Statistical Analysis Plan

Protocol Number: OMO-103-01

A Phase 1/2 Study to evaluate the Safety, Pharmacokinetics, and Anti-Tumour Activity of the Myc Inhibitor OMO-103 administered intravenously in Patients with Advanced Solid Tumours

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CONFIDENTIAL

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The undersigned have reviewed and revised this SAP and find it to be consistent with the study requirements:

Richard Morton, Head of Statistics, Simbec-Orion Clinical Services	Date
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GLOSSARY OF ABBREVIATIONS

ADA	Anti-Drug Antibody
AE	Adverse Event
APS	All Patients Set
CRC	Colorectal Cancer
CRF	Case Report Form
CT	Computed Tomography
DBL	Database Lock
DCR	Disease Control Rate
DLT	Dose-Limiting Toxicity
DOR	Duration of Response
ECG	Electrocardiogram
ECOG	Eastern Co-operative Oncology Group
EOT	End of Treatment
eCRF	Electronic Case Report Form
FAS	Full Analysis Set
FIH	First-In-Human
IMP	Investigational Medicinal Product
MRI	Magnetic Resonance Imaging
NSCLC	Non-Small Cell Lung Cancer
ORR	Objective Response Rate
OS	Overall Survival
PBMC	Peripheral Blood Mononuclear Cell
PD	Pharmacodynamics
PFS	Progression Free Survival
PK	Pharmacokinetics
PKS	Pharmacokinetic Analysis Set
PPS	Per-Protocol Set
RECIST	Response Evaluation Criteria in Solid Tumours
RP2D	Recommended Phase 2 Dose
SAE	Serious Adverse Event
SAF	Safety Analysis Set
SAP	Statistical Analysis Plan

TFL	Tables, Figures and Listings
TNBC	Triple-Negative Breast Cancer
TTP	Time To Progression
TTR	Time To Response

1 INTRODUCTION

1.1 GENERAL

This statistical analysis plan (SAP) describes the statistical methods to be used during the reporting and analyses of data and should be read in conjunction with the study protocol and case report form (CRF).

This version of the plan has been developed using the current approved protocol amendment version Final v2.0 dated 18 November 2021 and annotated CRF version dated 19 July 2021. Any further changes to the protocol or CRF will be reviewed for potential impact on the SAP which will be amended if it is deemed necessary.

Draft versions of the SAP will undergo review by the Statistical Reviewer, Statistical Programmer, Project Manager, Medical Writer, Principal Investigator and the Sponsor representative. The analysis plan will be finalised and approved by the Sponsor prior to Database Lock (DBL).

1.2 CHANGES FROM PROTOCOL

Primary endpoint for part 2 will be Progression-Free Survival (PFS) instead of Objective Response Rate (ORR).The protocol stipulates 5 dose levels will be used. It was later established that more than 5 dose levels could be used if decided by the Safety Monitoring Committee (SMC).

1.3 CHANGES FROM PREVIOUS VERSIONS OF THE SAP

Protocol amendment v2.0 (dated 18 November 2021) states that an interim analysis will be conducted for part 1 and this SAP will reflect that change.

2 STUDY OBJECTIVES

Part 1 – Dose Escalation

Primary Objective:

- To evaluate the safety and tolerability of OMO-103 in adult patients with advanced solid tumours.

Secondary Objectives:

- To establish and confirm the recommended Phase 2 dose (RP2D) and dosing regimen of OMO-103 for further development.
- To characterise the pharmacokinetics (PK) of OMO-103.
- To evaluate preliminary anti-tumour activity in the dose escalation part.
- To assess the development of human anti-drug antibodies (ADA) to OMO-103.

Part 2 – Dose Expansion

Primary Objective:

- To assess the preliminary anti-tumour activity of OMO-103 monotherapy as measured by progression free survival (PFS) according to standard criteria (Response Evaluation Criteria in Solid Tumours [RECIST] v1.1 [Eisenhauer 2009]).

Secondary Objectives:

- To confirm the RP2D and dosing regimen of OMO-103 for further development.
- To assess the type, incidence, severity, timing, seriousness, and relatedness of adverse events (AEs) and laboratory abnormalities.
- To characterise the PK of OMO-103.
- To assess other efficacy parameters in patients with advanced solid tumours including disease control rate (DCR), objective response rate (ORR), overall survival (OS), time to progression (TTP), time to response (TTR) and duration of response (DOR) by RECIST v1.1.
- To assess the development of human ADA to OMO-103.
- To evaluate the effect of OMO-103 on Quality of Life (QoL) measured by the Quality of Life questionnaire.

Exploratory (Both Parts 1 and 2):

- Evaluation of potential biomarkers.
- Myc expression levels.

3 STUDY DESIGN

3.1 OVERVIEW

This study is an open label, two-part, FIH Phase 1/2a dose-finding study designed to determine the safety, tolerability, PK, PD and proof-of-concept of OMO-103 in patients with advanced solid tumours.

The study consists of two parts:

Part 1 - General

- Dose escalation in patients with solid tumours, including 5 or more OMO-103 dose levels.

  Approximately 11 to 24 patients in total will be enrolled in Part 1, covering 5 or more dose levels with the primary objective of determining the safety and tolerability of OMO-103 and defining an appropriate dose for further evaluation in Part 2.

The study will start with an accelerated-titration dose-escalation scheme enrolling one evaluable patient per cohort for the first 2 dose levels followed by a classic 3+3 design.

Part 1 - Timings and assessments

- Screening period: 28 days to 1 day prior 1st dose
- Treatment period:
  - Cycle 1 (Dose-limiting toxicity [DLT] period): C1D1, C1D2, C1D3, C1D4, C1D5, (Days 3 to 5 only from dose level 3 onwards for PK evaluation), C1D8, C1D15, C1D16/C1D17 (Biopsy)
  - Cycle 2: C2D1, C2D8, C2D15
  - Cycle 3*: C3D1, C3D2, C3D3, C3D4, C3D5, (Days 3 to 5 only from dose level 3 onwards for PK evaluation), C3D8, C3D15

    *NOTE: Assumed 3 cycles but these are unlimited
  - End-of-treatment (EOT) visit
- Follow-up period: 1-Month Follow-up visit

Part 2 - General

- Dose expansion where at least 3 parallel groups of patients with advanced Non-Small Cell Lung Cancer (NSCLC), Triple-Negative Breast Cancer (TNBC) and Colorectal Cancer (CRC) will be treated at the RP2D of OMO-103 to further characterise the safety, tolerability, PK, PD and anti-tumour activity of OMO-103.

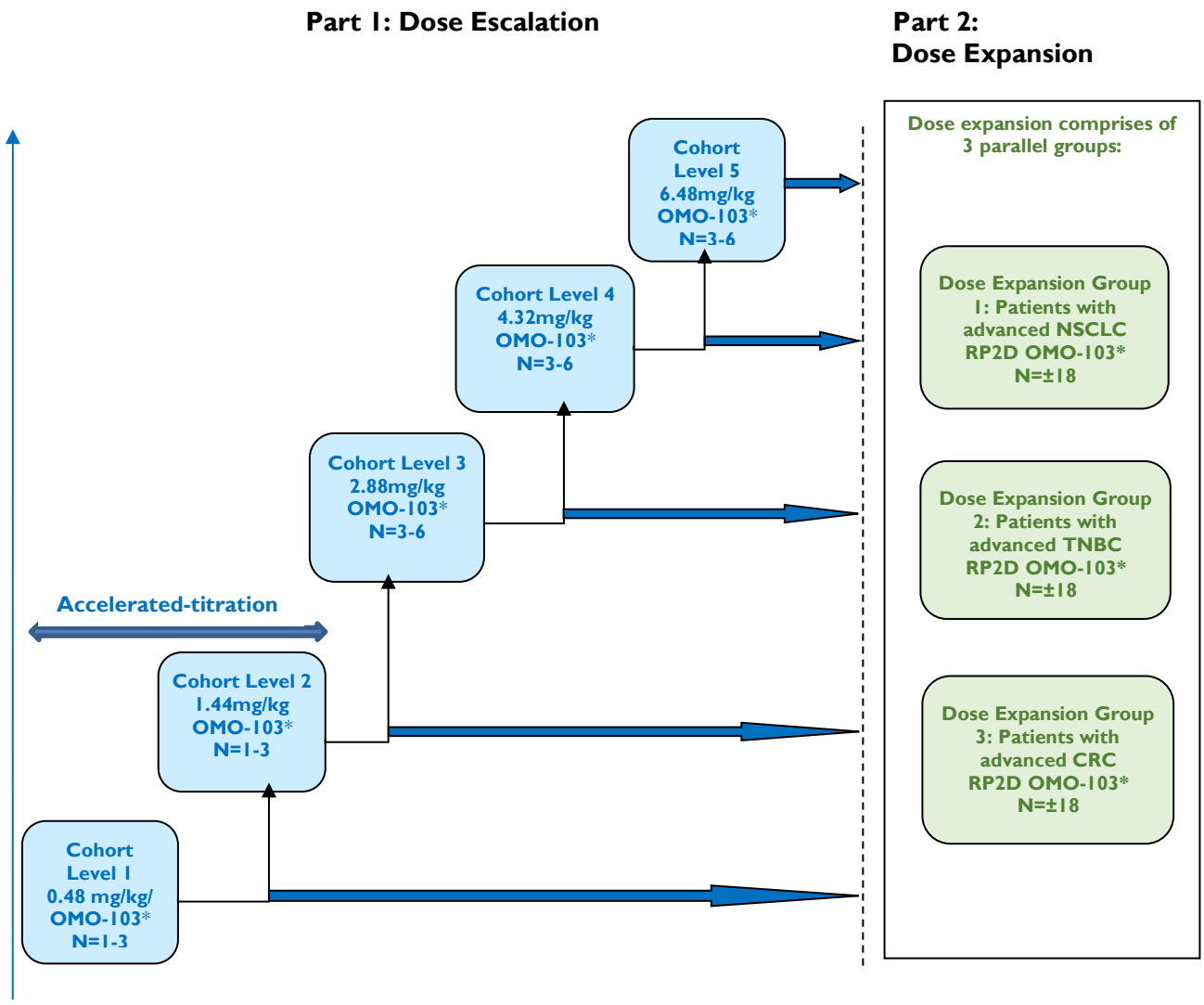
  Approximately 18 patients will be enrolled in each of the 3 parallel groups of patients (NSCLC, TNBC, CRC) in Part 2.

