 5. Analysis sets

POPULATION: ENR

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)	Not Randomized (N = XX)
Number of Patients in the Enrolled Analysis Set (ENR)	n (%)	xx	xx	xx	xx
Number of Patients in the Intent-to-Treat Set (ITT)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients Excluded from the ITT	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason 01	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason 02	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients in the Safety Analysis Set (SAF)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients Excluded from the SAF	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason 01	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason 02	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients in the Per Protocol Analysis Set (PP)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients Excluded from the PP	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason 01	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason 02	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ENR population by arm.
Patients may be counted in more than one reason for exclusion.

The all patients enrolled (ENR) set contains all patients who provided informed consent for this study.

- The Intent-to-Treat (ITT) set contains all randomized patients.
- The Safety Analysis set (SAF) contains all enrolled patients who received at least one dose of study medication.
- The Per Protocol Analysis set (PP) contains all randomized patients who did not report any major protocol deviations

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 6. Demographics

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Age (years)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Gender at birth				
Male	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race				
White/Caucasian	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black/African American	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
American Indian or Alaska Native	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Pacific Islander	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnic Origin				
Hispanic/Latino	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic/Latino	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mixed Ethnicity	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Age (years) was calculated as: integer [(Date of informed consent – 15/JUL/year of birth)/365.25].

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 7. Vital Signs and ECOG PS at screening

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Body Weight (Kg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Height (cm)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
BMI (kg/m2)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Systolic Supine Blood Pressure (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Diastolic Supine Blood Pressure (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Heart rate (bpm)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Body temperature (°C)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Respiratory Rate (breaths/min)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
ECOG PS				
0	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

5	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 8. Disease History of Melanoma: Initial diagnosis

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Melanoma type				
Cutaneous	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mucosal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ocular	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unknown	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If mucosal, primary site of mucosal melanoma (*)				
Head and neck	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Esophagus	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Stomach	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Small intestine	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Colon	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Rectum	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Vagina	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Bladder	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If cutaneous, primary site of cutaneous melanoma (#)				
Head	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neck	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trunk	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Legs	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Arms	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Buttocks	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Melanoma Subtype				
Superficial spreading	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lentigo maligna	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Nodular	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Desmoplastic	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unknown	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Time from first diagnosis of melanoma to study enrolment (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Stage at initial diagnosis				
0	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
I	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ia	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ib	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
...	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
IVc	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Time from first diagnosis of melanoma to study enrolment (months) was calculated as: [(Date of informed consent – date of first diagnosis of melanoma)/30.4].
(*) Percentages are calculated relative to the total number of patients in the ITT set with mucosal melanoma by treatment arm.
(#) Percentages are calculated relative to the total number of patients in the ITT set with cutaneous melanoma by treatment arm.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 9. Disease History of Melanoma: Current diagnosis

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Stage at current diagnosis				
IIIa	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
IIIb	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
IIIc	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
IV – M1a	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
IV – M1b	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
IV – M1c	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recurrence / Relapse				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Time from first recurrence/relapse (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Time from most recent recurrence/relapse (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Time from first recurrence/relapse (months) was calculated as: [(Date of informed consent – date of first recurrence/relapse)/30.4].
Time from most recent recurrence/relapse (months) was calculated as: [(Date of informed consent – date of most recent recurrence/relapse)/30.4].

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 10. Molecular status

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Molecular status (local) mutant				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Type of mutation (*)				
Exon 15 V600E	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Exon 15 V600K	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Exon 15 V600D	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Exon 15 V600R	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
(*) Percentages are calculated relative to the total number of patients in the ITT population with molecular status mutant by treatment arm.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 11. Childbearing potential status and pregnancy test at screening

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Childbearing potential				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Post-menopausal				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Accepted to use an adequate contraception for the total study duration?				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Serum pregnancy test done				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Applicable	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result (*)				
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note:
Percentages are calculated relative to the total number of female patients in the ITT population by treatment arm.
(*) Percentages are calculated relative to the total number of female patients in the ITT population who performed serum pregnancy test by treatment arm.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 12. HIV test at screening

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
HIV test performed				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not applicable	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result (*)				
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
(*) Percentages are calculated relative to the total number of patients in the ITT population who performed HIV test by treatment arm.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 13. Summary of medical history – concomitant diseases

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of Patients with any concomitant disease	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Surgical/Medical History terms were coded using MedDRA thesaurus version XX.X.
This table includes medical terms reported as “Ongoing” in the Medical History CRF Form.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14. Summary of medical history – previous diseases

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of Patients with any previous disease	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Surgical/Medical History terms were coded using MedDRA thesaurus version XX.X.
This table includes medical terms reported as not "Ongoing" in the Medical History CRF Form.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 15. Summary of clinically significant physical examination abnormalities

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of Patients with any clinically significant abnormality	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Physical examination abnormalities were coded using MedDRA thesaurus version XX.X.
This table includes medical terms reported as “Abnormal” and “Clinically significant” in the Physical Examination CRF Form.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 16. Summary of not clinically significant physical examination abnormalities

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of Patients with any not clinically significant abnormality	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<PT>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
Physical examination abnormalities were coded using MedDRA thesaurus version XX.X.
This table includes medical terms reported as “Abnormal” and “Not Clinically significant” in the Physical Examination CRF Form.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 17. Summary of prior systemic treatments

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients who received any prior systemic treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup AAA>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup BBB>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >				
< Level subgroup ZZZ>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT set by treatment arm.
Prior systemic treatments were those treatments captured on the eCRF form “Prior Systemic Treatment”, reported as not “Ongoing” and which stopped prior to the first dose of study medication.
Prior systemic treatments were coded using the WHO-DRL Dictionary version XXXX .
Treatments were classified according to 3rd level ATC codes and Generic name.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 18. Summary of concomitant systemic treatments

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients who received any concomitant systemic treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup AAA>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup BBB>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >				
< Level subgroup ZZZ>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT set by treatment arm.
Concomitant systemic treatments were those treatments captured on the eCRF form “Prior Systemic Treatment” and reported as “Ongoing”.
Concomitant systemic treatments were coded using the WHO-DRL Dictionary version XXXX .
Treatments were classified according to 3rd level ATC codes and Generic name.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 19. Summary of prior radiation treatments

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients who received any prior radiation treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup AAA>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup BBB>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >				
< Level subgroup ZZZ>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT set by treatment arm.
Prior radiation treatments were those treatments captured on the eCRF form “Prior radiation treatment”.
Prior radiation treatments were coded using the WHO-DRL Dictionary version XXXX .
Treatments were classified according to 3rd level ATC codes and Generic name.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 20. Summary of prior melanoma-related surgeries

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients who received any prior melanoma-related surgery	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup AAA>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup BBB>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >				
< Level subgroup ZZZ>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT set by treatment arm.
Prior melanoma-related surgeries were those surgeries captured on the eCRF form “Prior surgery (melanoma related)”.
Prior melanoma-related surgeries were coded using the WHO-DRL Dictionary version XXXX .
Surgeries were classified according to 3rd level ATC codes and Generic name.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 21. Summary of prior medications

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients who received any prior medication	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup AAA>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup BBB>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >				
< Level subgroup ZZZ>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT set by treatment arm.
Prior medications were those medications captured on the eCRF form “Concomitant Medications” and which stopped prior to the first dose of study medication.
Prior medications were coded using the WHO-DRL Dictionary version XXXX .
Medications were classified according to 3rd level ATC codes and Generic name.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 22. Summary of concomitant medications

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of patients who received any concomitant medication	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup AAA>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Level subgroup BBB>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >				
< Level subgroup ZZZ>	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #1 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #2 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
< Generic Name #3 >	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT set by treatment arm.
Concomitant medications were those medications captured on the eCRF form "Concomitant Medications" and which:

- Started prior to, on or after the first dose of study medication or were ongoing at the date of last study dose AND
- Ended on or after the date of first dose of study medication or were ongoing at the date of last study dose.

Concomitant medications were coded using the WHO-DRL Dictionary version XXXX .
Medications were classified according to 3rd level ATC codes and Generic name.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 23. Study medication exposure

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Overall duration of exposure (weeks)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Duration of exposure to LGX818 (weeks)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Duration of exposure to MEK162 (weeks)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Duration of exposure to Nivolumab (weeks)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Duration of exposure to Ipilimumab (weeks)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 24. Compliance to oral IMPs (LGX818 and MEK162)

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Compliance to LGX818 (%)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx
Compliance to MEK162 (%)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx / xx	xx / xx	xx / xx

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 25. Analysis of Primary Endpoint: Summary of Overall Survival (OS)

POPULATION: ITT

		Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Overall Survival (months)		25th [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
		Median [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
		95th [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
Number of patients	Events	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Censored	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes:
Overall Survival (OS) is defined as the time from the date of randomization to the date of death.
OS (months) = [(Date of death or last contact – date of randomization +1)]/30.4.
Any patient not known to have died at the time of data analysis will be censored at the time of the last recorded date on which the patient was known to be alive.
Percentages are calculated relative to the total number of the patients in the ITT set by treatment arm.
OS (months) will be estimated using Kaplan-Meier method.

TABLE 25. Analysis of Primary Endpoint: Summary of Overall Survival (OS) (cont.)

