Statistical Analysis Plan

AstraZeneca Pharma India Limited

D0816R00025

A Prospective, Multicentre, Phase-IV Clinical Trial of Olaparib in Indian Patients with Platinum Sensitive Relapsed Ovarian Cancer who are in Complete or Partial Response Following Platinum Based Chemotherapy and Metastatic Breast Cancer with Germline BRCA1/2 Mutation (SOLI Study)

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Glossary of Abbreviations:

Abbreviation	Term
AE	Adverse Event
ALT	Alanine Aminotransferase
APTT	Activated Partial Thromboplastin True
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Chemical
BC	Breast Cancer
BMI	Body Mass Index
BRCA	Breast Cancer susceptibility gene
CRF	Case report form
CSR	Clinical Study Report
ECG	Electrocardiogram
EOS	End Of Study
EOT	End Of Treatment
gBRCAm	Germline BRCA mutation
HA	Health Authority
Hb	Haemoglobin
HER	human epidermal growth factor receptor
ICF	Informed Consent Form
ICH	International Conference on Harmonization
MedDRA	Medical Dictionary for Regulatory Activities
NCI-CTCAE	National Cancer Institute-Common Terminology Criteria for Adverse Events
OC	Ovarian Cancer
PS	Performance Status
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
TFLs	Tables, Figures and Listings
WHO	World Health Organization

STATISTICAL ANALYSIS PLAN AMENDMENT 1

Not Applicable.

1. Source Documents

This document describes the planned statistical analyses for Protocol D0816R00025. This analysis plan is meant to supplement the study protocol. Any deviations from this analysis plan will be described in the Clinical Study Report.

The Statistical Analysis Plan (SAP) was written based on the following documentation:

Document	Date	Version
Protocol	19OCT2019	2.0
CRF	26NOV2021	1.6

2. Protocol Details

2.1 Study Objectives

2.1.1. Primary Objective

To assess the safety of olaparib in Indian patients with:

- platinum sensitive relapsed ovarian cancer who are in complete or partial response following platinum-based chemotherapy, and
- HER – 2 negative metastatic breast cancer with germline BRCA1/2 mutation.

2.2 Overall Study Design

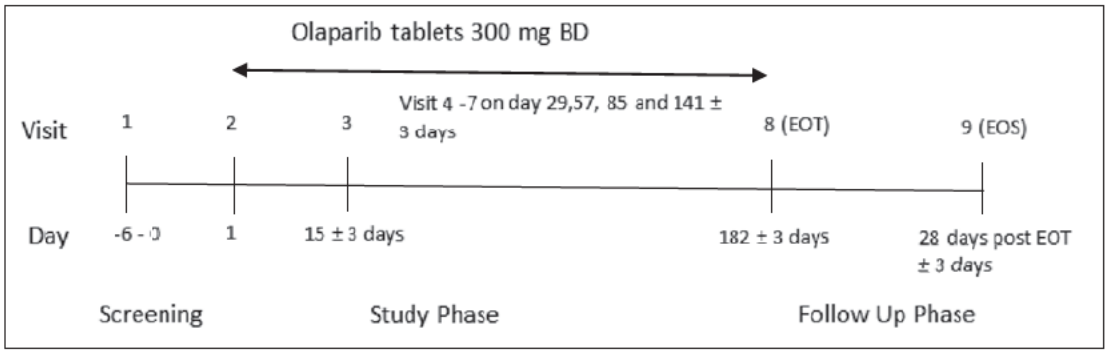
This is a prospective, single - arm, multicentre, interventional phase – IV trial investigating the safety of olaparib in Indian adult patients receiving olaparib as per the local approved prescribing information. The investigator will be trained on the locally approved prescribing information before the enrolment of the first patient at their site to ensure compliant and proper dosing of the study drug.

Patient participation will include following phases:

- Screening/Enrolment Phase (7 days prior to Day 1)
- Treatment Phase (extend from Day 1 to Day 182; or until study drug discontinuation due to either disease progression or unacceptable toxicity; or other reasons, whichever occurs first).
- Follow-up Phase (will begin once a patient discontinues study drug during Treatment Phase, and will continue until 28 days after last dose, death, loss to follow - up, consent withdrawal for study participation, or study end, whichever occurs first).

Patients who are observed to continue to receive clinical benefit from olaparib at end of Treatment Phase will continue treatment in Extension Phase as long-term clinical benefit is observed or until the investigator decides it is not in the best interest of the patient to continue olaparib treatment.

Schema:



EOT: End Of treatment; EOS: End Of Study

Number of Patients:

No. of total screened patients: Approximately 225 (180 for Ovarian and 45 for Breast)

No. of total enrolled patients: Approximately 200 (160 for Ovarian and 40 for Breast)

Approximate No. of study sites: 15

End of Study Definition:

The end of study is defined as the last expected visit/contact of the last patient undergoing the study.

A patient is considered to have completed the study when he/she has completed his/her end of study visit as per the planned study schedule mentioned in the study protocol.

2.3 Sample Size and Power

There is no formal sample size calculation as this study is being conducted as a regulatory requirement for a phase IV study including Indian patients in the approved indications post marketing of olaparib. The primary endpoint is to demonstrate the

safety profile of olaparib in routine clinical practice as assessed by the incidence of AEs (serious and non-serious) observed during trial.

Assuming the true incidence rate of any adverse event (mentioned as part of the labelling information of Olaparib) of severity grade 3 or higher to be 40%, corresponding data from approximately 190 Indian adult patients satisfying the protocol specified eligibility criteria will be required in this study for estimating the sample (study based) incidence rate with 7% error margin and using 95% confidence interval. In this study, we expect to recruit 160 patients from platinum sensitive relapsed ovarian cancer and 40 patients from gBRCAm positive metastatic breast cancer as per the Indian HA approved indication to satisfy the Lynparza MA conditional approval.

3. Efficacy and Safety Variables

3.1 Primary Efficacy Endpoint(s)

Not Applicable.

3.2 Secondary Efficacy Endpoints

Not Applicable.

3.3 Safety Variables

The safety variables to be analysed include:

- Adverse Events
- Clinical laboratory tests (haematology and clinical chemistry)
- Physical examination results
- Vital parameters
- World Health Organization (WHO) performance status (PS)
- Deaths, as observed by participating physician

4. Pharmacokinetic/Pharmacodynamic variables

Not Applicable.

5. Analysis populations

5.1 Enrolled

All patients who sign the ICF (Informed Consent Form) and are screened with eligibility verified as per the Inclusion-Exclusion criteria mentioned in study protocol are considered to be enrolled.

This population will be used for presenting data on patient disposition, demographic and baseline characteristics, medical or surgical history and prior and concomitant medications and for any patient data that will be collected on screening visit only.

5.2 Safety Analysis Set

All patients randomly assigned to Study treatment and who take at least 1 dose of study drug.

6. Data Handling

6.1 Time points and Visit Windows

Day 1 is defined as the day of first dose of study drug (i.e. Day 1 in treatment Phase phase).

The baseline value will be defined as last value collected prior to the first dose of study drug.

Relative days after Day 1 are calculated as (assessment date – Day 1 date) + 1. Relative days prior to Day 1 are calculated as (assessment date – Day 1 date). The day prior to Day 1 is Day -1.

Safety will be evaluated throughout the evaluation phase and during the follow - up of patients who discontinue treatment before end of Treatment Phase by physical exams including vital signs, AE/SAE monitoring, laboratory evaluations and recording of concomitant medications. The sponsor shall provide the laboratory investigations for safety evaluation including haematology and biochemistry as mentioned in the Time and Events Schedule in the protocol to monitor the safety throughout the study period. A window period of +/- 3 days will be allowed for visits 3 – 9.

All data will be analyzed using nominal study visits as defined in the Study Schedule and CRF.

6.2 Handling of Dropouts, Missing Data, and Outliers

Missing results/events will not be imputed.

Adverse events and concomitant medications with completely or partially missing assessment dates will have imputation performed as explained below for the purposes of calculation of durations or relativity to study medication.

For the end of a concomitant medication or adverse event:

- **If only Day of end date is missing**:

  The last date of the month and year reported or the date of the final contact with the patient, whichever is earlier, will be used as the end date;

- **If Day and Month of end date are missing**:

  The last date of year i.e. December 31 of the year reported or the date of the last study contact with the patient, whichever is earlier, will be used as the end date;

- **If Year of end date or complete end date is missing:**

  If the adverse event or concurrent medication continues after the last study contact date, then no end date or time will be estimated.