Part 2 - Timings and assessments

- Screening period: 28 days to 1 day prior 1st dose
- Treatment period:
  - Cycle 1: C1D1, C1D2, C1D3, C1D4, C1D5, C1D8, C1D15
  - Cycle 2: C2D1, C2D8, C2D15, C2D16/C2D17 (Biopsy)
  - Cycle 3: C3D1, C3D2, C3D3, C3D4, C3D5, C3D8, C3D15,
  - Cycle 4: C4D1, C4D8, C4D15,
  - Cycle 5: C5D1, C5D8, C5D15,
  - Cycle 6*: C6D1, C6D2, C6D3, C6D4, C6D5, C6D8, C6D15,

    *NOTE: Assumed 6 cycles but these are unlimited
  - EOT visit
- Follow-up period: 6-Month Follow-up period, including monthly visits if feasible. Telephone visits may be allowed if considered appropriate, e.g. hospice patients

Parts 1/2 – Study Flowchart



* OMO-103, administered IV weekly (Q1W) and one cycle of treatment is 3 weeks (Q3W).

3.2 INCLUSION AND EXCLUSION CRITERIA

To be eligible for inclusion into this study, each subject must fulfil all inclusion criteria and not violate any exclusion criteria (for the protocol version under which they are entered) during screening. Details of the inclusion and exclusion criteria are presented within the protocol (sections 10.2, 10.3).

3.3 STUDY TIMEPOINTS

3.3.1 Study Flow Chart Part 1: Dose Escalation

	Screening	**Treatment period**								**End of treatment ±3 days [1]**	**1-month follow-up ±3 days [2]**
		Cycle 1 (DLT period)					**Cycle 2 + (unlimited)**				
Protocol Activities (Window, Days)	28 days to 1 day prior 1st dose	Day 1 ±1 day	Day 2	Days 3, 4, 5 [16]	Day 8 ±1 day	Day 15 ±1 day [13]	Day 1 ±1 day	Day 8 ±1 day	Day 15 ±1 day [13]		
Baseline Documentation											
Informed Consent	X										
Eligibility Assessment	X										
Medical/Oncological History [3]	X										
Physical Examination [4]	X	X	X		X	X	X	X	X	X	X
ECOG Performance Status	X	X					X			X	X
12-Lead ECG [7]	X	X			X	X	X			X	
Laboratory Studies											
Safety Blood Sampling [5]	X	X	X		X	X	X	X	X	X	X
Urinalysis [5]	X	X	X		X	X	X	X	X	X	X
PK Assessment [6]		X	X (also for C3D2)	X (also for C3D3, C3D4, C3D5)			X				

Study Flow Chart Part 1: Dose Escalation (continued)

ADAs	X				X (Pre-dose)	X (Pre-dose)	X (Pre-dose)			X	X
Autoimmunity [12]	X						X			X	
Efficacy/PD Assessments											
CT/MRI [8]	X								C3 [8]	X	
Tumour Biopsy [9]	X					D16 or D17 [9]				X (optional)	
PD markers [10]	X	X	X				X			X	
Other Clinical Assessments											
Hospital Admission [15]		X									
Vital Signs	X	X	X		X	X	X	X	X	X	X
AEs/Con Meds and Treatments [11]	X	X	X	X (AEs only)	X	X	X	X	X	X	X
OMO-103 dosing [14]		X			X	X	X	X	X		

Footnotes for items [1]-[15] are listed in the protocol.

3.3.2 Study Flow Chart Part 2: Dose Expansion

Protocol Activities (Window, Days)	Screening	Treatment period							End of treatment ±3 days [1]	6-month follow-up (monthly visits ±3 days) [2]
		Cycle 1				Cycle 2+ (unlimited)				
	28 days to 1 day prior 1st dose	Day 1 ±1 day	Day 2	Day 8 ±1 day	Day 15 ±1 day [14]	Day 1 ±1 day	Day 8 ±1 day	Day 15 ±1 day [14]		
Baseline Documentation										
Informed Consent	X									
Eligibility Assessment	X									
Medical/Oncological History [3]	X									
Physical Examination [4]	X	X	X	X	X	X	X	X	X	X
ECOG Performance Status	X	X				X			X	X
12-Lead ECGs [7]	X	X				X			X	
Laboratory Studies										
Safety Blood Sampling [5]	X	X	X	X	X	X	X	X	X	X
Urinalysis [5]	X	X	X	X	X	X	X	X	X	X
PK Assessment [6]		X	X			X				
ADAs	X			X (Pre-dose)	X (Pre-dose)	X (Pre-dose)			X	X [16]

Study Flow Chart Part 2: Dose Expansion (continued)

Autoimmunity [12]	X					X			X	
Efficacy/PD Assessments										
CT/MRI [8]	X							C3 [8]	X	
Tumour Biopsy [9]	X							C2 D16 or D17 [9]	X (optional)	
PD markers [10]	X	X	X			X		C2 D16 or D17 [10]	X	X
PBMC blood PD markers [11]		X	X			X		C2 D16 or D17 [11]	X	X
Other Clinical Assessments										
Vital Signs	X	X	X	X	X	X	X	X	X	X
AEs/Con Meds and Treatments [13]	X	X	X	X	X	X	X	X	X	X
OMO-103 dosing [15]		X		X	X	X	X	X		

Footnotes for items [1]-[15] are listed in the protocol.

3.4 SAMPLE SIZE CONSIDERATIONS

This is an exploratory study, therefore the sample sizes listed below are not based on a formal statistical estimation (sample size or power calculation are not required) but are considered to be adequate to meet the objectives of the study. A sufficient number of subjects will be initially screened for enrolment in both parts to ensure that the planned sample size is achieved.

In part 1, the dose escalation phase, approximately 11 to 24 patients in total will be enrolled, covering 5 or more dose levels. If more than 5 dose levels are required these numbers may increase proportionally.

In part 2, the dose expansion phase, approximately 18 patients will be enrolled to each of the 3 groups of patients with pre-defined advanced tumours of different types (up to 54 patients total)

There will be the potential to add 1 or more further groups to the dose expansion phase where the addition of such a group is thought to have efficacious potential. Any such groups will also aim to recruit 18 patients.

In total, it is anticipated that with 3 dose expansion groups, that up to 78 eligible patients will be enrolled. Should the dose expansion phase recruit additional groups as outlined above, this total will increase by up to 18 patients for each group added.

3.5 RANDOMISATION

As an open label design, there will be no randomisation for this study in either the dose excalation or dose expansion parts.

4 STUDY VARIABLES AND COVARIATES

4.1 PRIMARY VARIABLES

The primary endpoints are as follows:

Part 1: Dose Escalation:

- Number of patients with a DLT;
- Number of patients with ≥1 related AE;
- Number of patients discontinuing study treatment due to related AEs.

The RP2D will be determined at the conclusion of Part 1.

Part 2: Dose Expansion

- Progression free survival (PFS) based on RECIST v1.1 as assessed by the Investigator.

4.2 SECONDARY VARIABLES

The secondary endpoints of the study are the PK profile, as well as tumour response.

- PK parameters of OMO-103

- C_{min} Minimum observed concentration;
- C_{max} Maximum observed concentration;
- t_{max} Time to maximum observed concentration;
- $t_{1/2}$ Terminal elimination half-life;
- AUC_{0-t} Area under the concentration-time curve (AUC) from the time of administration to the time of the last measurable concentration;
- AUC_{0-inf} AUC extrapolated to infinity;

- Additional PK analyses will be performed as deemed necessary upon review of the data.

- RECIST v1.1 criteria (see Protocol section **Error! Reference source not found.**2).
- The scores and changes from Day 0 in QoL Questionnaire scores.

4.3 EXPLORATORY VARIABLES

Exploratory endpoints of the study are the PD profile.