POPULATION: ITT

Arm A

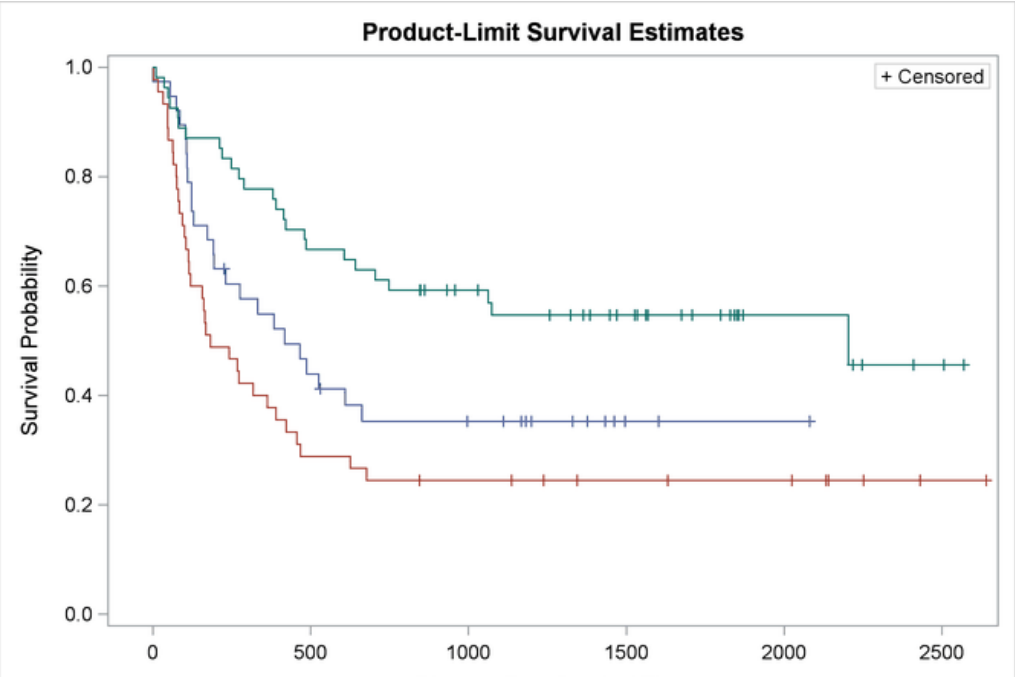
Time Interval (months)	Censoring Indicator	Survival Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	Number Left	SDF Lower 95% Confidence Limit	SDF Upper 95% Confidence Limit
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: This must be produced for each arm separately>

TABLE 25. Analysis of Primary Endpoint: Summary of Overall Survival (OS) (cont.)

POPULATION: ITT



Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 26. Analysis of Primary Endpoint: Predictive factors of Overall Survival (months)

POPULATION: ITT

The PHREG Procedure

Model Information

Data Set	xxxx	
Dependent Variable	xxxx	Overall Survival (Months)
Censoring Variable	xxxx	Censor
Censoring Value(s)	0	
Ties Handling	BRESLOW	

Number of Observations Read	xxx
Number of Observations Used	xxx

Summary of the Number of Event and Censored Values

Total	Event	Censored	Percent Censored
xxx	xx	xx	xx.xx

Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Without Covariates	With Covariates
-2 LOG L	xxxx.xxx	xxxx.xxx
AIC	xxxx.xxx	xxxx.xxx
SBC	xxxx.xxx	xxxx.xxx

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	xx.xxxx	xx	x.xxxx
Score	xx.xxxx	xx	x.xxxx
Wald	xx.xxxx	xx	x.xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 26. Analysis of Primary Endpoint: Predictive factors of Overall Survival

POPULATION: ITT

The PHREG Procedure

Analysis of Maximum Likelihood Estimates

Parameter	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Confidence Interval Lower	Upper
VAR1	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR2	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR3	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR4	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
…								
VARn	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx

Note for programming:

List of predictive factors to be included in the Cox's model:

a) Treatment sequence assigned: Arm A, Arm B, Arm C;
b) Age (years): continuous variable;
c) Gender: Male and Female;
d) Melanoma Type: Cutaneous, Mucosal, Ocular;
e) Stage at current diagnosis: IIIa, IIIb, IIIc, IV – M1a, IV – M1b, IV – M1c;
f) Baseline LDH level: continuous variable;
g) ECOG PS at baseline: 0, ≥1;

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 27. Analysis of Primary Endpoint: Summary of Overall Survival (OS)

POPULATION: PP

< Note for SAS Programmer: Please repeat the Table 25 for "Per-Protocol Population">

TABLE 28. Analysis of Primary Endpoint: Predictive factors of Overall Survival (months)

POPULATION: PP

< Note for SAS Programmer: Please repeat the Table 27 for "Per-Protocol Population">

TABLE 29. Analysis of Secondary Endpoint: Summary of Total Progression Free Survival (TPFS)

POPULATION: ITT

		Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Total Progression Free Survival (months)		25th [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
		Median [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
		95th [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
Number of patients	Events	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Censored	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes:
Total Progression Free Survival (TPFS) is defined as the time from the date of randomization to the date of second progression (i.e. the progression to second treatment); any progression or death will be considered as an event if patient cannot complete treatment sequence.
TPFS (months) = [(Date of second progression or any progression/death or last contact – date of randomization +1)]/30.4.
Any patient not known to have experienced progression or died at the time of data analysis will be censored at the time of the last recorded date on which the patient was known to be alive without progression.
Percentages are calculated relative to the total number of the patients in the ITT set by treatment arm.
TPFS (months) will be estimated using Kaplan-Meier method.

TABLE 29. Analysis of Secondary Endpoint: Summary of Total Progression Free Survival (TPFS) (cont.)

POPULATION: ITT

Arm A

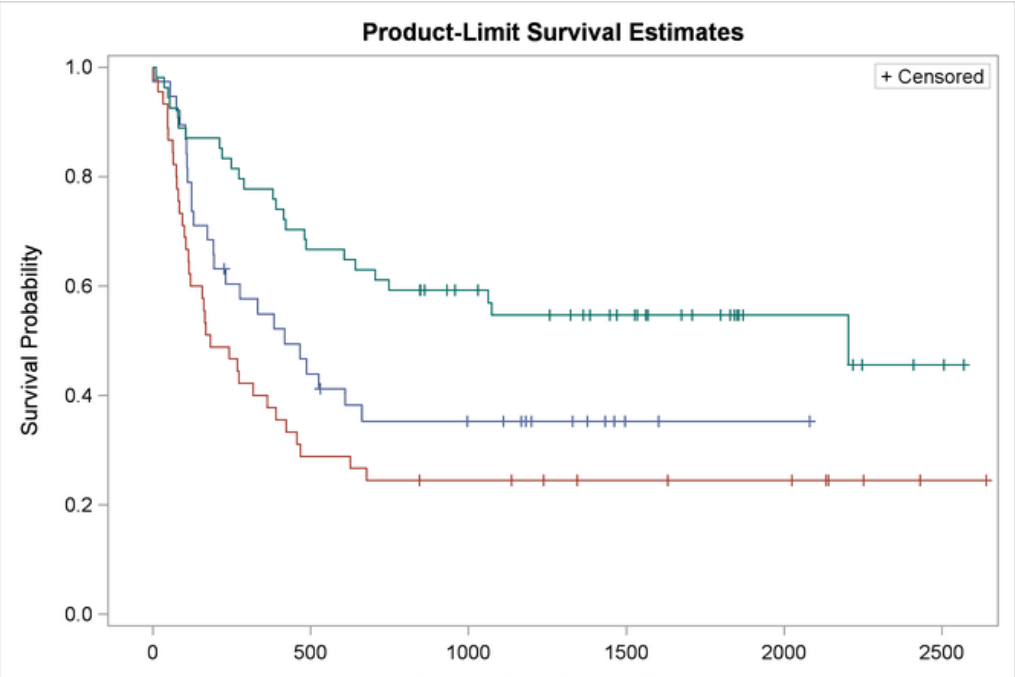
Time Interval (months)	Censoring Indicator	Survival Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	Number Left	SDF Lower 95% Confidence Limit	SDF Upper 95% Confidence Limit
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: This must be produced for each arm separately>

TABLE 29. Analysis of Secondary Endpoint: Summary of Total Progression Free Survival (TPFS) (cont.)

POPULATION: ITT



Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 30. Analysis of Secondary Endpoint: Predictive factors of Total Progression Free Survival

POPULATION: ITT

The PHREG Procedure

Model Information

Data Set	xxxx	
Dependent Variable	xxxx	Total Progression Free Survival (Months)
Censoring Variable	xxxx	Censor
Censoring Value(s)	0	
Ties Handling	BRESLOW	

Number of Observations Read	xxx
Number of Observations Used	xxx

Summary of the Number of Event and Censored Values

Total	Event	Censored	Percent Censored
xxx	xx	xx	xx.xx

Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Without Covariates	With Covariates
-2 LOG L	xxxx.xxx	xxxx.xxx
AIC	xxxx.xxx	xxxx.xxx
SBC	xxxx.xxx	xxxx.xxx

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	xx.xxxx	xx	x.xxxx
Score	xx.xxxx	xx	x.xxxx
Wald	xx.xxxx	xx	x.xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 30. Analysis of Secondary Endpoint: Predictive factors of Total Progression Free Survival

POPULATION: ITT

The PHREG Procedure

Analysis of Maximum Likelihood Estimates

Parameter	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Confidence Interval Lower	Upper
VAR1	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR2	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR3	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR4	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
…								
VARn	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx

Note for programming:

List of predictive factors to be included in the Cox's model:

a) Treatment sequence assigned: Arm A, Arm B, Arm C;
b) Age (years): continuous variable;
c) Gender: Male and Female;
d) Melanoma Type: Cutaneous, Mucosal, Ocular;
e) Stage at current diagnosis: IIIa, IIIb, IIIc, IV – M1a, IV – M1b, IV – M1c;
f) Baseline LDH level: continuous variable;
g) ECOG PS at baseline: 0, ≥1;