For the start of a concomitant medication or adverse event:

- **If only Day of start date is missing:**
  - If the start year and month of medication/event are the same as that for the first dose date, then following approach will be used:
    - If the end date of medication/event is NOT before the first dose date or end date of medication/event is completely missing, then
      - Impute the start day as the day of first dose date;
    - Otherwise, impute the start day as 1.
  - If the start year and month of medication/event are NOT same as that for the first dose date, then
    - Impute the start day as 1.
- **If Day and Month of start date are missing:**
  - If start year of medication/event is same as first dose year, then following approach will be used:

    i. For medication, impute the start Month as January and the Day as 1;

    ii. For adverse event,
    - If the end date of event is NOT before the first dose date or end date of event is completely missing, then
      - Impute the start Month and Day as the Month and Day of first dose date;
    - Otherwise, impute the start Month as January and the Day as 1;
  - If start year of medication/event is NOT same as first dose year, then
    - Impute start Month as January and the Day as 1.

- **If Year of start date or complete start date is missing:**

If the year of start of medication/event is missing or start date is completely missing, then no start date or time will be imputed.

Also for AE, compare the end date to the first dose date. If the AE end date is before the first dose date, then the AE should be considered as a medical history. Otherwise, the AE will be considered as TEAE.

No rules for outlier detection are planned.

7. Statistical Methods

7.1 General Principles

The data across the participating sites will be pooled for reporting the statistical analyses. No formal hypothesis testing will be conducted.

The table summaries will be produced by grouping the patients with ovarian cancer (OC), breast cancer (BC), Both (Combination of OC and BC) and overall. The listings will be produced for each patient with information of site and cancer type being OC and/or BC.

All data processing, summarization and analyses will be performed using SAS Environment / Version 9.4 (or later) of the SAS® statistical software package.

The following principles will be applied to all TFLs unless otherwise stated:

Principle	Value	Suggested Alternative Values
Significant tests	Not Applicable	Not Applicable
Treatment group labels and order presented	OC, BC, Both and Overall	Not Applicable
Tables	Data in summary tables presented by treatment group and visit (where applicable).	Not Applicable
Listings	All data collected presented by treatment group, site, patient, and visit (where applicable), unless otherwise specified.	Not Applicable
Descriptive summary statistics for continuous variables	Number of patients (n), mean, standard deviation (SD), median, minimum and maximum.	Not Applicable
Descriptive summary statistics for categorical variables	Frequency counts and percentages [n (%)] <u>For Adverse events:</u> Frequency counts with percentages [n (%)] and the number of events.	Not Applicable

Principle	Value	Suggested Alternative Values
Denominator for percentages	Number of patients in the analysis population, unless stated otherwise in table shell(s)	Not Applicable
Include "Missing" as category	No, only in below: • Demographics and Other Baseline Characteristics • Shift table for haematology • Shift table for clinical chemistry	Not Applicable
Display for 0 percentages	Blank	Not Applicable
Display to one more decimal place than collected value	Mean Median	Not Applicable
Display to two more decimal places than collected value	Standard Deviation	Not Applicable
Limit of precision for displays	3 decimal places	Not Applicable
Date Format	DDMMMYYYY	Not Applicable

7.2 Patient Disposition and Data Sets Analyzed

Patient disposition will be summarized using standard descriptive statistics for all the patients as below:

- screened;
- enrolled;
- enrolled and not treated;
- included in Safety Analysis Set
- completed study
- discontinued study with further breakdown of primary reasons for discontinuation for Safety Analysis Set.

A listing will be presented to describe dates of screening, assigned treatment, screen failed with reason (if available), completion, early withdrawal, and the reason for early discontinuation, if applicable, for each patient.

7.3 Protocol Deviations

A full list of protocol deviations reported during the study will be compiled prior to database closure. This data will be listed as appropriate for all enrolled patients.

7.4 Demographics and Other Baseline Characteristics

Demographic and baseline characteristics will be summarized and listed for all enrolled patients. Standard descriptive statistics will be presented for:

- Continuous variables:
  - Age (years)
  - Weight at screening(kg);
  - Height at screening(cm);
  - Body mass index (kg/m^2) [calculated as ($weight/height^2$) where weight is in kg and height is in m];
- Categorical variables:
  - child bearing potential
  - WHO PS at screening
  - Histology type at screening
  - Stage/FIGO stage at screening
  - Biopsy tissue type at screening
  - Organ involved at screening
  - gBRCA result at screening
  - Size or Direct Extent of Primary Tumor at Screening
  - Degree of Spread of Cancer to Regional Lymph Nodes at Screening
  - Distant Metastases at Screening
  - Previous Cancer Therapy Regimen

  No formal tests of statistical significance will be performed on the demographic and baseline data.

7.4.1 Medical and Surgical History

Medical and surgical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) [Version 24.1].

All medical or surgical history will be listed for each enrolled patient.

The standard descriptive statistics will be used for summarizing all enrolled patients with any medical or surgical history by system organ class (SOC) and preferred term (PT).

7.4.2 Prior and Concomitant Medication

Medications received prior to or concomitantly with study drug will be coded by using the WHODrug Dictionary [Version Sep2021].

Prior medications and concomitant medications are defined as follows:

Prior medications are those taken prior to the first dose date of study drug.

Concomitant medications are those that were taken while on study drug including the ones that started before the first dose of study drug. The medications that started after the discontinuation of study drug will also be termed as 'Concomitant'.

Prior medications and concomitant medications will be listed together and summarized separately for all the enrolled patients.

Standard descriptive statistics will be used to summarize patients using various prior or concomitant medications/procedures using Anatomical therapeutic class (ATC-Level 2) and Preferred Term (PT).

7.5 Efficacy

No efficacy analyses will be performed on the patients enrolled in this study.

7.5.1 Primary Efficacy Analysis

Not Applicable.

7.5.2 Secondary Efficacy Analysis

Not Applicable.

7.5.3 Sensitivity Analysis

Not Applicable.

7.5.4 Subgroup Analysis

Not Applicable.

7.5.5 Exploratory Analysis

Not Applicable.

7.6 Safety

7.6.1 Extent of Exposure

Duration of study drug exposure will be defined in days as:

Date of last dose – Date of first dose + 1 day

Duration of exposure will be listed and summarized using standard descriptive statistics for all the patients included in the Safety Analysis Set.

7.6.2 Adverse Events

All adverse events (AEs) recorded on the CRF will be coded by System Organ Class (SOC) and Preferred Term (PT) using the MedDRA dictionary [Version 24.1].

Assessment of AE severity will be based on the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE, latest version).

Treatment –Emergent AEs (TEAEs) are events with start date on or after the date of first dose of study drug. Also, the adverse events that are a consequence of a pre-existing condition that has worsened later during the treatment phase (i.e. events having start date before the date of first dose of study drug and have worsened in severity while on study treatment) will be termed as "Treatment-Emergent".

AEs (both in terms of MedDRA preferred terms and CTCAE grade) will be listed individually by patient.

Any AE occurring before treatment with olaparib will be included in the data listings but will not be included in the summary tables of AEs.

Any AE occurring within 28 days of discontinuation of study drug (i.e., the last dose of olaparib) will be included in the AE summaries.

An overall summary of adverse events will be summarized using standard descriptive statistics for the following:

- AEs
- Non-TEAEs
- TEAEs
- Grade 3 and above TEAEs
- Grade 3 and above treatment-related TEAEs
- Treatment-related TEAEs
- Treatment-related serious TEAEs
- TEAEs leading to dose reduction/ interruption/ discontinuation
- Treatment related TEAEs leading to dose reduction/ interruption/ discontinuation
- Serious TEAEs
- Fatal TEAEs
- Related Fatal TEAEs

- Adverse Events of Special Interest (AESIs) [MDS (Myelodysplastic Syndrome), AML (Acute Myeloid Leukamia), Pneumonitis/ILD, Secondary Malignancies]

Using standard descriptive statistics, following summaries will be presented by SOC and PT:

- TEAEs
- Treatment-related TEAEs
- Treatment-emergent SAEs
- Grade 3 and above TEAEs
- Grade 3 and above treatment-related TEAEs
- TEAEs leading to dose reduction/ interruption/ discontinuation

In the above summaries, patients with more than one AE within a particular SOC are counted only once for that SOC. Similarly, patients with more than one AE within a particular PT are counted only once for that PT.

Following adverse events data listings will also be presented for individual patients.

- Any adverse event
- Serious adverse event
- TEAEs leading to drug interruption
- TEAEs leading to drug reduction/
- TEAEs leading to drug discontinuation
- AESI

7.6.3 Laboratory Evaluations

Data for the following haematology, clinical chemistry, coagulation and urinalysis parameters captured on CRF will be listed for all the patients who are included in the Safety Analysis Set.

The haematology and clinical chemistry data will be summarized using standard descriptive statistics for each laboratory parameter at baseline and for observed values and changes from baseline at each post-baseline visit.

The coagulation and urinalysis data will be provided in listings only for each patient for all available visits.

