Statistical Analysis Plan

Study ID: 213362

Official Title of Study: An Open-Label, Randomized-Sequence, Multicenter, Single-Crossover Study to Assess the Relative Bioavailability and Bioequivalence of Niraparib Tablet Formulation Compared to Niraparib Capsule Formulation in Patients With Advanced Solid Tumors

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Statistical Analysis Plan

AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS

GSK/TESARO Protocol Number:	213362/3000-01-004
Protocol Version:	6.0 (Amendment 5)
Compound Number:	GSK 3985771, MK-4827
Study Drug Name:	Niraparib
Phase:	Phase 1
Methodology:	Open-Label, Cross-Over
Sponsor:	TESARO, GSK Company
Analysis Plan Date:	12 July 2023
Analysis Plan Version:	Version 7.0

SPONSOR SIGNATURE PAGE

Protocol Title:	AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS
Protocol Number:	3000-01-004
Sponsor:	TESARO, a GSK Company 980 Great West Road Brentford Middlesex, TW8 9GS UK

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidance and guidelines.

Author: Alina Striha Principal Statistician Plus-Project Ltd.	Signature: Date:
Approver: Wenlei Liu Statistics Director GSK Company	Signature: Date:

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TABLES INCLUDED IN THE TEXT

FIGURES INCLUDED IN THE TEXT

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE(s)	adverse event(s)
AESI	Adverse Events of Special Interest
ALT	alanine aminotransferase
ALP	alkaline phosphatase
AML	Acute Myeloid Leukemia
AST	aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	area under the plasma concentration-time curve
BA	bioavailability
BE	bioequivalence
BMI	body mass index
CI	confidence interval
CL/F	apparent total body clearance
C_{max}	Maximum observed plasma concentration
CSR	clinical study report
CV	coefficient of variation
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
EOT	end-of-treatment
FE	food effect
ICF	informed consent form
ICH	International Council for Harmonisation
LLN	lower limit of normal
LS mean	least-squares mean
CCI [redacted]	
MDRP	Medical Data Review Plan
MDS	Myelodysplastic Syndromes
MedDRA	Medical Dictionary for Regulatory Activities
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
PI	Package Insert
PK	pharmacokinetics
PT	preferred term

Abbreviation	Definition
Q_1	first quartile
Q_3	third quartile
QD	one time per day
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class
$t_{1/2}$	termination elimination half-life
TEAE	treatment-emergent adverse event
t_{max}	Time to reach C_{max}
US	United States
ULN	upper limit of normal
Vz/F	apparent terminal volume of distribution
WHO	World Health Organization

1. Information from the Study Protocol

1.1. Introduction and Objectives

1.1.1. Introduction

The approved niraparib drug product is an immediate release hard gelatin capsule dosage form that contains 100 mg of niraparib per capsule. The labelled starting dose for niraparib is 300 mg. Facilitating this dose requires the administration of three 100 mg capsules.

It is the Sponsor's intent to introduce a tablet dosage form that provides the 100 mg, 200 mg and 300 mg dose in single dose strength tablets to reduce the pill burden on the patients.

To this end, the Sponsor has developed a tablet dosage form with the specific intent to provide comparable performance to the approved capsule dosage form. The formulation and manufacturing process of the tablet were selected to produce a tablet with comparable in-vitro performance to the capsule.

This study is an open-label Phase 1 study to evaluate the relative bioavailability (BA) and bioequivalence (BE) of niraparib administered as a tablet formulation compared to the reference capsule formulation manufactured by the same process as currently marketed in the United States. Specifically, a 300 mg niraparib tablet will be compared to three (3) niraparib capsules (3 × 100 mg). In addition, this study will evaluate the effect of a high-fat meal on the pharmacokinetics (PK) of the niraparib 300 mg tablet formulation (Stage 3). The Extension Phase of this study is to enable patients enrolled in the study to continue to receive treatment with niraparib if they are tolerating it and, in the Investigator's opinion, may receive benefit.

1.1.2. Study Objectives

The primary objectives of this study are as follows:

- Stage 1: To obtain preliminary assessment of the relative bioavailability of 300 mg niraparib administered as a tablet versus capsule formulation and to estimate the intra-subject variability of niraparib PK
- Stage 2: To evaluate if the tablet formulation (1 × 300 mg) of niraparib is bioequivalent to the capsule formulation (3 × 100 mg)
- Stage 3: To assess the effect of a high-fat meal on niraparib PK following a single 300 mg dose of the tablet formulation.

The secondary objectives of this study are as follows:

- Stage 1, Stage 2, and Stage 3: To evaluate the safety of single dose niraparib when administered as a tablet or capsule formulation in patients with advanced solid tumors
- Extension Phase: To evaluate the safety of continuously dosed niraparib in patients with advanced solid tumors.

The exploratory objectives of this study are as follows:

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1.1.3. Scope and Revision History

A separate PK analysis plan will be written to address the PK objectives and data for this study.

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analyses of non-pharmacokinetic study data. Patient populations to be used for analyses, data handling rules, statistical methods, and formats for data presentation are identified and provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial.

The SAP will outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

The SAP is a living document that will be created during the trial conduct. It will be maintained throughout the lifecycle of the trial. Important changes following approval of SAP v1.0 will be tracked in this section.

The following changes have been implemented in the Appendix containing shells of the Planned Statistical Tables, Listings and Figures.

Table/Listing Number	**Correction**	**Reason for Correction**
Table 14.1.1d	Footnotes [2] and [3] added to the table and in the footer.	Clarification why two patients have been double counted in Screening.
Table 14.1.3.1c	Footnote added to the shell.	Clarification added to the output for Extension Phase reporting effort.
Table 14.1.4d	Added "Missing" category to Cancer stage and Number of prior lines of therapy.	Data collected has missing information on the eCRF.
Table 14.3.1.1.2d	Removed "Any COVID-19 related TEAE".	Removing a duplicate entry row.
Table 14.3.1.14d	Removed "System Organ Class" from the table.	Line not required for the table in question as summary by Preferred Term is of interest.
Table 14.3.1.16.1c	Table shell added.	Table added for final study disclosure purposes of Extension Phase data.
Table 14.3.1.16d	Added footnote: "NOTE: Deaths due to progressive disease were not collected as adverse events."	Added to reflect data collection and management process and align with Stage 1 and Stage 2 programming practice.
Table 14.3.1.2.1.1d	Footnote added: Note: COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.	Added as per reviewer request.
Table 14.3.1.20d Table 14.3.1.21d Table 14.3.1.22d	Footnote [1] updated to: "Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with	Clarification of footnote explaining calendar placement of the Stages 1-3 during COVID-19 pandemic.

Table/Listing Number	Correction	Reason for Correction
	patients across all Stages ongoing until DDMMMYYYY." Table titles updated to: Table 14.3.1.20d Summary of Incidence of COVID-19 Related Adverse Events Over Time (Safety Population in the Stage 3 PK Phase) Table 14.3.1.21d Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender (Safety Population in the Stage 3 PK Phase) Table 14.3.1.22d Summary of Incidence of COVID-19 Related Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)	Clarification of titles to reflect the reporting effort of COVID-19 related AE incidence rates.
Table 14.4.1c	Summary table of Important Protocol Deviations for Open-Label Extension Phase added.	Added upon request from study team for CSR reporting purposes.
Table 14.4.1d	Summary table of Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population in the Stage 3 PK Phase). Footnotes and corresponding references added to the table.	Added upon request from study team for CSR reporting purposes. Added upon request for clarification.
Listing 16.2.2.2c	Footnote [1] updated to: "Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.	Clarification of footnote explaining calendar placement of the Stages 1-3 during COVID-19 pandemic.
Listing 16.2.5.1d	Added "PK Dose 1" and "PK Dose 2" date columns to the listing. Moved "Patient Number" into header row.	Added columns to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2. For readability purposes.
Listing 16.2.5.3d	Added "Rel Day [1]" column and [1] footnote: "[1] Relative to first dose during the PK Phase."	Added to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2.
Listing 16.2.5.5d	Columns "Full Dose Taken?", "If N, how much consumed?", "Reason for Change", "Nausea within specified time of dose?" removed from the listing.	Columns removed from Stage 3 listing as not applicable, as per study design.
Listing 16.2.8.1.1d and associated repeat listings	Programming note added regarding location of "Patient Number" in the outputs.	Depending on spacing/information displayed, "Patient Number" may be displayed in the header row after

Table/Listing Number	Correction	Reason for Correction
		"Treatment Sequence" in order to aid readability of the listing.
Listing 16.2.8.2d	Removed "Heart Rate" column.	Data collected under "Pulse" in Stage 3, added "Heart Rate" to the shells in error.
Listing 16.2.8.5d	Added text to footnote: "in the PK Phase"	Previously missing in error.
Listing 16.2.9.2c	Footnote [1] updated to: "Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.	Clarification of footnote explaining calendar placement of the Stages 1-3 during COVID-19 pandemic.
Listing 16.2.2c	Listing updated to include only "Important" protocol deviations; title updated to reflect change. "Protocol Deviation Severity" column dropped.	Updated upon request from study team for CSR reporting purposes. Obsolete field.
Listing 16.2.2.1d	Listing updated to include only "Important" protocol deviations; title updated to reflect change.	Updated upon request from study team for CSR reporting purposes.
Section 1.2	Definition of data cut has been amended.	Definition changed to reflect study reporting requirements upon request from study team.
Table 14.1.1c	Table has been updated to include Starting Dose (100 mg, 200 mg and 300 mg) and categorization by Stage (TABLET Stages 1, 2 and 3).	Updated upon request from study team for CSR reporting purposes.
Table 14.1.10c	Table added for Extension Phase.	Added upon request from study team for CSR reporting purposes.
Extension Phase tables	Treatment arm labels updated to be TABLET, CAPSULE and OVERALL, for consistency, throughout the shells	Updated for consistency.
Table 14.3.1.1.1c	Table shell spelled out for Extension Phase reporting effort, including COVID-19 summary categories.	Updated upon request from study team for CSR reporting purposes.
Table 14.3.1.1.1.1c	New repeat table added for Extension Phase.	Added upon request from study team for CSR reporting purposes.
Table 14.3.1.11.1a	New table added for PK Stage 1.	Required for plain text summary reporting effort.
Table 14.3.1.11.1b	New table added for PK Stage 2.	Required for plain text summary reporting effort.
Table 14.3.1.11.1c	New table added for Extension Phase.	Required for plain text summary reporting effort.
Table 14.3.1.11.1d	New table added for PK Stage 3.	Required for plain text summary reporting effort.
Table 14.3.1.23.1a	New table added for PK Stage 1.	Required for disclosure reporting effort.

Table/Listing Number	Correction	Reason for Correction
Table 14.3.1.23.1b	New table added for PK Stage 2.	Required for disclosure reporting effort.
Table 14.3.1.23.1c	New table added for Extension Phase.	Required for disclosure reporting effort.
Table 14.3.1.23.1d	New table added for PK Stage 3.	Required for disclosure reporting effort.
Table 14.3.1.23.2a	New table added for PK Stage 1.	Required for plain text summary reporting effort.
Table 14.3.1.23.2b	New table added for PK Stage 2.	Required for plain text summary reporting effort.
Table 14.3.1.23.2c	New table added for Extension.	Required for plain text summary reporting effort.
Table 14.3.1.23.2d	New table added for PK Stage 3.	Required for plain text summary reporting effort.
Table 14.3.1.14c	Footnotes omitted as not applicable for Extension phase reporting.	Updated for clarification.
Table 14.3.1.20c	Footnote updated to reflect reporting period for overall study population in Extension Phase.	Updated for clarification.
Table 14.3.1.21c	Table added for Extension Phase reporting.	Updated upon request from study team for CSR reporting purposes.
Table 14.3.1.22c	Table added for Extension Phase reporting.	Updated upon request from study team for CSR reporting purposes.
Table 14.3.4.1c	'Number of Cycles' changed to 'Maximum number of cycles'. Labels for dose interruptions/reductions/re-escalations modified for clarity. 'Median number of cycles started', 'Exposure duration (months)' and 'Dose intensity' added to output.	Updated to reflect changes requested by study team.
Table 14.3.4.5.1c	Table added for Extension Phase reporting.	Updated upon request from study team for CSR reporting purposes.
Listing 16.2.2.2c	Listing added for Extension Phase reporting.	Updated upon request from study team for CSR reporting purposes.
Listing 16.2.5.1.1c	Listing added for Extension Phase reporting.	Updated upon request from study team for CSR reporting purposes.
Listing 16.2.5.5c	"Tablets remaining" and "Was Full Dose Taken?" column dropped.	Data not collected consistently for study reporting purposes.
Listing 16.2.6.1c	"Visit" column dropped. "Tumor Type" column added.	Visit data not collected, only date of assessment. Added upon request from study team for CSR reporting purposes.
Listing 16.2.7.1c	Listing shell spelled out for Extension Phase reporting effort. 'Dose at onset of AE' variable dropped from listing.	Updated upon request from study team for CSR reporting purposes. Data not collected consistently for production of reliable results.
Listing 16.2.7.2c	Listing added for Extension Phase reporting.	Added upon request from study team for CSR reporting purposes
Listing 16.2.9.2c	Listing shell spelled out for Extension Phase reporting effort.	Updated upon request from study team for CSR reporting purposes.
Figure 14.3.4.3.1c	Figure shell added for Extension Phase reporting effort.	Updated upon request from study team for CSR reporting purposes.

Table 1 Revision History

SAP version	Protocol version	eCRF version	Changes from previous version
1.0	2.0	5.0 (26FEB2018)	First Draft
2.0	4.0	8.0 (12FEB2019)	Major changes to this draft of the SAP include the following: Incorporate changes based on amended protocol. Modify Stage 2 analysis of AEs to accommodate the increase in washout time between Period 1 and Period 2 for Stage 2. For the Extension Phase, specify that analysis will be performed by formulation and overall to accommodate allowance of both tablet and capsule formulation in the Extension Phase. Define the BA/BE evaluable population and add demographic and baseline characteristic summaries for this population. Clarify definition of concomitant medications and add additional table for Stage 2 to analyze only medications taken during the PK collection period. Clarifications to mock table and listing shells (e.g., numbering, footnotes).
3.0	5.0	10.0 (31JUL2019)	Major changes to this draft of the SAP include the following: • Incorporate changes based on amended protocol, including: o Updated numbers of patients enrolled to account for non-evaluability. o Specification of reasons for non-evaluability for the analysis of bioequivalence. • Focus Extension Phase laboratory summaries on select laboratory assessments hemoglobin, neutrophils, platelets, bilirubin, creatinine, AST, and ALT).
4.0	6.0	11.0 (16APR2020)	Major changes to this draft of the SAP include the following: • Incorporate changes based on amended protocol, to address the objectives for Stage 3 of the study. • Addition of sections relating to COVID-19 reporting.
5.0	6.0	13.0 (17MAR2021)	Primary changes to this draft associated with addition of Important Protocol Deviation table and updates to the associated listing to reporting effort. Minor updates to align Stage 1, 2 and 3 TLFs with shells, and associated update to Protocol Deviation reporting, as per the SAP.

SAP version	Protocol version	eCRF version	Changes from previous version
6.0	6.0	13.0 (17MAR2021)	Primary change to this draft of the SAP is change of the data cut for reporting of final Stage 3 analysis. Minor update to footnotes of Important Protocol Deviation summary table. Minor update to Section 5 formatting.
7.0	6.0	14.0 (17NOV2021)	Minor updates to template output/column header and title formatting to align with produced output header and title formatting. CRF versions updated to align with CRF booklet version upgrades starting from SAP version 4.0 onwards. COVID-19 related output shell added for Extension phase. Definitions of exposure and compliance derivations expanded to include dose intensity. Additional tables and listings have been added/modified for Extension Phase; disclosure and plain language summary reporting tables have been added across all study stages. Section 3.2 'Dose at onset of AE' has been removed from AE listings; output shells added for adverse event reporting in the Extension Phase/to cover time between end of PK Phase and start of Extension Phase. Section 2 updated to include definition for dose intensity in exposure table for Extension Phase. Section 4.4.2 updated AE classification for PK Period 1 for Stage 3.

1.2. Study Design

1.2.1. Synopsis of Study Design

This is a multicenter, open-label study in patients with advanced solid tumors. This is a 3-stage, randomized-sequence, single-crossover study to assess the relative BA and BE of niraparib tablet formulation relative to the capsule formulation. In addition, Stage 3 of the protocol is a single cohort, randomized-sequence, 2 period, single dose, crossover study to assess effect of food on the PK of the niraparib tablet formulation.

Pharmacokinetics (PK) Phase: In Stages 1 and 2, patients will be randomized 1:1 to receive tablet formulation followed by capsule formulation or capsule formulation followed by tablet formulation. In Stage 3, patients will be randomized 1:1 to receive tablet formulation in a fasted state followed by tablet taken with a high-fat meal, or by tablet taken with a high-fat meal followed by tablet formulation taken in a fasted state.

Stage 1: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet [1 × 300 mg] or capsule [3 × 100 mg]) followed by a 7-day (+1 day) Washout/PK period, followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day (+1 day) Washout/PK period for Stage 1 of the study followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 2: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet [1 × 300 mg] or capsule [3 × 100 mg]) followed by a 14-day (+/- 4 days) Washout/PK period followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 3: In Period 1, patients will receive a single 300 mg niraparib tablet either following a 10-hour fast or directly following consumption of a high-fat meal, followed by a 14-day (+4 days) PK sampling and Washout period. In Period 2, patients will be crossed over to receive a single 300 mg niraparib tablet in a fasted state or with a high-fat meal, followed by a 7-day PK sampling period. All patients will fast for a minimum of 4 hours post-dose in both periods. Patients receiving the tablet in the fasted state in the first treatment period will receive the tablet with a high-fat meal in the second treatment period and vice versa.

In the rare instance where a delay of the entire PK Period 2 is needed for any reason beyond the 4 day window specified above the site must contact the Sponsor's medical monitor to discuss the patient circumstances, the Sponsor will decide if the patient can continue with PK Period 2 with a delay. Similarly, should the laboratory results on Day 15 (D15) (the day of niraparib administration in PK Period 2) show changes in organ function such that the original inclusion criteria for laboratory values are no longer met, or in the event of a significant change of patient's clinical status as judged by the Investigator, the site must consult with the Sponsor to discuss the patient's continued participation in PK Period 2. Note that sites need not wait for the pre-dose laboratory results to begin PK Period 2, but rather consult the Sponsor once the results are available as needed. In Stage 2, patients who experience emesis within 9 hours of dosing or who miss a critical PK sample (such as the last PK sample on Day 8 in each period) will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. In Stage 3, patients who experience emesis within 10 hours of dosing will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. Patients who miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase.

For Stage 1, the PK parameters that will be estimated include area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUC_{0-t}), area under the plasma concentration-time curve from time 0 extrapolated to infinity ($AUC_{0-\infty}$), apparent total body clearance (CL/F), maximum observed plasma concentration (C_{max}), time to reach C_{max} (t_{max}), termination elimination half-life ($t_{1/2}$), apparent terminal volume of distribution (Vz/F) and BA of tablet formulation relative to the capsule formulation based on AUC_{0-t}, $AUC_{0-\infty}$, and C_{max}. Relative bioavailability will be assessed based on the ratio of geometric least-squares (LS) means of the test (tablet) to reference

(capsule). Additionally, the pharmacokinetics of CCI [redacted] will be determined (Stage 1 only).

For Stage 2, the same PK parameters as above will be estimated. To conclude bioequivalence, the 90% confidence interval (CI) of the ratio of geometric LS means of the test (tablet) to reference (capsule) product should be within 0.800 – 1.250 (80% – 125%) for $AUC_{0-\infty}$, AUC_{0-t}, and C_{max}.

For Stage 3, the same PK parameters as above will be estimated. In addition, t_{lag}, the time from administration of the dose to the first quantifiable concentration, will be determined, and t_{max} will be compared between the fed and fasted states. The relative bioavailability of the 300 mg niraparib tablet administered with a high-fat meal relative to fasted dosing will be based on the ratio of geometric LS means of AUC_{0-t}, $AUC_{0-\infty}$, and C_{max}.

Additional PK parameters may be estimated (e.g., residual area), if deemed appropriate.

Extension Phase: When patients complete the PK Phase of the study (at least 7-days from the beginning of PK Period 2), they may be eligible to participate in the Extension Phase following review of the Extension Phase inclusion criteria and completion of the required Extension Phase screening assessments. The starting dose of niraparib in the Extension Phase will be based on the patient's baseline actual body weight or platelet count. Patients with a baseline actual body weight of ≥77 kg and screening platelet count of ≥150,000/µL (obtained after completion of the PK Phase, as part of Extension Phase screening) will take one 300 mg strength tablet or 3 × 100 mg tablet/capsules at each dose administration (once a day [QD]). Patients with a baseline actual body weight of <77 kg or screening platelet count of <150,000/µL will take one 200 mg strength tablet or 2 × 100 mg tablet/capsules at each dose administration (QD). For patients whose initial starting dose is 200 mg QD, escalation to 300 mg QD is permitted after 2 cycles of therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor. Additional dose modifications will not be based upon changes in the patient's actual body weight during study participation. If laboratory values at the beginning of Extension Phase are outside of the range specified in the inclusion criteria, the patient may continue to participate in the study only upon Sponsor approval with consideration for an appropriately reduced dose. Should a patient start the Extension Phase at 100 mg, consideration may be given to escalate to 200 mg after 2 cycles of therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor.

Patients have up to 28 days (21 days for Stage 3 only; up to 28 days may be acceptable following discussion between the Sponsor and Investigator) after completion of the PK Phase to complete the screening assessments and the Extension Phase Screening Visit.

A tumor assessment is to be performed prior to the first dose of the Extension Phase (pre-Extension Phase). The pre-Extension Phase tumor assessment need not be completed if the baseline tumor assessment was performed ≤ 56 days before the first dose of the Extension Phase.