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 31. Analysis of Secondary Endpoint: 3-years Progression Free Survival Rate (PFSR)

POPULATION: ITT

Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
3-years PFSR [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]

Notes:
The PFSR at 3 years was estimated by the Kaplan-Meier method.
The 95% CIs for the PFSR were estimated using Greenwood's estimate of the standard error and a linear transformation of the PFS function.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 32. Analysis of Secondary Endpoint: Percentage of patients alive at 2 and 3 years

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Patients alive at 2 years	n (%) [95% CI]	xxx (xx.x) [xx.x;xx.x]	xxx (xx.x) [xx.x;xx.x]	xxx (xx.x) [xx.x;xx.x]
Patients alive at 3 years	n (%) [95% CI]	xxx (xx.x) [xx.x;xx.x]	xxx (xx.x) [xx.x;xx.x]	xxx (xx.x) [xx.x;xx.x]

Notes:
The 95% CIs were calculated using Wilson Score method.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: use the "binomial(Wilson)" option in FREQ procedure>

TABLE 33. Analysis of secondary endpoint: Best Overall Response (BOR) and Overall Response Rate (ORR)

POPULATION: ITT

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Best Overall Response (*)				
PD	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SD	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PR	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CR	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Overall Response Rate (°)	% [95% CI]	xx.x%[xx.x-xx.x]	xx.x%[xx.x-xx.x]	xx.x%[xx.x-xx.x]

Note:
Percentages are calculated relative to the total number of patients in the ITT population by treatment arm.
(*) Best overall response from the date of randomization to the date of objectively documented progression per RECIST version 1.1 criteria.
(°) Overall Response Rate is the percentage of patients with CR or PR before any evidence of progression per RECIST version 1.1 criteria. 95% CI was derived using Wilson Score interval.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 34. Analysis of Secondary Endpoint: Summary of Duration of Response (DoR)

POPULATION: ITT

		Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Duration of Response (months)		25th [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
		Median [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
		95th [95% CI]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]	xx.x [xx.x;xx.x]
Number of patients	Events	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Censored	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes:
Duration of Response (DoR) is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer;
DoR (months) = [(Date of first documented progression/death due to underlying cancer or date of last tumor assessment – date of first CR or PR +1)]/30.4.
If a patient with a CR or PR has no progression or death due to underlying cancer, the patient is censored at the date of last adequate tumor assessment.
Percentages are calculated relative to the total number of the patients in the ITT set by treatment arm.
DoR (months) will be estimated using Kaplan-Meier method.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 34. Analysis of Secondary Endpoint: Summary of Duration of Response (DoR) (cont.)

POPULATION: ITT

Arm A

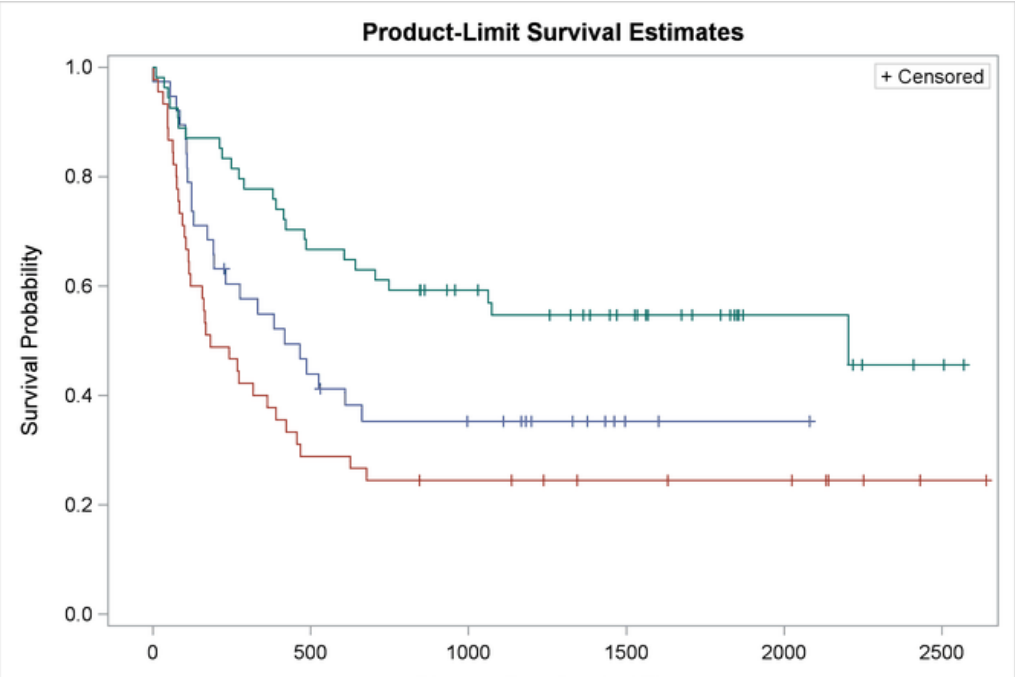
Time Interval (months)	Censoring Indicator	Survival Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	Number Left	SDF Lower 95% Confidence Limit	SDF Upper 95% Confidence Limit
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx
x.xxxx	x	x.xxxx	x	x	x	xx	x.xxxx	x.xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: This must be produced for each arm separately>

TABLE 34. Analysis of Secondary Endpoint: Summary of Duration of Response (DoR) (cont.)

POPULATION: ITT



Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 35. Analysis of Secondary Endpoint: Predictive factors of Duration of Response

POPULATION: ITT

The PHREG Procedure

Model Information

Data Set	xxxx	
Dependent Variable	xxxx	Duration of Response (Months)
Censoring Variable	xxxx	Censor
Censoring Value(s)	0	
Ties Handling	BRESLOW	

Number of Observations Read	xxx
Number of Observations Used	xxx

Summary of the Number of Event and Censored Values

Total	Event	Censored	Percent Censored
xxx	xx	xx	xx.xx

Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Without Covariates	With Covariates
-2 LOG L	xxxx.xxx	xxxx.xxx
AIC	xxxx.xxx	xxxx.xxx
SBC	xxxx.xxx	xxxx.xxx

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	xx.xxxx	xx	x.xxxx
Score	xx.xxxx	xx	x.xxxx
Wald	xx.xxxx	xx	x.xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

Table 35. Analysis of Secondary Endpoint: Predictive factors of Duration of Response

POPULATION: ITT

The PHREG Procedure

Analysis of Maximum Likelihood Estimates

Parameter	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Confidence Interval Lower	Upper
VAR1	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR2	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR3	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
VAR4	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx
…								
VARn	x	x.xxxxx	x.xxxxx	x.xxxx	x.xxxx	x.xxx	x.xxx	x.xxx

Note for programming:

List of predictive factors to be included in the Cox's model:

a) Treatment sequence assigned: Arm A, Arm B, Arm C;
b) Age (years): continuous variable;
c) Gender: Male and Female;
d) Melanoma Type: Cutaneous, Mucosal, Ocular;
e) Stage at current diagnosis: IIIa, IIIb, IIIc, IV – M1a, IV – M1b, IV – M1c;
f) Baseline LDH level: continuous variable;
g) ECOG PS at baseline: 0, ≥1;

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 36. Analysis of Secondary Endpoint: Change from baseline of Health-Related Quality of Life (HRQoL) by means of EORTC-QLQ-C30 – ARM A

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the EORTC-QLQ-C30 >**

	Statistic	Value	Change from Baseline (*)
Global Health Status / QoL			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 37. Analysis of Secondary Endpoint: Change from baseline of Health-Related Quality of Life (HRQoL) by means of EORTC-QLQ-C30 – ARM B

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the EORTC-QLQ-C30 >**

	Statistic	Value	Change from Baseline (*)
Global Health Status / QoL			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 38. Analysis of Secondary Endpoint: Change from baseline of Health-Related Quality of Life (HRQoL) by means of EORTC-QLQ-C30 – ARM C

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the EORTC-QLQ-C30 >**

	Statistic	Value	Change from Baseline (*)
Global Health Status / QoL			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:

(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 38. Analysis of Secondary Endpoint: Change from baseline of Health-Related Quality of Life (HRQoL) by means of EORTC-QLQ-C30 – ARM C (cont.)

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the EORTC-QLQ-C30 >**

	Statistic	Value	Change from Baseline (*)
Global Health Status / QoL			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 39. Analysis of Secondary Endpoint: Change from baseline of EQ-5D-5L by means of EQ-5D index – ARM A

POPULATION: ITT

	Statistic	Value	Change from Baseline (*)
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week <*Every 4 wks*> – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week <*Every 3 wks x 4 times*> – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week <*Every 4 wks*> – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 40. Analysis of Secondary Endpoint: Change from baseline of EQ-5D-5L by means of EQ-5D index – ARM B

POPULATION: ITT

	Statistic	Value	Change from Baseline (*)
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 41. Analysis of Secondary Endpoint: Change from baseline of EQ-5D-5L by means of EQ-5D index – ARM C

POPULATION: ITT

	Statistic	Value	Change from Baseline (*)
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:

(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 41. Analysis of Secondary Endpoint: Change from baseline of Health-Related Quality of Life (HRQoL) by means of EORTC-QLQ-C30 – ARM C (cont.)