Haematology	Clinical Chemistry	Coagulation	Urinalysis
Haemoglobin (Blood) Leucocytes, WBC (Blood) Platelets (Blood) Neutrophils, Absolute Count (Blood) Eosinophils, Absolute Count (Blood) Basophils, Absolute Count (Blood) Lymphocytes, Absolute Count (Blood) Monocytes, Absolute Count (Blood)	Alanine Aminotransferase (Serum/Plasma) Aspartate Aminotransferase (Serum/Plasma) Alkaline Phosphatase (Serum/Plasma) Creatinine (Serum/Plasma) Bilirubin, Total (Serum/Plasma) Albumin (Serum/Plasma) BUN (Blood Urea Nitrogen)	International normalized ratio (INR) Prothrombin time (PT) Activated partial thromboplastin time (aPTT)	Hb/Erythrocytes /Blood Glucose Albumin Protein

All laboratory data will be reported in International System of Units (SI)/ Conventional units. Out-of-reference-range values will be flagged as high (H) or low (L) in the listings.

For haematology, shift tables presenting movement in and out of reference range from baseline to each scheduled post-baseline visit will be provided.

For each laboratory analyte, the baseline value will be defined as last value collected prior to the first dose of study drug. For post-baseline, only data from scheduled visits will be included in the summary tables.

7.6.4 Vital Signs

The following vital signs will be measured in the study:

- systolic and diastolic blood pressure (mmHg);
- pulse rate (bpm);
- respiration rate (breaths/min);
- oral body temperature (°C).
- weight (kg)

The baseline and changes from baseline values in vital signs will be summarized by visit using standard descriptive statistics for the Safety Analysis Set. The baseline value will be defined as last value collected prior to the first dose of study drug. For

post-baseline, only data from scheduled visits will be included in the summary tables. The vital signs data will be listed for each patient for all the available visits.

7.6.5 Electrocardiograms (ECGs)

The ECG data will be summarized using standard descriptive statistics classified by normal, abnormal not clinically significant, abnormal clinically significant and not evaluable categories for all patients included in Safety Analysis Set. The ECG data will be listed for each patient for every visit.

The baseline value will be defined as last value collected prior to the first dose of study drug.

7.6.6 Physical Examination

For physical examination status and various body systems, the data will be summarized using standard descriptive statistics classified by normal, abnormal clinical significant and abnormal nonclinical significant categories for all scheduled visits for the Safety Analysis Set.

Physical examination results will be listed for each patient for all the available visits.

The baseline value will be defined as last value collected prior to the first dose of study drug.

7.6.7 WHO Performance Status (PS)

WHO PS classified as; (1= Normal activity, 2=Restricted activity, 3=In bed less than or equal to 50% of the time, 4=In bed more than 50% of the time, 5=100% bedridden) will be summarized per scheduled visit using standard descriptive statistics and listed for each patient for all available visits for the Safety Analysis Set.

The baseline value will be defined as last value collected prior to the first dose of study drug.

7.7 Interim Analysis

No interim analysis will be performed for this study.

8. Changes in Planned Analysis

Not Applicable.

9. Data Issues

Not Applicable.

10. Additional Listings

Following listings will be produced:

- Pathology at Diagnosis
- Tumour sample
- Germline BRCA test
- Extent of disease upon entry
- Previous cancer therapy
- Deaths during the study
- Discontinuation of study drug
- Laboratory tests for Hepatitis B and C
- Pregnancy test results
- Pregnancy reports
- Bone marrow biopsy
- CT scan reports
- Study drug administration
- Study Drug accountability
- Overdose reports
- Hospital admission details
- Hy's Law evaluation (if; data permits)

11. References

1 ICH. *Statistical Principles for Clinical Trials*, Guideline E9, 1998. Available at http://www.emea.eu.int/pdfs/human/ich/036396en.pdf

12. Appendices

Appendix 1: Document History

Document Version, Status, Date	Summary/Reason for Changes
Version FINAL, 13 January 2023	Not applicable; the final version

13. Table Shells and Specifications

General programming instructions:

Partial birth dates will be imputed as mentioned below for calculation of age-
If Day or Month of date of birth is missing, then impute the missing month as January and missing Day as 01 of the respective year.

For tables:

1. The precision of the summary statistics (mean, median, SD, min, max) and inferential statistics (SE, confidence limits) should be based on the raw data:

- Mean and median should be reported with 1 more place after the decimal as raw data were reported, for example, if raw data were reported as integer values (xx), the mean should be reported as xx.x.
- Standard deviation (SD), SE, and confidence limits (CLs) should be reported with 2 more places after the decimal as raw data were reported, for example, if raw data were reported as integer values (xx), the SD, SE, and CLs should be reported as xx.xx.
- Min and max should be reported with the same precision as the raw data.

2. All p-values should be reported with precision 0.xxxx. If the p-value is less than 0.0001, the p-value should appear in the table as "<0.0001".

3. Summary statistics for number of patients with data summarized/analyzed should be lower case 'n' or 'n (%)'. Capital 'N' should only be used in column or row headers when indicating the total in the denominator, for example (N=xx).

4. For all categorical parameters, in case of missing data, a "missing" category should be added.

5. When continuous data are being summarized, only the non-missing values should be used for computing summary statistics.

6. When displaying percentages, if count is 0, no percentage would be displayed.

For Listings:

For listings, if there is no observation in the listing, display the header portion, and display a message of "No observation" in the table body text.

Data Presentations

Category	Sr. No	Title
Table	14.1.1.1	Patient Disposition - All Patients
Table	14.1.2.1	Summary of Protocol Deviations - All Enrolled Patients
Table	14.1.3.1	Demographic and Baseline Characteristics - All Enrolled Patients
Table	14.1.4.1	Summary of Medical and Surgical History - All Enrolled Patients
Table	14.1.5.1	Summary of Prior Medications - All Enrolled Patients
Table	14.1.5.2	Summary of Concomitant Medications - All Enrolled Patients
Table	14.1.6.1	Extent of Treatment Exposure - Safety Analysis Set
Table	14.3.1.1	Overall Summary of Adverse Events - Safety Analysis Set
Table	14.3.1.2	Treatment Emergent Adverse Events by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.3	Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.4	Treatment Emergent Grade 3 and above Adverse Events by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.5	Treatment-Related TEAEs by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.6	Treatment-Related TEAEs and Grade 3 and above by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.7	Treatment Emergent Adverse Events leading to Dose Reduction by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.8	Treatment Emergent Adverse Events leading to Dose Interruption by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.1.9	Treatment Emergent Adverse Events leading to Dose Discontinuation by System Organ Class and Preferred Term - Safety Analysis Set

Category	Sr. No	Title
Table	14.3.1.10	Treatment Emergent Adverse Events of Special Interest by System Organ Class and Preferred Term - Safety Analysis Set
Table	14.3.4.1	Descriptive Summary of Haematology: Absolute and Change from Baseline values - Safety Analysis Set
Table	14.3.4.2	Descriptive Summary of Clinical Chemistry: Absolute and Change from Baseline values - Safety Analysis Set
Table	14.3.4.3	Shift Table of Haematology – safety Analysis Set
Table	14.3.4.4	Descriptive Summary of Vital Signs: Absolute and Change from Baseline values - Safety Analysis Set
Table	14.3.4.5	Summary of ECG - Safety Analysis Set
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Listing	16.2.1.2	Patient Disposition – All Enrolled Patients
Listing	16.2.1.3	Patient Visits – All Enrolled Patients
Listing	16.2.1.4	Listing of Study Completion or Withdrawal from study – All Enrolled Patients
Listing	16.2.1.5	Listing of Withdrawal of Main Consent – All Enrolled Patients
Listing	16.2.2.1	Protocol Deviations during the Study – All Enrolled Patients
Listing	16.2.4.1	Demographic and Baseline Characteristics- All Enrolled patients
Listing	16.2.4.2	Medical and Surgical History – All Enrolled Patients
Listing	16.2.4.3	Pathology at Diagnosis - All Enrolled Patients
Listing	16.2.4.4	Tumour Sample – All Enrolled Patients
Listing	16.2.4.5	Germline BRCA Test – All Enrolled Patients

Category	Sr. No	Title
Listing	16.2.4.6	Extent of Disease Upon Entry - All Enrolled Patients
Listing	16.2.4.7	Previous Cancer Therapy - All Enrolled Patients
Listing	16.2.4.8	Prior and Concomitant Medications – All Enrolled Patients
Listing	16.2.4.9	WHO Performance Status - Safety Analysis Set
Listing	16.2.4.10	Physical Examination - Safety Analysis Set
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Listing	16.2.4.12	ECG Test Results - Safety Analysis Set
Listing	16.2.5.1	Study Drug Exposure - Safety Analysis Set
Listing	16.2.5.2	Study Drug Accountability - Safety Analysis Set
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Listing	16.2.7.5	Serious Adverse Events - Safety Analysis Set
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Listing	16.2.7.7	Listing of Deaths - Safety Analysis Set
Listing	16.2.8.1	Listing of Haematology - Safety Analysis Set