Supporting study variables include biomarkers and Myc expression measurement. Additional biomarkers may be added if deemed relevant.

5 DEFINITIONS AND DERIVED VARIABLES

Product/IMP: Product/IMP is taken to mean the Myc Inhibitor OMO-103 administered intravenously.

Baseline: Unless stated otherwise, baseline is defined by subject and by variable as the last non-missing value (including repeat/unscheduled assessments) before the first use of IMP.

Protocol Deviation: a deviation related to study inclusion or exclusion criteria, conduct of the trial, subject management or subject assessment. This refers to any change, divergence, or departure from the study design or procedures defined in the protocol. Protocol deviations captured in the CRF will be reviewed on a regular basis during the study and discussed at the Data Review Meeting (DRM) before Database Lock (DBL). In addition, any deviations identified during the DRM will be discussed and included in the database as necessary. All protocol deviations within the study database will be classified as either 'Major' or 'Minor' prior to DBL, details of which will be included within the Protocol Deviations log within the CTMS and a protocol deviation listing.

6 ANALYSIS SETS

Membership of the analysis sets will be reviewed during the DRM and agreed prior to DBL. These will be reviewed by the Sponsor, Study Statistician, PK Analyst (PKS only) and Project Manager and included within the DRM minutes.

6.1 ALL PATIENTS SET (APS)

All subjects who were enrolled and not screening failures at Day 1 will constitute the All Patients Set. Subjects deemed eligible on Day 1 who do not partake in any IMP use will be listed and summarised for subject disposition only.

This analysis set will be used for study disposition and analysis set listings and summaries.

6.2 SAFETY SET (SAF)

All subjects in the APS who receive at least one dose of IMP will be included in the Safety Set.

This analysis set will be used for baseline and safety summaries as well as for all study listings.

6.3 FULL ANALYSIS SET (FAS)

All subjects within the SAF who record either a primary or secondary endpoint will be included in the Full Analysis Set.

This analysis set will be used for efficacy tables and some safety summaries.

6.4 PK SET (PKS)

Subjects from the SAF population will be assigned to the PK Set where they comply with the following criteria:

- Do not use a concomitant medication which renders the concentration profile unreliable;
- Have at least one sample with concentration above the lower limit of quantification (LLOQ);
- Do not violate the protocol in such a way that may invalidate or bias the results (major protocol deviation).

This analysis set will be used for summaries and statistical analyses of the PK data.

6.5 PER PROTOCOL SET (PPS)

All subjects within the FAS who complete the study without a major protocol deviation adjudged in the DRM to potentially affect any endpoint of the study will be included in the Per Protocol Set.

A PP analysis will only be performed for the dose expansion groups.

This analysis set will be used for efficacy tables.

7 SAFETY MONITORING

An interim analysis (for both safety and efficacy) will be conducted after half of the patients in the dose expansion part in each group have been treated for 3 cycles. This is detailed in section 8.

8 INTERIM ANALYSES

There will be an interim analysis performed at the end of Part 1.
In the dose expansion part, after half of the patients in all groups (i.e. 9 patients per group) have been included and treated for 3 cycles, efficacy and safety will be analysed. If no response (as per RECIST v1.1) is seen during the interim analysis for at least one patient regardless of group, or for safety reasons, recruitment could be stopped (or the dose reduced) following discussion between the Investigator, the SMC and the Sponsor.
If there are no safety concerns and a response is seen, the study will continue until 18 patients have been recruited in each group.

9 DATA

9.1 CRF DATA

Data captured in the CRF will be provided by Simbec-Orion Data Management to the Statistics department as SAS datasets in a standard format which will be used for programming the outputs to be included in the Clinical Study Report (CSR). Analysis dataset and tables, figures and listings (TFL) programming will begin when populated SAS datasets are available.

9.2 EXTERNAL DATA

9.2.1 Laboratory Data

Transfers of safety laboratory data will be available from External Laboratories, delivered to Simbec-Orion Data Management via electronic transfer and stored within the study database. Details of laboratory data will be documented in the Data Management Plan (DMP). Either final data or a populated test transfer will be received before programming on laboratory data can begin.

The following results will be included (performed locally):

- **Haematology:** Haemoglobin, haematocrit, mean corpuscular volume, white blood cell differentials (neutrophils, basophils, eosinophils, lymphocytes and monocytes), Platelet count.
- **Serum Chemistry:** albumin, amylase, alkaline phosphatase, ALT, AST, urea, calcium, chloride, creatinine, creatinine clearance, CK, GGT, glucose, magnesium, phosphorus, potassium, sodium, total bilirubin, total protein, LDH, Lipase, CRP.
- **Urinalysis:** pH, Specific gravity, Ketones, Leucocytes, Protein, Glucose, Bilirubin, Urobilinogen, Blood, Sediment (if dipstick results are positive).

- **Coagulation:** INR, D-Dimer, AT, aPTT, TT, Fibrinogen.
- **Hormones:** βHCG (women of childbearing potential), LH, FSH, TSH, GH, PRL, ACTH.
- **Autoimmunity:** ANA, Anti-thyroglobulin, RF, ASMA.
- **Tumor markers:** CEA, CYFRA21-1, CA19-9, NSE, CA15-3, TPA.

9.2.2 Other non-CRF data

None

9.3 RANDOMISATION LIST

Not applicable.

9.4 PROGRAMMING AND DATA REVIEW

Programming of datasets, tables, figures and listings will be ongoing while study data management activities are in progress.

Prior to DBL, a review of the clinical database will be conducted. Listings for the data review will be produced. A DRM will be held to discuss the outcome of this review, any potential impact on the analyses, analysis sets and protocol deviations. Meeting minutes will be created and, once all data issues have been resolved, the analysis sets approved and protocol deviation classifications agreed, the database will be locked. These minutes will be finalised and signed off prior to DBL. Once the aforementioned actions have taken place the database can be locked. The post-lock analysis datasets will be generated, the TFLs will be run and quality control (QC) will take place.

10 STATISTICAL METHODS

10.1 GENERAL PRINCIPLES

- All statistical methods will be based on the International Conference on Harmonisation (ICH) E9 document "Statistical Principles for Clinical Trials".
- All data collected will be presented within data listings.
- Generally, data listings will be sorted by subject and by period/regimen where appropriate.
- Generally, data will be summarised by period/cohort. Baseline data will be summarised overall. The format of the summaries is defined in the shells at the end of this document.
- Repeated visits will be denoted with 'RPT'. Unscheduled visits will be denoted with 'UNS'.
- In summary and analysis tables of continuous variables, standard descriptive statistics (N [number within analysis set, or group, or subgroup], n [number of observations included in analysis], mean, standard deviation [SD], median, minimum and maximum) will be presented. Least squares means (LSMean) and 95% confidence intervals (CI) will be presented in the

statistical analysis outputs as appropriate. For PK summaries, geometric mean and coefficient of variation (%CV) will also be used to summarise the data.

- Unless otherwise specified, the minimum and maximum statistics will be presented in summary tables to the same number of decimal places as the original data. The mean, median, LSMean, and CI will be presented to one more decimal place than the original data. SD will be presented to two more decimal places than the original data.
- Derived PK parameters and concentration data listings and summaries will be presented to 3 significant figures (with the exception of CV%, which will be presented to 1 decimal place). The ratio of the geometric LSMeans and its associated confidence interval will be presented to 2 decimal places.
- In summary tables of categorical variables, the number of non-missing observations by category will be presented along with percentages. Unless otherwise specified, the denominator for each percentage will be the number of non-missing observations.
- All percentages will be presented to one decimal place.
- All plots will use a linear time scale for the nominal times of the visits and will be labelled by time point.
- For post-IMP assessments, only data obtained from scheduled visits/time points will be used in summary tables. Post-IMP repeat or unscheduled assessments will be listed only. For assessments occurring prior to IMP use (i.e. Screening, Day -1), the last repeat assessment for each visit will be included in the summary tables and, where repeats of baseline values occur, the last assessment will be used to calculate change from baseline. The derived baseline will be presented for each subject within the data listings and included within the summary tables.
- Dates and times for all output presentations will be presented as captured in the database.
- All statistical analysis will be performed using SAS 9.4 or higher.
- Generally, character values will be left aligned and numeric values will be decimally aligned.
- If no data is available for a specific output, the output will be produced stating an appropriate message indicating no data was present.
- If any of the assumptions underlying the formal statistical methods proposed are violated during the analysis of the final data, alternative statistical methods will be used and any changes documented in the statistical methods section of the clinical study report (CSR), including the rationale for use.
- For numeric data which includes non-numeric values (e.g. laboratory results reported as <10 or >100), results reported as $<x$ $\leq x$, $\geq x$ $>x$ will be treated as x for inclusion within the summaries/statistical analysis but will be listed as reported.

10.2 STRATIFICATION AND COVARIATE ADJUSTMENT

Not applicable.

10.3 INTERACTIONS

Not applicable.

10.4 MISSING DATA

No methods to account for missing safety data will be used.

10.5 POOLING OF SITES

Not applicable.

10.6 MULTIPLE COMPARISONS

Not applicable.

10.7 SUBGROUP ANALYSES

Not applicable.