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the EORTC-QLQ-C30 >**

	Statistic	Value	Change from Baseline (*)
Global Health Status / QoL			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 42. Analysis of Secondary Endpoint: Change from baseline of Impairment of work productivity and activity by means of WPAI:GH – ARM A

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the WPAI:GH >**

	Statistic	Value	Change from Baseline (*)
Percent work time missed due to health			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:

(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 43. Analysis of Secondary Endpoint: Change from baseline of Impairment of work productivity and activity by means of WPAI:GH – ARM B

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the WPAI:GH >**

	Statistic	Value	Change from Baseline (*)
Percent work time missed due to health			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 44. Analysis of Secondary Endpoint: Change from baseline of Impairment of work productivity and activity by means of WPAI:GH – ARM C

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the WPAI:GH >**

	Statistic	Value	Change from Baseline (*)
Percent work time missed due to health			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 4 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x

	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

Table 44. Analysis of Secondary Endpoint: Change from baseline of Impairment of work productivity and activity by means of WPAI:GH – ARM C (cont.)

POPULATION: ITT **< Note for SAS Programmer: the following must be presented for each scale of the WPAI:GH >**

	Statistic	Value	Change from Baseline (*)
Percent work time missed due to health			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 45. Summary of adverse events

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
Number of AEs	n	xx	xx	xx
Number of non-serious AEs	n	xx	xx	xx
Number of AEs related to Ipilimumab	n	xx	xx	xx
Number of AEs related to Nivolumab	n	xx	xx	xx
Number of AEs related to Combo Immuno Therapy	n	xx	xx	xx
Number of AEs related to LGX818	n	xx	xx	xx
Number of AEs related to MEK162	n	xx	xx	xx
Number of AEs related to Combo Target Therapy	n	xx	xx	xx
Number of serious AEs (SAE)	n	xx	xx	xx
Number of SAEs related to Ipilimumab	n	xx	xx	xx
Number of SAEs related to Nivolumab	n	xx	xx	xx
Number of SAEs related to Combo Immuno Therapy	n	xx	xx	xx
Number of SAEs related to Combo LGX818	n	xx	xx	xx
Number of SAEs related to Combo MEK162	n	xx	xx	xx
Number of SAEs related to Combo Target Therapy	n	xx	xx	xx
Number of AEs leading to hospitalization	n	xx	xx	xx
Number of AEs leading to death	n	xx	xx	xx
Number of AEs leading to withdrawal from the study	n	xx	xx	xx
Number of AEs of special interest (AESI)	n	xx	xx	xx
Number of Patients with at Least One AE	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One non-serious AE	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE related to Ipilimumab	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE related to Nivolumab	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE related to Combo Immuno Therapy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE related to LGX818	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE related to MEK162	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE related to Combo Target Therapy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One serious AE (SAE)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One SAE related to Ipilimumab	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One SAE related to Nivolumab	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One SAE related to Combo Immuno Therapy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One SAE related to Combo LGX818	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One SAE related to Combo MEK162	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One SAE related to Combo Target Therapy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE leading to hospitalization	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AE leading to withdrawal from the study	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One AESI	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: a) Percentages are calculated relative to the total number of patients in the SAF population by treatment arm.
b) An AE is defined as "related" to a study drug if relationship is "Certain", "Probable" or "Possible" to that specific drug. Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 46. Incidence of AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version 20.0.
d) n = number of patients, E = number of events.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 47. Incidence of Ipilimumab-related AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is “related” to a study drug if relationship is “Certain”, “Probable” or “Possible”. Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 48. Incidence of Nivolumab-related AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is “related” to a study drug if relationship is “Certain”, “Probable” or “Possible”. Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 49. Incidence of Combo Immuno Therapy-related AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is "related" to a study drug if relationship is "Certain", "Probable" or "Possible". Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 50. Incidence of LGX818-related AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is “related” to a study drug if relationship is “Certain”, “Probable” or “Possible”. Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 51. Incidence of MEK162-related AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is “related” to a study drug if relationship is “Certain”, “Probable” or “Possible”. Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 52. Incidence of Combo Target Therapy-related AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is “related” to a study drug if relationship is “Certain”, “Probable” or “Possible”. Missing data were considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 53. Incidence of Serious AEs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 54. Incidence of AEs leading to hospitalization by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 55. Incidence of AEs leading to study withdrawal by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.
e) An AE is “related” to a study drug if relationship is “Certain”, “Probable” or “Possible”. Missing data have been considered as Related.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 56. Incidence of AESIs by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 57. Incidence of AEs leading to death by primary System Organ Class and Preferred Term

POPULATION: SAF

	Statistic	Arm A (N = XX)	Arm B (N = XX)	Arm C (N = XX)
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<Primary SOC>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
<PT>	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: a) Percentages are calculated relative to the total number of patients in the SAF Population by treatment arm.
b) Each patient is counted at most once within each SOC and PT.
c) AEs were coded using MedDRA version XX.X.
d) n = number of patients, E = number of events.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 58. Hematology – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each hematology parameter >**

	Statistic	Value	Change from Baseline (*)
Hemoglobin			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 59. Hematology – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each hematology parameter >**

	Statistic	Value	Change from Baseline (*)
Hemoglobin			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 60. Hematology – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each hematology parameter >**

	Statistic	Value	Change from Baseline (*)
Hemoglobin			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx

	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 60. Hematology – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each hematology parameter >**

	Statistic	Value	Change from Baseline (*)
Hemoglobin			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 61. Blood chemistry – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each blood chemistry parameter >**

	Statistic	Value	Change from Baseline (*)
Glucose			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 62. Blood Chemistry – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each blood chemistry parameter >**

	Statistic	Value	Change from Baseline (*)
Glucose			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 63. Blood Chemistry – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each blood chemistry parameter >**

	Statistic	Value	Change from Baseline (*)
Glucose			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 63. Blood Chemistry – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each blood chemistry parameter >**

	Statistic	Value	Change from Baseline (*)
Glucose			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 64. Coagulation – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each coagulation parameter >**

	Statistic	Value	Change from Baseline (*)
INR			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 65. Coagulation – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each coagulation parameter >**

	Statistic	Value	Change from Baseline (*)
INR			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 66. Coagulation – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each coagulation parameter >**

	Statistic	Value	Change from Baseline (*)
INR			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx

	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 66. Coagulation – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each coagulation parameter >**

	Statistic	Value	Change from Baseline (*)
INR			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 67. Thyroid function test – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each thyroid function parameter >**

	Statistic	Value	Change from Baseline (*)
TSH			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 68. Thyroid function test – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each thyroid function parameter >**

	Statistic	Value	Change from Baseline (*)
TSH			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 69. Thyroid function test – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each thyroid function parameter >**

	Statistic	Value	Change from Baseline (*)
TSH			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 69. Thyroid function test – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each thyroid function parameter >**

	Statistic	Value	Change from Baseline (*)
TSH			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 70. Cardiac Muscle Enzymes – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each cardiac muscle enzymes >**

	Statistic	Value	Change from Baseline (*)
Creatine Kinase			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 71. Cardiac Muscle Enzymes – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each cardiac muscle enzymes >**

	Statistic	Value	Change from Baseline (*)
Creatine Kinase			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 72. Cardiac Muscle Enzymes – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each cardiac muscle enzymes >**

	Statistic	Value	Change from Baseline (*)
Creatine Kinase			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx

	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 72. Cardiac Muscle Enzymes – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each cardiac muscle enzymes >**

	Statistic	Value	Change from Baseline (*)
Creatine Kinase			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 73. Endocrine Panel – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for Total Cortisol as well >**

	Statistic	Value	Change from Baseline (*)
ACTH			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 74. Endocrine Panel – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for Total Cortisol as well >**

	Statistic	Value	Change from Baseline (*)
ACTH			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 75. Endocrine Panel – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for Total Cortisol as well >**

	Statistic	Value	Change from Baseline (*)
ACTH			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 76. Urinalysis (categorical parameters – Part I) – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for protein, blood, bilirubin, ketones, leukocytes as well >**

	Statistic	Arm A (N=XX)
Glucose		
Baseline 1		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 4 wks>* – Combo Target		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Baseline 2		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 2 wks>* – Nivolumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM A in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 76. Urinalysis (categorical parameters – Part I) – ARM A (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for protein, blood, bilirubin, ketones, leukocytes as well >**

	Statistic	Arm A (N=XX)
End of Treatment		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Follow-up		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM A in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 77. Urinalysis (categorical parameters – Part I) – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for protein, blood, bilirubin, ketones, leukocytes as well >**

	Statistic	Arm B (N=XX)
Glucose		
Baseline 1		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 2 wks>* – Nivolumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Baseline 2		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 4 wks>* – Combo Target		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM B in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 77. Urinalysis (categorical parameters – Part I) – ARM B (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for protein, blood, bilirubin, ketones, leukocytes as well >**

	Statistic	Arm B (N=XX)
End of Treatment		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Follow-up		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM B in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 78. Urinalysis (categorical parameters – Part I) – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for protein, blood, bilirubin, ketones, leukocytes as well >**

	Statistic	Arm C (N=XX)
Glucose		
Baseline 1		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Day 1 – Combo Target		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week 4 – Combo Target		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Baseline 2		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM C in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 78. Urinalysis (categorical parameters – Part I) – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for protein, blood, bilirubin, ketones, leukocytes as well >**