Category	Sr. No	Title
Listing	16.2.8.2	Listing of Clinical Chemistry - Safety Analysis Set
Listing	16.2.8.3	Listing of Urinalysis - Safety Analysis Set
Listing	16.2.8.4	Listing of Coagulation - Safety Analysis Set
Listing	16.2.8.5	Listing of Laboratory Test for Hepatitis B and C - Safety Analysis Set
Listing	16.2.8.6	Listing of Hy's Law Evaluation - Safety Analysis Set
Listing	16.2.8.7	Pregnancy Test – Safety Analysis Set
Listing	16.2.9.1	Pregnancy Report - Safety Analysis Set
Listing	16.2.9.2	Listing of Bone Marrow Biopsy - Safety Analysis Set
Listing	16.2.9.3	Listing of CT scan Report capture - Safety Analysis Set

Table 14.1.1.1
Patients Disposition
All Patients

	Ovarian Cancer	Breast Cancer	Both Ovarian Cancer and Breast Cancer	Overall
Number of Patients Screened	xx	xx	xx	xx
Number of Patients Enrolled	xx	xx	xx	xx
Number of Patients Enrolled and not Treated	xx	xx	xx	xx
Number of Patients Treated*	xx	xx	xx	xx
Number (%) of Patients who Completed Study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number (%) of Patient in Safety Analysis Set	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number (%) of Patients who Discontinued from Study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reasons for Discontinuation, n (%)				
Subject decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Eligibility criteria not fulfilled	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Percentages are based on the total number of patients treated in the respective cancer type.
Percentages for primary reason of discontinuation are based on the total number of patients discontinued from the study in the respective cancer type.
All patients who sign the ICF (Informed Consent Form) and are screened with eligibility verified as per the Inclusion-Exclusion criteria mentioned in study protocol are considered to be enrolled.
*Patients who take at least one dose of study drug.
Safety Analysis Set is defined as patients who take at least one dose of study drug.

Reference Listing: x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

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Table 14.1.2.1
Summary of Protocol Deviations
All Enrolled patients

	Ovarian Cancer (N=xx) n (%)	Breast Cancer (N=xx) n (%)	Both Ovarian Cancer and Breast Cancer (N=xx) n (%)	Overall (N=xx) n (%)
Number of patients with at least one Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Major Protocol Deviations	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Minor Protocol Deviations	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of patients by Major Protocol Deviations Category				
Category 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				

All patients who sign the ICF (Informed Consent Form) and are screened with eligibility verified as per the Inclusion-Exclusion criteria mentioned in study protocol are considered to be enrolled.
Percentages are based on the total number of enrolled patients (N).
Patients can be categorized in more than one deviation category

Reference Listing: x.x.x.x
Program: xx.sas Table Generation: DDMMMYYYY hh:mm

Table 14.1.3.1
Demographic and Baseline Characteristics
All Enrolled Patients

	Ovarian Cancer (N=xx)	Breast Cancer (N=xx)	Both Ovarian Cancer and Breast Cancer (N=xx)	Overall (N=xx)
Age (years)				
n	xx	xx	xx	xx
Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx
SD	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Height (cm)				
n	xx	xx	xx	xx
Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx
SD	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Weight (kg)				
n	xx	xx	xx	xx
Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx
SD	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
BMI (kg/m^2)				
n	xx	xx	xx	xx
Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx
SD	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx

Histology Type [n (%)]				
Serous Low Grade	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serous High Grade	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc…				
Child Bearing Potential[n (%)]				
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Size or Direct Extent of Primary Tumor at Screening [n (%)]				
T0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TX	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
T1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc..				
Degree of Spread of Cancer to Regional Lymph Nodes at Screening [n (%)]				
N0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
N1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc..				
Distant Metastases at Screening [n (%)]				
M0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MX	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc..				
Stage/FIGO Stage of Cancer at Screening [n (%)]				
Stage IA	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stage IB	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc..	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Biopsy tissue type at screening [n (%)]				
Primary tumor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic tumor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Organ involved at screening [n (%)]				
Abdomen	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adrenal Gland	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc….	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
gBRCA results at screening [n (%)]				
BRCA1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
BRCA2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Both	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
VUS (Variant of Uncertain significance) in BRCA 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
VUS (Variant of Uncertain significance) in BRCA 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Previous Cancer Therapy [n (%)]				
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 Cancer Therapy Regimen	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 Cancer Therapy Regimens	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>2 Cancer Therapy Regimens	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO Performance Status [n (%)]				
Normal activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Restricted activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
In bed less than or equal to 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
In bed more than 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

100% bedridden	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Percentages are based on the total number of enrolled patients (N) in the respective cancer type.
All patients who sign the ICF (Informed Consent Form) and are screened with eligibility verified as per the Inclusion-Exclusion criteria mentioned in study protocol are considered to be enrolled.
If age is missing, it is calculated as (informed consent date-date of birth+1)/365.25
SD: Standard Deviation; Min: Minimum; Max: Maximum.
BMI: Body Mass Index

Reference Listing x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

<Note to Programmer:
Include all possible Sub Categories for the categories given in table as per CRF/ SAP.>

Table 14.1.4.1
Summary of Medical and Surgical History
All Enrolled Patients

System Organ Class (SOC) Preferred Term (PT)	Ovarian Cancer (N=xx) n (%)	Breast Cancer (N=xx) n (%)	Both Ovarian Cancer and Breast Cancer (N=xx) n (%)	Overall (N=xx) n (%)
Patients with at least one Medical/Surgical History	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				

Percentages are based on the total number of enrolled patients (N) in the respective cancer type.
All patients who sign the ICF (Informed Consent Form) and are screened with eligibility verified as per the Inclusion-Exclusion criteria mentioned in study protocol are considered to be enrolled.
MedDRA (version 24.1) coding dictionary applied.
A patient with two or more medical/surgical history terms in the same System Organ Class (or with the same preferred term) is counted only once for that System Organ Class (or preferred term).
System Organ Classes are sorted in alphabetical order. Preferred terms are sorted by descending order of frequency of overall preferred terms.

Reference Listing: x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

Table 14.1.5.1
Summary of Prior Medications
All Enrolled Patients

ATC (Level 2) Preferred Term (PT)	Ovarian Cancer (N=xx) n (%)	Breast Cancer (N=xx) n (%)	Both Ovarian Cancer and Breast Cancer (N=xx) n (%)	Overall (N=xx) n (%)
Patients with at least one Prior Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				

Percentages are based on the total number of enrolled patients (N) in the respective cancer type.
All patients who sign the ICF (Informed Consent Form) and are screened with eligibility verified as per the Inclusion-Exclusion criteria mentioned in study protocol are considered to be enrolled.
Prior medications are those taken only prior to the first dose date of study drug.
Medications are coded using WHODrug (version September, 2021).
A patient with two or more prior medications in the same ATC Level 2 (or with the same preferred term) is counted only once for that ATC Level 2 (or preferred term).
ATC Level 2 terms are sorted in alphabetical order. Preferred terms are sorted by descending order of frequency of overall preferred terms.
ATC: Anatomical Therapeutic Chemical Classification.

Reference Listing: x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer:
Above format will be used to create following Tables,
Table 14.1.5.2: Summary of Concomitant Medications - All Enrolled Patients
Instead of 'Prior Medication' in the first line, add 'Concomitant Medication' and same update is applicable to footnote as well>

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Table 14.1.6.1
Extent of Treatment Exposure
Safety Analysis Set

	Statistics	Ovarian Cancer (N=xx)	Breast Cancer (N=xx)	Both Ovarian Cancer and Breast Cancer (N=xx)	Overall (N=xx)
Duration of Exposure (days) *					
	n	xx	Xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

* Duration of Exposure (days) = Last Date of Dosing – First Date of Dosing + 1.
SD: Standard Deviation; Min: Minimum; Max: Maximum.