10.8 STATISTICAL ISSUES

None.

11 STATISTICAL OUTPUT

General principles for layout of the statistical output are described in Section 10.1. Layout and specifications are illustrated for each unique table in the table shells in Section 14.

11.1 SUBJECT DISPOSITION

The subject disposition table will summarise the following data:

- The number of subjects receiving IMP under each dose level
- The number (%) of subjects who withdrew from the study and the associated reasons for withdrawal and timing of withdrawal.
- The number (%) of subjects in each analysis set

Screening and study completion/termination data (including informed consent information) will also be listed. A listing of all protocol deviations will be presented including major/minor classification. A data classification. A data listing presenting subject eligibility for each analysis set and the reason for exclusion from an analysis set will also be presented.

Disposition data will be summarised and listed using the All Patients Set (APS) population.

11.2 SUBJECT CHARACTERISTICS AT BASELINE

11.2.1 Demographic and Baseline Characteristics

Demographic data will be listed and descriptive statistics (N, n, arithmetic mean, standard deviation (SD), minimum, median and maximum) for the continuous variables age, height, weight and number of pre-treatments per patient at Screening and frequencies (n, %) for the categorical variables race and gender will be tabulated.

Demographic data will be listed and summarised using the Safety Set and the FAS.

11.3 EFFICACY ANALYSES

The primary efficacy endpoint of the study will be:

- Anti-tumour activity will be assessed by PFS using RECIST v1.1 assessed by the Investigator.

Secondary endpoints are:

- DOR
- DCR
- TTR
- TTP
- ORR

- OS (only Part 2).

All efficacy endpoints will be summarised and analysed descriptively, using the FAS and SAF populations. Kaplan Meier plots will be presented for time to event endpoints. Waterfall plots will be presented for RECIST data. The primary efficacy analysis will be repeated using the PP set.

Quality of Life Questionnaire:

Absolute values and change from baseline for total score will be presented using descriptive statistics for QoL Questionnaire scores. Overall there are 30 questions.

Only physical, emotional, fatigue and global related scores will be summarized.

Physical Functioning related questions are: Q1, Q2, Q3, Q4, Q5.

Emotional Functioning related questions are: Q21, Q22, Q23, Q24.

Fatigue relates questions are: Q10, Q12, Q18.

Global questions are: Q29, Q30.

Grouped scores for physical, emotional, fatigue, global scales and total scores will be normalised to the range 0-100 prior to being summarised.

All questions with the corresponding scores will be listed.

Other analysis:

- OMO-103 dosing will be summarised and listed using the SAF.

11.4 PK ANALYSES

No pk analysis will be perform by Simbec-Orion.

11.5 SAFETY ANALYSES

11.5.1 Adverse Events

All adverse events (AEs) will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary version 24.0.

All AEs, including those which occurred prior to the first IMP use, will be listed. Only treatment emergent adverse events (TEAEs), i.e., existing conditions that worsen or events that occur during the course of the study after first IMP use, will be included within the summary tables. AEs that occur intermittently will be reported as separate events.

Adverse events will be summarised by

- Summary of Treatment Emergent Adverse Events
- Summary of Treatment Emergent Adverse Events – Event Count

- Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term
- Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Event Count
- Summary of Treatment Emergent Adverse Events by Preferred Term
- Summary of Treatment Emergent Adverse Events by Severity, System Organ Class and Preferred Term
- Summary of Treatment Emergent Adverse Events by Relationship to IMP, System Organ Class and Preferred Term

A subject with multiple occurrences of any AE is counted only once at the maximum level of severity or the strongest relationship to IMP.

The number of TEAEs and the number and % of subjects reporting at least 1 TEAE will be tabulated by system organ class (SOC) and preferred term (PT). A subject reporting multiple episodes of a particular AE will only contribute 1 count towards the corresponding SOC and PT.

In order to highlight the most frequently reported TEAEs, the number of TEAEs and the number and % of subjects reporting at least 1 TEAE will be tabulated by PT in order of descending frequency of subjects then events. A subject reporting multiple episodes of a particular AE will only contribute 1 count towards the corresponding PT.

The derived variable, 'Duration' will be presented where full date (events => 1 day) and time (events < 1 day) are present. If partial dates or times are present for any parameter required in the calculation, the variable will not be populated. The following will be used to calculate the variables:

Duration: (events => 1 day) (Date of Resolution – Date of Onset) ;

(events < 1 day) (Time of Resolution - Time of Onset) + 1 minute;

The derived variable 'Time from dose' will be assessed from the most recent infusion date and time. Where full date and time are present, both day from dose and time from dose will be presented. If partial dates are present for any parameter required in the calculation, only day from dose will be populated.

The following will be presented in listing format within the data summaries:

- Serious Adverse Events – If there are none present, the listing will be produced stating: '*No subjects experienced any serious adverse events.*'.

- Adverse Events which Led to Withdrawal – If there are none present, the listing will be produced stating: '*No subjects experienced any adverse events that led to withdrawal.*'.

Adverse event data will be listed and summarised using the Safety Set.

11.5.2 Laboratory Data

Routine safety clinical laboratory tests will be carried out at Screening.

The laboratory parameters required for this study are listed in section 9.2.1.

Laboratory safety data listings will be presented in two ways:

- Out of range values - any values that fall outside of the normal/alert ranges based on the reference ranges provided by the local/central laboratory (presented in listing format within the data summaries)
- All safety laboratory data (including physician's review (Normal, Abnormal-NCS, Abnormal-CS)) with any out of range values flagged (presented within the data listings).

Pregnancy test, post-menopausal assessment and any unplanned laboratory parameters will also be listed.

If there are no further parameters databased other than those specified in section 9.2.1 then the 'Other Laboratory Data' listings should display, '*No other laboratory parameters to report.'*

Laboratory data will be listed using the Safety Set.

11.5.3 Vital Signs

Vital Signs will be recorded at Screening, Cycle 1 [Day 1, Day 2, Day 8, Day 15], cycle 2 [Day1, Day 8, Day 15], Cycle X [Day1, Day 8, Day 15],, End of treatment and Follow-up visit.

Vital signs parameters (systolic and diastolic blood pressure, pulse rate, respiratory rate and temperature) will be summarised and listed using the SAF.

11.5.4 Electrocardiogram

Single 12-lead ECGs will be performed at Screening, Cycle 1 [Day 1, Day 2, Day 8, Day 15], cycle 2 [Day1], Cycle X Day 1 and End of treatment visit.

Single 12-lead ECG parameters (heart rate, PR interval, QRS, QT interval, QT interval corrected using Fridericia's formula (QTcF)) will be summarised using a shift table and listed using the SAF.

11.5.5 Physical Examination

Physical examination will be performed at Screening, Cycle 1 [Day 1, Day 2, Day 8, Day 15], Cycle 2 [Day1, Day 2 and Day 15], Cycle X [Day1, Day 2 and Day 15] and End of treatment visit.

Physical examination (Normal, Abnormal Clinically Significant and Abnormal Not Clinically Significant) will be summarised and listed using the SAF.

11.5.6 ECOG

ECOG will be performed at Screening, Cycle 1 Day 1, Cycle 2 Day1, Cycle X Day 1, End of treatment and Follow-up visit.

ECOG status will be summarised and listed using the SAF.

11.6 OTHER DATA

Data related to the following will be presented if required:

- Medical history
- Oncology history
- CT/MRI
- Tumour biopsies

11.6.1 Prior and Concomitant Medication

All prior and concomitant medications will be classified using the World Health Organisation Drug Dictionary (WHODD) coding dictionary (version as documented within the DMP) and listed using the ATC Level 4 class, Preferred Term and verbatim text.

Any administered medication will be assigned as concomitant if it starts on or after first IMP use or ends after first IMP use regardless of start date. Any medication that stops prior to first IMP use will be assigned as prior medication.

Where there are only partial dates/times recorded for a medication, the medication will be assigned as concomitant if it cannot be ruled out it is concomitant based on the partial information.

Prior and concomitant medications will be listed by period/regimen using the Safety Set (SAF).

Derivations within listings:

Analysis sets: Detail whether subject should be included within each of the analysis sets and provide reason for exclusion, as appropriate.

Inclusion/Exclusion criteria: Only failures to be presented. If there are no failures display '*All subjects passed all inclusion/exclusion criteria.*'

Protocol deviations: Major/minor classification to be assigned and confirmed by Sponsor.

12 VALIDATION

All datasets, tables, figures and listings will be subject to independent quality control and visual review. Datasets and tables will be independently double-programmed, figures and listings subject to spot checks and visual QC.

13 LITERATURE CITATIONS/REFERENCES

None.