	Statistic	Arm C (N=XX)
Glucose		
Week *<Every 2 wks>* – Nivolumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Baseline 3		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Week *<Every 4 wks>* – Combo Target		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
End of Treatment		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)
Follow-up		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)
4+	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM C in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 79. Urinalysis (categorical parameters – Part II) – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Arm A (N=XX)
UWBC/HPF		
Baseline 1		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 4 wks>* – Combo Target		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Baseline 2		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 2 wks>* – Nivolumab		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
End of Treatment		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Follow-up		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM A in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 80. Urinalysis (categorical parameters – Part II) – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Arm B (N=XX)
UWBC/HPF		
Baseline 1		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab		
Neg	n (%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)
Week *<Every 2 wks>* – Nivolumab		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Baseline 2		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 4 wks>* – Combo Target		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
End of Treatment		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Follow-up		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM B in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 81. Urinalysis (categorical parameters – Part II) – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Arm C (N=XX)
UWBC/HPF		
Baseline 1		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Day 1 – Combo Target		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week 4 – Combo Target		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Baseline 2		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 2 wks>* – Nivolumab		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Baseline 3		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Week *<Every 4 wks>* – Combo Target		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
End of Treatment		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)
Follow-up		
Not present	n (%)	xx (xx.x%)
Present	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM C in the SAF set.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 82. Urinalysis (continuous parameters) – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for continuous values of URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Value	Change from Baseline (*)
UWBC/HPF			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:

(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 83. Urinalysis (continuous parameters) - ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for continuous values of URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Value	Change from Baseline (*)
UWBC/HPF			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* - Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* - Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* - Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:

(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 84. Urinalysis (continuous parameters) – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for continuous values of URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Value	Change from Baseline (*)
UWBC/HPF			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x

	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 84. Urinalysis (continuous parameters) – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for continuous values of URBC/HPF, Casts/LPF, Bacteria, Other as well >**

	Statistic	Value	Change from Baseline (*)
UWBC/HPF			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 85. ECG Parameters – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for QT, QRS, QTcB, cardfiac axis, Ejection Fraction value as well >**

	Statistic	Value	Change from Baseline (*)
PR interval (ms)			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 12 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *4* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 12 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 86. ECG Parameters - ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for QT, QRS, QTcB, cardfiac axis, Ejection Fraction value as well >**

	Statistic	Value	Change from Baseline (*)
PR interval (ms)			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week 4 – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 12 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 12 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 87. ECG Parameters – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for continuous values of URBC/HPF, Bacteria, Other as well >**

	Statistic	Value	Change from Baseline (*)
PR interval (ms)			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week 4 – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 12 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 12 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 88. Cardiological Assessments – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each visit during the study >**

	Statistic	Arm A (N=XX)
<Visit n>		
ECG Result		
Normal	n (%)	xx (xx.x%)
Abnormal	n (%)	xx (xx.x%)
Interpretation of abnormality (*)		
Not clinically significant	n (%)	xx (xx.x%)
Clinically significant	n (%)	xx (xx.x%)
Type of LVEF scan		
ECHO	n (%)	xx (xx.x%)
MUGA	n (%)	xx (xx.x%)
Interpretation of ECHO/MUGA scan		
Normal	n (%)	xx (xx.x%)
Abnormal, NCS	n (%)	xx (xx.x%)
Normal, CS	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM A in the SAF set.
(*) Percentages are calculated relative to the total number of patients of ARM A in the SAF set with abnormal ECG.
NCS = Not Clinically Significant; CS = Clinically Significant.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 89. Cardiological Assessments – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each visit during the study >**

	Statistic	Arm B (N=XX)
<Visit n>		
ECG Result		
Normal	n (%)	xx (xx.x%)
Abnormal	n (%)	xx (xx.x%)
Interpretation of abnormality (*)		
Not clinically significant	n (%)	xx (xx.x%)
Clinically significant	n (%)	xx (xx.x%)
Type of LVEF scan		
ECHO	n (%)	xx (xx.x%)
MUGA	n (%)	xx (xx.x%)
Interpretation of ECHO/MUGA scan		
Normal	n (%)	xx (xx.x%)
Abnormal, NCS	n (%)	xx (xx.x%)
Normal, CS	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM B in the SAF set.
(*) Percentages are calculated relative to the total number of patients of ARM B in the SAF set with abnormal ECG.
NCS = Not Clinically Significant; CS = Clinically Significant.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 90. Cardiological Assessments – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each visit during the study >**

	Statistic	Arm C (N=XX)
<Visit n>		
ECG Result		
Normal	n (%)	xx (xx.x%)
Abnormal	n (%)	xx (xx.x%)
Interpretation of abnormality (*)		
Not clinically significant	n (%)	xx (xx.x%)
Clinically significant	n (%)	xx (xx.x%)
Type of LVEF scan		
ECHO	n (%)	xx (xx.x%)
MUGA	n (%)	xx (xx.x%)
Interpretation of ECHO/MUGA scan		
Normal	n (%)	xx (xx.x%)
Abnormal, NCS	n (%)	xx (xx.x%)
Normal, CS	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM C in the SAF set.
(*) Percentages are calculated relative to the total number of patients of ARM C in the SAF set with abnormal ECG.
NCS = Not Clinically Significant; CS = Clinically Significant.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 91. Vital signs – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each vital sign >**

	Statistic	Value	Change from Baseline (*)
Body weight (Kg)			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 92. Vital signs – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each vital sign >**

	Statistic	Value	Change from Baseline (*)
Body weight (Kg)			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values after Baseline 2. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.

n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 93. Vital signs – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each vital sign >**

	Statistic	Value	Change from Baseline (*)
Body weight (Kg)			
Baseline 1	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Day 1 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4 – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 2	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 3 wks x 4 times>* – Nivolumab + Ipilimumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week *<Every 2 wks>* – Nivolumab	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Baseline 3	n	xx	
	Mean (SD)	xx.x (x.x)	
	Median	xx.x	
	Min/Max	xx/xx	
Week *<Every 4 wks>* – Combo Target	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 93. Vital signs – ARM C (cont.)

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each vital sign >**

	Statistic	Value	Change from Baseline (*)
Body weight (Kg)			
End of Treatment	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Follow-up	n	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Notes:
(*) Change from baseline is calculated relative to Baseline 1 for values between Baseline 1 and Baseline 2; Baseline 2 for values between Baseline 2 and Baseline 3; Baseline 3 for values after Baseline 3. Change from baseline values include only those patients with both a Baseline value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 94. Ophthalmological Examinations during the study

POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline 1				
Ophthalmological examination performed?				
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Applicable	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Eye(s) assessed (*)				
Left Eye	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Right Eye	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Both	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Baseline 2				
Ophthalmological examination performed?				
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Applicable	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Eye(s) assessed (*)				
Left Eye	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Right Eye	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Both	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Baseline 3				
Ophthalmological examination performed?				
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Applicable	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Eye(s) assessed (*)				
Left Eye	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Right Eye	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Both	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the SAF set by treatment arm.
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 95. Visual Acuity during the study

POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline 1				
Visual Acuity assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Total Visual Acuity Score (ETDRS) - Left Eye (OS)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity Score (ETDRS) - Right Eye (OD)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity snelles equivalent - Left Eye (OS)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity snelles equivalent - Right Eye (OD)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Baseline 2				
Visual Acuity assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Total Visual Acuity Score (ETDRS) - Left Eye (OS)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity Score (ETDRS) - Right Eye (OD)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity snelles equivalent - Left Eye (OS)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx

Total Visual Acuity snelles equivalent – Right Eye (OD)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

Table 95. Visual Acuity during the study (cont.)

POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline 3				
Visual Acuity assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Total Visual Acuity Score (ETDRS) - Left Eye (OS)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity Score (ETDRS) - Right Eye (OD)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity snelles equivalent - Left Eye (OS)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Total Visual Acuity snelles equivalent - Right Eye (OD)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 96. Intraocular pressure during the study

POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline 1				
Intraocular Pressure Assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Intraocular pressure – Left Eye (OS) (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Intraocular pressure – Right Eye (OD) (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Baseline 2				
Intraocular Pressure Assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Intraocular pressure – Left Eye (OS) (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Intraocular pressure – Right Eye (OD) (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Baseline 3				
Intraocular Pressure Assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Intraocular pressure – Left Eye (OS) (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx
Intraocular pressure – Right Eye (OD) (mmHg)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Min/Max	xx/xx	xx/xx	xx/xx

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 97. Dilated fundoscopy during the study

POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline <N>				
Dilated fundoscopy Assessed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Eye(s) assessed (#)				
Left Eye	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Right Eye	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Both	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Right Eye assessment (§)				
Viterous				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Retina				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Macula				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Choroid				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Optic nerve pallor				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Other				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
(#) Percentages are calculated relative to the total number of patients in the SAF set for whom dilated fundoscopy was assessed by treatment arm.
(§) Percentages are calculated relative to the total number of patients in the SAF set for whom assessment was done on right eye by treatment arm.
(^) Percentages are calculated relative to the total number of patients in the SAF set for whom assessment was done on left eye by treatment arm.

Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: in this table data from all baseline visits must be reported >

Table 97. Dilated fundoscopy during the study (cont.)
POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline <N>				
Left Eye assessment (^)				
Viterous				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Retina				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Macula				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Choroid				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Optic nerve pallor				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Other				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
(#) Percentages are calculated relative to the total number of patients in the SAF set for whom dilated fundoscopy was assessed by treatment arm.
(§) Percentages are calculated relative to the total number of patients in the SAF set for whom assessment was done on right eye by treatment arm.
(^) Percentages are calculated relative to the total number of patients in the SAF set for whom assessment was done on left eye by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: in this table data from all baseline visits must be reported >

TABLE 98. Slit lamp examination during the study
POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline <N>				
Slit lamp examination performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Eye(s) assessed (#)				
Left Eye	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Right Eye	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Both	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Right Eye assessment (§)				
Lids/lashes				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Cornea				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Conjunctiva				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Iris				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Lens				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Anterior chamber				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Other				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
(#) Percentages are calculated relative to the total number of patients in the SAF set for whom dilated fundoscopy was assessed by treatment arm.