Reference Listing: x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

Table 14.3.1.1
Overall Summary of Adverse Events
Safety Analysis Set

	Ovarian Cancer (N=xx)				Breast Cancer (N=xx)				Both Ovarian Cancer and Breast Cancer (N=xx)				Overall (N=xx)			
	n	%	(95% CI)	E	n	%	(95% CI)	E	n	%	(95% CI)	E	n	%	(95% CI)	E
Any AE*	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx
Any TEAE	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx
Any Non-TEAEs	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx
Any AE of Special Interest	.....															
Any TEAE of Special Interest																
Any Non-TEAE of Special Interest																
Treatment-Related TEAEs																
Serious TEAEs																
Treatment-Related serious TEAEs																
Grade 3 and above TEAEs																
Grade 3 and above Treatment-Related TEAEs																
TEAEs leading to Dose Reduction																
Treatment-Related TEAEs leading to Dose Reduction																
TEAEs leading to Dose Interruption																
Treatment-Related TEAEs leading to Dose Interruption																
Treatment-Related TEAEs leading to Dose Discontinuation																

Treatment-Related TEAEs leading to
Dose Discontinuation

Fatal TEAEs
Treatment-Related Fatal TEAEs

Percentages are based on the total number of patients (N) in the safety analysis set for the respective cancer type.
Adverse Events are coded using MedDRA (version 24.1). 95% CI are obtained using exact method based on binomial distribution.
*Any AE includes unique number of patients who experienced at least one AE regardless of whether AE is TEAE or non-TEAE.
Treatment –Emergent AEs (TEAEs) are events with start date on or after the date of first dose of study drug. Also, the adverse events that are a consequence of a pre-existing condition that has worsened later during the treatment phase (i.e. events having start date before the date of first dose of study drug and have worsened in severity while on study treatment) will be termed as "Treatment-Emergent".
Grade 3: Severe; Grade 4: Life-threatening or disabling; Grade 5: Death related to AE.
AE: Adverse Event; TEAE: Treatment-Emergent Adverse Event, n: Number of patients with any event, E: Number of events, CI: Confidence Interval.

Reference Listing x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

Table 14.3.1.2
Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	Ovarian Cancer (N=xx)				Breast Cancer (N=xx)				Both Ovarian Cancer and Breast Cancer (N=xx)				Overall (N=xx)			
	n	%	(95% CI)	E	n	%	(95% CI)	E	n	%	(95% CI)	E	n	%	(95% CI)	E
Patients with at least one TEAE	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx	xxx	xx.xx	(xx.xx, xx.xx)	xxx
SOC1	.....															
PT1																
PT2																
SOC2																
PT1																
PT2																
Etc.																

Percentages are based on the total number of patients (N) in the safety analysis set for the respective cancer type.
Adverse Events are coded using MedDRA (version 24.1). 95% CI are obtained using exact method based on binomial distribution.
A patient with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
System organ classes are sorted in alphabetical order, and within system organ class by descending order of frequency of overall preferred terms.
Treatment-Emergent Adverse Events (TEAEs) are events with start date on or after the date of first dose of study drug until 28 days after last dose of study drug. Also, the adverse events that are a consequence of a pre-existing condition that has worsened later during the treatment phase (i.e. events having start date before the date of first dose of study drug and have worsened in severity while on study treatment) are termed as 'Treatment-Emergent'.
TEAE: Treatment-Emergent Adverse Event, n: Number of patients with any event, E: Number of events, CI: Confidence Interval.Reference Listing: x.x.x.x

Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer:
Above format will be used to create following Tables,

Table 14.3.4.1
Descriptive Summary of Haematology: Absolute and Change from Baseline values
Safety Analysis Set

Parameter (unit): xxxxxxxxxxxxx (xxx)

Cancer Type	Visit Statistics	Value at Visit	Change from Baseline
Ovarian Cancer (N=xx)	Baseline (Visit1)		
	N	xx	
	Mean	x.xxx	
	SD	x.xxxx	
	Median	x.xxx	
	Min, Max	x.xx, x.xx	
	Visit2		
	N	xx	xx
	Mean	x.xxx	x.xxx
	SD	x.xxxx	x.xxxx
	Median	x.xxx	x.xxx
	Min, Max	x.xx, x.xx	x.xx, x.xx

Etc..

The baseline value will be defined as last value collected prior to the first dose of study drug.
Change from Baseline value = Post Baseline value - Baseline value
Only scheduled visits are included in the table.
SD: Standard Deviation; Min: Minimum; Max: Maximum.

Reference Listing x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss
< Note to Programmer: This table will be repeated for other parameters and treatment groups (Breast cancer, Both Ovarian and Breast Cancer and Overall). Above format will be used to create following Tables,
Table 14.3.4.2: Descriptive Summary of Clinical Chemistry: Absolute and Change from Baseline Values-Safety Analysis Set.
Table 14.3.4.4: Descriptive Summary of Vital Signs: Absolute and Change from Baseline Values-Safety Analysis Set (Do not include "height" and only for schedule visits)

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Table 14.3.4.3
Shift Table of Haematology
Safety Analysis Set

Cancer Type: Ovarian Cancer (N=xx)

Parameter (Unit)	Visit		Baseline				
			Above Normal n (%)	Normal n (%)	Below Normal n (%)	Missing* n (%)	Total n (%)
Hematocrit (%)							
	Visit 2	Above Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Below Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Missing*	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Visit 5	Above Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Below Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Missing*	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.....	Etc.						

Percentages are based on the total number of patients (N) in the safety analysis set for the respective cancer type.
The baseline value will be defined as last value collected prior to the first dose of study drug.
*Missing also includes patients who discontinued in previous visits.
Only scheduled visits are included in the table.

Reference Listing x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

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Table 14.3.4.5
Summary of ECG
Safety Analysis Set

Visit	Interpretation	Ovarian Cancer (N=xx) n (%)	Breast Cancer (N=xx) n (%)	Both Ovarian Cancer and Breast Cancer (N=xx) n (%)	Overall (N=xx) n (%)
Baseline	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal not Clinically Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal Clinically Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Visit 2	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal not Clinically Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal Clinically Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc..					

Percentages are based on the total number of patients (N) in the safety analysis set for the respective cancer type.
The baseline value will be defined as last value collected prior to the first dose of study drug.
Only scheduled visits are included in the table.

Reference Listing x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

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Table 14.3.4.6
Summary of Physical Examination
Safety Analysis Set

Visit	Parameters	Status	Ovarian Cancer (N=xx) n (%)	Breast Cancer (N=xx) n (%)	Both Ovarian Cancer and Breast Cancer (N=xx) n (%)	Overall (N=xx) n (%)
Baseline	Physical Examination	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Abnormal Clinical Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Abnormal Nonclinical Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	General Appearance	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Abnormal Clinical Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Abnormal Nonclinical Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc…	Etc..					

Percentages are based on the total number of patients (N) in the safety analysis set for the respective cancer type.
The baseline value will be defined as last value collected prior to the first dose of study drug.
Only scheduled visits are included in the table.

Reference Listing x.x.x.x
program name.SAS/DDMMMYYYY/hh:mm

< Note to Programmer: This table will be repeated for other parameters and scheduled visits>

Table 14.3.4.7
WHO Performance Status
Safety Analysis Set

Visit	Performance Status	Ovarian Cancer (N=xx) n (%)	Breast Cancer (N=xx) n (%)	Both Ovarian Cancer and Breast Cancer (N=xx) n (%)	Overall (N=xx) n (%)
Baseline	Normal activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Restricted activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	In bed less than or equal to 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	In bed more than 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100% bedridden	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Visit 4	Normal activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Restricted activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	In bed less than or equal to 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	In bed more than 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100% bedridden	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Visit 5	Normal activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Restricted activity	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	In bed less than or equal to 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	In bed more than 50% of the time	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100% bedridden	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Etc..

Percentages are based on the total number of patients (N) in the safety analysis set for the respective cancer type.
The baseline is defined as last value collected prior to the first dose of study drug.
Only scheduled visits are included in the table.

Reference Listing x.x.x.x
Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.1.1
Screened Patients
All Patients

Patient ID	Cancer Type	Age (Years)	Date of Screening	Date Informed Consent Signed	Required Inclusion and Exclusion Criteria Satisfied?	Failed Criterion Number/Type	Is Patient Treated? *
xxxx-xx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	Yes		Yes
xxxx-xx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	No	Xx/xxxxxxxxxx	No
xxxx-xx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	Yes		Yes

If age is missing, it is calculated as (informed Consent Date-Date of Birth+1)/365.25.

*Patients who take at least one dose of study medication.

Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.1.2
Patient Disposition
All Enrolled Patients

Patient ID	Cancer Type	Age (years)	Date of First Dose	Date of Last Dose	Duration of Treatment (in Days)	Status	Reason for Discontinuation
xxx-xxx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	xx	Discontinued	Adverse Event: AE page # xx: AE # xx
xxx-xxx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	xx	Discontinued	Sponsor decision
xxx-xxx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	xx	Discontinued	Other: xxxxxx
xxx-xxx	Xxxx	xx	DDMMMYYYY	DDMMMYYYY	xx	Completed	Sponsor decision

Patient has only one primary reason for discontinuation.
Duration of Treatment = (Date of last Dose of Treatment - Date of first Dose of Treatment) +1

program name.SAS/DDMMMYYYY/hh:mm

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Olaparib

Listing 16.2.1.3
Patient Visits
All Enrolled Patients

Patient ID	Cancer Type	Visit	Date of Visit	Was this Visit Performed?	Reason for Visit Not Performed
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	Yes	
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	No	xxxx
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	No	xxxx
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	No	xxxx

program name.SAS/DDMMMYYYY/hh:mm

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Listing 16.2.1.4
Listing of Study Completion or Withdrawal from Study
All Enrolled Patients

Patient ID	Cancer Type	Completed Study?	Date of Completion or Withdrawal	Reason for Withdrawal	Date of Disease Progression	Disease Progression Confirmed By?
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	xxxxxxxx	DDMMMYYYY	MRI
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	xxxxxxxxx	DDMMMYYYY	PET
xxx-xxx	Xxxx	xxxx	DDMMMYYYY			
xxx-xxx	Xxxx	xxxx	DDMMMYYYY	xxxxxxxxxx	DDMMMYYYY	MRI

CT: computerized Tomography, PET: Positron Emission Tomography

program name.SAS/DDMMMYYYY/hh:mm

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Olaparib

Listing 16.2.1.5
Listing of Withdrawal of Main Consent
All Enrolled Patients

Patient ID	Cancer Type	Date of Withdrawal	Reason for Withdrawal
xxx-xxx	Xxxx		
xxx-xxx	Xxxx		
xxx-xxx	Xxxx		
xxx-xxx	Xxxx		

program name.SAS/DDMMMYYYY/hh:mm

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Listing 16.2.2.1
Protocol Deviations During the Study
All Enrolled Patients

Patient ID	Cancer Type	Visit	Date of Deviation	Study Day*	Category of Deviation (Planned/ Unplanned)	Type of Deviation	Description of Deviation	Category (Major/Minor)
xxxx-xx	Xxxx	xxx xxx	DDMMMYYYY	xx	Planned	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	Minor
xxxx-xx	Xxxx	xxx xxx	DDMMMYYYY	xx	Unplanned	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	Major
xxxx-xx	Xxxx	xxx xxx	DDMMMYYYY	xx	Planned	xxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx x	Minor

*Study Day = Date of Deviation – Date of First Dose Administered +1

Program: xx.sas Table Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.1
Demographic and Baseline Characteristics
All Enrolled Patients

Patient ID	Cancer Type	Date of Birth	Age (in Years)	Height (cm)	Weight (kg)	BMI (kg/m^2)	Child Bearing Potential
xxx-xxx	Xxxx	DDMMMYYYY	xx	xx.xx	xx.xx	xx.xx	Yes
xxx-xxx	Xxxx	DDMMMYYYY	xx	xx.xx	xx.xx	xx.xx	No:xxxxxxxxx
xxx-xxx	Xxxx	DDMMMYYYY	xx	xx.xx	xx.xx	xx.xx	Yes
……							

If gae is missing, it is calculated as (Informed Consent Date - Date of Birth+1)/365.25

BMI: Body Mass Index

program name.SAS/DDMMMYYYY/hh:mm

Listing 16.2.4.2
Medical and Surgical History
All Enrolled Patients

Patient ID	Cancer Type	Category	MH Number	Condition or Surgical Procedure	System Organ Class / Preferred Term	Start Date of Condition or Date of Surgery	End Date of Condition	Condition, Past or Current	Any Current Medication?
xxxx-xx	Xxxx	Medical History	1	xxxxxxx	xxxx / xxxx	DDMMMYYYY	DDMMMYYYY	Past	No
			2	xxxxxxx	xxxx / xxxx	DDMMMYYYY	DDMMMYYYY	Past	No
			3	xxxxxxx	xxxx / xxxx	DDMMMYYYY		Current	Yes
		Surgical History		xxxxxxx	xxxx / xxxx	DDMMMYYYY			
xxxx-xx	Xxxx	Medical History	1	xxxxxxx	xxxx / xxxx	DDMMMYYYY	DDMMMYYYY	Past	Yes

MedDRA (version 24.1) coding dictionary applied.
MH: Medical History

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.3
Pathology at Diagnosis
All Enrolled Patients

Patient ID	Primary Tumour Location	Original Diagnosis Date	Histology Type	Primary Tumor	Regional Lymph Nodes	Distant Metastases	Stage/AJCC Stage
xxxx-xx	Ovarian Cancer	DDMMMYYYY	Serous Low Grade	T2	N0	M1	Stage IIB
xxxx-xx	Breast Cancer	DDMMMYYYY	Serous High Grade	T4	N1	M1a	Stage IA
xxxx-xx	Both	DDMMMYYYY	Clear Cell	T3	N2	M1	Stage IIIA
xxxx-xx	Breast Cancer	DDMMMYYYY	Other:xxxxxxxxxxx	T2	NX	M1	Stage IIB
xxxx-xx	Both	DDMMMYYYY	Unknown	T4	N0	M1a	Stage IA

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.4
Tumour Sample
All Enrolled Patients

Patient ID	Cancer Type	Visit	Sample Collected?	Date of Sample Collection	Sample Collection Method	Biopsy Tissue Type	Organ	Sample Format
xxxx-xx	Xxxx/xxx	Screening	Yes	DDMMMYYYY	Biopsy	Primary tumor	Abdomen	FFPE
		EOT	Yes	DDMMMYYYY	Core needle biopsy	Primary tumor	Abdomen	FFPE
xxxx-xx	Xxxx/xxx	Screening	No	DDMMMYYYY	Effusion	Metastatic tumor	Adrenal Gland	Unstained section
		EOT	Yes	DDMMMYYYY	Core needle biopsy	Metastatic tumor	Adrenal Gland	Unstained section

FFPE: Formalin-Fixed Paraffin-Embedded
Sample collection category: Biomarkers/Exploratory Research/Diagnostic, Solid Tissue.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

Listing 16.2.4.5
Germline BRCA Test
All Enrolled Patients

Patient ID	Cancer Type	gBRCA Test Performed?	Date of Test Performed	Result
xxxx-xx	Xxxx	Yes	DDMMMYYYY	BRCA1
xxxx-xx	Xxxx	Yes	DDMMMYYYY	BRCA2

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.6
Extent of Disease Upon Entry
All Enrolled Patients

Patient ID	Cancer Type	Recurrence of Earlier Cancer (Yes/No)	Recent Progression Date	Site of Local/Metastatic Disease	Metastatic/ Locally Advanced	If Other Locally Advanced Site, Please Specify	If Other Metastatic Site, Please Specify
xxxx-xx	Xxxx	Yes	DDMMMYYYY	Brain/CNS Pleural effusion Respiratory	Locally advanced Metastatic Metastatic	xxxxxxxxxxxxxx	 xxxxxxxxxxxxxxx xxxxxxx
xxxx-xx	Xxxx	No	DDMMMYYYY		Metastatic		xxxxxxxxxxxxxxx xxxxxxx

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

Listing 16.2.4.7
Previous Cancer Therapy
All Enrolled Patients

Patient ID	Cancer Type	Number of Prior Cancer Therapies	ATC Level 2/ Preferred Term/ Cancer Therapy Agent	Start Date / End Date or Ongoing	No. of Cycles	Route/ Therapy Class	Best Response	Treatment Status	Reason for Therapy	Concomitant Chemo Radiotherapy
xxxx-xx	Xxxx	2	xxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx	DDMMMYYYY/ DDMMMYYYY	4	Oral/Cytotoxic chemotherapy	SD	First Line	Carcinoma Ovary	No
			xxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx	DDMMMYYYY/ DDMMMYYYY	2	Intravenous/ Cytotoxic chemotherapy	SD	Second Line	Carcinoma Ovary	No
			xxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx	DDMMMYYYY/ DDMMMYYYY	2	Oral/Other	SD	Second Line	Carcinoma Ovary	No
xxxx-xx	Xxxx	4	xxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx	DDMMMYYYY/ DDMMMYYYY	8	Oral/Other	SD	First Line	Carcinoma Ovary	No

Prior cancer therapies are coded using WHODrug (version September, 2021).

ATC: Anatomical Therapeutic Chemical Classification.
CR: Complete Response; PR: Partial Response; SD: Stable Disease; PD: Progressive Disease; NE: Not Evaluable; NA: Not Applicable.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

Listing 16.2.4.8
Prior and Concomitant Medications
All Enrolled Patients

Patient ID	Cancer Type	Medication No./ ATC Level 2/ Preferred Term/ Medication Name	Total Daily Dose/ Unit	Route/ Frequency	Start Date/ Stop Date or Ongoing	Indication/ Reason for Therapy	Therapy Reason, Other/ AE Number/ MH Number	Prior or Concomitant
xxxx-xx	Xxxx	xxxxxxxxxx/ xxxxxxxxxxx/ xxxxxxxxx	Xx/xxxx	Xxxx/Other: xxx	DDMMMYYYY/ Ongoing	xxxxxxxxx/ Medical History	MH No: xx	C*
		xxxxxxxxxxx/ xxxxxxxxxxx/ xxxxxxxxx	Xx/Other:xxxx	Xxxx/xxxx	DDMMMYYYY/ DDMMMYYYY	xxxxxxxxx/ Adverse Event	AE No: xx	P*
xxxx-xx	Xxxx	xxxxxxxxxx/ xxxxxxxxxxx/ xxxxxxxxx	Xx	Xxxx/Other: xxx	DDMMMYYYY/ Ongoing	xxxxxxxxx/ Other	xxxxxxxxxxx	C

Medications are coded using WHODrug (version September, 2021).
Prior medications are those taken only prior to the first dose date of study drug.