14 LIST OF TABLES, FIGURES AND LISTINGS

List of Tables and Figures Contained in Report Section 14

14.1 Disposition and Demographic Data

14.1.1 Disposition Data

14.1.2 Demographic Data and Baseline Characteristics

14.2 Efficacy Data

14.2.1 Efficacy parameters

14.3 Safety Data

14.3.1 Adverse Events

Table 14.3.1.1	Summary of Treatment Emergent Adverse Events	Safety Set
Table 14.3.1.1a	Summary of Treatment Emergent Adverse Events – Event Count	Safety Set
Table 14.3.1.2	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term	Safety Set
Table 14.3.1.2a	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Event Count	Safety Set
Table 14.3.1.3	Summary of Treatment Emergent Adverse Events by Preferred Term	Safety Set
Table 14.3.1.4	Summary of Treatment Emergent Adverse Events by Severity, System Organ Class and Preferred Term	Safety Set
Table 14.3.1.5	Summary of Treatment Emergent Adverse Events by Relationship to IMP, System Organ Class and Preferred Term	Safety Set
Table 14.3.1.6	Serious Adverse Events	Safety Set
Table 14.3.1.7	Adverse Events Leading to Withdrawal	Safety Set

14.3.2 Laboratory Safety

Table 14.3.2.1	Biochemistry Out of Normal Range Data	Safety Set
Table 14.3.2.2	Haematology Out of Normal Range Data	Safety Set
Table 14.3.2.3	Urinalysis Abnormal Values	Safety Set
Table 14.3.2.4	Autoimmune Values	Safety Set
Table 14.3.2.5	Frequency of Autoimmune Values	Safety Set

14.3.3 ECG Data

Table 14.3.3.1	Statistical summaries of ECG parameters by visit	Safety Set

14.3.4 ECOG Performance Status

Table 14.3.4.1	Statistical summaries of ECOG status by visit	Safety Set

14.3.5 Vital Signs

Table 14.3.5.1	Statistical summaries of Vital Signs by visit	Safety Set

14.3.6 Physical Examination

Table 14.3.6.1	Statistical summaries of Physical Examination by visit	Safety Set

14.4 Pharmacokinetics

No pk analysis will be perform by Simbec-Orion.

14.5 Pharmacodynamics

No pd analysis will be perform by Simbec-Orion.

Subject Data: Listings Contained in Report Appendix 16.2

16.2.1 Visit Dates, Dosing Information and Disposition		
Listing 16.2.1.1	Visit Dates	Safety Set
Listing 16.2.1.2	Subject Disposition	All Patients Set
16.2.2 Protocol Deviations		
Listing 16.2.2.1	Protocol Deviations	Safety Set
16.2.3 Analysis Sets		
Listing 16.2.3.1	Analysis Sets	All Patients Set
16.2.4 Demographic Data and Other Baseline Characteristics		
Listing 16.2.4.1	Demographic Information	Safety Set
Listing 16.2.4.2	Medical History	Safety Set
Listing 16.2.4.3	Inclusion/Exclusion Criteria Failures	Safety Set
16.2.5 Dosing		
Listing 16.2.5.1	Summary of OMO 103-01 dosing	Safety Set
16.2.7 Efficacy		
Listing 16.2.7.1	Summary of PFS	Safety Set
Listing 16.2.7.2	Summary of Efficacy parameters, DCR, ORR, OS, TTP, TTR and DOR	Safety Set
Listing 16.2.7.3	Summary of biomarkers	Safety Set
Listing 16.2.7.5	QoL Questionnaire	Safety Set
16.2.8 Adverse Events		
Listing 16.2.8.1	Adverse Events	Safety Set

16.2.9	Individual Laboratory Safety Measurements	
Listing 16.2.9.1	Biochemistry Data	Safety Set
Listing 16.2.9.2	Haematology Data	Safety Set
Listing 16.2.9.3	Urinalysis Data	Safety Set
Listing 16.2.9.4	Summary of Anti-drug antibodies (ADA) to OMO-103	Safety Set
Listing 16.2.9.5	Other Laboratory Data	Safety Set

16.2.10	Vital Signs	
Listing 16.2.10.1	Vital Signs Data	Safety Set

16.2.11	Physical Examination	
Listing 16.2.11.1	Physical Examination Data	Safety Set

16.2.12	ECG	
Listing 16.2.12.1	Single 12-lead ECG Data	Safety Set

16.2.13	Prior and Concomitant Medication	
Listing 16.2.13.1	Prior Medications	Safety Set
Listing 16.2.13.2	Concomitant Medications	Safety Set

16.2.15	ECOG scores	
Listing 16.2.15.1	ECOG scores	Safety Set

15 SHELLS FOR TABLES, FIGURES AND LISTINGS

The intended layouts for tables, figures and listings are presented. However, it may be appropriate to change the layouts, upon review of the data available, for completeness and clarity.

QCd output will be produced as Rich Text Format (.rtf) files for convenient inclusion in the CSR.
The default tables, figures and listings (TFL) layout will be as follows:

Orientation	A4 Landscape
Margins	Top: 2.54 cm Bottom: 2.54 cm Left: 2.54 cm Right: 2.54 cm
Font	Courier New 9pt
Headers (Centre)	Sponsor Protocol Number, TFL Number, Title, Analysis Set
Footers (Left)	Source Listing, Date/Time TFL Generated, Page Number, i.e. Page x of y

Listing shells are displayed within this document without the comments field but, should there be any comments recorded for the represented data, this field will be added to the listing. In addition, at the time of programming, footnotes will be added to the listing, table or figure as needed. All footnotes will be used for purposes of clarifying the presentation

Should the number of variables within a listing or table be too great to fit on one page without compromising clarity, then the variables will be split across multiple subsequent pages and key identifying variables replicated with these (i.e. subject number, visit etc). The differing pages will be identified using a sequential number which will follow the TFL title, i.e. xxxx - (1), xxxx - (2).

OMO-103-01
Table 14.1.1.1
Summary of Study Disposition – Part 1
All Patients Set

	Number of Subjects (%)
Consented	x
Screening Failures/Non-Runners	x
Dosed:	
0.48 mg/kg (Cohort 1)	x (x.x)
1.44 mg/kg (Cohort 2)	x (x.x)
……	x (x.x)
Completed Study	x (x.x)
Early Withdrawal	x (x.x)
Reason for Early Withdrawal	
ADVERSE EVENT	x (x.x)
LOST TO FOLLOW-UP	x (x.x)
WITHDRAWAL BY SUBJECT	x (x.x)
STUDY TERMINATED BY SPONSOR	x (x.x)
PHYSICIAN DECISION	x (x.x)
PREGNANCY	x (x.x)
PROTOCOL VIOLATION	x (x.x)
DEATH	x (x.x)
OTHER	x (x.x)
Safety Set	x (x.x)
Full Analysis Set	x (x.x)
Per Protocol Set	x (x.x)

Source Listing: 16.2.1.2, 16.2.3.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Percentages are based on the total number of dosed subjects.

Programming note: A similar table will be presented for Part 2 (Dose expansion)

OMO-103-01
Table 14.1.2.1
Summary of Demographic and Baseline Information – Part 1
Safety Set

Parameter	Statistic	All Subjects (N=x)
Age (yrs)	n	x
	Mean	x.x
	SD	x.xx
	Min	x
	Median	x.x
	Max	x
Height (cm)	n	x
	Mean	x.x
	SD	x.xx
	Min	x
	Median	x.x
	Max	x
Weight (kg)	n	x
	Mean	x.xx
	SD	x.xxx
	Min	x.x
	Median	x.xx
	Max	x.x
Number of pre-treatments per patient	n	x
	Mean	x.xx
	SD	x.xxx
	Min	x.x
	Median	x.xx
	Max	x.x

Source Listing: 16.2.4.1; Produced: yyyy-mm-ddThh:mm - Page x of y

Percentages are based on the total number of subjects within the Safety Set.

Programming note: A similar table will be presented for Part 2.

[*Continued overleaf…*]

OMO-103-01
Table 14.1.2.1
Summary of Demographic and Baseline Information – Part 1
Safety Set

Parameter		Statistic	All Subjects (N=x)
Race:	BLACK OR AFRICAN AMERICAN	n (%)	x (x.x)
	AMERICAN INDIAN OR ALASKA NATIVE	n (%)	x (x.x)
	ASIAN	n (%)	x (x.x)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	n (%)	x (x.x)
	WHITE	n (%)	x (x.x)
	MIXED	n (%)	x (x.x)
	OTHER	n (%)	x (x.x)
Gender:	M	n (%)	x (x.x)
	F	n (%)	x (x.x)

Source Listing: 16.2.4.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Percentages are based on the total number of subjects within the Safety Set.

Programming note: A similar table will be repeated for 14.1.2.2 (FAS).
A similar table will be presented for Part 2.

OMO-103-01
Table 14.2.1.1
Summary of Progression Free Survival (PFS) – Part 1
Safety Set

Parameter	Cohort	Statistic	
PFS	Cohort 1 (Dose 0.48 mg/kg) (N=x)	n	x
		Mean	x.x
		SD	x.xx
		Min	x
		Median	x.x
		Max	x
	Cohort 2 (Dose 1.44 mg/kg) (N=x)	n	x
		Mean	x.x
		SD	x.xx
		Min	x
		Median	x.x
		Max	x
	Cohort …		
	Overall (N=x)	n	x
		Mean	x.x
		SD	x.xx
		Min	x
		Median	x.x
		Max	x

Source Listing: 16.2.7.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Percentages are based on the total number of subjects within the Safety Set.