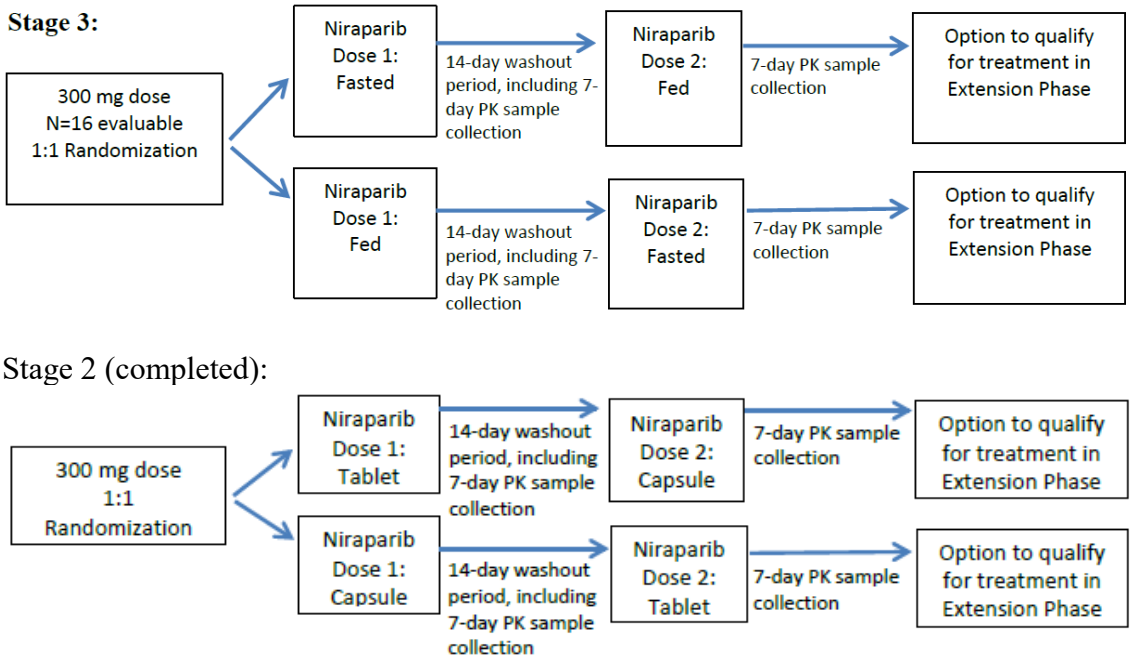
The Cycle 1/Day 1 Visit can occur on the same day as the Extension Phase Screening Visit, dependent upon availability of radiographic results obtained ≤ 56 days of the first planned dose in the Extension Phase. If the Extension Phase Screening Visit and the Cycle 1/Day 1 Visit occur on the same day, the clinical laboratory results will be reviewed by the study personnel prior to study drug administration to

ensure eligibility. At the Cycle 1/Day 1 Visit, patients will undergo safety assessments and will receive study drug supply for the duration of 1 cycle (300 mg or 200 mg tablets of niraparib for QD dosing or 3 × 100 mg or 2 × 100 mg tablet/capsules of niraparib for QD dosing, depending on availability). It is preferred that patients remain on the same formulation (tablet versus capsule) throughout the Extension Phase. Patients will return on the first day of every treatment cycle (28 ± 7 days) to receive study drug and for safety assessments. Visits will continue approximately every 4 weeks until treatment discontinuation. In line with the niraparib United States Package Insert (US PI), dose interruption (no longer than 28 days) will be allowed based on adverse events (AEs). In addition, dose reductions to 200 mg QD and subsequently to 100 mg QD will be allowed based on AEs (please refer to US PI). Any dose reductions differing from this must be discussed with the medical monitor. Patients can continue in the Extension Phase until the patient meets 1 of the withdrawal criteria.

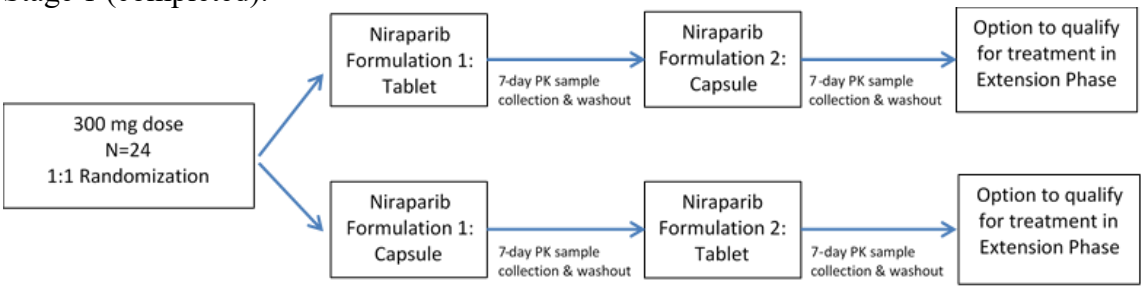
End-of-treatment (EOT) and Safety Follow-up Visits: The EOT visit will occur within 7 days of the decision to discontinue study drug, for any reason, or completion of the PK Phase for patients who participate in the Extension Phase (Stage 3 only), whichever occurs first. Should the first dose of a new anti-cancer therapy occur within 14 days of the decision to discontinue study drug, all assessments required for the Safety Follow-up visit should occur at the EOT visit and this visit will be considered the Safety Follow-up visit. If the first dose of the new anti-cancer therapy occurs >14 days of the decision to discontinue study, the Safety Follow-up visit will occur 30 +7 days after the last dose of the study drug, or at the start of any new anti-cancer therapy, whichever occur first.

For Stage 3 of the PK Phase only, the data cut will occur when all patients have completed the PK Phase. Data collected up to and including PK EOT visit prior to the data cut will be presented in the FE Stage 3 PK CSR for all randomized and treated patients. Additionally, the Sponsor will include safety data related to the PK Phase, as identified up to Cycle 1/Day 1 of the Extension Phase.

Figure 1 Study Design: Single-Crossover Study



Stage 1 (completed):



Abbreviations: PK = pharmacokinetics.

1.2.2. Randomization Methodology

Randomization will occur centrally using an interactive voice response system/integrated web response system. In Stage 1 and Stage 2, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: capsule formulation followed by tablet formulation, or vice versa. In Stage 3, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: dosing after receiving a high-fat meal (fed) followed by dosing after fasting, or vice versa. The period between randomization and Cycle 1/Day 1 should be no longer than 5 calendar days.

1.2.3. Unblinding

Unblinding is not applicable as this is an open-label study.

1.2.4. Study Procedures

Refer to the latest protocol for the schedule of assessments.

1.2.5. Efficacy, Safety, and Pharmacokinetic parameters

1.2.5.1. Efficacy parameters

Investigator assessment of response will occur every 3-cycles while on study or per the Institution's standard practice.

1.2.5.2. Safety parameters

Safety parameters to be assessed include:

- Treatment emergent adverse events (TEAE)
- Discontinuations due to AEs
- Physical examination (PE) findings
- Vital signs
- Clinical laboratory results (hematology, chemistry, urinalysis)
- Electrocardiograms (ECG)
- Use of concomitant medications.

1.2.5.3. PK parameters

PK parameters and analysis methodology will be addressed in the PK analysis plan.

2. Patient Population

2.1. Population Definitions

The following patient populations will be evaluated for analyses specified in this SAP. Additional populations, relevant to the PK analysis will be defined in the PK analysis plan.

- Safety Population in the Stage 1 PK Phase: All patients who receive any amount of niraparib during the Stage 1 PK Phase of the study.
- Safety Population in the Stage 2 PK Phase: All patients who receive any amount of niraparib during the Stage 2 PK Phase of the study.
- Safety Population in the Stage 3 PK Phase: All patients who receive any amount of niraparib during the Stage 3 PK Phase of the study.
- Safety Population in the Extension Phase: All patients who receive any amount of niraparib in the Open-Label Extension Phase of the study.
- BA/BE Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters, without significant niraparib carryover (baseline concentration > 5% of C_{max}), in both PK Periods. Patients who have significant niraparib carryover from Period 1 in Period 2 will be completely excluded from the BA/BE Evaluable Population. The terminology BA Evaluable Population will be used for Stage 1 and BE Evaluable Population will be used for Stage 2.
- Food effect (FE) Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters in both periods. Patients meeting non-evaluability criteria or having significant niraparib carryover (baseline concentration >5% of C_{max}) will be completely excluded from the FE Population.

2.2. Protocol Deviations

Protocol deviations will be assessed and classified as important and/or significant per Sponsor's SOP. The Medical Data Review Plan (MDRP) prospectively identifies classification criteria for important deviations. All protocol deviations will be identified, classified and finalized prior to database lock.

A listing of protocol deviations will be provided for the Stage 1 PK Phase, Stage 2 PK Phase; for Stage 3 PK Phase and the Open-Label Extension Phase a listing of only "Important" protocol deviations will be provided.

For Stage 3 PK Phase and Open-Label Extension Phase, tables summarizing "Important" protocol deviations will be provided.

3. General Statistical Methods

3.1. Sample Size Justification

Stage 1

No formal sample size calculation was performed for Stage 1. Approximately 24 patients will be enrolled in Stage 1. This sample size is considered adequate for preliminary assessment of the relative bioavailability of the tablet compared to the capsules and for estimating the intra-subject coefficient of variation, after accounting for patient drop-outs and potential carryover.

Stage 2

Based on estimates from Stage 1, 100 BA/BE evaluable patients are required in Stage 2. With 100 evaluable patients, assuming the intra-subject coefficient of variation (CV) is 25% and the true ratio of means is 0.89 (89%), there is at least 90% power to demonstrate the bioequivalence (bioequivalence range: 0.80 to 1.250 [80% – 125%], alpha=0.05). Power calculations were also performed under alternative assumptions for the CV and mean ratio. Assuming the CV is 30% and the true ratio of means is 0.89 (89%), with 100 evaluable patients, there is at least 82% power to demonstrate bioequivalence. Assuming the true ratio is 0.90 (90%), the power is 96% and 88% assuming CVs of 25% and 30%, respectively.

The final analysis of bioequivalence will be based on Stage 2 BA/BE evaluable patients only, with a target sample size of 100 evaluable patients. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

- Emesis within 9 hours of dosing,
- Dosing errors,
- Patient did not fast prior to dosing,
- Missing critical PK sample on Day 8,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

In this patient population, approximately 170 total patients are targeted for enrollment, assuming a 35% non-evaluability rate during the study conduct, and an additional 10% non-evaluability rate during PK analysis. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 100 BA/BE evaluable patients.

Stage 3

Assuming the true ratio of means is 1 and the intra-subject CV is 20% for AUC_{0-t} and $AUC_{0-\infty}$, with 16 evaluable patients, there is approximately 83% probability that the 90% CI of the ratio of geometric means will be within 0.800 and 1.250 (80% - 125%). Based on the results of a FE study conducted using the capsule formulation, an effect of a high-fat meal on C_{max} is possible. The sample size of 16 patients is deemed adequate to characterize this effect. AUC_{0-t} and $AUC_{0-\infty}$ will be the primary parameters for analysis.

The primary analysis will be based on the FE Evaluable Population as it is the most conservative approach, which maximizes the benefits of the crossover design, where each patient serves as their own control. Results for the PK Evaluable Population will also be summarized and reported for this study.

To account for non-evaluable patients, approximately 20 total patients are targeted for enrollment. The final analysis will be based on Stage 3 FE evaluable patients only. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

- Emesis within 10 hours of dosing,

- Dosing errors,
- Patient did not follow dietary requirements prior to dose and post-dose,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

Patients who miss critical PK samples or miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 16 evaluable patients.

3.2. General Methods

All statistical analyses will be performed using SAS statistical software v9.4 or later, unless otherwise noted. All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files, sorted and labeled according to the International Council for Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

For categorical variables, summary tabulations of the number and percentage of patients within each category of the parameter will be presented. Percentages will be based on the patients with a non-missing parameter unless missing category is presented. Percentages will be reported to one decimal place. Percentages will not be presented for zero counts.

For continuous variables, the number of patients, mean, standard deviation (SD), median, first quartile (Q_1), third quartile (Q_3), minimum, and maximum values will be presented. Mean, median, Q_1, and Q_3 will be reported to 1 more decimal place than the raw data, while the SD will be reported to 2 more decimal places than the raw data.

All data listings that contain an evaluation date will also contain a relative study day. A unique relative study day will be calculated for the PK Phase and Extension Phase based on the first date of dosing within the respective study phase. Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study drug which is designated as Day 1. The preceding day is Day -1, the day before that is Day -2, etc. Post-treatment study days are numbered relative to the first dose and are designated as Day +1, Day +2, etc.

In addition:

- Medical history and AEs will be coded using the most up-to-date version of Medical Dictionary for Regulatory Activities (MedDRA).
- Laboratory parameter changes during the Extension Phase for selected laboratory tests will be described using shift tables, relative to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03.
- Concomitant medications will be coded using the latest version of the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification.
- CIs will be presented to one more decimal place than the raw data.

Summaries in the Extension Phase will be performed by formulation and overall, regardless of starting dose, unless otherwise specified. The niraparib formulation will be included in the listing for the Extension Phase.

All tables, figures, and listings will include footers at the bottom of the page reflecting the programs used to generate the tables, figures, and listings, and date and time of the generation of the output.

Some minor modifications may be necessary to the planned design of tables, figures, and listings to accommodate data collected during the actual study conduct.

3.3. Baseline Definitions

For all analyses unless otherwise noted, baseline is defined as the most recent measurement prior to the first administration of study drug, for each phase of the study. Baseline can be the same date as first dose, given the measurement is expected prior to first dose when only date information is available.

3.4. Methods of Pooling Data

Data will be pooled across study sites.

3.5. Adjustments for Covariates

No formal statistical analyses that adjust for possible covariate effects are planned for the safety endpoints.

3.6. Multiplicity Adjustment

Multiplicity is not adjusted in this study.

3.7. Subpopulations

Not applicable.

3.8. Withdrawals, Drop-outs, Loss to Follow-up

Patients will not be replaced during Stage 1. During Stage 2 and Stage 3, patients who do not complete Period 1 or Period 2, or who are missing PK samples which render the determination of the primary PK parameters not possible, will be replaced. After evaluation, patients receiving concomitant medications which may affect the final analysis may be replaced.

3.9. Missing Data

In general, there will be no imputations made to accommodate missing data points. All data recorded on the eCRF will be included in data listings for the CSR.

When tabulating AE data, partial dates will be handled as follows:

- If the day of the month is missing, the onset day will be set to the first day of the month unless it is the same month and year as first study treatment. In this case, in order to conservatively report the event as treatment-emergent, the onset date will be assumed to be the date of first study treatment.
- If the onset day and month are both missing, the day and month will be assumed to be January 1, unless the event occurred in the same year as the first study treatment. In this case, the event onset will be coded to the day of first study treatment in order to conservatively report the event as treatment-emergent.

- A missing onset date will be coded as the first day of study treatment. If the resulting onset date is after a reported date of resolution, the onset date will be set equal to the date of resolution, after considering any required imputation.

Imputation of partial dates is used only to determine whether an event is treatment-emergent; data listings will present the partial date as recorded in the eCRF.

Partial start dates for prior/concomitant medication, growth factor and transfusion data will be handled in the same way as described above for adverse events. Stop dates will be imputed as follows:

- If only day of the month is missing, the end day will be set to the last day of the month.
- If end day and end month are missing, and the year is not missing, then the day and month will be set to December 31 (or date of study discontinuation/completion if earlier than December 31).
- If the stop date is completely missing, it will be set to the date of study discontinuation/completion.
- If the imputed stop date is greater than the date of study discontinuation/completion then the date will be set to the date of study discontinuation/completion.

3.10. Visit Windows

By-visit summaries and analyses will be performed by nominal visit. All data will be tabulated per the evaluation visit as recorded on the eCRF even if the assessment is outside of the visit window for analysis.

3.11. Interim Analysis

There will be no interim analysis for this study.

3.12. COVID-19

COVID-19 pandemic may impact the conduct of clinical studies. Challenges may arise from quarantines, site closures, travel limitations interruptions to the supply chain for the investigational product or other considerations if site personnel or patients become infected with COVID-19. These challenges may lead to difficulties in meeting protocol specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing.

This study was initiated by TESARO, which was subsequently acquired by GSK. Prior to the acquisition, protocol deviations were classified using TESARO definitions. The TESARO protocol deviation system was decommissioned in May 2020, and thereafter, protocol deviations were classified using GSK definitions.

All protocol deviations collected during the study will be reviewed by the TESARO (for Stage 1 and Stage 2) or GSK (for Stage 3 only) study team, as appropriate, in order to identify TESARO "Significant"/"Important" protocol deviations and GSK "Important" protocol deviations, respectively. Consistent with ICH E3 guidance, only protocol deviations identified as "Important" (GSK) are evaluated in the CSR for impact on the Stage 3 primary endpoint.

4. Study Analyses

4.1. Patient Disposition

A by-patient data listing of patient disposition information will be presented for each phase.

For the PK Phase (Stage 1, Stage 2, and Stage 3 separately), patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients screened
- Patients randomized
- Patients treated with each formulation (Stage 1 and 2)
- Patients treated in fed and fasted state (Stage 3)
- Patients in the Safety Population
- Patients completing the PK Phase
- Primary reason for discontinuation from the PK Phase
- Primary reason for discontinuation from the study, for patients who do not continue to the Extension Phase.

For the Open-Label Extension Phase, patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients treated with at least one dose
- Patients who discontinue treatment and the reason(s) for withdrawal
- Patients who discontinue the study and the reason(s) for withdrawal.

4.2. Demographics, Baseline Characteristics and Medical History

Demographics, baseline characteristics, primary cancer history, and medical history information will be summarized for the PK Safety Population by sequence and overall (Stage 1, Stage 2 and Stage 3 separately) and for the Open-Label Extension Phase, using descriptive statistics for the Safety Population. No formal statistical comparisons will be performed. Demographics and baseline characteristics will also be summarized for the BA for Stage 1, BE Evaluable Population for Stage 2 and FE Evaluable Population for Stage 3.

The demographic and baseline characteristics tables will include the following variables:

- Age at time of screening (years)
- Age categories (18 to <65, 65 to <75, ≥75; and ≥65)
- Sex
- Race (White, Black, Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, Other and Not Reported)
- Ethnicity (Hispanic or Latino, not-Hispanic or Latino, Not Reported and Unknown)
- Baseline weight (in kilograms)
- Baseline height (in centimeters)
- Baseline body mass index (BMI) (kg/m^2), calculated using the patient's height and weight at screening [BMI (kg/m^2) = weight (kg) / height $(m)^2$]
- Eastern Cooperative Oncology Group (ECOG) performance status at baseline.

Primary cancer history will be summarized for the safety population and will include the following variables:

- Tumor type
- Time from first diagnosis to informed consent (years)
- Cancer stage (most recent) (Locally advanced, Metastatic)
- Number of prior lines of therapy
- Any prior radiotherapy.

Prior anti-cancer treatments will be coded using the most current version of the WHO Drug Dictionary. The number and percentage of patients reporting the use of at least one preferred term will be reported for the Safety Population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Safety Population in the Extension Phase.

Medical history will be coded using the most current version of MedDRA, and the number and percentage of patients experiencing at least one such diagnosis by MedDRA System Organ Class (SOC) and preferred term (PT) will be reported for the Safety Population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Safety Population in the Extension Phase.

Demographics, baseline characteristics, primary cancer history, and medical history information for each patient will be provided in data listings.

4.3. Investigator Assessment of Response

Investigator assessment of response will be provided in data listings for the Extension Phase. Additional descriptive summaries of response may be performed by tumor type.

4.4. Safety Evaluation

4.4.1. Treatment Exposure and Compliance

PK Phase

The number and percentage of patients receiving capsules and tablets during the PK Phase (Stage 1 and Stage 2, separately) will be summarized. For Stage 3, the number of tablets received will be summarized by fed/fasted state.

A by-patient listing of the niraparib treatment data will be produced for the PK Safety Population.

Extension Phase

Study treatment exposure and compliance will be summarized by formulation (Capsule; Tablet) and overall, including:

- Number and percentage of patients who initiated 1, 2, 3, 4, 5, ≥6 treated cycles (Maximum Number of Cycles).
- Median number of cycles started.
- Duration of treatment (months), defined as:
  [last dose date - first dose date in the Extension Phase + 1] / 30.4375.
- Duration on study (months), defined as:

[last contact date - first dose date in the Extension Phase + 1] / 30.4375, where last contact date is the last visit date or date of death.

- Dose intensity (mg/day), defined as:
  Sum of daily doses consumed / [last dose date - first dose date in Extension Phase + 1]
- Number of patients with at least one dose interruption.
- Number of patients with at least one dose reduction.
- Number of patients with at least one dose re-escalation.

In addition, the starting niraparib dose for each cycle will be summarized.

A by-patient listing of the niraparib treatment data will be produced for the Open-Label Extension Phase safety population.

4.4.2. Adverse Events

All AEs will be classified by SOC and PT using the most up-to-date version of MedDRA.

Per protocol, all SAEs will be collected from the signing of the ICF for this study through 90 days after the last dose of study drug (or until the start of alternate anticancer therapy, whichever occurs first, and recorded in the eCRF.

All AEs, regardless of the source of identification (e.g., physical examination, laboratory assessment, ECG, or reported by patient), will be collected and recorded in the eCRF for each patient from the time of randomization and/or treatment assignment until 30 days after the last dose of study drug.

All AEs experienced by a patient, regardless of the suspected causality, will be monitored until the AE or SAE has resolved, until AE(s) or SAE(s) have returned to baseline or normal levels, until stabilized with a satisfactory explanation for the changes observed, until the patient is lost to follow-up, or until the patient has died, starts alternate anti-cancer therapy, or until the patient withdraws consent.

For analysis, TEAEs will be defined as any AEs collected with a start date on or after the first dose of study drug. Any AEs recorded in the database that occur from the time of ICF to first dose will be listed only and not included in safety analyses. Pre-existing conditions will be recorded in the eCRF on the Medical History or appropriate page.

The severity of the toxicities will be graded according to the NCI CTCAE v4.03. Within the same MedDRA PT, only the most severe AE for each patient will be counted in tabulations by severity. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for the most severe AE reported.

The Investigator must provide a causality assessment (related or not related) regarding the relationship of the event with the study drug and/or study procedure for all AEs. In Stage 1, for analysis of the PK Phase, AEs considered related to either tablet or capsule will be considered to be related to study drug. Any AEs for which the relationship is missing (for either tablet or capsule during the Stage 1 PK Phase) will be considered related to study treatment. During Stage 2 PK Phase, Stage 3 PK Phase and Extension Phase, relationship relative to niraparib will be considered. Within the same MedDRA PT, only the AE with the highest ranked relationship to treatment for each patient will be counted in tabulations by relationship to treatment. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for

the AE that is most related to treatment. The imputation for a missing relationship will take place prior to determining the most related AE within a SOC or PT for a given patient.

If the start date is missing for an AE and the actual start date cannot be determined from a partial date, the AE will be considered treatment-emergent.

Adverse Events of Special Interest (AESI) for niraparib are the following:

- Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML)
- Secondary cancers (new malignancies [other than MDS or AML])
- Pneumonitis (for Stage 1 and Stage 2 only)
- Embryo-fetal toxicity (for Stage 1 and Stage 2 only).

AEs will be classified into the following time periods for analysis.

- PK Phase (for Stage 1, Stage 2, and Stage 3 separately):
    - Period 1: Any AE that begins on or after Dose 1 but prior to Dose 2.
        - For Stage 1, Period 1 will be defined as 7-days post Dose 1 for patients who do not receive Dose 2.
        - For Stage 2 and Stage 3, Period 1 will be defined as 14-days post Dose 1 for patients who do not receive Dose 2.
    - Period 2: Any AEs that begins on or after Dose 2 but prior to the end of the PK Phase as defined by 7-days post Dose 2.
    - Safety Follow-Up/Extension Screening Period:
        - For patients not participating in the Extension Phase, AEs that begin after the end of the PK Phase.
        - For patients participating in the Extension Phase, AEs that begin after the end of the PK Phase until the date of first dose in the Extension Phase.
- Open-Label Extension Phase:
    - Any AEs that start on or after the first dose in the Extension Phase.
- Any AEs with onset during the PK Phase/Safety Follow-Up/Extension Screening Period and ongoing/ resolved during the Extension Phase will be listed separately.

The analyses indicated below will be performed for each of the above-mentioned phases.

A high-level overview of TEAEs will be presented in a summary table. This table will include the number and percentage of patients for the following categories:

- Any TEAE
- Any related TEAEs
- Any serious TEAEs
- Any related serious TEAEs
- Any TEAEs with CTCAE toxicity grade 3 or above
- Any related TEAEs with CTCAE toxicity grade 3 or above
- Any TEAEs leading to treatment discontinuation
- Any related TEAEs leading to treatment discontinuation

- Any TEAEs leading to dose interruption
- Any TEAEs leading to dose reduction
- Any TEAEs leading to death.