Concomitant medications are those that were taken while on study drug including the ones that started before the first dose of study drug. The medications that started after the discontinuation of study drug will also be termed as 'Concomitant'.

* Medications are taken 4 weeks prior to the initial dose of study drug.
ATC: Anatomical Therapeutic Chemical Classification; MH: Medical History; AE: Adverse Event; P: Prior; C: Concomitant.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.9
WHO Performance Status
Safety Analysis Set

Patient ID	Cancer Type	Visit	Assessment Performed?	If No, Specify Reason	Assessment Date	Performance Status
xxxx-xx	Xxxx	Baseline	Yes		DDMMMYYYY	Restricted activity
		Visit 4	Yes		DDMMMYYYY	Restricted activity
		Visit 5	Yes		DDMMMYYYY	Restricted activity
		.....	...		.....	.....
		.....	...		.....	.....
xxxx-xx	Xxxx	Baseline	Yes		DDMMMYYYY	In bed more than 50% of the time
		Visit 4	No	xxxxxxxxx		
		Visit 5	Yes		DDMMMYYYY	In bed more than 50% of the time
		.....	...		.....	.....
		.....	...		.....	.....

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.10
Physical Examination
Safety Analysis Set

Patient ID	Cancer Type	Visit	Examination Performed?	Examination Date	Examination	Status	Specification of Abnormality
xxxx-xx	Xxxx	xxxxx	Yes	DDMMMYYYY	Physical examination status	Normal	
					General Appearance	Abnormal Clinical Significant	
					Respiratory		
					Cardiovascular		
					Abdomen		
					Lymph Nodes		
					Musculoskeletal system		
		xxxxx	No:xxxxx				
		Etc...					
xxxx-xx	Xxxx	Etc.....	Yes	DDMMMYYYY	Etc.....		

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.11
Vital Signs
Safety Analysis Set

Patient ID	Cancer Type	Visit	Vital Signs Performed?	Assessment Date/Time	Pulse Rate (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Respiratory Rate(breaths /min)	Oral Temperature (ºC)	Weight (kg)	Height (cm)	BMI (kg/m²)
xxxx-xx	Xxxx	xxxxxx	Yes	DDMMMYYYY/ hh:mm	xx	Xx	xx	xx	xx	xx	xx	xx
		xxxxxx	Yes	DDMMMYYYY/ hh:mm	xx	Xx	xx	xx				
		xxxxxx	No:xxxxxx									
xxxx-xx	Xxxx	Screening	Yes	DDMMMYYYY/ hh:mm	xx	Xx	xx	xx	xx	xx	xx	xx

BMI: Body Mass Index

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.4.12
ECG Test Results
Safety Analysis Set

Patient ID	Cancer Type	Visit	Assessment Performed?	Date/Time of ECG	ECG Result	Details of Specification of Abnormal Condition
xxxx-xx	Xxxx	xxxxxxx	Yes	DDMMMYYYY/hh:mm	Normal	xxxxxxx
		xxxxxxx	Yes	DDMMMYYYY/hh:mm	Normal	
		Etc..	No:xxxxxxxx			
xxxx-xx	Xxxx	xxxxxxx	Yes	DDMMMYYYY/hh:mm	Abnormal	xxxxxxxxx

m: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.5.1
Study Drug Exposure
Safety Analysis Set

Patient ID	Cancer Type	Total Daily Dose	Dose Unit	Dosing Frequency	Start Date/ Stop Date	Action Taken to Study Drug	Main Reason of Action Taken	Reason for dose change	AE Number
xxxx-xx	Xxxx	xxx	xx	xxxx	DDMMMYYYY/ DDMMMYYYY	Dose Not Changed	Surgery		
xxxx-xx	Xxxx	xxx	xx	xxxx	DDMMMYYYY/ DDMMMYYYY	Dose Reduced	Other:xxxxxxxxxx	xxxxxxxxxx	
xxxx-xx	Xxxx	xxx	xx	xxxx	DDMMMYYYY/ DDMMMYYYY	Drug Permanently Discontinued	Adverse Event		xxxx /xxxx

OD: Once in a day; BD: Twice in a day; BID: Twice in a day; NA: Not Applicable; AE: Adverse Event.
Study Drug: Olaparib

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer:

If there are multiple AEs, they should be displayed separated by "/" >

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Listing 16.2.5.2
Study Drug Accountability
Safety Analysis Set

Patient ID	Cancer Type	Dispensed Cycle/ Return Cycle	Date Dispensed/ Date Returned	Kit Number or Bottle Number	Number of Tablets			Comments
					Dispensed	Returned	Damaged or Lost	
xxxx-xx	Xxxx	xxxx/ xxxx	DDMMMYYYY/ DDMMMYYYY	Xxxx/xxxx	xx	xx	xx	
		xxxx/ xxxx	DDMMMYYYY/ DDMMMYYYY	Xxxx/xxxx	xx	xx	xx	xxxxxxxxxxxxxxx
		Etc...						
xxxx-xx	Xxxx	xxxx/ xxxx	DDMMMYYYY/ DDMMMYYYY	Xxxx/xxxx				xxxxxxxxxxxxxxx
		Etc..	DDMMMYYYY/ DDMMMYYYY	Xxxx/xxxx				xxxxxxxxxxxxxxx

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.5.3
Discontinuation of Study Drug
Safety Analysis Set

Patient ID	Cancer Type	Permanently Discontinued?	Final Dosing Date	Main Reason for Discontinuation	If Other, Please Specify
xxxx-xx	Xxxx	Yes	DDMMMYYYY	Subject decision	
xxxx-xx	Xxxx	Yes	DDMMMYYYY	Other	xxxxxxxxxxxxxxx
xxxx-xx	Xxxx	Yes	DDMMMYYYY	Adverse Event	

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer:

Only display the records where Study Drug is Discontinued Permanently >

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Listing 16.2.5.4
Study Drug Overdose
Safety Analysis Set

Patient ID	Cancer Type	Start Date/ Stop Date	Trade Name/ Generic Name/ Study Treatment	Total Dose	Unit	Route	Intentional Overdose?	Overdose Associated with AE?	AE Number	Further Information for non SAE
xxxx-xx	Xxxx	DDMMMYYYY	xxxxx	xx	mg	Oral	Yes	No		xxxxxxxxxxxxx
xxxx-xx	Xxxx	DDMMMYYYY	xxxxx	xx	mg	Oral	No	Yes	xx	xxxxxxxxxxx
xxxx-xx	Xxxx	DDMMMYYYY	xxxxx	xx	mg	Oral	No	Yes	xx/ xx	xxxxxxxxx

AE: Adverse Event, SAE: Serious Adverse Event

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer:

In case of multiple adverse event associated with overdose, separate the AE numbers by "/" >

Listing 16.2.7.1
Adverse Events
Safety Analysis Set

Patient ID	Cancer Type	AE Number/ System Organ Class/ Preferred Term/ Reported Term	Start Date [Start Day]/ Stop Date [Stop Day] or AE Ongoing	Treatment Name	CTCAE Grade at Start/ CTCAE Grade at End/ Maximum CTCAE Grade	Serious/ TEAE	Action Taken with Study Drug/ Relationship to Study Drug/ Outcome/	Treatment Given for AE	Comments
xxxx-xx	Xxxx	xx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx*	DDMMMYYYY [xx]/ DDMMMYYYY [xx]	Olaprib	Mild AE/ Moderate AE/ Severe AE	No/ Yes	Dose Not Changed/ Yes/ Recovered/Resolved	Yes	
		xx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	DDMMMYYYY/	Other:xxxxxxxx	Mild AE/	Yes/ Yes	Dose Reduced/ Yes/ Not recovered/Not resolved	Yes	