Programming note: A similar table will be presented for Table 14.2.1.2 (FAS) and Table 14.2.1.3 (PPS)
All tables will be repeated for Part 2.

OMO-103-01
Table 14.2.2.1
Summary of Efficacy parameters, DCR, ORR, TTP, TTR and DOR – Part 1
Safety Set

Parameter	Cohort	Component	Statistics	Result
DCR	Cohort 1 (Dose 0.48 mg/kg) (N=x)	DCR	Ratio (%)	x.x %
		Complete Response	N	x
		Partial Response	N	x
		Stable Disease	N	x
	Cohort 2 (Dose 1.44 mg/kg) (N=x)	DCR	Ratio (%)	x.x %
		Complete Response	N	x
		Partial Response	N	x
		Stable Disease	N	x
	Cohort 2 Escalation	DCR	Ratio (%)	x.x %
	…	Complete Response	N	x
		Partial Response	N	x
		Stable Disease	N	x
	Overall (N=x)	DCR	Ratio (%)	x.x %
		Complete Response	N	x
		Partial Response	N	x
		Stable Disease	N	x
ORR……				
TTP	Cohort 1 (Dose 0.48 mg/kg) (N=x)		N	X
			Mean	x.x
			SD	x.xx
			Min	x

Parameter	Cohort	Component	Statistics	Result
			Median	x.x
			Max	X
	….			
TTR…				
DOR				

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
Percentages are based on the total number of subjects within the Safety Set

Programming note: A similar table will be presented for Table 14.2.2.2 (FAS) and Table 14.2.2.3 (PPS – Part 2 only)
Recommend one page be given to each of the 6 parameters (then repeated for 3 populations as above)
A similar table will be presented for Part 2 with Overall Survival (OS) included.

OMO-103-01
Table 14.2.5
Dosing of OMO 103-101 – Part 1
Safety Set

Cohort	Statistic	
Cohort 1	n	x
	Mean	x.x
	SD	x.xx
	Min	x
	Median	x.x
	Max	x
Cohort 2	n	x
	Mean	x.x
	SD	x.xx
	Min	x
	Median	x.x
	Max	x
……		

Source Listing: 16.2.5.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Percentages are based on the total number of subjects within the Safety Set.

Programming note: A similar table will be presented (within the same table number) for Part 2 Dosing

OMO-103-01
Table 14.2.6
Change from Baseline: Quality of Life Questionnaire – Part 1
Safety Set

<Question's group> (Physical, Emotional, Fatigue, Global)

		COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	...	Overall (N=xx)
Baseline	n	xx (xx.x %)	xx (xx.x %)		xx (xx.x %)
	Mean	xx.xx	xx.xx		xx.xx
	SD	xx.xx	xx.xx		xx.xx
	Minimum	xx.x	xx.x		xx.x
	Maximum	xx.x	xx.x		xx.x
	Median	xx.xx	xx.x		xx.xx
Visit	n	xx (xx.x %)	xx (xx.x %)		xx (xx.x %)
	Mean	xx.xx	xx.xx		xx.xx
	Etc				
Change from Baseline to Visit	n	xx (xx.x %)	xx (xx.x %)		xx (xx.x %)
	Mean	xx.xx	xx.xx		xx.xx
	Etc				
Etc					

Source Listing: 16.2.7.5; Produced: yyyy-mm-ddThh:mm - Page x of y
The denominator for each percentage is the number of patients within the column.
Physical functioning = sum of Q1, Q2, Q3, Q4 and Q5 scores.
Emotional functioning = sum of Q21, Q22, Q23, and Q24 scores.
Fatigue = sum of Q10, Q12 and Q18 scores.
Global = sum of Q29 and Q30.

Programming note: A similar table will be presented for Part 2.

OMO-103-01
Figure 14.2.6.1
Kaplan-Meier Plot of Time from Start of IMP to TTP
Full Analysis Set

Figure Specifications

Procedure: PROC LIFETEST – survival plot

By: Treatment

x axis: Time
x axis: Label: Time Post-Dose (h)
x axis: values: As appropriate

Y axis: Survival proportion
Y axis Label: Proportion without TTP
Y axis values: As appropriate

Legend:
(dose) OMO 103-101 (N=X) – linestyle = solid, colour = blue

The number of subjects at risk should be presented (option plots=survival(asterisk)).

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
Censoring occurs where a subject did not record TTP within the study.

This layout also applies to:
Figures 14.2.6.2 (Repeat of above for PPS), 14.2.7.1 (Repeat of above for TTR), 14.2.7.2 (Repeat of 14.2.7.2 for PPS)

OMO-103-01
Table 14.3.1.1
Summary of Treatment Emergent Adverse Events – Part 1
Safety Set

	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
Number (%) of subjects with TEAE by grade and relationship to study drug:				
GRADE 1	x (x.x)	x (x.x)	x (x.x)	x (x.x)
NOT RELATED	x (x.x)	x (x.x)	x (x.x)	x (x.x)
POSSIBLY RELATED	x (x.x)	x (x.x)	x (x.x)	x (x.x)
RELATED	x (x.x)	x (x.x)	x (x.x)	x (x.x)
GRADE 2	x (x.x)	x (x.x)	x (x.x)	x (x.x)
NOT RELATED	x (x.x)	x (x.x)	x (x.x)	x (x.x)
POSSIBLY RELATED	x (x.x)	x (x.x)	x (x.x)	x (x.x)
RELATED	x (x.x)	x (x.x)	x (x.x)	x (x.x)
GRADE …	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
A subject with multiple adverse events is counted only once at the maximum level of severity or the strongest relationship to study drug.
Percentages will be calculated from the number of subjects in the Safety Set within a cohort.

Programming note: A similar table will be presented for Part 2, with the column headers for each of the 3 groups.
A similar table will be presented for Table 14.3.1.1a replacing patient counts by AE event counts.

OMO-103-01
Table 14.3.1.2
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Part 1
Safety Set

	Number of Events / Subjects (%)			
System Organ Class Preferred Term	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
Any TEAEs	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<SYSTEM ORGAN CLASS TERM>				
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<SYSTEM ORGAN CLASS TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
A subject is counted only once per system organ class and preferred term.
Percentages will be calculated from the number of subjects in the Safety Set within a cohort.
MedDRA version <*x.x*>.

Programming note: A similar table will be presented for Part 2, with the column headers for each of the 3 groups

OMO-103-01
Table 14.3.1.2a
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Event Count – Part 1
Safety Set

	Number of Events (%)			
System Organ Class Preferred Term	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
<SYSTEM ORGAN CLASS TERM>				
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<SYSTEM ORGAN CLASS TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm – Page x of y
Percentages will be calculated from the number of events in the Safety Set within a cohort.
MedDRA version <*x.x*>.

Programming note: A similar table will be presented for Part 2, with the column headers for each of the 3 groups

OMO-103-01
Table 14.3.1.3
Summary of Treatment Emergent Adverse Events by Preferred Term – Part 1
Safety Set

	Number of Events / Subjects (%)			
Preferred Term	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	………	Overall (N=x)
Any TEAEs	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
A subject is counted only once per preferred term.
Percentages will be calculated from the number of subjects in the Safety Set within a cohort.
MedDRA version <*x.x*>.

Programming note: A similar table will be presented for Part 2, with the column headers for each of the 3 groups

OMO-103-01
Table 14.3.1.4
Summary of Treatment Emergent Adverse Events by Grade, System Organ Class and Preferred Term– Part 1
Safety Set

<GRADE X>

	Number of Events / Subjects (%)			
System Organ Class Preferred Term	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
<SYSTEM ORGAN CLASS TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<SYSTEM ORGAN CLASS TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
A subject is counted only once per system organ class, preferred term and severity.
Percentages will be calculated from the number of subjects in the Safety Set within a cohort.
MedDRA version <*x.x*>.

Programming note: A similar table will be presented for Part 2, with the column headers for each of the 3 groups

OMO-103-01
Table 14.3.1.5
Summary of Treatment Emergent Adverse Events by Relationship to IMP, System Organ Class and Preferred – Part 1
Safety Set

<RELATIONSHIP>

	Number of Events / Subjects (%)			
System Organ Class Preferred Term	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
<SYSTEM ORGAN CLASS TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<SYSTEM ORGAN CLASS TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)	x / x (x.x)	x / x (x.x)	x / x (x.x)

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
A subject is counted only once per system organ class, preferred term and relationship.
Percentages will be calculated from the number of subjects in the Safety Set within a cohort.
MedDRA version <*x.x*>.

Programming note: A similar table will be presented for Part 2, with the column headers for each of the 3 groups

OMO-103-01
Table 14.3.1.6
Serious Adverse Events - Part 1 - (1)
Safety Set

<Cohort X>

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Onset Date /Time	End Date/ Time/Ongoing	Date Reported	Severity	Relationship to Study Drug
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xxxxxxx	xxxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xxxxxxx	xxxxxxxx
	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xxxxxxx	xxxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xxxxxxx	xxxxxxxx

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).
SAE = Serious Adverse Event.
MedDRA version <*x.x*>.

Programming Note: This table will be repeated on a new page for each cohort (or group in part 2)
This table will be repeated for Part 2. Similar tables will be presented for Adverse Events Leading to Withdrawal – Part 1 and Part 2 (Table 14.3.1.7).