The number and percentage of patients reporting a TEAE will be summarized in the following additional AE tables. AE tabulations will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

- TEAE by SOC and PT
- Related TEAE by SOC and PT
- Treatment emergent SAEs by SOC and PT
- Related treatment emergent SAEs by SOC and PT
- TEAE with toxicity grade 3 or above by SOC and PT
- Related TEAE with toxicity grade 3 or above by SOC and PT
- TEAEs leading to treatment discontinuation by SOC and PT
- TEAEs leading to dose interruption by SOC and PT (Extension Phase Only)
- TEAEs leading to dose reduction by SOC and PT
- TEAEs leading to death by SOC and PT
- TEAE by PT (sorted by frequency)
- TEAE by SOC, PT, and maximum toxicity grade
- Treatment emergent AESI.

For Stage 1 and Stage 2 PK Phase, primary tabulations for the PK Phase data will be provided by formulation (regardless of period), those occurring during the Follow-up/Extension Screening, and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and formulation. For Stage 3 PK Phase, primary tabulations for the PK Phase data will be provided by fed/fasted state (regardless of period), and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and fed/fasted state. For the Open-Label Extension Phase, data will be summarized by formulation and for all patients overall.

The following by-patient listings will be produced for the PK Phase (Stage 1, Stage 2, and Stage 3 separately) and the Open-Label Extension Phase:

- All TEAEs
- Treatment emergent SAEs
- All Deaths
- TEAEs leading to dose interruption (Extension Phase Only)
- TEAEs leading to dose reduction
- TEAEs leading to treatment discontinuation
- Any TEAEs with onset during PK Phase (including Safety Follow-Up/Extension Screening Period) and ongoing/resolved during Extension Phase.

4.4.3. Laboratory Data

Laboratory assessments for safety oversight are performed locally at each center's laboratory by means of their established methods. All laboratory values will be converted to SI units and classified as normal, low, or high based on normal ranges supplied by the local laboratories and upon employing standardization.

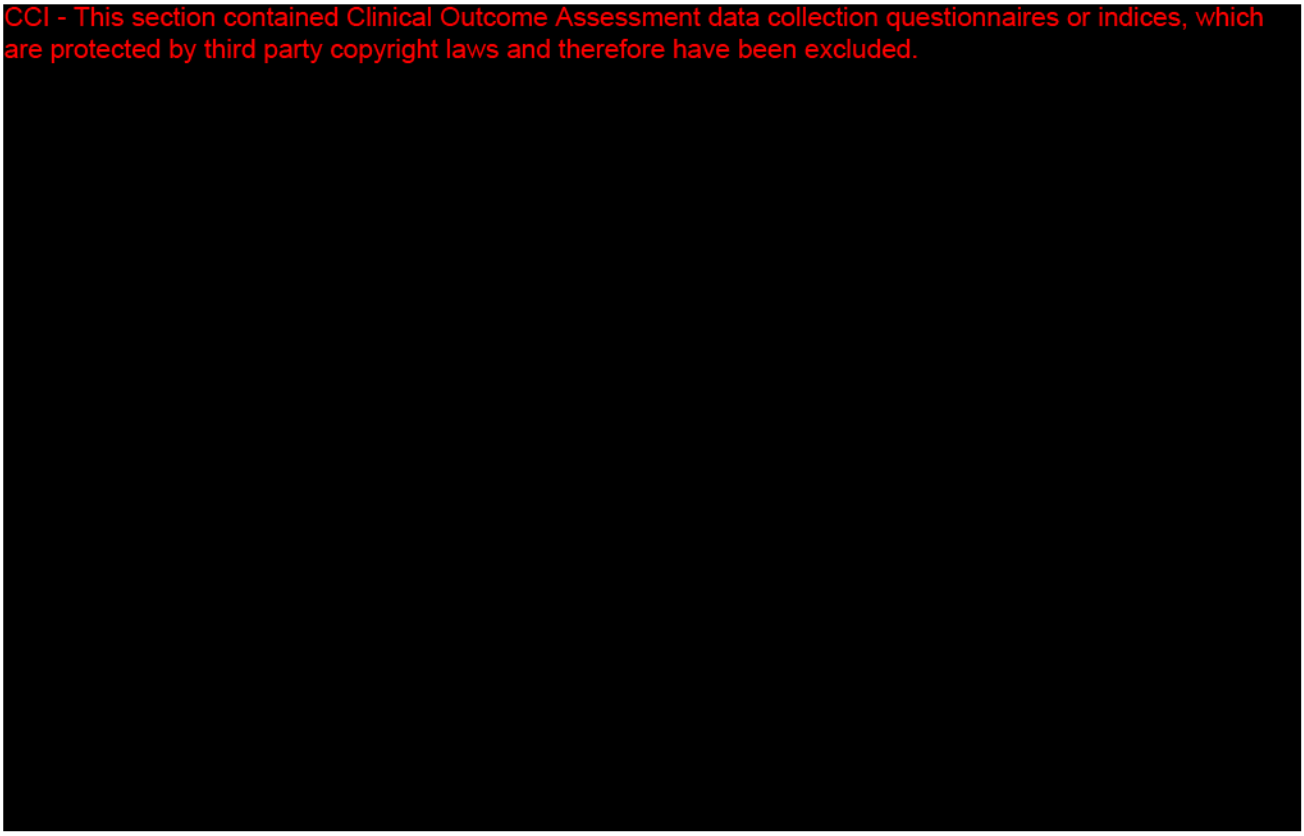
A by-patient listing of all laboratory data will be provided, with laboratory reference ranges and abnormal values highlighted, and including center, patient identifier, and visit for the PK Phase and the Extension Phase of the study.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry (bilirubin, creatinine, aspartate aminotransferase [AST] and alanine aminotransferase [ALT]) will be analyzed using change from baseline by visit.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry tests (bilirubin, creatinine, ALT, and AST), baseline and post-baseline results will be categorized by NCI CTCAE v4.03 grade (Table 2). Shift tables will be produced by maximum post-baseline grade. Results that are considered 'normal' will be assigned a Grade 0.

Table 2 NCI Common Terminology Criteria for Adverse Events v4.03 (CTCAE)

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.



4.4.4. Vital Signs and Physical Examination

Vital sign measurements will be presented for each patient in a data listing.

Baseline physical examination findings will be presented in a data listing. Any new or changed condition will be captured as an adverse event and will be summarized in the AE tables and listings.

4.4.5. Electrocardiogram

Standard 12-lead ECGs will be performed locally for patients in the study. Any ECG findings that are assessed as clinically significant and are reported as an AE or SAE will be summarized in the AE tables and listings.

All ECG results (i.e., interpretations) for each patient will be provided in a data listing.

4.4.6. Prior and Concomitant Mediations

Medications collected at Screening and during the study will be coded using the current version of the WHO Drug dictionary. Study treatment, prior anti-cancer treatments for primary cancer, transfusions and growth factors are collected and summarized separately. For each of the study phases (Stage 1 PK, Stage 2 PK, Stage 3 PK and Extension Phase), medications will be categorized as prior or concomitant using the following definitions:

- Prior medications during the PK Phase: any medications which started prior to the first dose date of study treatment during the PK Phase.
- Concomitant medications during the PK Phase: any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase.
    - For Stage 2 PK Phase, concomitant medications will be further identified as those taken during the PK collection period, defined by dates of the first PK-draw to last PK-draw.
- Prior medications during the Extension Phase: any medications which started prior to the first dose date of study treatment during the Extension Phase.
- Concomitant medications during the Extension Phase: any medications on or after the first treatment dosing date in the Extension Phase through 30 days after the last dose of treatment.
- Any concomitant medication taken during PK Phase that were ongoing during the Extension Phase will be classified as Both, i.e., concomitant and prior, for the purposes of the Extension Phase.

Note: medications can be classified as both prior and concomitant.

Both prior medications and concomitant medications will be summarized by ATC classification drug class and WHO preferred name using the number and percentage of patients for each cohort. A patient reporting the same medication more than once will be counted only once when calculating the number and percentage of patients who received that medication in a given time category (prior or concomitant). The summary of concomitant medications will be ordered alphabetically by drug class and then by descending frequency of preferred name in total within the drug class. For drugs with the same frequency, sorting will be done alphabetically. Summaries will be based on the safety population.

For PK Stage 2, an additional summary of concomitant medications used during the PK collection period will be provided for the BE Evaluable Population.

For each phase of the study, all prior and concomitant medications will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

4.4.7. Prior and Concomitant Transfusions and Growth Factors

The number and percentage of patients receiving prior and concomitant growth factors during the PK Phase and Extension Phase will be summarized. The data will be classified as prior or concomitant using similar logic as provided in Section 4.4.6.

For each phase of the study, all prior and concomitant transfusions and growth factor use will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

4.4.8. COVID-19

The PK Phase Stage 3 of the trial takes place during COVID-19 pandemic, as a result, some of the trial procedures could be impacted in terms of missing visits and/or assessments. Missing protocol required data/visits due to COVID-19 must be noted in participant notes and recorded as COVID-19-related protocol deviations.

A summary of the following COVID-19 assessments will be produced: case diagnosis, COVID-19 test performed, and results of the COVID-19 test.

The incidence of COVID-19 related AEs and SAEs will be summarized as part of the safety reporting summaries along with COVID-19-related as reasons for treatment discontinuation.

A listing of all patients with COVID-19 assessments and symptom assessments will be produced and will include the following:

- Treatment sequence
- Patient number
- COVID-19 case diagnosis
- COVID-19 test performed
- Result of the COVID-19 test
- Assessments and symptom assessments performed
- Results of the assessments and symptom assessments.

For PK Phase Stage 3, a separate listing defining “Important” GSK protocol deviations related to COVID-19 will be presented.

For protocol deviation reporting during the Extension Phase, a listing will be produced to present TESARO Classification of protocol deviations for patients continuing from Stage 1 and Stage 2, and GSK Classification of protocol deviations for patients continuing from Stage 3.

5. Changes to Planned Analyses

There is no change between the protocol-defined statistical analyses and those planned in this SAP.

4.5. Changes in v5.0 of the SAP

Section 2.2 updated to include a summary tables of Important protocol deviations for Stage 3 PK Phase and Open-Label Extension Phases, as well as clarification of associated deviation listings presenting only protocol deviations classified as “Important”.

4.6. Changes in v6.0 of the SAP

Section 1.2 updated to reflect the change in PK data cut requirements for final Stage 3 analysis.

4.7. Changes in v7.0 of the SAP

Case record form (CRF) versions updated to align with CRF booklet version upgrades starting from SAP version 4.0 onwards.

Section 2 updated to include definition for dose intensity in exposure table for Extension Phase.

Section 3.2 'Dose at onset of AE' column removed from AE listings.

Section 4.4.2 updated AE classification for PK Period 1 for Stage 3.

Table 2 header row labels updated to correct CTCAE version.

Table numbering and output header formatting updated to reflect the produced outputs.

Header row labels for Extension Phase updated to TABLET, CAPSULE and OVERALL for consistency.

Additional tables and listings have been added/modified for Extension Phase; disclosure and plain language summary reporting tables added across all study stages.

All-Cause Mortality table added for final study disclosure reporting purposes of the Extension Phase.

6. Appendix

6.1. Planned Statistical Tables, Listings, and Figures

TABLES

General guidelines:
Tables will be provided for the Stage 1 PK Phase, Stage 2 PK Phase, Stage 3 PK Phase and the Open-Label Extension Phase.
For the PK Phase (Stage 1, Stage 2 and Stage 3):

- Treatment=Sequence and Overall, in general. For PK and AE data, please see mock tables.
- Population=Safety Population in Stage 1 PK (Stage 2 PK or Stage 3 PK) Phase, unless otherwise specified.
- PK Phase Data:
    - For patients who do not continue to Extension Phase, PK Phase is any data collected.
    - For patients who do continue to Extension Phase,
        - AEs – prior to first dose in Extension Phase
        - Prior meds/procedures/etc. – prior to first dose in PK Phase
        - Concomitant meds – meds prior to first dose in Extension Phase.
- Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) – use visit to identify data.

For the Extension Phase:

- Treatment=Niraparib Tablet or Capsule (regardless of starting dose); Summarize by Tablet; Capsule; Overall, unless otherwise specified.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Extension Phase Data:
    - For patients who do not continue to Extension Phase, there is no Extension Phase data.
    - For patients who do continue to Extension Phase,
        - AEs – on or after first dose in Extension Phase
        - Prior meds/procedures/etc. – prior to first dose in Extension Phase
        - Concomitant meds – meds on or after the first dose in Extension Phase
        - Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) – use visit to identify data.

Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

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Table 14.1.1a
Subject Disposition in the PK Phase (All Patients in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE	Sequence CAPSULE/TABLET	Overall
Number of Patients				
Screened	n	--	--	xx
Randomized	n	x	x	x
Received Tablet	n	x	x	x
Received Capsule	n	x	x	x
Received Both Tablet and Capsule	n	x	x	x
PK Phase Safety Population	n	x	x	x
Completed PK Phase	n	x	x	x
Discontinuation from PK Phase	n	x	x	x
Reason1	n	x	x	x
Reason2	n	x	x	x
Participate in Extension Phase	n	x	x	x
Discontinuation from Study Prior to Entering the Extension Phase				
Reason1	n	xx	xx	xx
Reason2	n	xx	xx	xx

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Only include DC from study for those patients who do not enter the Extension Phase.

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Table 14.1.1b
Subject Disposition in the PK Phase (All Patients in the Stage 2 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE	Sequence CAPSULE/TABLET	Overall
Number of Patients				
Screened	n	--	--	xx
Randomized	n	x	x	x
Not Treated	n	x	x	x
Received Tablet	n	x	x	x
Received Capsule	n	x	x	x
Received Both Tablet and Capsule	n	x	x	x
PK Phase Safety Population	n	x	x	x
Completed PK Phase	n	x	x	x
Discontinuation from PK Phase [1]	n	x	x	x
Reason 1	n	x	x	x
Reason 2	n	x	x	x
Participate in Extension Phase	n	x	x	x
Discontinuation from Study Prior to Entering the Extension Phase				
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx

[1] Includes patients in the Safety Population (i.e., treated patients) only.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Only include DC from study for those patients who do not enter the Extension Phase.

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Table 14.1.1c
Subject Disposition in the Extension Phase (All Patients in the Extension Phase)

Parameter	Statistic	TABLET	CAPSULE	OVERALL
Number of Patients				
Dosed	n	xx	xx	xx
By Stage:				
Dosed in Stage 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dosed in Stage 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dosed in Stage 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
By Starting Dose:				
100mg/d	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
200mg/d	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
300mg/d	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued Treatment After Receiving at Least 1 Dose	n	xx	xx	xx
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx
Discontinued Study	n	xx	xx	xx
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx

NOTE: The starting dose of 100 mg/day was selected based on Investigator decision.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.1.1d
Subject Disposition in the PK Phase (All Patients in the Stage 3 PK Phase)

Parameter	Statistic	Sequence NIRAPARIB TABLET FASTED/FED	Sequence NIRAPARIB TABLET FED/FASTED	OVERALL
Number of Patients				
Screened [1]	n	--	--	xx
Randomized	n	x	x	x
Not Treated	n	x	x	x
Received Tablet in Fasted State	n	x	x	x
Received Tablet in Fed State	n	x	x	x
Received Tablet in Both Fasted and Fed State	n	x	x	x
PK Phase Safety Population	n	x	x	x
Completed PK Phase	n	x	x	x
Discontinuation from PK Phase [2]	n	x	x	x
Reason 1	n	x	x	x
Reason 2	n	x	x	x
Participate in Extension Phase	n	x	x	x
Discontinuation from Study Prior to Entering the Extension Phase				
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx

[1] Patient xxxxxx-xxxx (Screen Failure ID: XXi) and xxxxxx-xxxx (Screen Failure ID: YYi) re-screened and reconsented after screen failure are counted twice in Screening.
[2] Includes patients in the Safety Population (i.e., treated patients) only.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Note]
XXi/YYi is ID that was SF.
Programming, please note footnote references changed order in the shell and footer.

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Table 14.1.2a
Demographics (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Age (yrs)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Age Group				
18 -< 65	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
65 -< 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex				
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race				
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
African American	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or other Pacific Islander	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity				
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.2.1a Demographics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.2.1b Demographics (Safety Population in the Stage 2 PK Phase)

Table 14.1.2.2b Demographics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.2c Demographics (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- Add footnote: "Note: Age was collected at PK Phase entry only."

Table 14.1.2.1d Demographics (Safety Population in the Stage 3 PK Phase)

Table 14.1.2.2d Demographics (FE Evaluable Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL.

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Table 14.1.3a
Baseline Characteristics (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Weight (kg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Height (cm)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
ECOG Performance Status				
0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

ECOG = Eastern Cooperative Oncology Group:
0=Fully active, able to carry on all pre-disease performance without restriction
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.3.1a Baseline Characteristics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.3.1b Baseline Characteristics (Safety Population in the Stage 2 PK Phase)

Table 14.1.3.2b Baseline Characteristics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.3c Baseline Characteristics (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- Add footnote for Extension Phase and relevant reference in the table:
- [1] Only weight and ECOG Performance Status were repeated at Extension Phase entry.

Table 14.1.3.1d Baseline Characteristics (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

Table 14.1.3.2d Baseline Characteristics (FE Evaluable Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.4a
Primary Cancer History (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Tumor Type				
Xxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time from first diagnosis to informed consent (years)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Cancer Stage (most recent)				
Locally advanced	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of prior lines of therapy				
0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=6	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any prior radiotherapy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.4b Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Table 14.1.4c Primary Cancer History (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

Table 14.1.4d Primary Cancer History (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.5a
Prior Anti-Cancer Treatment (Safety Population in the Stage 1 PK Phase)

Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Agent 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Agent 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Agent 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort by decreasing frequency in the OVERALL column.

Repeat for:
Table 14.1.5b Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Table 14.1.5c Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

Table 14.1.5d Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED AND OVERALL.

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Table 14.1.6a
Medical History (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any condition	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort alphabetically by SOC/PT.

Repeat for:
Table 14.1.6b Medical History (Safety Population in the Stage 2 PK Phase)

Table 14.1.6c Medical History and Prior Blood Disorders (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- Add footnote: "Note: The table summarizes combined data from Medical History and Prior Blood Disorders eCRFs. Duplicate events reported across both eCRFs are counted only once per patient in this table."

Table 14.1.6d Medical History (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.7a
Prior Medications by ATC and PT (Safety Population in the Stage 1 PK Phase)

ATC (Level 3) Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any prior medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				

Note: Prior medications are any medications with a start date earlier than the first dose date of study treatment and are coded using WHO Drug Dictionary version YYYYMM. Study treatment, prior anti-cancer treatments for primary cancer, transfusions and growth factors are not included.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:
Table 14.1.7b Prior Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.7c Prior Medications by ATC and PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]
- Footnote – Extension Phase: Prior medications are any medications, other than study treatments and pre-medications for study treatment, with a start date earlier than the first dose date of study treatment during the Extension Phase and are coded using WHO Drug Dictionary version YYYYMM.
- Prior anti-cancer treatments for primary cancer are not included.

Table 14.1.7d Prior Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)
- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL.

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Table 14.1.8a
Concomitant Medications by ATC and PT (Safety Population in the Stage 1 PK Phase)

ATC (Level 3) Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any concomitant medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				

Note: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:
Table 14.1.8.1b Concomitant Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.8.2b Concomitant Medications During the PK Collection Period by ATC and PT (BE Evaluable Population in the Stage 2 PK Phase)

- Footnote: Concomitant medications during the PK collection period are any concomitant medications taken between the first PK-draw until the last PK-draw. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8c Concomitant Medications by ATC and PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]

- Footnote – Extension Phase: Concomitant medications are any medications being taken on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8d Concomitant Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL
- Footnote – Stage 3: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

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Table 14.1.9a
Concomitant Transfusions and Growth Factors (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any Concomitant Transfusions	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Red Blood Cells	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Platelet	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Concomitant Growth Factors	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
G-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
GM-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Recombinant Erythropoietin	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.9b Concomitant Transfusions and Growth Factors (Safety Population in the Stage 2 PK Phase)

Table 14.1.9c Concomitant Transfusions and Growth Factors (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]

- Footnote – Extension Phase: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose.

Table 14.1.9d Concomitant Transfusions and Growth Factors (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL
- Footnote – Stage 3: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

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Table 14.1.10c
Summary of Investigator-Assessed Best Response by Tumor Type (Safety Population in the Extension Phase)

Treatment: <TABLET, CAPSULE> (N=xx)

	Investigator Assessment					
Tumor type [1]	Complete Response (CR)	Partial Response (PR)	Stable Disease (SD)	Progressive Disease (PD)	Not Evaluable (NE)	Total [2]
Prostate Cancer	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mesothelioma Malignant	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Duodenal Adenocarcinoma	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Colon Cancer	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Malignant Melanoma	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...						
Other: xxx						
Total	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

N=Number of patients in Safety Population.
Note: 'Total' represents the number of patients with non-missing investigator assessment.
[1] The percentages are based on row totals.
[2] The percentages are based on overall response totals.

Source: Listing 16.2.6.1c. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Present by decreasing order of total frequency of tumor types observed, in the event of tie, sort in alphabetical order.
If better fit requires taking Treatment out into the header row, split table across pages with each treatment on a new page.

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Table 14.3.1.1.1a
Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 1 PK Phase)

	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.1.1b Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.1.1c
Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Extension Phase)

	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: This table reports Treatment Emergent Adverse Events (TEAEs) with onset during Extension Phase only.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

Repeat for:
Table 14.3.1.1.1.1c Overall Summary of Treatment Emergent Adverse Events Ongoing from PK Phase (Safety Population in the Extension Phase)

[Programming Notes for Table 14.3.1.1.1.1c]
Footnote: "Note: This table reports Treatment Emergent Adverse Events (TEAEs) with onset during PK Phase of the study.

This table summarizes data from Listing 16.2.7.2c, please use this listing as source reference in the footnote.

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Table 14.3.1.1.1d
Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 3 PK Phase)

	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.1.2a
Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 1 PK Phase)

	Sequence TABLET/CAPSULE (N=xx)			Sequence CAPSULE/TABLET (N=xx)		
	TABLET Period 1 (N=xx)	CAPSULE Period 2 (N=xx)	FU/Ext Screening (N=xx)	CAPSULE Period 1 (N=xx)	TABLET Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.1.2b Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.1.2d
Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 3 PK Phase)

	Sequence NIRAPARIB TABLET FASTED/FED (N=xx)			Sequence NIRAPARIB TABLET FED/FASTED (N=xx)		
	NIRAPARIB TABLET FASTED Period 1 (N=xx)	NIRAPARIB TABLET FED Period 2 (N=xx)	FU/Ext Screening (N=xx)	NIRAPARIB TABLET FED Period 1 (N=xx)	NIRAPARIB TABLET FASTED Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.2.1a
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

Table 14.3.1.2.1b Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.2.1c
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Extension Phase)

System Organ Class Preferred Term	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

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Table 14.3.1.2.1d
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 3 PK Phase)

System Organ Class Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

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Table 14.3.1.2.1.1d
Summary of COVID-19 related Adverse Events by SOC and PT (Safety Population in the Stage 3 PK Phase)

System Organ Class Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any COVID-19 related TEAE	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[1] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes COVID-19 related TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.
Select only COVID-19 related TEAEs.