(§) Percentages are calculated relative to the total number of patients in the SAF set for whom assessment was done on right eye by treatment arm.
(^) Percentages are calculated relative to the total number of patients in the SAF set for whom assessment was done on left eye by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: in this table data from all baseline visits must be reported >

Table 98. Slit lamp examination during the study (cont.)
POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline <N>				
Left Eye assessment (^)				
Lids/lashes				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Cornea				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Conjunctiva				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Iris				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Lens				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Anterior chamber				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Other				
Normal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormal	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
(#) Percentages are calculated relative to the total number of patients in the SAF set for whom slit lamp examination was performed by treatment arm.
(§) Percentages are calculated relative to the total number of patients in the SAF set for whom esamination was done on right eye by treatment arm.
(^) Percentages are calculated relative to the total number of patients in the SAF set for whom esamination was done on left eye by treatment arm.
Baseline 3 is applicable to Arm C only.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: in this table data from all baseline visits must be reported >

TABLE 99. Visual field testing and optical coherence tomography during the study
POPULATION: SAF

	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline 1				
Visual field testing performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormalities? (§)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Optical coherence tomography performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormalities? (#)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Baseline 2				
Visual field testing performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormalities? (§)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Optical coherence tomography performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormalities? (#)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Baseline 3				
Visual field testing performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Abnormalities? (§)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Optical coherence tomography performed (*)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)

Abnormalities? (#)				
No	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)
Yes	n (%)	xx (xx.x%)	x (xx.x%)	x (xx.x%)

Notes:
(*) Percentages are calculated relative to the total number of patients in the SAF set who performed the ophthalmological examination by treatment arm.
(§) Percentages are calculated relative to the total number of patients in the SAF set who performed the visual field testing by treatment arm.
(#) Percentages are calculated relative to the total number of patients in the SAF set who performed the optical coherence tomography by treatment arm.
Baseline 3 is applicable to Arm C only.
Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 100. Dermatological examination during the study – ARM A

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each visit: Baseline 1, Q8W, Baseline 2, Q8W >**

	Statistic	Arm A (N=XX)
<Visit n>		
Dermatological Examination performed		
No	n (%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)
Result (*)		
Normal	n (%)	xx (xx.x%)
Abnormal	n (%)	xx (xx.x%)
Diagnosis (§)		
Squamous cell carcinoma	n (%)	xx (xx.x%)
Keratoacanthomas	n (%)	xx (xx.x%)
Other pathology findings	n (%)	xx (xx.x%)
Evidence of severe or uncontrolled systemic disease or concurrent undesirable condition		
No	n (%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM A in the SAF set.
(*) Percentages are calculated relative to the total number of patients of ARM A in the SAF set who performed the dermatological examination.
(§) Percentages are calculated relative to the total number of patients of ARM A in the SAF set who resulted abnormal.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 101. Dermatological examination during the study – ARM B

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each visit: Baseline 1, Q8W, Baseline 2, Q8W >**

	Statistic	Arm B (N=XX)
<Visit n>		
Dermatological Examination performed		
No	n (%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)
Result (*)		
Normal	n (%)	xx (xx.x%)
Abnormal	n (%)	xx (xx.x%)
Diagnosis (§)		
Squamous cell carcinoma	n (%)	xx (xx.x%)
Keratoacanthomas	n (%)	xx (xx.x%)
Other pathology findings	n (%)	xx (xx.x%)
Evidence of severe or uncontrolled systemic disease or concurrent undesirable condition		
No	n (%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM B in the SAF set.
(*) Percentages are calculated relative to the total number of patients of ARM B in the SAF set who performed the dermatological examination.
(§) Percentages are calculated relative to the total number of patients of ARM B in the SAF set who resulted abnormal.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 102. Dermatological examination during the study – ARM C

POPULATION: SAF **< Note for SAS Programmer: the following must be presented for each visit: Baseline 1, Baseline 2, Q8W, Baseline 3>**

	Statistic	Arm C (N=XX)
<Visit n>		
Dermatological Examination performed		
No	n (%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)
Result (*)		
Normal	n (%)	xx (xx.x%)
Abnormal	n (%)	xx (xx.x%)
Diagnosis (§)		
Squamous cell carcinoma	n (%)	xx (xx.x%)
Keratoacanthomas	n (%)	xx (xx.x%)
Other pathology findings	n (%)	xx (xx.x%)
Evidence of severe or uncontrolled systemic disease or concurrent undesirable condition		
No	n (%)	xx (xx.x%)
Yes	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of ARM C in the SAF set.
(*) Percentages are calculated relative to the total number of patients of ARM C in the SAF set who performed the dermatological examination.
(§) Percentages are calculated relative to the total number of patients of ARM C in the SAF set who resulted abnormal.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 103. Performance Status during the study – ARM A

POPULATION: SAF

ECOG PS	Statistic	Arm A (N=XX)
<Visit n>		
0	n (%)	xx (xx.x%)
1	n (%)	xx (xx.x%)
2	n (%)	xx (xx.x%)
3	n (%)	xx (xx.x%)
4	n (%)	xx (xx.x%)
5	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of the SAF set in the ARM A.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: In this table ECOG PS at all visits must be reported.>

TABLE 104. Performance Status during the study – ARM B

POPULATION: SAF

ECOG PS	Statistic	Arm B (N=XX)
<Visit n>		
0	n (%)	xx (xx.x%)
1	n (%)	xx (xx.x%)
2	n (%)	xx (xx.x%)
3	n (%)	xx (xx.x%)
4	n (%)	xx (xx.x%)
5	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of the SAF set in the ARM B.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: In this table ECOG PS at all visits must be reported.>

TABLE 105. Performance Status during the study – ARM C

POPULATION: SAF

ECOG PS	Statistic	Arm C (N=XX)
<Visit n>		
0	n (%)	xx (xx.x%)
1	n (%)	xx (xx.x%)
2	n (%)	xx (xx.x%)
3	n (%)	xx (xx.x%)
4	n (%)	xx (xx.x%)
5	n (%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients of the SAF set in the ARM C.

Source: XXXX.SAS, Run on DDMMMYYYY

< Note for SAS Programmer: In this table ECOG PS at all visits must be reported.>

TABLE 106. Pregnancy test during the study

POPULATION: SAF

ECOG PS	Statistic	Arm A (N=XX)	Arm B (N=XX)	Arm C (N=XX)
Baseline 1				
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Every 6 weeks>				
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Follow-up visit				
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Long-term follow-up visit				
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of female patients of the SAF set by treatment arm.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 1) Screening Failures

POPULATION: ENR

Site	Patient Number	Category	Criteria violated number	Criteria Description
XXX	XXXXXXXX	Inclusion/Exclusion	X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	XXXXXXXX	XXXXXXXX	X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	XXXXXXXX	XXXXXXXX	X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	XXXXXXXX	XXXXXXXX	X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 2) Inclusion Criteria

POPULATION: ENR

			Inclusion Criteria							
Treatment Arm	Site	Patient Number	#1	#2	#3	#4	#5	..	#14	#15
XXXXXXXX	XXX	XXXXXXXX	Y/N	X	X	X	X	X	X	X
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 3) Exclusion Criteria

POPULATION: ENR

			Exclusion Criteria							
Treatment Arm	Site	Patient Number	#1	#2	#3	#4	#5	..	#13	#14
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X
XXXXXXXX	XXX	XXXXXXXX	X	X	X	X	X	X	X	X

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 4) End of treatment

POPULATION: ENR

Site	Patient Number	Treatment Arm	Date of visit (DDMMMYYYY)	Date when the IMP was last taken (DDMMMYYYY)	Has the subject completed the trial?	Date of termination (DDMMMYYYY)	Date of withdrawal (DDMMMYYYY)	Primary reason for withdrawal	Please specify	If SAE was the reason for withdrawal, has it been reported to the Sponsor?
XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXXXXXX	XXX
XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXXXXXX	XXX
XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXXXXXX	XXX
XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXXXXXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 5) Analysis Sets

POPULATION: ENR

Site	Patient Number	Treatment Arm	Inclusion in ENR?	Inclusion in ITT?	Reason for exclusion from ITT	Inclusion in SAF?	Reason for exclusion from SAF	Inclusion in PP?	Reason for exclusion from PP
XXX	XXXXXXXX	XXXXXXXX	X	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX
XXX	XXXXXXXX	XXXXXXXX	X	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX
XXX	XXXXXXXX	XXXXXXXX	X	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX
XXX	XXXXXXXX	XXXXXXXX	X	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX	X	XXXXXXXXXXXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 6) Major Protocol Deviations

POPULATION: ENR

Site	Patient Number	Treatment Arm	Gender	Age (yrs)	Type	Description of major protocol deviation
XXX	XXXXXXXX	XXX	XXX	XXX	XXXXXXXXXXXX	XXXXXXXXXXX
XXX	XXXXXXXX	XXX	XXX	XXX	XXXXXXXXXXXX	XXXXXXXXXXX
XXX	XXXXXXXX	XXX	XXX	XXX	XXXXXXXXXXXX	XXXXXXXXXXX
XXX	XXXXXXXX	XXX	XXX	XXX	XXXXXXXXXXXX	XXXXXXXXXXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 7) Enrollment visit and signature of informed consent