OMO-103-01
Table 14.3.1.6
Serious Adverse Events - Part 1 - (2)
Safety Set

<Cohort X>

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Duration (dd:hh:mm)	Day Post Dose	Time Post Dose (xx:xx)	SAE	SAE Criteria	Action	Outcome	Comment
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xx:xx:xx	xx	xx:xx	x	xxxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xx:xx:xx	xx	xx:xx	x	xxxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx
	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xx:xx:xx	xx	xx:xx	x	xxxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xx:xx:xx	xx	xx:xx	x	xxxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).
SAE = Serious Adverse Event.
MedDRA version <*x.x*>.

Programming Note: This table will be repeated on a new page for each cohort (or group in part 2)
This table will be repeated for Part 2. Similar tables will be presented for Adverse Events Leading to Withdrawal – Part 1 and Part 2 (Table 14.3.1.7).

OMO-103-01
Table 14.3.2.1
Biochemistry Out of Normal Range Data – Part 1
Safety Set

								Normal Range	
Subject	Visit/ Time Point	Sample Date/Time	Sample ID	Parameter	Result	Unit	Flag	Low	High
xxx	xxxxxx	xxxxxxxxxx	xxxxx	xxxxxxx	x.xx	xxx	x	x.x	x.xx
				xxxxxxx	x.xx	xxx	x	x.x	x.xx
	xxxxxx	xxxxxxxxxx	xxxxx	xxxxxxx	x.xx	xxx	x	x.x	x.xx
				xxxxxxx	x.xx	xxx	x	x.x	x.xx
				xxxxxxx	x.xx	xxx	x	x.x	x.xx
	xxxxxx	xxxxxxxxxx	xxxxx	xxxxxxx	x.xx	xxx	x	x.x	x.xx
				xxxxxxx	x.xx	xxx	x	x.x	x.xx
				xxxxxxx	x.xx	xxx	x	x.x	x.xx
	xxxxxx	xxxxxxxxxx	xxxxx	xxxxxxx	x.xx	xxx	x	x.x	x.xx
				xxxxxxx	x.xx	xxx	x	x.x	x.xx

Source Listing: 16.2.9.1; Produced: yyyy-mm-ddThh:mm – Page x of y
H = Above Normal Range; Lo = Below Normal Range.

Programming Note: This table will be repeated for Part 2. Similar tables will be produced for Hematology Out of Normal Range Data – Part 1 and Part 2 (Table 14.3.2.2) and Urinalysis Out of Normal Range Data (Table 14.3.2.3).

OMO-103-01
Table 14.3.2.4
Autoimmune values – Part 1
Safety Set

<*Parameter* (<*units*>)>

Visit/ Time Point	n	Mean	SD	Min	Median	Max
SCREENING	x	x.xx	x.xxx	x.x	x.xx	x.x
CYCLE 3 DAY 01	x	x.xx	x.xxx	x.x	x.xx	x.x
CYCLE 4 DAY 01	x	x.xx	x.xxx	x.x	x.xx	x.x
…						

Source Listing: Listing 16.2.9.5; Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: This table will be repeated for Part 2.

OMO-103-01
Table 14.3.2.5
Frequency of Autoimmune values – Part 1
Safety Set

<Parameter (<*units*>)>

Visit/ Time Point		COHORT 1 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
SCREENING	N	x (x.x)		x (x.x)
	Positive	x (x.x)		x (x.x)
	Negative	x (x.x)		x (x.x)
CYCLE 3 DAY 01	N	x (x.x)		x (x.x)
	Positive	x (x.x)		x (x.x)
	Negative	x (x.x)		x (x.x)
CYCLE 4 DAY 01	N	x (x.x)		x (x.x)
	Positive	x (x.x)		x (x.x)
	Negative	x (x.x)		x (x.x)

Source Listing: 16.2.9.5; Produced: yyyy-mm-ddThh:mm - Page x of y

Programming note: A similar table will be presented for Part 2

OMO-103-01
Table 14.3.3.1
Summary of 12-Lead ECG Data – Part 1
Safety Set

Visit/ Time Point		COHORT 1 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
SCREENING	N	x (x.x)		x (x.x)
	Normal	x (x.x)		x (x.x)
	Abnormal NCS	x (x.x)		x (x.x)
	Abnormal CS	x (x.x)		x (x.x)
TREATMENT PERIOD	N	x (x.x)		x (x.x)
	Normal	x (x.x)		x (x.x)
	Abnormal NCS	x (x.x)		x (x.x)
	Abnormal CS	x (x.x)		x (x.x)
FOLLOW-UP PERIOD	N	x (x.x)		x (x.x)
	Normal	x (x.x)		x (x.x)
	Abnormal NCS	x (x.x)		x (x.x)
	Abnormal CS	x (x.x)		x (x.x)

Source Listing: 16.2.12.1; Produced: yyyy-mm-ddThh:mm - Page x of y

Programming note: A similar table will be presented for Part 2

OMO-103-01
Table 14.3.4.1
Statistical summaries of ECOG status by visit – Part 1
Safety Set

Visit/ Time Point		COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
SCREENING	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	0	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	1	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	2	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	3				
	4				
	5				
BASELINE	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	1	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	2	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	3	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	4				
	5				
VISITS	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	1	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	2	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	3	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	4				
	5				
FOLLOW-UP PERIOD	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	1	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	2	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	3	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	4				
	5				

Visit/ Time Point	COHORT 1 (Dose xx mg/ml) (N=x)	COHORT 2 (Dose xx mg/ml) (N=x)	.....	Overall (N=x)

Source Listing: 16.2.15.1; Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Table 14.3.5.1
Statistical summaries of Vital Signs by visit – Part 1
Safety Set

<Parameter>

Visit/ Time Point		COHORT 1 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
BASELINE	n	x (x.x)		x (x.x)
	Mean	xx		xx
	SD	xx		xx
	Min	xx		xx
	Max	xx		xx
	Median	xx		xx
CYCLE 1 DAY 01	n	x (x.x)		x (x.x)
	Mean	xx		xx
	SD	xx		xx
	Min	xx		xx
	Max	xx		xx
	Median	xx		xx
Change from BASELINE to CYCLE 1 DAY 01	n	x (x.x)		x (x.x)
	Mean	xx		xx
	SD	xx		xx
	Min	xx		xx
	Max	xx		xx
	Median	xx		xx

Source Listing: 16.2.10.1; Produced: yyyy-mm-ddThh:mm - Page x of y

Programming note: Repeat pages will be required for further visits.

Table will be repeated for each vital sign parameter.
A similar table will be presented for Part 2

OMO-103-01
Table 14.3.6.1
Statistical summaries of Physical Examination by visit – Part 1
Safety Set

<Body system>

Visit/ Time Point		COHORT 1 (Dose xx mg/ml) (N=x)	……	Overall (N=x)
SCREENING	N	x (x.x)		x (x.x)
	Normal	x (x.x)		x (x.x)
	Abnormal NCS	x (x.x)		x (x.x)
	Abnormal CS	x (x.x)		x (x.x)
BASELINE	N	x (x.x)		x (x.x)
	Normal	x (x.x)		x (x.x)
	Abnormal NCS	x (x.x)		x (x.x)
	Abnormal CS	x (x.x)		x (x.x)
CYCLE 1 DAY 01	N	x (x.x)		x (x.x)
	Normal	x (x.x)		x (x.x)
	Abnormal NCS	x (x.x)		x (x.x)
	Abnormal CS	x (x.x)		x (x.x)

Source Listing: 16.2.11.1; Produced: yyyy-mm-ddThh:mm – Page x of y

Programming note: Repeat pages will be required for further visits.
Table will be repeated for each body system.
A similar table will be presented for Part 2

OMO-103-01
Listing 16.2.1.1
Visit Dates
Safety Set

<Study part> - <Cohort>

Subject	Visit	Treatment	Date
xxx	xxxxxxx		xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx		xxxxxx
xxx	xxxxxxx		xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx		xxxxxx
xxx	xxxxxxx		xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx	xxxxx	xxxxxx
	xxxxxxx		xxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: Date may be split into Start Date and End Date if a visit spans multiple days.

OMO-103-01
Listing 16.2.1.2
Subject Disposition – (1)
All Patients Set

<Study part> - <Cohort>

			Informed Consent			Informed Re-Consent	
Subject	Screening Number	Screening Failure	Date/Time	Version	Physician Obtaining Informed Consent	Date/Time	Version
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx
xxx	xxxx	x	xxxxxxTxx:xx	xxxxx	xxxxx	xxxxxxTxx:xx	xxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: Study part sub-header will be blank for screening failures.