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Table 14.3.1.2.2a
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	Sequence TABLET/CAPSULE (N=xx)			Sequence CAPSULE/TABLET (N=xx)		
	TABLET Period 1 (N=xx)	CAPSULE Period 2 (N=xx)	FU/Ext Screening (N=xx)	CAPSULE Period 1 (N=xx)	TABLET Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Table 14.3.1.2.2b Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.2.2d
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 3 PK Phase)

	Sequence NIRAPARIB TABLET FASTED/FED (N=xx)			Sequence NIRAPARIB TABLET FED/FASTED (N=xx)		
System Organ Class Preferred Term	NIRAPARIB TABLET FASTED Period 1 (N=xx)	NIRAPARIB TABLET FED Period 2 (N=xx)	FU/Ext Screening (N=xx)	NIRAPARIB TABLET FASTED Period 1 (N=xx)	NIRAPARIB TABLET FED Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Using Mock Shell (Table 14.3.1.2.1a, Table 14.3.1.2.1b, Table 14.3.1.2.1c, Table 14.3.1.2.1d)
Repeat for:
Table 14.3.1.3a Summary of Related TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.3b Summary of Related TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.3c Summary of Related TEAE by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.3d Summary of Related TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.4a Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.4b Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.4c Summary of Serious TEAE by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.4d Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.5a Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.5b Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.5c Summary of Related Serious TEAE by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.5d Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.6a Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.6b Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.6c Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.6d Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.7a Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.7b Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.7c Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.7d Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.8a Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.8b Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.8c Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.8d Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.9c Summary of TEAE Leading to Treatment Dose Interruption by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.10a Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.10b Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.10c Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.10d Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.11a Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.11b Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.11c Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.11d Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.11.1a Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.11.1b Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.11.1c Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Extension Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.11.1d Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.12a Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.12b Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.12c Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.12d Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.23.1a Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Stage 1 PK Phase)

[Programming notes] – TABLE FOR DISCLOSURE PURPOSES ONLY.

Table 14.3.1.23.1b Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Stage 2 PK Phase)

[Programming notes] – TABLE FOR DISCLOSURE PURPOSES ONLY.

Table 14.3.1.23.1c Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Extension Phase)

[Programming notes] – TABLE FOR DISCLOSURE PURPOSES ONLY.

Table 14.3.1.23.1d Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Stage 3 PK Phase)

[Programming notes] – TABLE FOR DISCLOSURE PURPOSES ONLY.

Table 14.3.1.23.2a Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.23.2b Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.23.2c Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Extension Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.23.2d Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

[Programming notes] – TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

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Table 14.3.1.13a
Summary of Treatment Emergent Adverse Events by SOC and PT and CTCAE Toxicity Grade (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Grade 1				
...				
Grade 5				
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Grade 1				
...				
Grade 5				
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Grade 1				
...				
Grade 5				
...				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.13b Summary of Treatment Emergent Adverse Events by SOC and PT and Maximum Toxicity (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.13c Summary of Treatment Emergent Adverse Events by SOC and PT and Maximum Toxicity (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported. Within each PT, sort by presented maximum toxicity grade.

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Table 14.3.1.13d
Summary of Treatment Emergent Adverse Events by SOC and PT and CTCAE Toxicity Grade (Safety Population in the Stage 3 PK Phase)

System Organ Class Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
...	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
...	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
...	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
...				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.14a
Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 1 PK Phase)

Preferred Term	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.14b Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.14c Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- [1], [2], [3] and [4] are not applicable.

[Programming Notes]
Sort PTs by descending overall frequency of events reported.

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Table 14.3.1.14d
Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 3 PK Phase)

Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.15a
Listing of Serious TEAEs During PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Dosing Period/ Niraparib Treatment	Adverse Event [P]MedDRA Preferred Term [S]System Organ Class	Start Date Time/ (Rel Day [1])	Stop Date Time (Rel Day [1])	TEAE?	SAE/ Reason [2]	Severity	Action Taken on Study Treatment[3]	Other Action Taken	Relationship [3]	Outcome
	Period 1/ Capsule	XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd hh:mm [x]	yyyy-mm-dd [x]	Y	N	Grade 1	T: NA C: Dose Not Changed		T: NA C: Related	Recovered/ Resolved
	Period 2/ Tablet	XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd hh:mm [x]	yyyy-mm-dd [x]	Y	N	Grade 1	T: Dose Not Changed C: NA		T: Related C: NA	Recovered/ Resolved
	PK Safety FU										

[1] Relative to the date of first dose in PK Phase.
[2] Reason for SAE: 1 = Result in death; 2 = Life threatening; 3 = Result in persistent or significant disability/incapacity; 4 = Requires or prolongs hospitalization; 5 = Congenital abnormality/birth defect; 6 = Other medically important event.
[3] T=Tablet; C=Capsule.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]
Please add time to Start Date column for PK Phase Stage 2 and Extension Phase.

Repeat for:
Table 14.3.1.15b Listing of Serious TEAEs During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.15c Listing of Serious TEAEs During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.15d Listing of Serious TEAEs During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.16a Listing of Deaths During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.16b Listing of Deaths During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.16c Listing of Deaths During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.16d Listing of Deaths During the PK Phase (Safety Population in the Stage 3 PK Phase)

- Footnote: 'NOTE: Deaths due to progressive disease were not collected as adverse events.'

Table 14.3.1.17c Listing of TEAE Leading to Dose Interruption During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.17d Listing of TEAE Leading to Dose Interruption During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.18a Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.18b Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.18c Listing of TEAE Leading to Dose Reduction During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.18d Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.19a Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.19b Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.19c Listing of TEAE Leading to Treatment Discontinuation During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.19d Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes]

- Stage 3: Treatment Sequence will be NIRAPARIB TABLET FASTED/FED and NIRAPARIB TABLET FED/FASTED.
- Stage 3: Column 2: Dosing Period/Treatment – Treatment should be NIRAPARIB FASTED or NIRAPARIB FED.
- Stage 3: Treatment discontinuation during PK Phase – add column to record if discontinuation was due to COVID-19 ["COVID-19 Reason" with Options "COVID-19 infection" or "Issues rel. to COVID-19 pandemic"].
- Extension Phase: Replace column for Dosing Period/Treatment with Treatment (TABLET, CAPSULE) and Starting Dose.
- Extension Phase: Do not need time with start/stop dates.
- Extension Phase: Footnote: [1] Relative to first dose during the Extension Phase.

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Table 14.3.1.16.1c
All-Cause Mortality (Safety Population in the Extension Phase)

	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
Death due to any cause	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

NOTE: Deaths occurring outside 30-day window following end of Extension Phase treatment are included in the counts.

Source: Listing 16.2.1c. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
This table is for final disclosure reporting purposes ONLY. All deaths reported/recorded in the database should be included.

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Table 14.3.1.20d
Summary of Incidence of COVID-19 Related Adverse Events Over Time (Safety Population in the Stage 3 PK Phase)

	Period during COVID-19 Pandemic [1]	NIRAPARIB TABLET FASTED (N=xx)	NIRAPARIB TABLET FED (N=xx)
		n/Patients at Risk (%)	n/Patients at Risk (%)
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)

[1] TABLET PK Phase Stage 3 opened to recruitment on DDMMMYYYY, with first patient consented on DDMMMYYYY, placing the start of the recruitment during the COVID-19 pandemic.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.20c
Summary of Incidence of COVID-19 Related Adverse Events Over Time
(Safety Population in the Extension Phase)

	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
	n/Patients at Risk (%)	n/Patients at Risk (%)	n/Patients at Risk (%)
Any COVID-19 Related AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related SAE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related Grade ≥3 AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)

Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
N accounts for all patients in Safety Population of the Extension Phase.
n – number of patients with an event related to COVID-19.
Patients at Risk (%) – number of patients who were ongoing on Extension Phase treatment on or after 20MAR2020.

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Table 14.3.1.21d
Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender (Safety Population in the Stage 3 PK Phase)

Report on separate page for each: <Gender: Male, Female>

	Period during COVID-19 Pandemic [1]	NIRAPARIB TABLET FASTED (N=xx)	NIRAPARIB TABLET FED (N=xx)
		n/Patients at Risk (%)	n/Patients at Risk (%)
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)

[1] TABLET PK Phase Stage 3 opened to recruitment on DDMMMYYYY, with first patient consented on DDMMMYYYY, placing the start of the recruitment during the COVID-19 pandemic.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.22d Summary of Incidence of Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)

- Use the FDAAA age groups <=18, 18-64, >=65.

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Table 14.3.1.21c
Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender
(Safety Population in the Extension Phase)

Report on separate page for each: <Gender: Male, Female>

	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
	n/Patients at Risk (%)	n/Patients at Risk (%)	n/Patients at Risk (%)
Any COVID-19 Related AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related SAE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related Grade ≥3 AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)

Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.22c Summary of Incidence of Adverse Events Over Time by Age Group (Safety Population in the Extension Phase)

- Use the FDAAA age groups <=18, 18-64, >=65.

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Table 14.3.4.1a
Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 1 PK Phase)

	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
# of 100 mg Capsules Received				
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
# of 300 mg Tablets Received				
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.4.1b Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 2 PK Phase)

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Table 14.3.4.1c
Summary of Study Treatment Exposure During the Extension Phase (Safety Population in the Extension Phase)

Parameters	Statistic	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
Maximum Number of Cycles				
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...	...	...	...	...
≥ 6	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Median number of cycles started	n	xx	xx	xx
Duration of Treatment (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Duration on Study (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Exposure duration (Months)	n	xx	xx	xx
<1 Month	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 - <2 Months	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 - <3 Months	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 3 Months	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 6 Months	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 12 Months	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Number of Patients with at least 1 dose interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Number of Patients with at least 1 dose reduction	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Number of Patients with at least 1 dose re-escalation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dose intensity (mg/day) [1]	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

[1] Dose intensity was calculated as sum of daily doses consumed divided by overall treatment exposure, in days.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Protocol: XXXXX

Table 14.3.4.1d
Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 3 PK Phase)

	Statistic	NIRAPARIB FASTED (N=XX)	NIRAPARIB FED (N=XX)	OVERALL (N=xx)
# of 300 mg Tablets Received				
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.4.2c
Summary of Niraparib Dose by Cycle (Safety Population in the Extension Phase)

Cycle	Starting Niraparib Dose (mg)	Statistic	TABLET	CAPSULE	OVERALL
1		N	xxx	xxx	xxx
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2		N	xxx	xxx	xxx
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3		N	xxx	xxx	xxx
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
….					

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.4.3.1c
Summary and Change from Baseline of Select Hematology Parameters by Visit During the Extension Phase
(Safety Population in the Extension Phase)

			TABLET (N=xx)		CAPSULE (N=xx)		OVERALL (N=xx)	
Parameter	Visit	Statistic	Actual	Change	Actual	Change	Actual	Change
Parameter 1	Baseline	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx		xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx		xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	
	Cycle 1 – Day 8	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	Cycle 1 – Day 15	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	Cycle 1 – Day 22	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	Cycle 2 – Day 1	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	…….	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	EOT	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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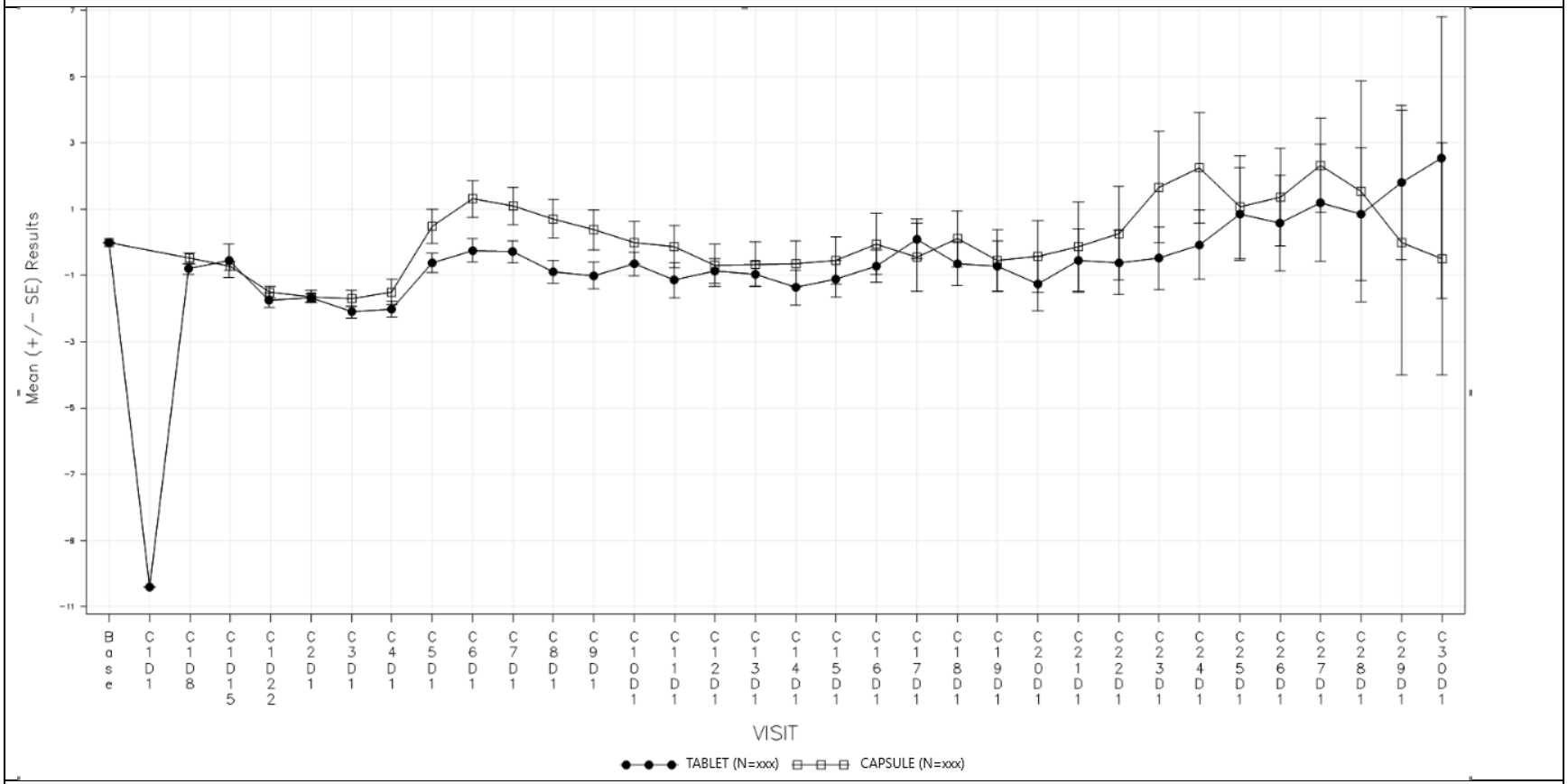
Figure 14.3.4.3.1c
Change from Baseline (± SE) of Select Hematology Parameters Over Time
(Safety Population in the Extension Phase)

Parameter (unit)



SE=Standard Error, calculated as standard deviation (SD) divided by square root of sample size (N).

Source: Table 14.3.4.3.1c. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Programming Notes:

- Report hemoglobin, neutrophils and platelets only.

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Table 14.3.4.3.2c
Shift Summary of Select Hematology Parameters During the Extension Phase (Safety Population in the Extension Phase)

Treatment Group			Post-Baseline Maximum CTCAE Grade						
TABLET	Laboratory Test	Baseline CTCAE Grade	Statistic	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
	xxxxx	Grade 0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	xxxxx								

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Include TABLET, CAPSULE and OVERALL.

Repeat for:
Table 14.3.4.4.1c Summary and Change from Baseline of Select Chemistry Parameters by Visit During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.4.4.2c Shift Summary of Select Chemistry Parameters in Maximum Toxicity Grade During the Extension Phase (Safety Population in the Extension Phase)

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Protocol: XXXXX

Table 14.3.4.4.1d
Summary of COVID-19 Assessments for Patients with Suspected, Probable or Confirmed COVID-19 Case Diagnosis
(Safety Population in the Stage 3 PK Phase)

Assessment	NIRAPARIB TABLET FASTED (N=XX)	NIRAPARIB TABLET FED (N=XX)
COVID-19 Case Diagnosis [1]	xx (xx.x%)	xx (xx.x%)
Confirmed	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)
COVID-19 Test Performed [2]		
n	xx	xx
No	xx/xx (xx.x%)	xx/xx (xx.x%)
Yes	xx/xx (xx.x%)	xx/xx (xx.x%)
Result from the COVID-19 Test		
n	xx	xx
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)
Indeterminate	xx/xx (xx.x%)	xx/xx (xx.x%)

[1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[2] COVID-19 Test Performed is only captured for patients with a COVID-19 Case Diagnosis.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For COVID-19 Test Performed, the small n is based on the number of subjects with a COVID-19 Case Diagnosis. For Result of the COVID-19 Test, the small n is based on the COVID-19 Test Performed=Yes.

IDSL standard shell PAN1.

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Table 14.3.4.5.1c
Summary of COVID-19 Assessments for Patients with Suspected, Probable or Confirmed COVID-19 Case Diagnosis
(Safety Population in the Extension Phase)

Assessment	TABLET (N=XX)	CAPSULE (N=XX)	OVERALL (N=XX)
COVID-19 Case Diagnosis [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Confirmed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
COVID-19 Test Performed [2]			
n	xx	xx	xx
No	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Yes	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Result from the COVID-19 Test			
n	xx	xx	xx
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Indeterminate	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)

[1] COVID-19 Case Diagnosis is based on WHO Definition as of 20MAR2020.
[2] COVID-19 Test Performed is only captured for patients with a COVID-19 Case Diagnosis.
Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.4.1c
Summary of Important Protocol Deviations (Safety Population in the Extension Phase)

Category/Coded Term	TABLET (N=XX)	CAPSULE (N=XX)	TOTAL (N=XX)
Any important protocol deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
….			
CATEGORY 2	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
…			

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

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Protocol: XXXXX

Table 14.4.1d
Summary of Important Protocol Deviations for the PK Phase Occurring Through End of Treatment
(Safety Population in the Stage 3 PK Phase)

Category/Coded Term	NIRAPARIB TABLET FASTED [1] (N=XX)	NIRAPARIB TABLET FED [2] (N=XX)	TOTAL [3] (N=XX)
Any important protocol deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
….			
CATEGORY 2	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
…			

[1] Includes protocol deviations with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes protocol deviations with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] Includes protocol deviations occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

LISTINGS

General guidelines:

Listings are separated for the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Open-Label Extension Phase.

For the PK Phase:

- Treatment=Sequence (for Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET; for Stage 3: NIRAPARIB TABLET FASTED/FED or NIRAPARIB TABLET FED/FASTED).
- Population=Safety Population in the PK Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all data assessments relative to the PK Phase.
    - For patients who do not continue to the Extension Phase, include all EOT/Safety FU data. Also include Extension Phase Screening for those patients who DO not proceed to the Extension Phase.
- Relative day: With respect to first date of dosing in PK period.

For the Extension Phase:

- Treatment=TABLET; CAPSULE.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all assessments relative to the Extension Phase.
    - Any assessment specific to Extension Phase, including Screening Data.
- Relative day: With respect to first date of dosing in Extension Phase.
    - "-" event taking place prior to first dose in Extension Phase.
    - "*" event taking place after EOT in Extension Phase.

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Protocol: XXXXX

Listing 16.2.1a
Disposition for PK Phase (All Patients Enrolled in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Date of Last Niraparib Dose During PK Phase (Rel Day)	Date of Discontinuation From PK Phase (Rel Day)	Reason for Discontinuation from PK Phase	Date of Discontinuation from Study (Rel Day)	Reason for Discontinuation from Study	Date of Death (Rel Day)	Date of Progression (Rel Day)	Protocol Version
			Other: specify					
			Completion					

Relative Day calculated relative to first dose in PK Phase.

Only study discontinuations, disease progressions and deaths that occur during PK Phase (i.e., before 1st dose of extension or prior to discontinuing the study for patients not entering the Extension Phase) are listed.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes – PK Phase]

- Include only data that falls before first-dose Open-Label Extension Phase, i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase.

Repeat for:
Listing 16.2.1b Disposition for PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.1c Disposition for Open-Label Extension Phase (All Patients Enrolled for the Extension Phase)

Listing 16.2.1d Disposition for PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes – Extension Phase]

- Change 'PK Phase' to 'Extension' Phase in respective columns.
- Treatment: Niraparib Tablet or Niraparib Capsule.
- Footnote: Relative Day calculated relative to first dose in Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT .

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Protocol: XXXXX

Listing 16.2.1.2a
Reasons for Screen Failure (Patients who Failed Screening in the Stage 1 PK Phase)

Treatment Sequence: <SCREEN FAILURE>

Patient Number	Protocol Version	Inclusion/Exclusion Criteria Not Met
xxxxxx-xxxx	Version 1.0 (original)	INPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx-xxxx	Version 1.0 (original)	EXPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.1.2b Reasons for Screen Failure (Patients who Failed Screening in the Stage 2 PK Phase)

Listing 16.2.1.2d Reasons for Screen Failure (Patients who Failed Screening in the Stage 3 PK Phase)

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Protocol: XXXXX

Listing 16.2.2a
Protocol Deviations for the PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment: < Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET>

Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS

[Programming Notes]

- Include only data that falls before first-dose Open-Label Extension Phase (i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase)

Repeat for:
Listing 16.2.2b Protocol Deviation for the PK Phase (Safety Population in the Stage 2 PK Phase)

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Protocol: XXXXX

Listing 16.2.2c

Important Protocol Deviations for the Open-Label Extension Phase (Safety Population in the Extension Phase)

Treatment: <TABLET, CAPSULE>

Patient Number	Visit	Protocol Deviation Category	Description of Protocol Deviation	TESARO Classification [1]	GSK Classification [2]
				<<SIGNIFICANT/ IMPORTANT>>	<<IMPORTANT/NON-IMPORTANT>>

[1] For Stages 1 & 2, protocol deviation classification is done based on TESARO Protocol Deviation Management System only. GSK Classification will remain blank.
[2] For Stage 3, protocol deviation classification is done based on GSK Protocol Deviation Management System only. TESARO Classification will remain blank.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]

For Stage 3 Extension Phase, patients will receive NIRAPARIB TABLET formulation only.

For Stages 1 and 2 reporting, only TESARO Classifications will be populated, for Stage 3 – only GSK Classification will be populated.

Only include protocol deviation classified as Important.

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Protocol: XXXXX

Listing 16.2.2.1d

Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population for Stage 3 PK Phase)

Treatment: <NIRAPARIB FASTED or NIRAPARIB FED>

Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]:

- Only include protocol deviation classed as Important.

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Protocol: XXXXX

Listing 16.2.2.2d
GSK Protocol Deviations related to COVID-19 (Safety Population for Stage 3 PK Phase)

Treatment: <NIRAPARIB FASTED or NIRAPARIB FED>

Patient Number	Deviation Category	Description of Deviation	GSK Classification	Date
			<IMPORTANT/NOT-IMPORTANT>	

Note: * Patients with probable, suspected or confirmed COVID-19.
Note: This listing only includes COVID-19 related protocol deviations.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Protocol: XXXXX

Listing 16.2.2.2c
GSK Protocol Deviations related to COVID-19 (Safety Population in the Extension Phase)

Treatment: <TABLET, CAPSULE>

Patient Number	Deviation Category	Description of Deviation	GSK Classification	Date
			<IMPORTANT/NOT-IMPORTANT>	

Note: * Patients with probable, suspected or confirmed COVID-19.
Note: This listing only includes COVID-19 related protocol deviations.
Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.
Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.3a
Study Populations for the PK Phase (All Patients Enrolled in the Stage 1 PK Phase)

Treatment: <TABLET/CAPSULE or CAPSULE/TABLET or SCREEN FAILURE>

Patient Number	PK Phase Safety (SAF) Population	Informed Consent Date	Randomization Date
	Y		

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.3b Study Populations for the PK Phase (All Patients Screened in the Stage 2 PK Phase)

- For Stage 2 PK, add column for BE Evaluable Population (Y/N).