POPULATION: ENR

Site	Patient Number	Treatment Arm	Date of enrollment visit (DDMMMYYYY)	Was informed consent obtained?	Date of signature of informed consent (DDMMMYYYY)	Was optional translational research informed consent obtained?	Date of signature of optional informed consent (DDMMMYYYY)
XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	DDMMMYYYY
XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	DDMMMYYYY
XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	DDMMMYYYY
XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	DDMMMYYYY

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 8) Demographic Characteristics

POPULATION: ITT

Treatment Arm	Site	Patient Number	Gender at birth	Year of birth (YYYY)	Derived Age (years)	Race	Ethnic origin	Weight (Kg)	Height (cm)	BMI (kg/m^2)
XXX	XXX	XXX	XXX	YYYY	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	YYYY	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	YYYY	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	YYYY	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 9) Disease History of Melanoma: Initial Diagnosis

POPULATION: ITT

Treatment Arm	Site	Patient Number	Melanoma Type	If mucosal specify primary site	If cutaneous, specify primary site	Melanoma Subtype	Date of first diagnosis of melanoma (DDMMMYYYY)	Time from first diagnosis of melanoma (months)	Stage at initial diagnosis
XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 10) Disease History of Melanoma: Current Diagnosis

POPULATION: ITT

Treatment Arm	Site	Patient Number	Stage at current diagnosis	Date of first recurrence/relapse (DDMMMYYYY)	Date of most recent recurrence/relapse (DDMMMMYYY)	Time from first recurrence/ relapse (months)	Time from most recent recurrence/ relapse (months)
XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 11) BRAF mutation testing and molecular status

POPULATION: ITT

Treatment Arm	Site	Patient Number	Date of assessment (DDMMMYYYY)	Molecular status (local) mutant	Type of mutation	If other, specify
XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 12) Childbearing potential status

POPULATION: ITT

Treatment Arm	Site	Patient Number	Childbearing potential / sexually active with women childbearing potential?	Is the subject post-menopausal?	Does the subject accept to use adequate contraception for the total study duration?
XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 13) HIV test at screening

POPULATION: ITT

Treatment Arm	Site	Patient Number	Has an HIV test been performed?	If not performed, specify reason	Date of HIV test (DDMMMYYYY)	HIV test result
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 14) Medical History: previous diseases

POPULATION: ITT

Treatment Arm	Site	Patient Number	Verbatim	SOC	Preferred Term	Start Date (DDMMMYYYY)	Stop Date (DDMMMYYYY)	Ongoing?	Under treatment?
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX

Note: Medical History: previous diseases were coded using the MedDRA Version XX.X.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 15) Medical History: concomitant diseases

POPULATION: ITT

Treatment Arm	Site	Patient Number	Verbatim	SOC	Preferred Term	Start Date (DDMMMYYYY)	Stop Date (DDMMMYYYY)	Ongoing?	Under treatment?
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX

Note: Medical History: concomitant diseases were coded using the MedDRA Version XX.X.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 16) Prior Systemic Treatments

POPULATION: ITT

Treatment Arm	Site	Patient Number	MED (#)	Type	Other, specify	Drug	Generic name	3rd level ATC subgroup	Dosage	Unit	Start Date (DDMMMYYYY)	Stop Date (DDMMMYYYY)	Ongoing
XXX	XXX	XXX	XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
XXX	XXX	XXX	XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
XXX	XXX	XXX	XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX

Note: Prior Systemic Treatments were coded using the WHO-DRL Version XXXX.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 17) Concomitant Systemic Treatments

POPULATION: ITT

Treatment Arm	Site	Patient Number	MED (#)	Type	Other, specify	Drug	Generic name	3rd level ATC subgroup	Dosage	Unit	Start Date (DDMMMYYYY)	Stop Date (DDMMMYYYY)	Ongoing
XXX	XXX	XXX	XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
XXX	XXX	XXX	XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX
XXX	XXX	XXX	XX	XXXXXX X	XXXXXXX	XXXXXX X	XXXXXXX	XXXXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX

Note: Concomitant Systemic Treatments were coded using the WHO-DRL Version XXXX.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 18) Prior Radiation Treatments

POPULATION: ITT

Treatment Arm	Site	Patient Number	MED (#)	Site	Generic name	3rd level ATC subgroup	Total cumulative dose (Gy)	Start Date of the last radiotherapy (DDMMMYYYY)	Stop Date of the last radiotherapy (DDMMMYYYY)	Purpose
XXX	XXX	XXX	XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
XXX	XXX	XXX	XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX
XXX	XXX	XXX	XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	DDMMMYYYY	XXX

Note: Prior Radiation Treatments were coded using the WHO-DRL Version XXXX.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 19) Prior melanoma-related surgery

POPULATION: ITT

Treatment Arm	Site	Patient Number	SURG (#)	Procedure	If other, specify	Anatomic Site involved	If other, specify	Generic name	3rd level ATC subgroup	Date of surgery (DDMMMYYYY)	Type of resection (if applicable)	Specify if remarkable comments
XXX	XXX	XXX	XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
			XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXX	XX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	XXXXXXX	DDMMMYYYY	XXX	XXX

Note: Prior melanoma-related surgery was coded using the WHO-DRL Version XXXX.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 20) Serum/urine pregnancy test

POPULATION: ITT

Treatment Arm	Site	Patient Number	Serum Pregnancy test performed?	If not performed, specify reason	Date of pregnancy test (DDMMMYYYY)	Beta Serum pregnancy test result (mIU/ml)	If abnormal, CS or NCS?	Urine pregnancy test result
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			Etc.					
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			Etc.					
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			Etc.					
XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
			Etc.					

Note: CS = Clinically Significant; NCS = Not Clinically Significant.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 21) Vital signs and ECOG PS

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	Vital signs measured?	If not, Reason	Date of assessment (DDMMMYYYY)	Supine SBP (mmHg)	Supine DBP (mmHg)	Heart Rate (bpm)	Cardiovascular signs/symptoms?	If yes, specify	Body temperature (°C)	Respiratory Rate (breaths/min)	ECOG PS
XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.											
XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.											
XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.											
XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.											

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 22) Physical Examination

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	Physical Examination performed?	If not performed, reason	Date of physical examination (DDMMMYYYY)	Body area	Examination finding	If abnormal, specify	SOC	Preferred Term
XXX	XXX	XXX	XXXXXXX	XXX	XXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
							XXX	XXX	XXX	XXX	XXX
							XXX	XXX	XXX	XXX	XXX
							XXX	XXX	XXX	XXX	XXX
			XXXXXXX	XXX	XXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
							XXX	XXX	XXX	XXX	XXX
							XXX	XXX	XXX	XXX	XXX
							XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXXXXXX	XXX	XXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX

Note: Physical Examination were coded using the MedDRA Version XX.X.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 23) Hematology

POPULATION: SAF

															SI	
Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Sample date (DDMMMYYYY)	Exam	Done?	Result	Unit	LLN	ULN	Normal reference	If abnormal, CS?	Result	Unit
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX Etc.	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX Etc.	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX Etc.	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX Etc.	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 24) Blood Chemistry

POPULATION: SAF

															SI	
Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Sample date (DDMMMYYYY)	Exam	Done?	Result	Unit	LLN	ULN	Normal reference	If abnormal, CS?	Result	Unit
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 25) Coagulation

POPULATION: SAF

															SI	
Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Sample date (DDMMMYYYY)	Exam	Done?	Result	Unit	LLN	ULN	Normal reference	If abnormal, CS?	Result	Unit
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 26) Urinalysis (dipstick analysis)

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Date of assessment (DDMMMYYYY)	Exam	Done?	Result	If abnormal, CS?
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 27) Microscopic analysis

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Date of assessment (DDMMMYYYY)	Exam	State	Value	If abnormal, CS?
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			Etc.							
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			Etc.							
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			Etc.							
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
			Etc.							

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 28) Thyroid Function Test

POPULATION: SAF

															SI	
Treatmen t Arm	Site	Patient Number	Visit	Sample collec ted?	If not, specify reason	Sample date (DDMMMYYYY)	Exa m	Done?	Result	Uni t	LLN	ULN	Normal referenc e	If abnormal , CS?	Result	Uni t
XXX	XXX	XXXXXXX X	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXX X	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXX X	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXX X	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 29) Cardiac Muscle Enzyme

POPULATION: SAF

															SI	
Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Sample date (DDMMMYYYY)	Exam	Done?	Result	Unit	LLN	ULN	Normal reference	If abnormal, CS?	Result	Unit
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 30) Endocrine Panel

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Sample collected?	If not, specify reason	Sample date (DDMMMYYYY)	Exam	Done?	Result	Unit	LLN	ULN	Normal reference	If abnormal, CS?	SI	
															Result	Unit
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			Etc.													