OMO-103-01
Listing 16.2.1.2
Subject Disposition – (2)
All Patients Set

<Study part> - <Cohort>

		Enrollment		Study Completion/Termination			Number of cycles*
Subject	Screening Number	Date	Study Part	Study Completed	Date of Completion/ Withdrawal	Reason for Early Withdrawal	
xxx	xxxx	xxxxxx	x	x	xxxxxx		xx
xxx	xxxx	xxxxxx	x	x	xxxxxx		x
xxx	xxxx	xxxxxx	x	x	xxxxxx	xxxxxxxxxx	xxx
xxx	xxxx	xxxxxx	x	x	xxxxxx		xx
xxx	xxxx	xxxxxx	x	x	xxxxxx		
xxx	xxxx	xxxxxx	x	x	xxxxxx		x
xxx	xxxx	xxxxxx	x	x	xxxxxx		Xx
xxx	xxxx	xxxxxx	x	x	xxxxxx	xxxxxxxxxx	x
xxx	xxxx	xxxxxx	x	x	xxxxxx		
xxx	xxxx	xxxxxx	x	x	xxxxxx		

* Cycle count includes partial cycles.
Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: Study part sub-header will be blank for screening failures.

OMO-103-01
Listing 16.2.2.1
Protocol Deviations
Safety Set

<Study part> - <Cohort>

Subject	Deviation Number	Date of Deviation	Deviation Type	Deviation	Major/ Minor
xxx	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
xxx	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
xxx	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.3.1
Analysis Sets

<Study part> - <Cohort>

Subject	Screening Number	Population	Included (Y/N)
xxx	xxxx	All Patients	x
		Safety	x
		Full Analysis	x
		Per-Protocol	x
xxx	xxxx	x	x
……			

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: Study part sub-header will be blank for screening failures.

OMO-103-01
Listing 16.2.4.1
Demographic Information
Safety Set

<Study part> - <Cohort>

Subject	Screening Number	Year of Birth	Age (Yrs)	Gender	Race	If Mixed or Other, Specify	Height (cm)	Weight (kg)
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx	xxxxxxxxxx	xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx	xxxxxxxxxx	xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx
xxx	xx	xxxxx	xxx	x	xxxxxxx		xxx	xxx

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.4.2
Medical History
Safety Set

<Study part> - <Cohort>

Subject	Medical History Number	System Organ Class/ Preferred Term/ Reported Term	Date of Onset	Date Resolved/ Ongoing	Medication Taken/Treatment given?	Clinically Significant
xxx	x	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxx	x	x
	x	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxx	x	x
	x	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxx	x	x

Produced: yyyy-mm-ddThh:mm - Page x of y
MedDRA version *<x.x>*.

OMO-103-01
Listing 16.2.4.3
Inclusion/Exclusion Criteria Failures
Safety Set

<Study part> - <Cohort>

Subject	Visit	Inclusion/ Exclusion	Criteria Number	Result
xxx	xxxxxx	xxxxxx	xx	xxxxxx
xxx	xxxxxx	xxxxxx	xx	xxxxxx
xxx	xxxxxx	xxxxxx	xx	xxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: If there are no inclusion/exclusion criteria failures, display 'All subjects complied with the inclusion/exclusion criteria'.

OMO-103-01
Listing 16.2.5.1
Summary of OMO 103-01 dosing
Safety Set

<Study part> - <Cohort>

Subject	Cohort	Theoretical Total Dose	Actual Total Dose	Theoretical Date of Sample	Actual Date of Sample
xxx	xxxxxxxx	xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx
		xx	xx	xxxxxx	xxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.7.1
Summary of PFS
Safety Set

<Study part> - <Cohort>

Subject	Cohort	Date	PFS Value
xxx	xxxxxxxx	xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx
		xx	xx

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: Listing will be repeated for 16.2.7.2 – 16.2.7.4

OMO-103-01
Listing 16.2.7.5
QoL Questionnaire
Safety Set

<Study Part> - <Cohort>

Subject	Cohort	Visit	Question	Result
xxxxxx	xxxx	xxx	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	x
			Do you have any trouble taking a long walk?	x
			Etc	
			How would you rate your overall quality of life during the past week?	x
		Etc		
Etc				

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.8.1
Adverse Events - (1)
Safety Set

<Study Part> - <Cohort> - <Treatment phase>

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Onset Date /Time	End Date/ Time/Ongoing	Date Reported	Duration (dd:hh:mm)	Time Post Dose (dd:hh:mm)	Severity
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xx:xx:xx	xx:xx:xx	xxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xx:xx:xx	xx:xx:xx	xxxxxxx
	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xx:xx:xx	xx:xx:xx	xxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxx Txx:xx	xxxxxxx Txx:xx	xxxxxx	xx:xx:xx	xx:xx:xx	xxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).
SAE = Serious Adverse Event.
MedDRA version *<x.x>*.

OMO-103-01
Listing 16.2.8.1
Adverse Events - (2)
Safety Set

<Study Part> - <Cohort> - <Treatment phase>

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Relationship to Study Drug	SAE	SAE Criteria	Action	Outcome	Comment
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxxx	x	xxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxxx	x	xxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx
	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxxx	x	xxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx
xxx	x	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	xxxxxxxx	x	xxxxxxxxxxx	xxxxxx	xxxxxx	xxxxxxxxx

Source Listing: 16.2.7.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).
SAE = Serious Adverse Event.
MedDRA version <*x.x*>.

OMO-103-01
Listing 16.2.9.1
Biochemistry Data
Safety Set

<Study part> - <Cohort>

Subject	Visit	Sample Date/Time	Sample ID	Parameter	Result	Units	Flag	Normal Range Lower	Normal Range Upper	Interpretation	Repeat Req.
xxx	xxxxxx	xxxxxxxxT	xxxxxxx	xxxxxxxx	x.xx	xxxx	x	x.x	x.xx	xxxxxxxxxxxxx	x
		xx:xx		xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx	x	x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx	x	x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx	x	x.x	x.xx	xxxxxxxxxxxxx	
				xxxxxxxx	x.xx	xxxx		x.x	x.xx	xxxxxxxxxxxxx	

Produced: yyyy-mm-ddThh:mm - Page x of y
H = Above Normal Range; Lo = Below Normal Range.

Programming note: Similar Listings will be produced for haematology (Listing 16.2.9.2), urinalysis (Listing 16.2.9.3) and other laboratory data (Listing 16.2.9.4).

OMO-103-01
Listing 16.2.10.1
Vital Signs Data
Safety Set

<Study Part> - <Cohort>

Subject	Visit/ Time Point	Date/Time	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse Rate (beats/ min)	Investigator's Interpretation
xxx	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx
	xxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.11.1
Physical Examination
Safety Set

<Study Part> - <Cohort>

Subject	Visit	Performed	Date	Time
xxx	xxxxxxx	x	xxxxxx	xx:xx
	xxxxxxx	x	xxxxxx	xx:xx
	xxxxxxx	x	xxxxxx	xx:xx
	xxxxxxx	x	xxxxxx	xx:xx
xxx	xxxxxxx	x	xxxxxx	xx:xx
	xxxxxxx	x	xxxxxx	xx:xx
	xxxxxxx	x	xxxxxx	xx:xx
	xxxxxxx	x	xxxxxx	xx:xx

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.12.1
12-Lead ECG Data
Safety Set

<Study Part> - <Cohort>

Subject	Period	Treatment	Visit/ Time Point	Date/Time	Heart Rate (beats/min)	PR Interval (msec)	QRS Width (msec)	QT Interval (msec)	QTcB Interval (msec)	Investigator Comment
xxx			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
	xxxxx	xxxxxx	xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
	xxxxx	xxxxxx	xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx
			xxxxxxx	xxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

OMO-103-01
Listing 16.2.13.1
Prior Medications
Safety Set

<Study Part> - <Cohort>

Subject	Medication Number	ATC Level 4/ Preferred Term/ Medication	Dose	Dose Unit	Frequency	Indication/ AE Number	Route	Start Date /Time	Stop Date/ Time/ Ongoing
xxx	x	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	xxx	xx	xxxxxx	xxxxxxxx	xxxx	xxxxxxTxx:xx	xxxxxxTxx:xx
xxx	x	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	xxx	xx	xxxxxx	xxxxxxxx	xxxx	xxxxxxTxx:xx	xxxxxxTxx:xx
xxx	x	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	xxx	xx	xxxxxx	xxxxxxxx	xxxx	xxxxxxTxx:xx	xxxxxxTxx:xx

Produced: yyyy-mm-ddThh:mm - Page x of y
WHO DDE version <*XXXXXX*>.

Programming Note: Listing to be repeated for Concomitant Medications (Listing 16.2.13.2).

16 APPENDICES

16.1 NORMAL RANGES

Vital Sign Parameters		
Parameter	**Normal Range**	**Unit**
Pulse Rate	40 - 100	Beats per minute (bpm)
Systolic Blood Pressure	90 – 140	mmHg
Diastolic Blood Pressure	50 - 90	mmHg
Respiratory Rate	12 - 18	Breaths per minute
Temperature	35.0 - 37.5	Degrees Celsius

ECG Parameters		
Parameter	**Normal Range**	**Unit**
Heart Rate	40 - 100	Beats per minute (bpm)
PR Interval	120 – 220	Millisecond (msec)
QRS Width	70 – 120	Millisecond (msec)
QT Interval	N/A	Millisecond (msec)
QTc Interval (Bazett's & Fridericia's formulae)	350 – 450 (males) 350 – 450 (females)	Millisecond (msec) Millisecond (msec)