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Listing 16.2.3c

Study Populations for the Open-Label Extension Phase (All Patients Enrolled in the Extension Phase)

Treatment: <TABLET or CAPSULE>

Patient Number	Extension Phase Safety (SAF) Population								
	Y								

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.3d

Study Populations for the PK Phase (All Patients Enrolled in the Stage 3 PK Phase)

Treatment: <FASTED/FED or FED/FASTED or SCREEN FAILURE>

Patient Number	PK Phase Safety (SAF) Population	FE Population	Informed Consent Date	Randomization Date
	Y	Y		
		N		

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.4.1a
Demographics (Safety Population in the Stage 1 PK Phase)

Study Treatment: <Stage 1 & 2: NOT DOSED or TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: NOT DOSED or FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Age (yrs)	Sex	Child-Bearing Potential	Ethnicity	Race	Height (cm)	Weight (kg)	BMI (kg/m^2)	ECOG Performance Status
					Other: specify				

ECOG = Eastern Cooperative Oncology Group:
0=Fully active, able to carry on all pre-disease performance without restriction
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.1b Demographics (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.1c Demographics (Safety Population in the Extension Phase)

Add footnote for Extension Phase and relevant reference in the listing:
[1] Only weight and ECOG Performance Status were repeated at Extension Phase entry.

Listing 16.2.4.1d Demographics (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.4.2a
Medical History (Safety Population in the Stage 1 PK Phase)

PK Phase Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	System Organ Class Preferred Term Medical Condition or Event	Start Date	Ongoing at Study Start?	Stop Date

Includes only patients with major medical conditions.

Note: MedDRA version XX.X.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.2b Medical History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.2c Medical History (Safety Population in the Extension Phase)

Listing 16.2.4.2d Medical History (Safety Population in the Stage 3 PK Phase)

[Programming notes]

- For Stage 3, the latest available MedDRA version is to be used.

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Listing 16.2.4.3a
Prior Anti-Cancer Treatment (Safety Population in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Regimen Number	-Verbatim Term --Preferred Term	Reason for Administration	Best Response
			Other: specify	

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.3b Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.3c Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

Listing 16.2.4.3d Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.4.4a
Primary Cancer History (Safety Population in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Tumor Type	Date of First Diagnosis	Cancer Stage (Most Recent)	Number of Prior Lines of Therapy
	<Other: specify>			

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.4b Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.4c Primary Cancer History (Safety Population in the Extension Phase)

Listing 16.2.4.4d Primary Cancer History (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.4.5a
Prior/Concomitant Radiotherapy (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Site or Region	Date Started	Date Stopped	Total Grays	Prior/ Concomitant Flag

Note: Includes patients with prior or concomitant radiotherapy with respect to the PK Phase.
P=Prior (radiotherapy with start date earlier than the first dose date of study treatment).
C=Concomitant (radiotherapy occurring on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.5b Prior/Concomitant Radiotherapy (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.5c Prior/Concomitant Radiotherapy (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]
Note: Includes patients with prior or concomitant radiotherapy with respect to the Extension Phase.
P=Prior (radiotherapy with start date earlier than the first dose date of Extension Phase treatment).
C=Concomitant (radiotherapy occurring on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).

Listing 16.2.4.5d Prior/Concomitant Radiotherapy (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.1a
Prior and Concomitant Medications (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable
Patient Number = xxxxxx-xxxx

ATC/ Preferred Term/ Verbatim Term	Dose per Administration	Dose Unit	Frequency	Indication	Route of Administration	Start/ Stop Date	Ongoing	Prior/ Concomitant Flag	PK Dose 1	PK Dose 2
									YYYY-MM-DD	YYYY-MM-DD

Note: Includes patients with prior or concomitant medications taken during the PK Phase.
P=Prior medication only; C=Concomitant medication only; B=Both prior and concomitant medications.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.
- If ATC3 not available, use a footnote [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:
Listing 16.2.5.1b Prior and Concomitant Medications (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.1c Prior and Concomitant Medications (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]
Note: Includes patients with prior or concomitant medications during the Extension Phase.
P=Prior (any medication taken earlier than the first dose date of Extension Phase treatment).
C=Concomitant (any medication on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).
Prior and concomitant medications taken during PK Phase only are classified as Prior medications during Extension Phase.
Concomitant medications taken during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant medications during Extension Phase.

- Drop 'PK Dose 1' column and replace 'PK Dose 2' with 'Extension Phase'.

Listing 16.2.5.1d Prior and Concomitant Medications (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.1.1c
Treatment Exposure and Duration (Safety Population in the Extension Phase)

Study Stage/Formulation: <Stage 1: TABLET/CAPSULE/EXT, CAPSULE/TABLET/EXT> <Stage 2: TABLET/CAPSULE/EXT, CAPSULE/TABLET/EXT > <Stage 3: TABLET>, as applicable

Patient Number	Randomization Date	Stage	Treatment Sequence	PK Dose 1/ Rel Day [1]	PK Dose 2/ Rel Day [1]	Extension Phase Dose 1	Time between PK and Extension Phase doses [2]
xxxxxx-xxxx	YYYY-MM-DD	<Stage 1/2>	<TABLET/CAPSULE/EXT, CAPSULE/TABLET/EXT>	YYYY-MM-DD/ -xx	YYYY-MM-DD/ -xx	YYYY-MM-DD	xx
xxxxxx-xxxx	YYYY-MM-DD	Stage 3	<TABLET/EXT>	YYYY-MM-DD/ -xx	YYYY-MM-DD/ -xx	YYYY-MM-DD	xx

Note: Randomized patients who did not start PK Phase treatment and proceeded to Extension Phase treatment directly will have time between PK and Extension Phase dosing set to missing.
[1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase.
[2] The time between last non-missing PK dose and first Extension Phase dose (in days).

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For treatment sequence use actual sequence labels, as displayed in ADaMs.
Randomized patients who did not start PK Phase treatment and proceeded to Extension Phase treatment directly will have time between PK and Extension Phase dosing set to '.'.
Treatment sequence displays actual treatment formulation received during Stages 1 and 2 (T/C, C/T), and for Stage 3 displays TABLET formulation irrespective of fasting (FED/FASTED) status.

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Listing 16.2.5.2a
Prior/Concomitant Procedures During PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Procedure Date	Rel Day [1]	Procedure	Results/Findings	AE/SAE?	Indication	Prior/Concomitant Flag
xxxxxx-xxxx							

[1] Relative to first dose during the PK Phase.
Note: Includes patients with prior or concomitant procedures during the PK Phase.
P=Prior (any procedure earlier than the first dose date of study treatment).
C=Concomitant (any procedure on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for
Listing 16.2.5.2b Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.2c Prior/Concomitant Procedures During the Extension Phase (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

- Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.

  Note: Includes patients with prior or concomitant procedures during the Extension Phase.
  P=Prior (any procedure undertaken earlier than the first dose date of Extension Phase treatment).
  C=Concomitant (any procedure undertaken on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).
  Prior and concomitant procedure undertaken during PK Phase only are classified as Prior procedure during Extension Phase.
  Concomitant procedures performed during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant procedure during Extension Phase.

Listing 16.2.5.2d Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.3a
Prior and Concomitant Transfusions (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Received Transfusion within 14 days of first dose or during study?	Type of Administration	Units	Transfusion Date	Rel Day [1]	Prior/ Concomitant Flag
		Other: specify				

[1] Relative to first dose during the PK Phase.
Note: Includes patients with prior or concomitant transfusions during the PK Phase.
P=Prior (any transfusion earlier than the first dose date of study treatment).
C=Concomitant (any transfusion on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.

Repeat for:
Listing 16.2.5.3b Prior and Concomitant Transfusions (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.3c Prior and Concomitant Transfusions (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]
Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.
Note: Includes patients with prior or concomitant transfusions during the Extension Phase.
P=Prior (any transfusion started earlier than the first dose date of Extension Phase treatment).
C=Concomitant (any transfusion started on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).
Prior and concomitant transfusion completed during PK Phase only are classified as Prior transfusion during Extension Phase.
Concomitant transfusion started during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant transfusion during Extension Phase.

Listing 16.2.5.3d Prior and Concomitant Transfusions (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.4a
Prior and Concomitant Growth Factors (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Received growth factor within 14 days of first dose or during study?	Type of Administration	Dose	Unit	Administration Date	Prior/ Concomitant Flag
		Other: specify		Other: specify		

Note: Includes patients with prior or concomitant growth factors during the PK Phase.
P=Prior (any growth factor earlier than the first dose date of study treatment).
C=Concomitant (any growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.

Repeat for:
Listing 16.2.5.4b Prior and Concomitant Growth Factors (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.4c Prior and Concomitant Growth Factors (Safety Population in the Extension Phase)

[Programming Notes]
Note: Includes patients with prior or concomitant growth factors during the Extension Phase.
P=Prior (any growth factors administered earlier than the first dose date of Extension Phase treatment).
C=Concomitant (any growth factors administered on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).
Prior and concomitant growth factors administered during PK Phase only are classified as Prior growth factors during Extension Phase.
Concomitant growth factors administered during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant growth factors during Extension Phase.

Listing 16.2.5.4d Prior and Concomitant Growth Factors (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.5a
Study Treatment (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET>

Patient Number	Visit	Formulation	Date:Time of Administration (Rel Day [1])	Full Dose Taken?	If No, how much consumed?	Reason for Change	Bottle Number	Fast 8 hrs prior to administration?	Vomit within 8 hours of dose?

[1] Relative to first dose during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.5.5b Study Treatment (Safety Population in the Stage 2 PK Phase)

[For Stage 2 PK Phase]

- Modify label for Vomiting Question, 'Vomit within specified time of dose'.
- Add column for Nausea Question, 'Nausea within specified time of dose'.

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Listing 16.2.5.5c
Study Treatment (Safety Population in the Extension Phase)

TREATMENT: < TABLET or CAPSULE>

Patient Number	Visit	Dose Prescribed (mg)	Start Date (Rel Day [1])/ Stop Date (Rel Day [1])	Action Taken	Reason for Modification	Bottle number Dispensed	Bottle Number Returned
					Other <specify reason>		

[1] Relative to first dose during the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.5d
Study Treatment (Safety Population in the Stage 3 PK Phase)

Treatment Sequence: <FASTED/FED or <FED/FASTED>

Patient Number	Visit	Fasted or Fed State	Date:Time of Administration (Rel Day [1])	Bottle Number	Fast 10 hrs prior to administration?	Vomit within protocol specified hours from dose?	Fast for minimum of 4 hours post dose?

[1] Relative to first dose during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.6b
Subsequent Anti-Cancer Therapy (Safety Population in the Stage 2 PK Phase)

Treatment Sequence: TABLET/CAPSULE or CAPSULE/TABLET

Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]	

[1] Relative to first dose during the PK Phase.
Note: Includes only patients with subsequent anti-cancer therapy recorded for patients who do not continue to Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.6c
Subsequent Anti-Cancer Therapy (Safety Population in the Extension Phase)

Treatment: < TABLET or CAPSULE>

Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]	

[1] Relative to first dose during the Extension Phase. '*' Rel day post 30-day safety window from EOT.
Note: Includes only patients with subsequent anti-cancer therapy recorded as initiated after last dose of the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.6d
Meal Status (Safety Population in the Stage 3 PK Phase)

Treatment Sequence: <FASTED/FED or <FED/FASTED>

Patient Number	Visit	Meal Start Date	Meal Start Time	Meal End Time	% of Meal Consumed

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.6.1c
Investigator Assessment of Response (Safety Population in the Extension Phase)

TREATMENT: < TABLET or CAPSULE>

Patient Number	Tumor Type	Date	Rel Day [1]	Overall Response
				NE: <Reason>

Abbreviations: CP=Complete Response, PD=Progressive Disease, PR=Partial Response, SD=Stable Disease, NE=Not Evaluable.
[1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.7.1a
Adverse Events (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Dosing Period/ Niraparib Treatment	Adverse Event MedDRA Preferred Term System Organ Class	Start Date:Time (Rel Day [1]) End Date (Rel Day [1])	TEAE?	SAE/ Reason [2]	Severity	Action Taken on Study Treatment	Other Action Taken	Relation-ship	Outcome
	Period 1/ Capsule	XXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved
	Period 2/ Tablet	XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved
	PK Safety FU									

[1] Relative to the date of first dose in PK Phase.
[2] Reason for SAE: 1 = Result in death; 2 = Life threatening; 3 = Result in persistent or significant disability/incapacity; 4 = Requires or prolongs hospitalization; 5 = Congenital abnormality/birth defect; 6 = Other medically important event.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.7.1b Adverse Events (Safety Population in the Stage 2 PK Phase)

Listing 16.2.7.1d Adverse Events (Safety Population in the Stage 3 PK Phase)

[Programming Notes]
- Stage 3: Treatment Sequence will be Fasted/Fed and Fed/Fasted.
- Stage 3: Column 2: Dosing Period/Treatment – Treatment should be Niraparib FASTED or Niraparib FED.

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Listing 16.2.7.1c
Adverse Events (Safety Population in the Extension Phase)

Treatment: <TABLET or CAPSULE>, as applicable
Patient ID = XXXXXX-XXXX

Adverse Event MedDRA Preferred Term System Organ Class	Start Date (Rel Day [1]) End Date (Rel Day [1])	TEAE?	SAE/ Reason [2]	Severity	Action Taken on Study Treatment	Other Action Taken	Relationship	Outcome
XXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved
XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved

[1] Relative to the date of first dose during the Extension Phase. '*' Rel day post 30-day safety window from EOT.
[2] Reason for SAE: 1 = Result in death; 2 = Life threatening; 3 = Result in persistent or significant disability/incapacity; 4 = Requires or prolongs hospitalization; 5 = Congenital abnormality/birth defect; 6 = Other medically important event.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Listings 16.2.7.1c and 16.2.7.2c should be mutually exclusive. Any AEs with onset during PK Phase or after, but prior to first dose of Extension Phase should be in Listing 16.2.7.2c. If the AE is ongoing from before 1st dose of Extension Phase, and the Grade is increased, it is still an ongoing AE.
There should be no records with relative days prior to first dose of Extension Phase. If an AE has onset after EOT, indicate this with '*'.

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Listing 16.2.7.2c
Adverse Events Ongoing from PK Phase (Safety Population in the Extension Phase)

Treatment: <TABLET or CAPSULE>, as applicable
Patient ID = XXXXXX-XXXX

Adverse Event MedDRA Preferred Term System Organ Class	Start Date (Rel Day [1]) End Date (Rel Day [1])	TEAE?	SAE/ Reason [2]	Severity	Action Taken on Study Treatment	Other Action Taken	Relationship	Outcome
XXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved
XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved

[1] Relative to the date of first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.
[2] Reason for SAE: 1 = Result in death; 2 = Life threatening; 3 = Result in persistent or significant disability/incapacity; 4 = Requires or prolongs hospitalization; 5 = Congenital abnormality/birth defect; 6 = Other medically important event.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Only include AEs with date of onset during PK Phase/prior (including Extension Phase Screening/EOT for PK Phase/Safety follow-up) to first dose of Extension Phase and ongoing/resolved during Extension Phase.
Rel Day [1] should always be either zero or negative (with onset during PK Phase, Extension Screening etc.).

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Listing 16.2.8.1.1a
Hematology Results in the PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Parameter (unit)	Visit	Rel Day [1]	Sample date/time	Result	Change from baseline	Normal range	Out of range flag	Clinically significant flag
					xx.x	xx.x	xx.x – xx.x		

[1] Relative to the date of first dose in the PK Phase.
Scheduled and unscheduled visits through the extension screening phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the extension screening phase are not included.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]:

- If required for readability, move 'Patient Number' into Header row after 'Treatment Sequence'.

Repeat for:
Listing 16.2.8.1.1b Hematology Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.1.1c Hematology Results (Safety Population in the Extension Phase)

Listing 16.2.8.1.1d Hematology Results Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

Listing 16.2.8.1.2a Chemistry Results (Safety Population in the Stage 1 PK Phase)

Listing 16.2.8.1.2b Chemistry Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.1.2c Chemistry Results (Safety Population in the Extension Phase)

Listing 16.2.8.1.2d Chemistry Results Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

Listing 16.2.8.1.3a Urinalysis Results (Safety Population in the Stage 1 PK Phase)

Listing 16.2.8.1.3b Urinalysis Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.1.3c Urinalysis Results (Safety Population in the Extension Phase)

Listing 16.2.8.1.3d Urinalysis Results Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase]:

- Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.

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Listing 16.2.8.1.4c

Liver Function Tests – Potential Hy's Law Cases (Safety Population in the Extension Phase)

TREATMENT: < TABLET or CAPSULE>

Patient Number	Visit	Sample Collection Date	Day [1]	Laboratory Analyte (result/xULN)			
				ALT (U/L)	AST (U/L)	Total Bilirubin (umol/L)	ALP (U/L)
		DDMMMYYYY		150/3.3	100/2.7	40/2.3	100/0.7

ALP=alkaline phosphatase. ALT=alanine aminotransferase. AST=aspartate aminotransferase. ULN=upper limit of normal.

[1] Relative to first dose during the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Include all visits for any Patients with ALT or AST >3×ULN with bilirubin >2×ULN and ALP <2×ULN at any time in Extension Phase.

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Listing 16.2.8.2a
Vital Signs (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Visit	Assessment Date	Rel Day [1]	Height (cm)	Weight (kg)	Temperature (°C)	Pulse (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)

[1] Relative to the date of first dose in the PK Phase.
Data is listed only when the vital sign assessment was performed.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.2b Vital Signs (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.2c Vital Signs (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:

- Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.
- Drop Height column.

Listing 16.2.8.2d Vital Signs Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.8.3a
ECG Results (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Visit	Date	Rel Day [1]	ECG Interpretation

[1] Relative to the date of first dose in the PK Phase.
NCS = Not Clinically Significant, CS = Clinically Significant.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.3b ECG Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.3c ECG Results (Safety Population in the Extension Phase)

Listing 16.2.8.3d ECG Results (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase]:

- Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.

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Listing 16.2.8.4a
ECOG Performance Status (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Visit	Assessment Date	Rel Day [1]	Performance Status

[1] Relative to the date of first dose in the PK Phase. Data is listed only when the ECOG Performance Status assessment was performed.
ECOG = Eastern Cooperative Oncology Group:
0=Fully active, able to carry on all pre-disease performance without restriction
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.4b ECOG Performance Status (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.4c ECOG Performance Status (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:

- Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.

Listing 16.2.8.4d ECOG Performance Status Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.8.5a
Baseline Physical Examination Findings (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Visit	Date Performed	Rel Day [1]	Body System	Status	Abnormality Description

[1] Relative to the date of first dose in the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.5b Baseline Physical Examination Findings (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.5c Baseline Physical Examination Findings (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:
Footnote: [1] Relative to first dose during the Extension Phase.

Listing 16.2.8.5d Baseline Physical Examination Findings (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.8.6a
Pregnancy Test (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Visit	Was Pregnancy Test Performed?	Date of Test	Rel Day [1]	Type	Result

[1] Relative to the date of first dose in the PK Phase.
Scheduled and unscheduled visits through the Extension Screening Phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the Extension Screening Phase are not included.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.6b Pregnancy Test (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.6c Pregnancy Test (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:
Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '*' Rel day post 30-day safety window from EOT.

Listing 16.2.8.6d Pregnancy Test (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.9.2d
Listing of COVID-19 Assessments and Symptom Assessments for Patients with COVID-19 Adverse Events
(Safety Population in the Stage 3 PK Phase)

Treatment Sequence: <Stage 3: Period 1: FASTED or FED; Period 2: FASTED or FED>

Patient Number	Treatment Period (State)	Adverse Event	AE Start Date	COVID-19 Case Diagnosis [1]	COVID-19 Test Performed/ Test Date/ Results	Assessments and Symptom Assessments	Result
xxxx	1 (FASTED)	Coronavirus infection	2020-04-16	Suspected	Yes/ 2020-04-17/ Indeterminate	Travel to Location with Community Transmission [2]	No
						Visited Health Care Facility [2]	No
						Contact with COVID-19 Confirmed/Probable Case [2]	Unknown
						Medication Taken to Treat COVID-19	Yes
						Fever	Yes
						Cough	Yes
						Shortness of Breath	Yes
						Sore Throat	No
						Loss of Appetite	No
						Nausea	No
						Vomiting	No
						Diarrhea	No
						Abdominal Pain	No
						Fatigue	No
						Loss of Smell	No
						Loss of Taste	No
						Asymptomatic	No
						Home Quarantined/Isolated	Unknown
	2 (FED)					...	

AE=Adverse event.
[1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[2] Within 14 days prior to symptom onset.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
The COVID-19 AE terms include: Asymptomatic COVID-19, Coronavirus infection, COVID-19, COVID-19 pneumonia, Suspected COVID-19.
Note that the number of COVID-19 AE terms may change.

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Listing 16.2.9.2c
Listing of COVID-19 Assessments and Symptom Assessments for Patients with COVID-19 Adverse Events
(Safety Population in the Extension Phase)

Treatment: <CAPSULE or TABLET>

Patient Number	Formulation	Adverse Event	AE Start Date	COVID-19 Case Diagnosis [1]	COVID-19 Test Performed/ Test Date/ Results	Assessments and Symptom Assessments	Result
xxxx	TABLET	Coronavirus infection	2020-04-16	Suspected	Yes/ 2020-04-17/ Indeterminate	Travel to Location with Community Transmission [2]	No
						Visited Health Care Facility [2]	No
						Contact with COVID-19 Confirmed/Probable Case [2]	Unknown
						Medication Taken to Treat COVID-19	Yes
						Fever	Yes
						Cough	Yes
						Shortness of Breath	Yes
						Sore Throat	No
						Loss of Appetite	No
						Nausea	No
						Vomiting	No
						Diarrhea	No
						Abdominal Pain	No
						Fatigue	No
						Loss of Smell	No
						Loss of Taste	No
						Asymptomatic	No
						Home Quarantined/Isolated	Unknown
	CAPSULE					...	

AE=Adverse event.
[1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[2] Within 14 days prior to symptom onset.
Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.
Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Signature Page for 213362 TMF-16339705 v1.0

Reason for signing: Approved	Name: PPD Role: Author Date of signature: 12-Jul-2023 13:42:14 GMT+0000

Reason for signing: Approved	Name: PPD Role: Approver Date of signature: 12-Jul-2023 15:14:33 GMT+0000

Signature Page for TMF-16339705 v1.0

Statistical Analysis Plan

AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS

GSK/TESARO Protocol Number:	213362/3000-01-004
Protocol Version:	6.0 (Amendment 5)
Compound Number:	GSK 3985771, MK-4827
Study Drug Name:	Niraparib
Phase:	Phase 1
Methodology:	Open-Label, Cross-Over
Sponsor:	TESARO, a Glaxo Smith Kline Company
Analysis Plan Date:	21 December 2021
Analysis Plan Version:	Version 6.0

SPONSOR SIGNATURE PAGE

Protocol Title:	AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS
Protocol Number:	3000-01-004
Sponsor:	TESARO, a Glaxo Smith Kline Company 980 Great West Road Brentford Middlesex, TW8 9GS UK

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidance and guidelines.