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 31) ECG

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Was ECG performed?	If not, specify reason	Date of assessment (DDMMMYYYY)	Result	If abnormal, NCS/CS	PR interval (ms)	QT interval (ms)	QRS interval (ms)	QTcB interval (ms)	Cardiac axis(°)
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 32) Left Ventricular Ejection Fraction

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Was the LVEF performed?	If not, specify reason	Date of scan (DDMMMYYYY)	Type of scan	Ejection Fraction Value (%)	Scan interpretation	Specify
XXX	XXX	XXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 33) Ophthalmological examination: Visual Acuity and Intraocular pressure

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Performed?	Eye(s) assessed?	Visual acuity assessed?	If not, reason	Total Visual Acuity Score (ETDRS) – Left Eye (OS)	Total Visual Acuity Score (ETDRS) – Right Eye (OD)	Total Visual Acuity snellens equivalent – Left Eye (OS)	Total Visual Acuity snellens equivalent – Right Eye (OD)	Intraocular pressure assessed?	Intraocular pressure – left eye (OS) (mmHg)	Intraocular pressure – Right Eye (OD) (mmHg)
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 34) Ophthalmological examination: Indirect Dilated Fundoscopy (ophthalmoscopy)

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Dilated fundoscopy performed?	If not, reason	Date of assessment (DDMMMYYYY)	Eye(s) assessed	Eye	Area	Done?	Assessment	If abnormal, specify
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Right	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Left	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 35) Ophthalmological examination: Slit Lamp Examination

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Slit lamp examination performed?	If not, reason	Date of assessment (DDMMMYYYY)	Eye(s) assessed	Eye	Area	Done?	Assessment	If abnormal, specify
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Right	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Left	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX
									XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 36) Ophthalmological examination: Visual Field testing and optical coherence tomography

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Visual Field Testing performed?	If not, reason	Date of test (DDMMMYYYY)	Are there any abnormalities?	If abnormal, specify	Optical coherence tomography performed?	If not, reason	Date of tomography (DDMMMYYYY)	Are there any abnormalities?	If abnormal, specify
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 37) Dermatological examination

POPULATION: SAF

Treatment Arm	Site	Patient Number	Visit	Dermatological examination performed?	If not, reason	Date of visit (DDMMMYYYY)	Result	Result abnormal, specify	Result abnormal, diagnosis	Evidence of severe or uncontrolled systemic disease or any concurrent condition
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 38) Work Productivity and Activity Impairment Questionnaire (WPAI:GH)

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	WPAI:GH questionnaire completed?	If not, reason	Date of visit (DDMMMYYYY)	Item #1	Item #2	..	Item #6	Percent work time missed due to health	Percent impairment while working due to health	Percent overall work impairment due to health	Percent activity impairment due to health
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 39) General Health status EQ-5D-5L

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	EQ-5D-5L questionnaire completed?	If not, reason	Date of visit (DDMMMYYYY)	Item #1	Item #2	..	Item #5	Health State	EQ-5D-5L index
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 40) Health-related quality of life EORTC QLQ-C30: items

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	EORTC-QLQ-C30 questionnaire completed?	If not, reason	Date of visit (DDMMMYYYY)	Item #1	Item #2	..	Item #30
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 41) Health-related quality of life EORTC QLQ-C30: scale scores

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	EORTC-QLQ-C30 questionnaire completed?	If not, reason	Date of visit (DDMMMYYYY)	QL2	PF2	..	FI
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 42) Admnistration with Investigational Products

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	IMP	IMP administered?	If not, reason	Date of dispensation (DDMMMYYYY)	Start therapy date (DDMMMYYYY)	End therapy date (DDMMMYYYY)	Dose	Unit	Administration	Reason for reduction/delay/definite interruption	Reduced dose
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
				XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
				XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
			XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
				XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 43) LGX818

POPULATION: ITT

Trt Arm	Site	Pt Nr.	Visit	Date of dispensation (DDMMMYYYY)	Batch #1 (50 mg)	Batch #2 (100 mg)	Batch #3 (100 mg)	Batch #4 (100 mg)	Batch #5 (100 mg)	Dose	Taken correctly?	If not, reason	Nr. of capsules returned
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 44) MEK162

POPULATION: ITT

Trt Arm	Site	Pt Nr.	Visit	Date of dispensation (DDMMMYYYY)	Batch #1 (15 mg)	Batch #2 (15 mg)	Batch #3 (15 mg)	Total Daily Dose	Taken correctly?	If not, reason	Nr. of capsules returned	Diary completed correctly and returned?
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 45) Nivolumab

POPULATION: ITT

Trt Arm	Site	Pt Nr.	Visit	Start therapy date (DDMMMYYYY)	Batch #1	Batch #2)	Dose (mg)	Total volume prepared (ml)	Total Volume infused (ml)	Infusion Start time (hh:mm)	Infusion End time (hh:mm)
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 46) Ipilimumab

POPULATION: ITT

Trt Arm	Site	Pt Nr.	Visit	Start therapy date (DDMMMYYYY)	Batch #1	Batch #2)	Dose (mg)	Total volume prepared (ml)	Total Volume infused (ml)	Infusion Start time (hh:mm)	Infusion End time (hh:mm)
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
			XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
				DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 47) Duration of exposure to IMPs and compliance

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	Overall duration of exposure to study drugs (weeks)	Duration of exposure to LGX818 (weeks)	Duration of exposure to MEK162 (weeks)	Duration of exposure to Nivolumab (weeks)	Duration of exposure to Ipilimumab (weeks)	Compliance to LGX818 (%)	Compliance to MEK162 (%)
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 48) Tumor assessment: target lesions

POPULATION: ITT

Treatment Arm	Site	Patient Number	TA #	Date of assessment (DDMMMYYYY)	Organ Site	If other, specify	Location of lesion	Method of assessment	Longest diameter (mm)	Shortest diameter (mm)
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXX X	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 49) Tumor assessment: non-target lesion

POPULATION: ITT

Treatment Arm	Site	Patient Number	TA #	Date of assessment (DDMMMYYYY)	Organ Site	If other, specify	Location of lesion	Method of assessment	If other, specify	Status
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXX	DDMMMYYYY	XXXXXXXX	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 50) Tumor assessment: tumor response according to RECIST criteria v.1.1

POPULATION: ITT

Treatment Arm	Site	Patient Number	Visit	Date of assessment (DDMMMYYYY)	Sum of Target lesions (mm)	Target lesions	Non-target lesions	New lesions	Overall response
XXX	XXX	XXXXXXXX	XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
			XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
			XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
			XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
			XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	XXXXXXXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 51) Overall survival

POPULATION: ITT

Treatment Arm	Site	Patient Number	Date of randomization (DDMMMYYYY)	Date of death from any cause / last contact date (DDMMMYYYY)	Censoring (0=censored, 1=event)	OS (months)	Alive at 2 years (Yes/No)	Alive at 3 years (Yes/No)
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 52) Total progression free survival, 3-years PFS and BORR

POPULATION: ITT

Treatment Arm	Site	Patient Number	Date of randomization (DDMMMYYYY)	Date of second progression / last contact date (DDMMMYYYY)	Censoring (0=censored, 1=event)	Total PFS (months)	3-years PFS (Yes/No)	BORR
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX	XXX	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 53) Duration of Response (DoR)

POPULATION: ITT

Treatment Arm	Site	Patient Number	Date of first documented response (CR or PR) (DDMMMYYYY)	Date of first progression or death du to cancer / last tumor assessment date (DDMMMYYYY)	Censoring (0=censored, 1=event)	DoR (months)
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX
XXX	XXX	XXXXXXXX	DDMMMYYYY	DDMMMYYYY	X	XXX

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 54) Adverse events

POPULATION: SAF

Patient Number	AE#	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY)/ End Date (DDMMMYYYY)	Causality	Ongoing?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 55) Adverse events related to Ipilimumab

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 56) Adverse events related to Nivolumab

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 57) Adverse events related to Combo Immuno Therapy

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 58) Adverse events related to LGX818

POPULATION: SAF

Patient Number	AE#	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 59) Adverse events related to MEK162

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 60) Adverse events related to Combo Target Therapy

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req. ?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 61) Serious Adverse events

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 62) Adverse events leading to death

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 63) Adverse events leading to hospitalization

POPULATION: SAF

Patient Number	AE#	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 64) Adverse events leading to study withdrawal

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXXX	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 65) Adverse events of special interest (AESI)

POPULATION: SAF

Patient Number	AE #	Date on which the investigator finds out of the event (DDMMMYYYY)	Description of event	Preferred Term	SOC	Start Date (DDMMMYYYY) / End Date (DDMMMYYYY)	Causality	Ongoing ?	Related to	SAE	AESI	Grade	Outcome	Action taken	Trt. Req.?
XXXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXX X	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXX X	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXX X	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXX X	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
XXXX	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXX X	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx
	X	DDMONYYYY	XXXXXX	XXXXXXXX	XXXXXXX X	DDMONYYYY / DDMONYYYY	XXXXXX	XXXXXX	XXXXXX	X	X	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 66) Prior Medications

POPULATION: ITT

Site	Patient Number	CM (#)	Drug	Generic name	3rd level ATC subgroup	Dose	Unit	Start Date (DDMMMYYYY)	End Date (DDMMMYYYY)	Ongoing?	Route	Frequency	Indication	AE #
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX

Notes:
Prior Medications were coded using the WHO-DRL Version XXXX.

CD = Drug prescribed for concomitant disease, P = Drugs administered prophylactically, AEn = Number of corresponding AE.
Prior medications are those which stopped prior to the first dose of study medication.

Source: XXXX.SAS, Run on DDMMMYYYY

Listing 67) Concomitant Medications

POPULATION: ITT

Site	Patient Number	CM (#)	Drug	Generic name	3rd level ATC subgroup	Dose	Unit	Start Date (DDMMMYYYY)	End Date (DDMMMYYYY)	Ongoing?	Route	Frequency	Indication	AE #
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX
XXX	XXXXXXXX	XXX	XXXXXXXX	XXXX	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX

Notes:
Concomitant Medications were coded using the WHO-DRL Version XXXX.
CD = Drug prescribed for concomitant disease, P = Drugs administered prophylactically, AEn = Number of corresponding AE.
Concomitant Medications are those medications which:
started prior to, on or after the first dose of study medication and started no later than date of last study dose,
AND
ended on or after the date of first dose of study medication or were ongoing at the end of the study.

Source: XXXX.SAS, Run on DDMMMYYYY