Adverse Events are coded using MedDRA (version 24.1).
Treatment –Emergent AEs (TEAEs) are events with start date on or after the date of first dose of study drug. Also, the adverse events that are a consequence of a pre-existing condition that has worsened later during the treatment phase (i.e. events having start date before the date of first dose of study drug and have worsened in severity while on study treatment) will be termed as "Treatment-Emergent".
Start Day= AE start date – Date of First Dose Administered +1. Stop Day= AE stop date – Date of First Dose Administered +1
*AE occurred within 28 days after discontinuation.
AE: Adverse Event; TEAE: Treatment-Emergent Adverse Event; CTCAE: Common Terminology Criteria for Adverse Events.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer: Above format will be used to create following Listing,
Listing 16.2.7.2: Treatment Emergent Adverse Events leading to Dose Reduction - Safety Analysis Set
Listing 16.2.7.3: Treatment Emergent Adverse Events leading to Dose Interruption - Safety Analysis Set
Listing 16.2.7.4: Treatment Emergent Adverse Events leading to Treatment discontinuation - Safety Analysis Set>
Listing 16.2.7.6:Adverse Events of Special interest - Safety Analysis Set

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Listing 16.2.7.5
Serious Adverse Events
Safety Analysis Set

Patient ID	Cancer Type	AE Number/ System Organ Class/ Preferred Term/ Reported Term	Date/ Day AE met criteria for SAE	Date Investigator Aware of SAE/ Date AZ aware of SAE/Email Alert to Patient Safety	Seriousness Criteria	Date of Hospitalization/ Discharge	SAE caused by Other Medication/ Study Procedure(s)	If Yes, Specify Trade Name(s)/ Procedure	TEAE	Description
xxxx-xx	Xxxx	xx/ xxxxxxxxxxxxxxx/xx xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	DDMMMYYYY/DDMMMYYYY/ DDMMMYYYY/Yes		Inpatient hospitalization or prolongation of existing inpatient hospitalization	DDMMMYYYY/ DDMMMYYYY	Yes/ No	xxxxxxxxxxxxx	Yes	xxxxxx
		xx/ xxxxxxxxxxxxxxx/xx xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	DDMMMYYYY/DDMMMYYYY/ DDMMMYYYY/Yes		Death		No No		Yes	xxxxx

Adverse Events are coded using MedDRA (version 24.1).

Treatment –Emergent AEs (TEAEs) are events with start date on or after the date of first dose of study drug. Also, the adverse events that are a consequence of a pre-existing condition that has worsened later during the treatment phase (i.e. events having start date before the date of first dose of study drug and have worsened in severity while on study treatment) will be termed as "Treatment-Emergent".

Day AE met criteria for SAE = Date AE met SAE criteria – Date of First Dose Administered +1.

AE: Adverse Event; TEAE: Treatment-Emergent Adverse Event; SAE: Serious Adverse Events, AZ: AstraZeneca.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.7.7
Listing of Deaths
Safety Analysis Set

Patient ID	Cancer Type	Date of Death [Day of Death]	Autopsy Performed?	Death Related to Disease Under Investigation?	Death Related to TEAEs	System Organ Class/ Preferred Term/ Primary Cause of Death	System Organ Class/ Preferred Term/ Secondary Cause of Death
xxxx-xx	Xxxx	DDMMMYYYY [xx]	Yes	Yes	Yes	xxxxxxxxxxxxxxxx	xxxxxxxxxxxxx
xxxx-xx	Xxxx	DDMMMYYYY [xx]	No	Yes	Yes	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxx
xxxx-xx	Xxxx	DDMMMYYYY [xx]	Yes	No	No	xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxx
xxxx-xx	Xxxx	DDMMMYYYY [xx]	Yes	Yes	Yes	xxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx

Day of death= Date of death – Date of First Dose Administered +1.
Primary and secondary cause of death are coded using MedDRA (version 24.1).
Treatment-Emergent Adverse Events (TEAEs) are events with start date on or after the date of first dose of study drug until 28 days after last dose of study drug. Also, the adverse events that are a consequence of a pre-existing condition that has worsened later during the treatment phase (i.e. events having start date before the date of first dose of study drug and have worsened in severity while on study treatment) are termed as 'Treatment-Emergent'.
TEAE: Treatment-Emergent Adverse Event; NA: Not Available.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.8.1
Listing of Haematology
Safety Analysis Set

Patient ID	Cancer Type	Visit	Sample Collected?	Sampling Date/Time	Lab Test	Unit	Normal Limits	Result		CS Abnormality Details	Test Done?
xxxx-xx	Xxxx	xxxxx	Yes	DDMMMYYYY/hh:mm	xxxxxxxx	xxxxx	xxx-xxx	xx.x	L		
					xxxxxx	Other: xxxx	xxx-xxx	x.x			
					xxxxxxxxx	xxxxx	xxx-xxx	xx.xx	H		
					xxxxxxxxx	xxx	xxx-xxx	xx			
		xxxxxx	Yes	DDMMMYYYY/hh:mm	xxxxxxxx	Other: xxxx	xxx-xxx	xx.x			
					xxxxxx	xxx	xxx-xxx	xx			
					xxxxxxxxx	xxxxx	xxx-xxx	xx.xx	L		
					xxxxxxxxx	xxxx	xxx-xxx	xx			
		Etc...	No:xxxxxxx								

L: Low (Below the normal limits), H: High (Above the normal limits), CS: Clinically Significant

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

< Note to Programmer: Above format will be used to create following Listing,
Listing 16.2.8.2: Listing of Clinical Chemistry – Safety Analysis Set>
Listing 16.2.8.3: Listing of Urinalysis - Safety Analysis Set >
Listing 16.2.8,4: Listing of Coagulation - Safety Analysis Set >
Listing 16.2.8.5: Listing of Laboratory Test for Hepatitis B and C - Safety Analysis Set >
Listing 16.2.8.6: Listing of Hy's Law Evaluation - Safety Analysis Set >

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Listing 16.2.8.7
Pregnancy Test
Safety Analysis Set

Patient ID	Cancer Type	Visit	Assessment Applicable?	Sample Collected?	If No, Specify Reason	Sampling Date	Result
xxxx-xx	Xxxx	xxxxxxxx	Yes	Yes		DDMMMYYYY	Negative
		xxxxxxxx	Yes	No	xxxxxxxx		
		Etc.....	No				
xxxx-xx	Xxxx	xxxxxxxx	No				

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.9.1
Pregnancy Report
Safety Analysis Set

		Current Pregnancy			Previous Pregnancies					
Patient ID	Cancer Type	Last Menstrual Period Date	Expected Delivery Date	Use of hormonal contraception or IUD at time of conception	Overall Pregnancies	Number of Normal Deliveries	Spontaneous Miscarriages	No. of Other Previous Pregnancies/ If Other, Specify	Relevant Pregnancy Risk Factor	Relevant Family History
xxxx-xx	Xxxx	DDMMMYYYY	DDMMMYYYY	Yes:xxxxxxxxxx	xx					xxxx
xxxx-xx	Xxxx	DDMMMYYYY	DDMMMYYYY	No	xx				xxxxxxx	xxxxxx
xxxx-xx	Xxxx	DDMMMYYYY	DDMMMYYYY	No	xx					xxxxxxxxxxx

IUD: Intrauterine Device

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.9.2
Listing of Bone Marrow Biopsy
Safety Analysis Set

Patient ID	Cancer Type	Bone Marrow Biopsy/Aspiration Performed?	Date of Assessment/ Collection	Bone marrow involvement	Cytogenetics	
					Cell Morphology	Flow Cytometry
xxxx-xx	Xxxx	Yes	DDMMMYYYY	Yes	xxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx
xxxx-xx	Xxxx	Yes	DDMMMYYYY	No		
xxxx-xx	Xxxx	No: xxxxxxxxxxx				

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss

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Listing 16.2.9.3
Listing of CT Scan Report Capture
Safety Analysis Set

Patient ID	Cancer Type	Visit	CT Scan Performed?	Date Of CT Scan	Overall Response	Tumor or Lesion Type	Tumor or Lesion Number/ Area or Site Name	Tumor or Lesion Size in mm	Tumor or Lesion Response	Additional Comments, if Any
xxxx-xx	Xxxx	xxxx	Yes	DDMMMYYYY	xxxxxxxxxxx	xxxxxxx	Xxxxxxxxxx/ xxxxxxxxxx	xx.xxx	xxxxxxxxxx	xxxxxxxxxx
						xxxxxxx	Xxxxxxxxxx/ xxxxxxxxxx	xx.xxx	xxxxxxxxxx	
		xxx	No							
		Etc.....	Yes	DDMMMYYYY	xxxxxxxxxxx	xxxxxxx	Xxxxxxxxxx/ xxxxxxxxxx	xx.xxx	xxxxxxxxxx	xxxxxxxxxx
xxxx-xx	Xxxx	xxxxxx		DDMMMYYYY	xxxxxxxxxxx	xxxxxxx	Xxxxxxxxxx/ xxxxxxxxxxx	xx.xxx	xxxxxxxxxx	xxxxxxxxxx

CR: Complete Response; PR: Partial Response; SD: Stable Disease (Non-CR/Non-PD); PD: Progressive Disease; NE: Not Evaluable.

Program: xx.sas Listing Generation: ddmmmyyyy hh:mm:ss