Author: Alina Striha Senior Statistician Plus-Project Ltd.	Signature: Date:	PPD
Approver: Izabela Malinowska Medical Director Glaxo Smith Kline Company	Signature: Date:	

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TABLES INCLUDED IN THE TEXT

FIGURES INCLUDED IN THE TEXT

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE(s)	adverse event(s)
AESI	Adverse Events of Special Interest
ALT	alanine aminotransferase
ALP	alkaline phosphatase
AML	Acute Myeloid Leukemia
AST	aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	area under the plasma concentration-time curve
BA	bioavailability
BE	bioequivalence
BMI	body mass index
CI	confidence interval
CL/F	apparent total body clearance
C_{max}	Maximum observed plasma concentration
CSR	clinical study report
CV	coefficient of variation
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
EOT	end-of-treatment
FE	food effect
ICF	informed consent form
ICH	International Conference on Harmonisation
LLN	lower limit of normal
LS mean	least-squares mean
CCI [redacted]	
MDRP	Medical Data Review Plan
MDS	Myelodysplastic Syndromes
MedDRA	Medical Dictionary for Regulatory Activities
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
PI	Package Insert
PK	pharmacokinetics
PT	preferred term

Abbreviation	Definition
Q_1	first quartile
Q_3	third quartile
QD	one time per day
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class
$t_{1/2}$	termination elimination half-life
TEAE	treatment-emergent adverse event
t_{max}	Time to reach C_{max}
US	United States
ULN	upper limit of normal
Vz/F	apparent terminal volume of distribution
WHO	World Health Organization

1 INFORMATION FROM THE STUDY PROTOCOL

1.1 Introduction and Objectives

1.1.1 Introduction

The approved niraparib drug product is an immediate release hard gelatin capsule dosage form that contains 100 mg of niraparib per capsule. The labelled starting dose for niraparib is 300 mg. Facilitating this dose requires the administration of three 100 mg capsules.

It is Sponsor's intent to introduce a tablet dosage form that provides the 100 mg, 200 mg and 300 mg dose in single dose strength tablets to reduce the pill burden on the patients.

To this end, the Sponsor has developed a tablet dosage form with the specific intent to provide comparable performance to the approved capsule dosage form. The formulation and manufacturing process of the tablet were selected to produce a tablet with comparable in-vitro performance to the capsule.

This study is an open-label Phase 1 study to evaluate the relative bioavailability (BA) and bioequivalence (BE) of niraparib administered as a tablet formulation compared to the reference capsule formulation manufactured by the same process as currently marketed in the United States. Specifically, a 300 mg niraparib tablet will be compared to three (3) niraparib capsules (3 × 100 mg). In addition, this study will evaluate the effect of a high-fat meal on the pharmacokinetics (PK) of the niraparib 300 mg tablet formulation (Stage 3). The Extension Phase of this study is to enable patients enrolled in the study to continue to receive treatment with niraparib if they are tolerating it and, in the Investigator's opinion, may receive benefit.

1.1.2 Study Objectives

The primary objectives of this study are as follows:

- Stage 1: To obtain preliminary assessment of the relative bioavailability of 300 mg niraparib administered as a tablet versus capsule formulation and to estimate the intra-subject variability of niraparib PK
- Stage 2: To evaluate if the tablet formulation (1 × 300 mg) of niraparib is bioequivalent to the capsule formulation (3 × 100 mg)
- Stage 3: To assess the effect of a high-fat meal on niraparib PK following a single 300 mg dose of the tablet formulation.

The secondary objectives of this study are as follows:

- Stage 1, Stage 2, and Stage 3: To evaluate the safety of single dose niraparib when administered as a tablet or capsule formulation in patients with advanced solid tumors
- Extension Phase: To evaluate the safety of continuously dosed niraparib in patients with advanced solid tumors.

The exploratory objectives of this study are as follows:

CCI [redacted]

1.1.3 Scope and Revision History

A separate PK analysis plan will be written to address the PK objectives and data for this study.

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analyses of non-pharmacokinetic study data. Patient populations to be used for analyses, data handling rules, statistical methods, and formats for data presentation are identified and provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial.

The SAP will outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

The SAP is a living document that will be created during the trial conduct. It will be maintained throughout the lifecycle of the trial. Important changes following approval of SAP v1.0 will be tracked in this section.

The following changes have been implemented in the Appendix containing shells of the Planned Statistical Tables, Listings and Figures.

Table/Listing Number	**Correction**	**Reason for Correction**
Table 14.1.1D	Footnotes [2] and [3] added to the table and in the footer.	Clarification why two patients have been double counted in Screening.
Table 14.1.4D	Added "Missing" category to Cancer stage and Number of prior lines of therapy.	Data collected has missing information on the eCRF.
Table 14.3.1.1.2D	Removed "Any COVID-19 related TEAE".	Removing a duplicate entry row.
Table 14.3.1.14D	Removed "System Organ Class" from the table.	Line not required for the table in question as summary by Preferred Term is of interest.
Table 14.3.1.16D	Added footnote: "NOTE: Deaths due to progressive disease were not collected as adverse events."	Added to reflect data collection and management process and align with Stage 1 and Stage 2 programming practice.
Table 14.3.1.2.1.1D	Footnote added: Note: COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.	Added as per reviewer request.
Table 14.3.1.20D Table 14.3.1.21D Table 14.3.1.22D	Footnote [1] updated to: "[1] TABLET PK Phase Stage 3 opened to recruitment on DDMMMYYYY, with first patient consented on DDMMMYYYY, placing the start of the recruitment during the COVID-19 pandemic."	Clarification of footnote explaining calendar placement of the Stage 3 during COVID-19 pandemic.

	Table titles updated to • Table 14.3.1.20D Summary of Incidence of COVID-19 Related Adverse Events Over Time (Safety Population in the Stage 3 PK Phase) • Table 14.3.1.21D Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender (Safety Population in the Stage 3 PK Phase) • Table 14.3.1.22D Summary of Incidence of COVID-19 Related Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)	Clarification of titles to reflect the reporting effort of COVID-19 related AE incidence rates.
Table 14.4.1C	Summary table of Important Protocol Deviations for Open-Label Extension Phase added.	Added upon request from study team for CSR reporting purposes.
Table 14.4.1D	Summary table of Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population in the Stage 3 PK Phase). Footnotes and corresponding references added to the table.	Added upon request from study team for CSR reporting purposes. Added upon request for clarification.
Listing 16.2.5.1D	Added "PK Dose 1" and "PK Dose 2" date columns to the listing. Moved "Patient Number" into header row.	Added columns to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2. For readability purposes.
Listing 16.2.5.3D	Added "Rel Day [1]" column and [1] footnote: "[1] Relative to first dose during the PK Phase."	Added to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2.
Listing 16.2.5.5D	Columns "Full Dose Taken?", "If N, how much consumed?", "Reason for Change", "Nausea within specified time of dose?" removed from the listing.	Columns removed from Stage 3 listing as not applicable, as per study design.
Listing 16.2.8.1.1D and associated repeat listings	Programming note added regarding location of "Patient Number" in the outputs.	Depending on spacing/information displayed, "Patient Number" may be displayed in the header row after "Treatment Sequence" in order to aid readability of the listing.
Listing 16.2.8.2D	Removed "Heart Rate" column.	Data collected under "Pulse" in Stage 3, added "Heart Rate" to the shells in error.
Listing 16.2.8.5D	Added text to footnote: "in the PK Phase"	Previously missing in error.
Listing 16.2.2C	Listing updated to include only "Important" protocol deviations, title updated to reflect change.	Updated upon request from study team for CSR reporting purposes.
Listing 16.2.2.1D	Listing updated to include only "Important" protocol deviations, title updated to reflect change.	Updated upon request from study team for CSR reporting purposes.
Section 1.2	Definition of data cut has been amended.	Definition changed to reflect study reporting requirements upon request from study team.

Table 1 Revision History

SAP version	Protocol version	eCRF version	Changes from previous version
1.0	2.0	5.0 (26FEB2018)	First Draft
2.0	4.0	8.0 (12FEB2019)	Major changes to this draft of the SAP include the following: • Incorporate changes based on amended protocol. • Modify Stage 2 analysis of AEs to accommodate the increase in washout time between period 1 and period 2 for Stage 2. • For the Extension Phase, specify that analysis will be performed by formulation and overall to accommodate allowance of both tablet and capsule formulation in the Extension Phase. • Define the BA/BE evaluable population and add demographic and baseline characteristic summaries for this population. • Clarify definition of concomitant medications and add additional table for Stage 2 to analyze only medications taken during the PK collection period. • Clarifications to mock table and listing shells (e.g., numbering, footnotes).
3.0	5.0	10.0 (31JUL2019)	Major changes to this draft of the SAP include the following: • Incorporate changes based on amended protocol, including: o Updated numbers of patients enrolled to account for non-evaluability. o Specification of reasons for non-evaluability for the analysis of bioequivalence. • Focus Extension Phase laboratory summaries on select laboratory assessments hemoglobin, neutrophils, platelets, bilirubin, creatinine, AST, and ALT).
4.0	6.0	11.0 (23MAR2021)	Major changes to this draft of the SAP include the following: • Incorporate changes based on amended protocol, to address the objectives for Stage 3 of the study. • Addition of sections relating to COVID-19 reporting.
5.0	6.0	11.0 (23MAR2021)	Primary changes to this draft associated with addition of Important Protocol Deviation table and updates to the associated listing to reporting effort. Minor updates to align Stage 1, 2 and 3 TLFs with shells, and associated update to Protocol Deviation reporting, as per the SAP.

SAP version	Protocol version	eCRF version	Changes from previous version
6.0	6.0	11.0 (23MAR2021)	Primary change to this draft of the SAP is change of the data cut for reporting of final Stage 3 analysis. Minor update to footnotes of Important Protocol Deviation summary table. Minor update to Section 5 formatting.

1.2 Study Design

1.2.1 Synopsis of Study Design

This is a multicenter, open-label study in patients with advanced solid tumors. This is a 3-stage, randomized-sequence, single-crossover study to assess the relative BA and BE of niraparib tablet formulation relative to the capsule formulation. In addition, Stage 3 of the protocol is a single cohort, randomized-sequence, 2 period, single dose, crossover study to assess effect of food on the PK of the niraparib tablet formulation.

Pharmacokinetics (PK) Phase: In Stages 1 and 2, patients will be randomized 1:1 to receive tablet formulation followed by capsule formulation or capsule formulation followed by tablet formulation. In Stage 3, patients will be randomized 1:1 to receive tablet formulation in a fasted state followed by tablet taken with a high-fat meal, or by tablet taken with a high-fat meal followed by tablet formulation taken in a fasted state.

Stage 1: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet [1 × 300 mg] or capsule [3 × 100 mg]) followed by a 7-day (+1 day) Washout/PK period, followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day (+1 day) Washout/PK period for Stage 1 of the study followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 2: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet [1 × 300 mg] or capsule [3 × 100 mg]) followed by a 14-day (+/- 4 days) Washout/PK period followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 3: In period 1, patients will receive a single 300 mg niraparib tablet either following a 10-hour fast or directly following consumption of a high-fat meal, followed by a 14-day (+4 days) PK sampling and Washout period. In period 2, patients will be crossed over to receive a single 300 mg niraparib tablet in a fasted state or with a high-fat meal, followed by a 7-day PK sampling period. All patients will fast for a minimum of 4 hours post-dose in both periods. Patients receiving the tablet in the fasted state in the first treatment period will receive the tablet with a high-fat meal in the second treatment period and vice versa.

In the rare instance where a delay of the entire PK period 2 is needed for any reason beyond the 4 day window specified above the site must contact the Sponsor's medical monitor to discuss the patient circumstances, the Sponsor will decide if the patient can continue with PK period 2 with a delay. Similarly, should the laboratory results on Day 15 (D15) (the day of niraparib administration in PK period 2) show changes in organ function such that the original inclusion criteria for laboratory values are no longer met, or in the event of a significant change of patient's clinical status as judged by the Investigator, the site must consult with the Sponsor to discuss the patient's continued participation in PK period 2. Note that sites need not wait for the pre-dose laboratory results to begin PK period 2, but rather consult the Sponsor once the results are available as needed. In Stage 2, patients who experience emesis within 9 hours of dosing or who miss a critical PK sample (such as the last PK sample on Day 8 in each period) will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. In Stage 3, patients who experience emesis within 10 hours of dosing will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. Patients who miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase.

For Stage 1, the PK parameters that will be estimated include area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUC_{0-t}), area under the plasma concentration-time curve from time 0 extrapolated to infinity ($AUC_{0-\infty}$), apparent total body clearance (CL/F), maximum observed plasma concentration (C_{max}), time to reach C_{max} (t_{max}), termination elimination half-life ($t_{1/2}$), apparent terminal volume of distribution (Vz/F) and BA of tablet formulation relative to the capsule formulation based on AUC_{0-t}, $AUC_{0-\infty}$, and C_{max}. Relative bioavailability will be assessed based on the ratio of geometric least-squares (LS) means of the test (tablet) to reference (capsule). Additionally, the pharmacokinetics of CCI [redacted] will be determined (Stage 1 only).

For Stage 2, the same PK parameters as above will be estimated. To conclude bioequivalence, the 90% confidence interval (CI) of the ratio of geometric LS means of the test (tablet) to reference (capsule) product should be within 0.800 – 1.250 (80% – 125%) for $AUC_{0-\infty}$, AUC_{0-t}, and C_{max}.

For Stage 3, the same PK parameters as above will be estimated. In addition, $t_{lag,}$ the time from administration of the dose to the first quantifiable concentration, will be determined, and t_{max} will be compared between the fed and fasted states. The relative bioavailability of the 300 mg niraparib tablet administered with a high-fat meal relative to fasted dosing will be based on the ratio of geometric LS means of AUC_{0-t}, $AUC_{0-\infty}$, and C_{max}.

Additional PK parameters may be estimated (e.g., residual area), if deemed appropriate.

Extension Phase: When patients complete the PK Phase of the study (at least 7-days from the beginning of PK period 2), they may be eligible to participate in the Extension Phase following review of the Extension Phase inclusion criteria and completion of the required Extension Phase screening assessments. The starting dose of niraparib in the Extension Phase will be based on the patient's baseline actual body weight or platelet count. Patients with a baseline actual body weight of ≥77 kg and screening platelet count of ≥150,000/µL (obtained after completion of the PK phase, as part of Extension Phase screening) will take one 300 mg strength tablet or 3 × 100 mg tablet/capsules at each dose administration (once a day [QD]). Patients with a baseline actual body weight of <77 kg or screening platelet count of <150,000/µL

will take one 200 mg strength tablet or 2 × 100 mg tablet/capsules at each dose administration (QD). For patients whose initial starting dose is 200 mg QD, escalation to 300 mg QD is permitted after 2 cycles of therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor. Additional dose modifications will not be based upon changes in the patient's actual body weight during study participation. If laboratory values at the beginning of Extension Phase are outside of the range specified in the inclusion criteria, the patient may continue to participate in the study only upon Sponsor approval with consideration for an appropriately reduced dose. Should a patient start the Extension Phase at 100 mg, consideration may be given to escalate to 200 mg after 2 cycles, therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor.

Patients have up to 28 days (21 days for Stage 3 only; up to 28 days may be acceptable following discussion between the Sponsor and Investigator) after completion of the PK Phase to complete the screening assessments and the Extension Phase Screening Visit.

A tumor assessment is to be performed prior to the first dose of the Extension Phase (pre-Extension Phase). The pre-Extension Phase tumor assessment need not be completed if the baseline tumor assessment was performed ≤ 56 days before the first dose of the Extension Phase.

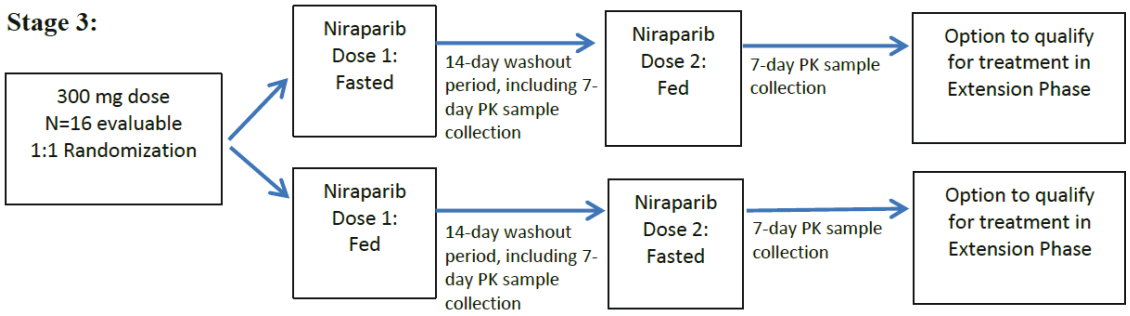
The Cycle 1/Day 1 Visit can occur on the same day as the Extension Phase Screening Visit, dependent upon availability of radiographic results obtained ≤ 56 days of the first planned dose in the Extension Phase. If the Extension Phase Screening Visit and the Cycle 1/Day 1 Visit occur on the same day, the clinical laboratory results will be reviewed by the study personnel prior to study drug administration to ensure eligibility. At the Cycle 1/Day 1 Visit, patients will undergo safety assessments and will receive study drug supply for the duration of 1 cycle (300 mg or 200 mg tablets of niraparib for QD dosing or 3 × 100 mg or 2 × 100 mg tablet/capsules of niraparib for QD dosing, depending on availability). It is preferred that patients remain on the same formulation (tablet versus capsule) throughout the Extension Phase. Patients will return on the first day of every treatment cycle (28 ± 7 days) to receive study drug and for safety assessments. Visits will continue approximately every 4 weeks until treatment discontinuation. In line with the niraparib United States Package Insert (US PI), dose interruption (no longer than 28 days) will be allowed based on adverse events (AEs). In addition, dose reductions to 200 mg QD and subsequently to 100 mg QD will be allowed based on AEs (please refer to US PI). Any dose reductions differing from this must be discussed with the medical monitor. Patients can continue in the Extension Phase until the patient meets 1 of the withdrawal criteria.

End-of-treatment (EOT) and Safety Follow-up Visits: The EOT visit will occur within 7 days of the decision to discontinue study drug, for any reason, or completion of the PK Phase for patients who participate in the Extension Phase (Stage 3 only), whichever occurs first. Should the first dose of a new anti-cancer therapy occur within 14 days of the decision to discontinue study drug, all assessments required for the Safety Follow-up visit should occur at the EOT visit and this visit will be considered the Safety Follow-up visit. If the first dose of the new anti-cancer therapy occurs >14 days of the decision to discontinue study, the Safety Follow-up visit will occur 30 +7 days after the last dose of the study drug, or at the start of any new anti-cancer therapy, whichever occur first.

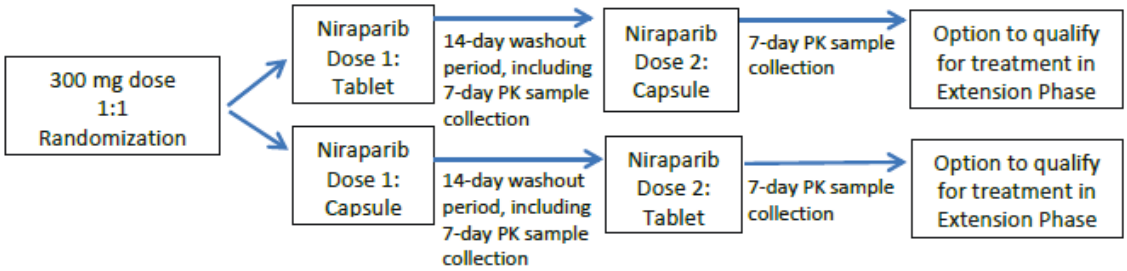
For Stage 3 of the PK Phase only, the data cut will occur when all patients have completed the PK Phase. Data collected up to and including PK EOT visit prior to the data cut will be presented in the FE Stage 3

PK CSR for all randomized and treated patients. Additionally, the Sponsor will include safety data related to the PK Phase, as identified up to Cycle 1/Day 1 of the Extension Phase.

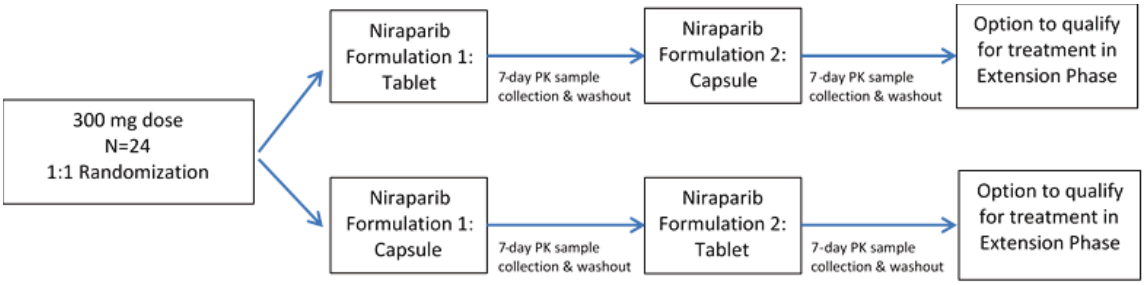
Figure 1 Study Design: Single-Crossover Study



Stage 2 (completed):



Stage 1 (completed):



Abbreviations: PK = pharmacokinetics.

1.2.2 Randomization Methodology

Randomization will occur centrally using an interactive voice response system/integrated web response system. In Stage 1 and Stage 2, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: capsule formulation followed by tablet formulation, or vice versa. In Stage 3, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: dosing after receiving a high-fat meal (fed) followed by dosing after fasting, or vice versa. The period between randomization and Cycle 1/Day 1 should be no longer than 5 calendar days.

1.2.3 Unblinding

Unblinding is not applicable as this is an open-label study.

1.2.4 Study Procedures

Refer to the latest protocol for the schedule of assessments.

1.2.5 Efficacy, Safety, and Pharmacokinetic parameters

1.2.5.1 Efficacy parameters

Investigator assessment of response will occur every 3-cycles while on study or per the Institution's standard practice.

1.2.5.2 Safety parameters

Safety parameters to be assessed include:

- Treatment emergent adverse events (TEAE)
- Discontinuations due to AEs
- Physical examination (PE) findings
- Vital signs
- Clinical laboratory results (hematology, chemistry, urinalysis)
- Electrocardiograms (ECG)
- Use of concomitant medications.

1.2.5.3 PK parameters

PK parameters and analysis methodology will be addressed in the PK analysis plan.

2 Patient Population

2.1 Population Definitions

The following patient populations will be evaluated for analyses specified in this SAP. Additional populations, relevant to the PK analysis will be defined in the PK analysis plan.

- Safety Population in the Stage 1 PK Phase: All patients who receive any amount of niraparib during the Stage 1 PK Phase of the study.
- Safety Population in the Stage 2 PK Phase: All patients who receive any amount of niraparib during the Stage 2 PK Phase of the study.
- Safety Population in the Stage 3 PK Phase: All patients who receive any amount of niraparib during the Stage 3 PK Phase of the study.
- Safety Population in the Extension Phase: All patients who receive any amount of niraparib in the Open-Label Extension Phase of the study.
- BA/BE Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters, without significant niraparib carryover (baseline concentration > 5% of C_{max}), in both PK Periods. Patients who have significant niraparib carryover from period 1 in period 2 will be completely excluded from the BA/BE

Evaluable Population. The terminology BA Evaluable Population will be used for Stage 1 and BE Evaluable Population will be used for Stage 2.

- Food effect (FE) Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters in both periods. Patients meeting non-evaluability criteria or having significant niraparib carryover (baseline concentration >5% of C_{max}) will be completely excluded from the FE Population.

2.2 Protocol Deviations

Protocol deviations will be assessed and classified as important and/or significant per Sponsor's SOP. The Medical Data Review Plan (MDRP) prospectively identifies classification criteria for important deviations. All protocol deviations will be identified, classified and finalized prior to database lock.

A listing of protocol deviations will be provided for the Stage 1 PK Phase, Stage 2 PK Phase; for Stage 3 PK Phase and the Open-Label Extension Phase a listing of only "Important" protocol deviations will be provided.

For Stage 3 PK Phase and Open-Label Extension Phase, tables summarizing "Important" protocol deviations will be provided.

3 GENERAL STATISTICAL METHODS

3.1 Sample Size Justification

Stage 1

No formal sample size calculation was performed for Stage 1. Approximately 24 patients will be enrolled in Stage 1. This sample size is considered adequate for preliminary assessment of the relative bioavailability of the tablet compared to the capsules and for estimating the intra-subject coefficient of variation, after accounting for patient drop-outs and potential carryover.

Stage 2

Based on estimates from Stage 1, 100 BA/BE evaluable patients are required in Stage 2. With 100 evaluable patients, assuming the intra-subject coefficient of variation (CV) is 25% and the true ratio of means is 0.89 (89%), there is at least 90% power to demonstrate the bioequivalence (bioequivalence range: 0.80 to 1.250 [80% – 125%], alpha=0.05). Power calculations were also performed under alternative assumptions for the CV and mean ratio. Assuming the CV is 30% and the true ratio of means is 0.89 (89%), with 100 evaluable patients, there is at least 82% power to demonstrate bioequivalence. Assuming the true ratio is 0.90 (90%), the power is 96% and 88% assuming CVs of 25% and 30%, respectively.

The final analysis of bioequivalence will be based on Stage 2 BA/BE evaluable patients only, with a target sample size of 100 evaluable patients. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

- Emesis within 9 hours of dosing,

- Dosing errors,
- Patient did not fast prior to dosing,
- Missing critical PK sample on Day 8,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

In this patient population, approximately 170 total patients are targeted for enrollment, assuming a 35% non-evaluability rate during the study conduct, and an additional 10% non-evaluability rate during PK analysis. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 100 BA/BE evaluable patients.

Stage 3

Assuming the true ratio of means is 1 and the intra-subject CV is 20% for AUC_{0-t} and $AUC_{0-\infty}$, with 16 evaluable patients, there is approximately 83% probability that the 90% CI of the ratio of geometric means will be within 0.800 and 1.250 (80% - 125%). Based on the results of a FE study conducted using the capsule formulation, an effect of a high-fat meal on C_{max} is possible. The sample size of 16 patients is deemed adequate to characterize this effect. AUC_{0-t} and $AUC_{0-\infty}$ will be the primary parameters for analysis.

The primary analysis will be based on the FE Evaluable Population as it is the most conservative approach, which maximizes the benefits of the crossover design, where each patient serves as their own control. Results for the PK Evaluable Population will also be summarized and reported for this study.

To account for non-evaluable patients, approximately 20 total patients are targeted for enrollment. The final analysis will be based on Stage 3 FE evaluable patients only. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

- Emesis within 10 hours of dosing,
- Dosing errors,
- Patient did not follow dietary requirements prior to dose and post-dose,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

Patients who miss critical PK samples or miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 16 evaluable patients.

3.2 General Methods

All statistical analyses will be performed using SAS statistical software v9.4 or later, unless otherwise noted. All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files,

sorted and labeled according to the International Conference on Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

For categorical variables, summary tabulations of the number and percentage of patients within each category of the parameter will be presented. Percentages will be based on the patients with a non-missing parameter unless missing category is presented. Percentages will be reported to one decimal place. Percentages will not be presented for zero counts.

For continuous variables, the number of patients, mean, standard deviation (SD), median, first quartile (Q_1), third quartile (Q_3), minimum, and maximum values will be presented. Mean, median, Q_1, and Q_3 will be reported to 1 more decimal place than the raw data, while the SD will be reported to 2 more decimal places than the raw data.

All data listings that contain an evaluation date will also contain a relative study day. A unique relative study day will be calculated for the PK Phase and Extension Phase based on the first date of dosing within the study phase. Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study drug which is designated as Day 1. The preceding day is Day -1, the day before that is Day -2, etc. Post-treatment study days are numbered relative to the first dose and are designated as Day +1, Day +2, etc.

In addition:

- Medical history and AEs will be coded using the most up-to-date version of Medical Dictionary for Regulatory Activities (MedDRA).
- Laboratory parameter changes during the Extension Phase for selected laboratory tests will be described using shift tables, relative to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03.
- Concomitant medications will be coded using the latest version of the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification.
- CIs will be presented to one more decimal place than the raw data.

Summaries in the Extension Phase will be performed by formulation and overall, regardless of starting dose, unless otherwise specified. The niraparib formulation and dose at onset will be included in the listing for the Extension Phase.

All tables, figures, and listings will include footers at the bottom of the page reflecting the programs used to generate the tables, figures, and listings, and date and time of the generation of the output.

Some minor modifications may be necessary to the planned design of tables, figures, and listings to accommodate data collected during the actual study conduct.

3.3 Baseline Definitions

For all analyses unless otherwise noted, baseline is defined as the most recent measurement prior to the first administration of study drug, for each phase of the study. Baseline can be the same date as first dose, given the measurement is expected prior to first dose when only date information is available.

3.4 Methods of Pooling Data

Data will be pooled across study sites.

3.5 Adjustments for Covariates

No formal statistical analyses that adjust for possible covariate effects are planned for the safety endpoints.

3.6 Multiplicity Adjustment

Multiplicity is not adjusted in this study.

3.7 Subpopulations

Not applicable.

3.8 Withdrawals, Drop-outs, Loss to Follow-up

Patients will not be replaced during Stage 1. During Stage 2 and Stage 3, patients who do not complete period 1 or period 2, or who are missing PK samples which render the determination of the primary PK parameters not possible, will be replaced. After evaluation, patients receiving concomitant medications which may affect the final analysis may be replaced.

3.9 Missing Data

In general, there will be no imputations made to accommodate missing data points. All data recorded on the eCRF will be included in data listings for the CSR.

When tabulating AE data, partial dates will be handled as follows:

- If the day of the month is missing, the onset day will be set to the first day of the month unless it is the same month and year as first study treatment. In this case, in order to conservatively report the event as treatment-emergent, the onset date will be assumed to be the date of first study treatment.
- If the onset day and month are both missing, the day and month will be assumed to be January 1, unless the event occurred in the same year as the first study treatment. In this case, the event onset will be coded to the day of first study treatment in order to conservatively report the event as treatment-emergent.
- A missing onset date will be coded as the first day of study treatment. If the resulting onset date is after a reported date of resolution, the onset date will be set equal to the date of resolution, after considering any required imputation.

Imputation of partial dates is used only to determine whether an event is treatment-emergent; data listings will present the partial date as recorded in the eCRF.

Partial start dates for prior/concomitant medication, growth factor and transfusion data will be handled in the same way as described above for adverse events. Stop dates will be imputed as follows:

- If only day of the month is missing, the end day will be set to the last day of the month.
- If end day and end month are missing, and the year is not missing, then the day and month will be set to December 31 (or date of study discontinuation/completion if earlier than December 31).

- If the stop date is completely missing, it will be set to the date of study discontinuation/completion.
- If the imputed stop date is greater than the date of study discontinuation/completion then the date will be set to the date of study discontinuation/completion.

3.10 Visit Windows

By-visit summaries and analyses will be performed by nominal visit. All data will be tabulated per the evaluation visit as recorded on the eCRF even if the assessment is outside of the visit window for analysis.

3.11 Interim Analysis

There will be no interim analysis for this study.

3.12 COVID-19

COVID-19 pandemic may impact the conduct of clinical studies. Challenges may arise from quarantines, site closures, travel limitations interruptions to the supply chain for the investigational product or other considerations if site personnel or patients become infected with COVID-19. These challenges may lead to difficulties in meeting protocol specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing.

This study was initiated by TESARO, which was subsequently acquired by GSK. Prior to the acquisition, protocol deviations were classified using TESARO definitions. The TESARO protocol deviation system was decommissioned in May 2020, and thereafter, protocol deviations were classified using GSK definitions.

All protocol deviations collected during the study will be reviewed by the TESARO (for Stage 1 and Stage 2) or GSK (for Stage 3 only) study team, as appropriate, in order to identify TESARO "Significant"/"Important" protocol deviations and GSK "Important" protocol deviations, respectively. Consistent with ICH E3 guidance, only protocol deviations identified as "Important" (GSK) are evaluated in the CSR for impact on the Stage 3 primary endpoint.

4 STUDY ANALYSES

4.1 Patient Disposition

A by-patient data listing of patient disposition information will be presented for each phase.

For the PK Phase (Stage 1, Stage 2 and Stage 3 separately), patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients screened
- Patients randomized
- Patients treated with each formulation (Stage 1 and 2)
- Patients treated in fed and fasted state (Stage 3)
- Patients in the safety population

- Patients completing the PK Phase
- Primary reason for discontinuation from the PK Phase
- Primary reason for discontinuation from the study, for patients who do not continue to the Extension Phase.

For the Open-Label Extension Phase, patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients treated with at least one dose
- Patients who discontinue treatment and the reason(s) for withdrawal
- Patients who discontinue the study and the reason(s) for withdrawal.

4.2 Demographics, Baseline Characteristics and Medical History

Demographics, baseline characteristics, primary cancer history, and medical history information will be summarized for the PK safety population by sequence and overall (Stage 1, Stage 2 and Stage 3 separately) and for the Open-Label Extension Phase, using descriptive statistics for the safety population. No formal statistical comparisons will be performed. Demographics and baseline characteristics will also be summarized for the BA for Stage 1, BE Evaluable Population for Stage 2 and FE Evaluable population for Stage 3.

The demographic and baseline characteristics tables will include the following variables:

- Age at time of screening (years)
- Age categories (18 to <65, 65 to <75, ≥75; and ≥65)
- Sex
- Race (White, Black, Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, Other and Not Reported)
- Ethnicity (Hispanic or Latino, not-Hispanic or Latino, Not Reported and Unknown)
- Baseline weight (in kilograms)
- Baseline height (in centimeters)
- Baseline body mass index (BMI) (kg/m^2), calculated using the patient's height and weight at screening [BMI (kg/m^2) = weight (kg) / height $(m)^2$]
- Eastern Cooperative Oncology Group (ECOG) performance status at baseline.

Primary cancer history will be summarized for the safety population and will include the following variables:

- Tumor type
- Time from first diagnosis to informed consent (years)
- Cancer stage (most recent) (Locally advanced, Metastatic)
- Number of prior lines of therapy
- Any prior radiotherapy.

Prior anti-cancer treatments will be coded using the most current version of the WHO Drug Dictionary. The number and percentage of patients reporting the use of at least one preferred term will be reported for

the safety population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the safety population in the Extension Phase.

Medical history will be coded using the most current version of MedDRA, and the number and percentage of patients experiencing at least one such diagnosis by MedDRA System Organ Class (SOC) and preferred term (PT) will be reported for the safety population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the safety population in the Extension Phase.

Demographics, baseline characteristics, primary cancer history, and medical history information for each patient will be provided in data listings.

4.3 Investigator Assessment of Response

Investigator assessment of response will be provided in data listings for the Extension Phase. Additional descriptive summaries of response may be performed by tumor type.

4.4 Safety Evaluation

4.4.1 Treatment Exposure and Compliance

PK Phase

The number and percentage of patients receiving capsules and tablets during the PK Phase (Stage 1 and Stage 2, separately) will be summarized. For Stage 3, the number of tablets received will be summarized by fed/fasted state.

A by-patient listing of the niraparib treatment data will be produced for the PK safety population.

Extension Phase

Study treatment exposure and compliance will be summarized by formulation and overall, including:

- Number and percentage of patients who initiated 1, 2, 3, 4, 5, ≥6 treated cycles.
- Duration of treatment (months), defined as:
  [last dose date - first dose date in the Extension Phase + 1] / 30.4375.
- Duration on study (months), defined as:
  [last contact date - first dose date in the Extension Phase + 1] / 30.4375, where last contact date is the last visit date or date of death.
- Number of patients with at least one dose interruption.
- Number of patients with at least one dose reduction.

In addition, the starting niraparib dose for each cycle will be summarized.

A by-patient listing of the niraparib treatment data will be produced for the Open-Label Extension Phase safety population.

4.4.2 Adverse Events

All AEs will be classified by SOC and PT using the most up-to-date version of MedDRA.

Per protocol, all SAEs will be collected from the signing of the ICF for this study through 90 days after the last dose of study drug (or until the start of alternate anticancer therapy, whichever occurs first, and recorded in the eCRF.

All AEs, regardless of the source of identification (e.g., physical examination, laboratory assessment, ECG, or reported by patient), will be collected and recorded in the eCRF for each patient from the time of randomization and/or treatment assignment until 30 days after the last dose of study drug.

All AEs experienced by a patient, regardless of the suspected causality, will be monitored until the AE or SAE has resolved, until AE(s) or SAE(s) have returned to baseline or normal levels, until stabilized with a satisfactory explanation for the changes observed, until the patient is lost to follow-up, or until the patient has died, starts alternate anti-cancer therapy, or until the patient withdraws consent.

For analysis, TEAEs will be defined as any AEs collected with a start date on or after the first dose of study drug. Any AEs recorded in the database that occur from the time of ICF to first dose will be listed only and not included in safety analyses. Pre-existing conditions will be recorded in the eCRF on the Medical History or appropriate page.

The severity of the toxicities will be graded according to the NCI CTCAE v4.03. Within the same MedDRA PT, only the most severe AE for each patient will be counted in tabulations by severity. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for the most severe AE reported.

The Investigator must provide a causality assessment (related or not related) regarding the relationship of the event with the study drug and/or study procedure for all AEs. In Stage 1, for analysis of the PK Phase, AEs considered related to either tablet or capsule will be considered to be related to study drug. Any AEs for which the relationship is missing (for either tablet or capsule during the Stage 1 PK Phase) will be considered as related to study treatment. During the PK Phase 2, PK Phase 3 and Extension Phase, relationship relative to niraparib will be considered. Within the same MedDRA PT, only the AE with the highest ranked relationship to treatment for each patient will be counted in tabulations by relationship to treatment. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for the AE that is most related to treatment. The imputation for a missing relationship will take place prior to determining the most related AE within a SOC or PT for a given patient.

If the start date is missing for an AE and the actual start date cannot be determined from a partial date, the AE will be considered treatment-emergent.

Adverse Events of Special Interest (AESI) for niraparib are the following:

- Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML)
- Secondary cancers (new malignancies [other than MDS or AML])
- Pneumonitis (for Stage 1 and Stage 2 only)
- Embryo-fetal toxicity (for Stage 1 and Stage 2 only).

AEs will be classified into the following time periods for analysis.

- PK Phase (for Stage 1, Stage 2 and Stage 3 separately):

    - Period 1: Any AE that begins on or after Dose 1 but prior to Dose 2.
        - For Stage 1, Period 1 will be defined as 7-days post Dose 1 for patients who do not receive Dose 2.
        - For Stage 2, Period 1 will be defined as 14-days post Dose 1 for patients who do not receive Dose 2.
    - Period 2: Any AEs that begins on or after Dose 2 but prior to the end of the PK Phase as defined by 7-days post Dose 2.
    - Safety Follow-Up/Extension Screening Period:
        - For patients not participating in the Extension Phase, AEs that begin after the end of the PK Phase.
        - For patients participating in the Extension Phase, AEs that begin after the end of the PK Phase until the date of first dose in the Extension Phase.
- Open-Label Extension Phase:
    - Any AEs that start on or after the first dose in the Extension Phase.

The analyses indicated below will be performed for each of the above-mentioned phases.

A high-level overview of TEAEs will be presented in a summary table. This table will include the number and percentage of patients for the following categories:

- Any TEAE
- Any related TEAEs
- Any serious TEAEs
- Any related serious TEAEs
- Any TEAEs with CTCAE toxicity grade 3 or above
- Any related TEAEs with CTCAE toxicity grade 3 or above
- Any TEAEs leading to treatment discontinuation
- Any related TEAEs leading to treatment discontinuation
- Any TEAEs leading to dose interruption
- Any TEAEs leading to dose reduction
- Any TEAEs leading to death.

The number and percentage of patients reporting a TEAE will be summarized in the following additional AE tables. AE tabulations will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

- TEAE by SOC and PT
- Related TEAE by SOC and PT
- Treatment emergent SAEs by SOC and PT
- Related treatment emergent SAEs by SOC and PT
- TEAE with toxicity grade 3 or above by SOC and PT
- Related TEAE with toxicity grade 3 or above by SOC and PT
- TEAEs leading to treatment discontinuation by SOC and PT
- TEAEs leading to dose interruption by SOC and PT (Extension Phase Only)

- TEAEs leading to dose reduction by SOC and PT
- TEAEs leading to death by SOC and PT
- TEAE by PT (sorted by frequency)
- TEAE by SOC, PT, and maximum toxicity grade
- Treatment emergent AESI.

For Stage 1 and Stage 2 PK Phase, primary tabulations for the PK Phase data will be provided by formulation (regardless of period), those occurring during the follow-up/extension screening and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and formulation. For Stage 3 PK Phase, primary tabulations for the PK Phase data will be provided by fed/fasted state (regardless of period), and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and fed/fasted state. For the Open-Label Extension Phase, data will be summarized by formulation and for all patients overall.

The following by-patient listings will be produced for the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Open-Label Extension Phase:

- All TEAEs
- Treatment emergent SAEs
- All Deaths
- TEAEs leading to dose interruption (Extension Phase Only)
- TEAEs leading to dose reduction
- TEAEs leading to treatment discontinuation.

4.4.3 Laboratory Data

Laboratory assessments for safety oversight are performed locally at each center's laboratory by means of their established methods. All laboratory values will be converted to SI units and classified as normal, low, or high based on normal ranges supplied by the local laboratories and upon employing standardization.

A by-patient listing of all laboratory data will be provided, with laboratory reference ranges and abnormal values highlighted, and including center, patient identifier, and visit for the PK Phase and the Extension Phase of the study.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry (bilirubin, creatinine, aspartate aminotransferase [AST] and alanine aminotransferase [ALT]) will be analyzed using change from baseline by visit.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry tests (bilirubin, creatinine, ALT, and AST), baseline and post-baseline results will be categorized by NCI CTCAE v4.03 grade (Table 2). Shift tables will be produced by maximum post-baseline grade. Results that are considered 'normal' will be assigned a grade 0.

Table 2 NCI Common Terminology Criteria for Adverse Events v4.03 (CTCAE)

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

4.4.4 Vital Signs and Physical Examination

Vital sign measurements will be presented for each patient in a data listing.

Baseline physical examination findings will be presented in a data listing. Any new or changed condition will be captured as an adverse event and will be summarized in the AE tables and listings.

4.4.5 Electrocardiogram

Standard 12-lead ECGs will be performed locally for patients in the study. Any ECG findings that are assessed as clinically significant and are reported as an AE or SAE will be summarized in the AE tables and listings.

All ECG results (i.e., interpretations) for each patient will be provided in a data listing.

4.4.6 Prior and Concomitant Mediations

Medications collected at Screening and during the study will be coded using the current version of the WHO Drug dictionary. Study treatment, prior anti-cancer treatments for primary cancer, transfusions and growth factors are collected and summarized separately. For each of the study phases (Stage 1 PK, Stage 2 PK, Stage 3 PK and Extension Phase), medications will be categorized as prior or concomitant using the following definitions:

- Prior medications during the PK Phase: any medications which started prior to the first dose date of study treatment during the PK Phase.

- Concomitant medications during the PK Phase: any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase.
    - For PK Stage 2, concomitant medications will be further identified as those taken during the PK collection period, defined by dates of the first PK-draw to last PK-draw.
- Prior medications during the Extension Phase: any medications which started prior to the first dose date of study treatment during the Extension Phase.
- Concomitant medications during the Extension Phase: any medications on or after the first treatment dosing date in the Extension Phase through 30 days after the last dose of treatment.

Note: medications can be classified as both prior and concomitant.

Both prior medications and concomitant medications will be summarized by ATC classification drug class and WHO preferred name using the number and percentage of patients for each cohort. A patient reporting the same medication more than once will be counted only once when calculating the number and percentage of patients who received that medication in a given time category (prior or concomitant). The summary of concomitant medications will be ordered alphabetically by drug class and then by descending frequency of preferred name in total within the drug class. For drugs with the same frequency, sorting will be done alphabetically. Summaries will be based on the safety population.

For PK Stage 2, an additional summary of concomitant medications used during the PK collection period will be provided for the BE Evaluable Population.

For each phase of the study, all prior and concomitant medications will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

4.4.7 Prior and Concomitant Transfusions and Growth Factors

The number and percentage of patients receiving prior and concomitant growth factors during the PK Phase and Extension Phase will be summarized. The data will be classified as prior or concomitant using similar logic as provided in Section 4.4.6.

For each phase of the study, all prior and concomitant transfusions and growth factor use will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

4.4.8 COVID-19

The Pharmacokinetics Phase Stage 3 of the trial takes place during COVID-19 pandemic, as a result of which some of the trial procedures could be impacted in terms of missing visits and/or assessments. Missing protocol required data/visits due to COVID-19 must be noted in participant notes and recorded as a COVID-19-related protocol deviations.

A summary of the following COVID-19 assessments will be produced: case diagnosis, COVID-19 test performed, and results of the COVID-19 test.

The incidence of COVID-19 related AEs and SAEs will be summarized as part of the safety reporting summaries along with COVID-19-related as reasons for treatment discontinuation.

A listing of all patients with COVID-19 assessments and symptom assessments will be produced and will include the following:

- Treatment sequence
- Patient number
- COVID-19 case diagnosis
- COVID-19 test performed
- Result of the COVID-19 test
- Assessments and symptom assessments performed
- Results of the assessments and symptom assessments.

For PK Phase Stage 3, a separate listing defining "Important" GSK protocol deviations related to COVID-19 will be presented.

For protocol deviation reporting during the Extension Phase, a listing will be produced to present TESARO Classification of protocol deviations for patients continuing from Stage 1 and Stage 2, and GSK Classification of protocol deviations for patients continuing from Stage 3.

5 CHANGES TO PLANNED ANALYSES

There is no change between the protocol-defined statistical analyses and those planned in this SAP.

5.1 Changes in v5.0 of the SAP

Section 2.2 has been updated to include a summary tables of Important protocol deviations for Stage 3 PK Phase and Open-Label Extension Phases, as well as clarification of associated deviation listings presenting only protocol deviations classified as "Important".

5.2 Changes in v6.0 of the SAP

Section 1.2 has been updated to reflect the change in PK data cut requirements for final Stage 3 analysis.

6 APPENDIX

6.1 Planned Statistical Tables, Listings, and Figures

TABLES

General guidelines:

Tables will be provided for the Stage 1 PK Phase, Stage 2 PK Phase, Stage 3 PK Phase and the Open-Label Extension Phase.

For the PK Phase (Stage 1, Stage 2 and Stage 3):

- Treatment=Sequence and Overall, in general. For PK and AE data, please see mock tables.
- Population=Safety Population in Stage 1 PK (Stage 2 PK or Stage 3 PK) Phase, unless otherwise specified.
- PK Phase Data:
    - For patients who do not continue to Extension Phase, PK Phase is any data collected.
    - For patients who do continue to Extension Phase,
        - AEs – prior to first dose in Extension Phase
        - Prior meds/procedures/etc. – prior to first dose in PK Phase
        - Concomitant meds – meds prior to first dose in Extension Phase.
- Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) – use visit to identify data.

For the Extension Phase:

- Treatment=Niraparib Tablet or Capsule (regardless of starting dose); Summarize by Tablet; Capsule; Overall, unless otherwise specified.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Extension Phase Data:
    - For patients who do not continue to Extension Phase, there is no Extension Phase data.
    - For patients who do continue to Extension Phase,
        - AEs – on or after first dose in Extension Phase
        - Prior meds/procedures/etc. – prior to first dose in Extension Phase
        - Concomitant meds – meds on or after the first dose in Extension Phase
        - Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) – use visit to identify data.

Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

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Table 14.1.1A
Subject Disposition in the PK Phase (All Patients in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE	Sequence CAPSULE/TABLET	Overall
Number of Patients				
Screened	n	--	--	xx
Randomized	n	x	x	x
Received Tablet	n	x	x	x
Received Capsule	n	x	x	x
Received Both Tablet and Capsule	n	x	x	x
PK Phase Safety Population	n	x	x	x
Completed PK Phase	n	x	x	x
Discontinuation from PK Phase	n	x	x	x
Reason1	n	x	x	x
Reason2	n	x	x	x
Participate in Extension Phase	n	x	x	x
Discontinuation from Study Prior to Entering the Extension Phase				
Reason1	n	xx	xx	xx
Reason2	n	xx	xx	xx

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Only include DC from study for those patients who do not enter the Extension Phase.

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Table 14.1.1B
Subject Disposition in the PK Phase (All Patients in the Stage 2 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE	Sequence CAPSULE/TABLET	Overall
Number of Patients				
Screened	n	--	--	xx
Randomized	n	x	x	x
Not Treated	n	x	x	x
Received Tablet	n	x	x	x
Received Capsule	n	x	x	x
Received Both Tablet and Capsule	n	x	x	x
PK Phase Safety Population	n	x	x	x
Completed PK Phase	n	x	x	x
Discontinuation from PK Phase [1]	n	x	x	x
Reason 1	n	x	x	x
Reason 2	n	x	x	x
Participate in Extension Phase	n	x	x	x
Discontinuation from Study Prior to Entering the Extension Phase				
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx

[1] Includes patients in the Safety Population (i.e., treated patients) only.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Only include DC from study for those patients who do not enter the Extension Phase.

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Table 14.1.1C
Subject Disposition in the Extension Phase (All Patients in the Extension Phase)

Parameter	Statistic	Niraparib Tablet	Niraparib Capsule	Niraparib Overall
Number of Patients				
Dosed	n	xx	xx	xx
Discontinued Treatment After Receiving at Least 1 Dose	n	xx	xx	xx
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx
Discontinued Study	n	xx	xx	xx
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx

Source: Listing XXXXXXXXX, Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.1.1D
Subject Disposition in the PK Phase (All Patients in the Stage 3 PK Phase)

Parameter	Statistic	Sequence NIRAPARIB TABLET FASTED/FED	Sequence NIRAPARIB TABLET FED/FASTED	OVERALL
Number of Patients				
Screened [1]	n	--	--	xx
Randomized	n	x	x	x
Not Treated	n	x	x	x
Received Tablet in Fasted State	n	x	x	x
Received Tablet in Fed State	n	x	x	x
Received Tablet in Both Fasted and Fed State	n	x	x	x
PK Phase Safety Population	n	x	x	x
Completed PK Phase	n	x	x	x
Discontinuation from PK Phase [2]	n	x	x	x
Reason 1	n	x	x	x
Reason 2	n	x	x	x
Participate in Extension Phase	n	x	x	x
Discontinuation from Study Prior to Entering the Extension Phase				
Reason 1	n	xx	xx	xx
Reason 2	n	xx	xx	xx

[1] Patient xxxxxx-xxxx (Screen Failure ID: XXi) and xxxxxx-xxxx (Screen Failure ID: YYi) re-screened and reconsented after screen failure are counted twice in Screening.
[2] Includes patients in the Safety Population (i.e., treated patients) only.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Note]
XXi/YYi is ID that was SF.
Programming, please note footnote references changed order in the shell and footer.

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Table 14.1.2A
Demographics (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Age (yrs)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Age Group				
18 -< 65	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
65 -< 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex				
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race				
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
African American	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or other Pacific Islander	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity				
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.2.1A Demographics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.2.1B Demographics (Safety Population in the Stage 2 PK Phase)

Table 14.1.2.2B Demographics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.2C Demographics (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

Table 14.1.2.1D Demographics (Safety Population in the Stage 3 PK Phase)

Table 14.1.2.2D Demographics (FE Evaluable Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL.

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Table 14.1.3A
Baseline Characteristics (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Weight (kg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Height (cm)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
ECOG Performance Status				
0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

ECOG = Eastern Cooperative Oncology Group:
0=Fully active, able to carry on all pre-disease performance without restriction
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.3.1A Baseline Characteristics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.3.1B Baseline Characteristics (Safety Population in the Stage 2 PK Phase)

Table 14.1.3.2B Baseline Characteristics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.3C Baseline Characteristics (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

Table 14.1.3.1D Baseline Characteristics (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

Table 14.1.3.2D Baseline Characteristics (FE Evaluable Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.4A
Primary Cancer History (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Tumor Type				
Xxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time from first diagnosis to informed consent (years)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Cancer Stage (most recent)				
Locally advanced	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of prior lines of therapy				
0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=6	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any prior radiotherapy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.4B Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Table 14.1.4C Primary Cancer History (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

Table 14.1.4D Primary Cancer History (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.5A
Prior Anti-Cancer Treatment (Safety Population in the Stage 1 PK Phase)

Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Agent 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Agent 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Agent 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort by decreasing frequency in the OVERALL column.

Repeat for:
Table 14.1.5B Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Table 14.1.5C Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

Table 14.1.5D Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED AND OVERALL.

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Table 14.1.6A
Medical History (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any condition	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort alphabetically by SOC/PT.

Repeat for:
Table 14.1.6B Medical History (Safety Population in the Stage 2 PK Phase)

Table 14.1.6C Medical History (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall.

Table 14.1.6D Medical History (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.7A
Prior Medications by ATC and PT (Safety Population in the Stage 1 PK Phase)

ATC (Level 3) Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any prior medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				

Note: Prior medications are any medications with a start date earlier than the first dose date of study treatment and are coded using WHO Drug Dictionary version YYYYMM. Study treatment, prior anti-cancer treatments for primary cancer, transfusions and growth factors are not included.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:
Table 14.1.7B Prior Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.7C Prior Medications by ATC and PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]
- Footnote – Extension Phase: Prior medications are any medications, other than study treatments and pre-medications for study treatment, with a start date earlier than the first dose date of study treatment during the Extension Phase and are coded using WHO Drug Dictionary version YYYYMM.
- Prior anti-cancer treatments for primary cancer are not included.

Table 14.1.7D Prior Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

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Table 14.1.8A
Concomitant Medications by ATC and PT (Safety Population in the Stage 1 PK Phase)

ATC (Level 3) Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any concomitant medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
. . .				

Note: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:
Table 14.1.8.1B Concomitant Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.8.2B Concomitant Medications During the PK Collection Period by ATC and PT (BE Evaluable Population in the Stage 2 PK Phase)

- Footnote: Concomitant medications during the PK collection period are any concomitant medications taken between the first PK-draw until the last PK-draw. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8C Concomitant Medications by ATC and PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

- Footnote – Extension Phase: Concomitant medications are any medications being taken on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8D Concomitant Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL
- Footnote – Stage 3: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

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Table 14.1.9A
Concomitant Transfusions and Growth Factors (Safety Population in the Stage 1 PK Phase)

Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
Any Concomitant Transfusions	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Red Blood Cells	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Platelet	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Concomitant Growth Factors	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
G-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
GM-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Recombinant Erythropoietin	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.1.9B Concomitant Transfusions and Growth Factors (Safety Population in the Stage 2 PK Phase)

Table 14.1.9C Concomitant Transfusions and Growth Factors (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

- Footnote – Extension Phase: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose.

Table 14.1.9D Concomitant Transfusions and Growth Factors (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL
- Footnote – Stage 3: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

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Table 14.3.1.1.1A
Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 1 PK Phase)

	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.1.1B Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.1.1C Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

- Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

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Table 14.3.1.1.1D

Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 3 PK Phase)

	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.1.2A

Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 1 PK Phase)

	Sequence TABLET/CAPSULE (N=xx)			Sequence CAPSULE/TABLET (N=xx)		
	TABLET Period 1 (N=xx)	CAPSULE Period 2 (N=xx)	FU/Ext Screening (N=xx)	CAPSULE Period 1 (N=xx)	TABLET Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.1.2B Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.1.2D

Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 3 PK Phase)

	Sequence NIRAPARIB TABLET FASTED/FED (N=xx)			Sequence NIRAPARIB TABLET FED/FASTED (N=xx)		
	NIRAPARIB TABLET FASTED Period 1 (N=xx)	NIRAPARIB TABLET FED Period 2 (N=xx)	FU/Ext Screening (N=xx)	NIRAPARIB TABLET FED Period 1 (N=xx)	NIRAPARIB TABLET FASTED Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any COVID-19 related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.2.1A
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

Table 14.3.1.2.1B Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.2.1C

Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Open-Label Extension Phase)

System Organ Class Preferred Term	Niraparib TABLET (N=xx)	Niraparib CAPSULE (N=xx)	Niraparib OVERALL (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX, Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

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Table 14.3.1.2.1D

Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 3 PK Phase)

System Organ Class Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

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Table 14.3.1.2.1.1D
Summary of COVID-19 related Adverse Events by SOC and PT (Safety Population in the Stage 3 PK Phase)

System Organ Class Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any COVID-19 related TEAE	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	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)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[1] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes COVID-19 related TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.
Select only COVID-19 related TEAEs.

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Table 14.3.1.2.2A
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 1 PK Phase)

	Sequence TABLET/CAPSULE (N=xx)			Sequence CAPSULE/TABLET (N=xx)		
System Organ Class Preferred Term	TABLET Period 1 (N=xx)	CAPSULE Period 2 (N=xx)	FU/Ext Screening (N=xx)	CAPSULE Period 1 (N=xx)	TABLET Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Table 14.3.1.2.2B Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.2.2D

Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 3 PK Phase)

	Sequence NIRAPARIB TABLET FASTED/FED (N=xx)			Sequence NIRAPARIB TABLET FED/FASTED (N=xx)		
System Organ Class Preferred Term	NIRAPARIB TABLET FASTED Period 1 (N=xx)	NIRAPARIB TABLET FED Period 2 (N=xx)	FU/Ext Screening (N=xx)	NIRAPARIB TABLET FASTED Period 1 (N=xx)	NIRAPARIB TABLET FED Period 2 (N=xx)	FU/Ext Screening (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	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)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Using Mock Shell (Table 14.3.1.2.1A, Table 14.3.1.2.1B, Table 14.3.1.2.1C, Table 14.3.1.2.1D)

Repeat for:

Table 14.3.1.3A Summary of Related TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.3B Summary of Related TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.3C Summary of Related TEAE by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.3D Summary of Related TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.4A Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.4B Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.4C Summary of Serious TEAE by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.4D Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.5A Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.5B Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.5C Summary of Related Serious TEAE by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.5D Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.6A Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.6B Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.6C Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.6D Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.7A Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.7B Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.7C Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.7D Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.8A Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.8B Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.8C Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.8D Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.9C Summary of TEAE Leading to Treatment Dose Interruption by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.10A Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.10B Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.10C Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.10D Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.11A Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.11B Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.11C Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.11D Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.12A Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.12B Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.12C Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Extension Phase)

Table 14.3.1.12D Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 3 PK Phase)

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Table 14.3.1.13A
Summary of Treatment Emergent Adverse Events by SOC and PT and CTCAE Toxicity Grade (Safety Population in the Stage 1 PK Phase)

System Organ Class Preferred Term	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Grade 1				
……..				
Grade 5				
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Grade 1				
……..				
Grade 5				
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Grade 1				
……..				
Grade 5				
……				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.13B Summary of Treatment Emergent Adverse Events by SOC and PT and Maximum Toxicity (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.13C Summary of Treatment Emergent Adverse Events by SOC and PT and Maximum Toxicity (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]
For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported. Within each PT, sort by presented maximum toxicity grade.

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Table 14.3.1.13D

Summary of Treatment Emergent Adverse Events by SOC and PT and CTCAE Toxicity Grade (Safety Population in the Stage 3 PK Phase)

System Organ Class Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
……..	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
……..	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
……..	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
……				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.14A
Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 1 PK Phase)

Preferred Term	TABLET [1] (N=xx)	CAPSULE [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.14B Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.14C Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]
Sort PTs by descending overall frequency of events reported.

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Table 14.3.1.14D
Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 3 PK Phase)

Preferred Term	NIRAPARIB TABLET FASTED [1] (N=xx)	NIRAPARIB TABLET FED [2] (N=xx)	FU/Ext Screening [3] (N=xx)	Total [4] (N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.
[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.15A
Listing of Serious TEAEs During PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Dosing Period/ Niraparib Treatment	Adverse Event [P]MedDRA Preferred Term [S]System Organ Class	Start Date Time/ (Rel Day [1])	Stop Date Time (Rel Day [1])	TEAE?	SAE/ Reason [2]	Severity	Action Taken on Study Treatment[3]	Other Action Taken	Relationship [3]	Outcome
	Period 1/ Capsule	XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd hh:mm [x]	yyyy-mm-dd [x]	Y	N	Grade 1	T: NA C: Dose Not Changed		T: NA C: Related	Recovered/ Resolved
	Period 2/ Tablet	XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd hh:mm [x]	yyyy-mm-dd [x]	Y	N	Grade 1	T: Dose Not Changed C: NA		T: Related C: NA	Recovered/ Resolved
	PK Safety FU										

[1] Relative to the date of first dose in PK Phase.
[2] Reason for SAE: 1 = Result in death; 2 = Life threatening; 3 = Result in persistent or significant disability/incapacity; 4 = Requires or prolongs hospitalization; 5 = Congenital abnormality/birth defect; 6 = Other medically important event.
[3] T=Tablet; C=Capsule.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]
Please add time to Start Date column for PK Phase Stage 2 and Extension Phase.

Repeat for:
Table 14.3.1.15B Listing of Serious TEAEs During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.15C Listing of Serious TEAEs During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.15D Listing of Serious TEAEs During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.16A Listing of Deaths During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.16B Listing of Deaths During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.16C Listing of Deaths During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.16D Listing of Deaths During the PK Phase (Safety Population in the Stage 3 PK Phase)

- Footnote: 'NOTE: Deaths due to progressive disease were not collected as adverse events.'

Table 14.3.1.17C Listing of TEAE Leading to Dose Interruption During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.17D Listing of TEAE Leading to Dose Interruption During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.18A Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.18B Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.18C Listing of TEAE Leading to Dose Reduction During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.18D Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.19A Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.19B Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.19C Listing of TEAE Leading to Treatment Discontinuation During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.19D Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes]

- Stage 3: Treatment Sequence will be NIRAPARIB TABLET FASTED/FED and NIRAPARIB TABLET FED/FASTED.
- Stage 3: Column 2: Dosing Period/Treatment – Treatment should be NIRAPARIB FASTED or NIRAPARIB FED.
- Stage 3: Treatment discontinuation during PK phase – add column to record if discontinuation was due to COVID-19 ["COVID-19 Reason" with Options "COVID-19 infection" or "Issues rel. to COVID-19 pandemic"].
- Extension Phase: Replace column for Dosing Period/Treatment with Treatment and Starting Dose.
- Extension Phase: Do not need time with start/stop dates.
- Extension Phase: Footnote: [1] Relative to first dose during the Extension Phase.
- Extension Phase: Add column for Dose at Onset of AE.

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Table 14.3.1.20D

Summary of Incidence of COVID-19 Related Adverse Events Over Time (Safety Population in the Stage 3 PK Phase)

	Period during COVID-19 Pandemic [1]	NIRAPARIB TABLET FASTED (N=xx) n/Patients at Risk (%)	NIRAPARIB TABLET FED (N=xx) n/Patients at Risk (%)
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)

[1] TABLET PK Phase Stage 3 opened to recruitment on DDMMMYYYY, with first patient consented on DDMMMYYYY, placing the start of the recruitment during the COVID-19 pandemic.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.1.21D
Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender (Safety Population in the Stage 3 PK Phase)

Report on separate page for each: <Gender: Male, Female>

	Period during COVID-19 Pandemic [1]	NIRAPARIB TABLET FASTED (N=xx)	NIRAPARIB TABLET FED (N=xx)
		n/Patients at Risk (%)	n/Patients at Risk (%)
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)

[1] TABLET PK Phase Stage 3 opened to recruitment on DDMMMYYYY, with first patient consented on DDMMMYYYY, placing the start of the recruitment during the COVID-19 pandemic.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.1.22D Summary of Incidence of Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)

- Use the FDAAA age groups <=18, 18-64, >=65

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Table 14.3.4.1A
Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 1 PK Phase)

	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)
# of 100 mg Capsules Received				
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
# of 300 mg Tablets Received				
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Table 14.3.4.1B Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 2 PK Phase)

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Table 14.3.4.1C

Summary of Study Treatment Exposure During the Extension Phase (Safety Population in the Extension Phase)

Parameters	Statistic	Niraparib TABLET (N=xx)	Niraparib CAPSULE (N=xx)	Niraparib OVERALL (N=xx)
Number of Cycles				
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...	...	...	...	...
≥ 6	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Duration of Treatment (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Duration on Study (months)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Total Number of Patients with dose interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Number of Patients with dose reduction	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Number of Patients with dose re-escalation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX, Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.4.1D

Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 3 PK Phase)

	Statistic	NIRAPARIB FASTED (N=XX)	NIRAPARIB FED (N=XX)	OVERALL (N=xx)
# of 300 mg Tablets Received				
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.4.2C
Summary of Niraparib Dose by Cycle (Safety Population in the Extension Phase)

Cycle	Starting Niraparib Dose (mg)	Statistic	Niraparib TABLET	Niraparib CAPSULE	Niraparib OVERALL
1		N	xxx	xxx	xxx
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2		N	xxx	xxx	xxx
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3		N	xxx	xxx	xxx
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
….					

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.4.3.1C
Summary and Change from Baseline of Select Hematology Parameters by Visit During the Extension Phase
(Safety Population in the Extension Phase)

			NIRAPARIB TABLET (N=xx)		NIRAPARIB CAPSULE (N=xx)		NIRAPARIB OVERALL (N=xx)	
Parameter	Visit	Statistic	Actual	Change	Actual	Change	Actual	Change
Parameter 1	Baseline	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx		xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx		xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	
	Cycle 1 – Day 8	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	Cycle 1 – Day 15	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	Cycle 1 – Day 22	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	Cycle 2 – Day 1	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	…….	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx
	EOT	n (missing) Mean (SD) Median Q1, Q3 Min, Max	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx	xx (xx) xx.x (xx.xx) xx.x xx.x, xx.x xx, xx

Source: Listing XXXXXXXXX, Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.3.4.3.2C

Shift Summary of Select Hematology Parameters During the Extension Phase (Safety Population in the Extension Phase)

Treatment Group			Post-Baseline Maximum CTCAE Grade						
Niraparib Tablet	Laboratory Test	Baseline CTCAE Grade	Statistic	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
	xxxxx	Grade 0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	xxxxx								

Source: Listing XXXXXXXXX, Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Include Tablet, Capsule and Overall

Repeat for:
Table 14.3.4.4.1C Summary and Change from Baseline of Select Chemistry Parameters by Visit During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.4.4.2C Shift Summary of Select Chemistry Parameters in Maximum Toxicity Grade During the Extension Phase (Safety Population in the Extension Phase)

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Table 14.3.4.4.1D
Summary of COVID-19 Assessments for Patients with Suspected, Probable or Confirmed COVID-19 Case Diagnosis
(Safety Population in the Stage 3 PK Phase)

Assessment	NIRAPARIB TABLET FASTED (N=XX)	NIRAPARIB TABLET FED (N=XX)
COVID-19 Case Diagnosis [1]	xx (xx.x%)	xx (xx.x%)
Confirmed	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)
COVID-19 Test Performed [2]		
n	xx	xx
No	xx/xx (xx.x%)	xx/xx (xx.x%)
Yes	xx/xx (xx.x%)	xx/xx (xx.x%)
Result from the COVID-19 Test		
n	xx	xx
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)
Indeterminate	xx/xx (xx.x%)	xx/xx (xx.x%)

[1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[2] COVID-19 Test Performed is only captured for patients with a COVID-19 Case Diagnosis.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Table 14.4.1C
Summary of Important Protocol Deviations (Safety Population in the Extension Phase)

Category/Coded Term	NIRAPARIB TABLET (N=XX)	NIRAPARIB CAPSULE (N=XX)	TOTAL (N=XX)
Any important protocol deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
….			
CATEGORY 2	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
…			

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

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Table 14.4.1D
Summary of Important Protocol Deviations for the PK Phase Occurring Through End of Treatment
(Safety Population in the Stage 3 PK Phase)

Category/Coded Term	NIRAPARIB TABLET FASTED [1] (N=XX)	NIRAPARIB TABLET FED [2] (N=XX)	TOTAL [3] (N=XX)
Any important protocol deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
….			
CATEGORY 2	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
…			

[1] Includes protocol deviations with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.
[2] Includes protocol deviations with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.
[3] Includes protocol deviations occurring at any time during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

LISTINGS

General guidelines:

Listings are separated for the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Open)-Label Extension Phase.

For the PK Phase:

- Treatment=Sequence (for Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET; for Stage 3: NIRAPARIB TABLET FASTED/FED or NIRAPARIB TABLET FED/FASTED).
- Population=Safety Population in the PK Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all data assessments relative to the PK Phase.
    - For patients who do not continue to the Extension Phase, include all EOT/Safety FU data. Also include Extension Phase Screening for those patients who DO not proceed to the Extension Phase.
- Relative day: With respect to first date of dosing in PK period.

For the Extension Phase:

- Treatment=Niraparib Tablet; Niraparib Capsule.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all assessments relative to the Extension Phase.
    - Any assessment specific to Extension Phase, including Screening Data.
- Relative day: With respect to first date of dosing in Extension Phase.

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Listing 16.2.1A
Disposition for PK Phase (All Patients Enrolled in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Date of Last Niraparib Dose During PK Phase (Rel Day)	Date of Discontinuation From PK Phase (Rel Day)	Reason for Discontinuation from PK Phase	Date of Discontinuation from Study (Rel Day)	Reason for Discontinuation from Study	Date of Death (Rel Day)	Date of Progression (Rel Day)	Protocol Version
			Other: specify					
			Completion					

Relative Day calculated relative to first dose in PK Phase.

Only study discontinuations, disease progressions and deaths that occur during PK phase (i.e., before 1st dose of extension or prior to discontinuing the study for patients not entering the Extension Phase) are listed.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes – PK Phase]

- Include only data that falls before first-dose Open-Label Extension Phase, i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase.

Repeat for:
Listing 16.2.1B Disposition for PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.1C Disposition for Open-Label Extension Phase (All Patients Enrolled for the Extension Phase)

Listing 16.2.1D Disposition for PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes – Extension Phase]

- Change 'PK Phase' to 'Open-Label Extension' Phase in respective columns.
- Treatment: Niraparib Tablet or Niraparib Capsule.
- Footnote: Relative Day calculated relative to first dose in Extension Phase.

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Listing 16.2.1.2A
Reasons for Screen Failure (Patients who Failed Screening in the Stage 1 PK Phase)

Treatment Sequence: <SCREEN FAILURE>

Patient Number	Protocol Version	Inclusion/Exclusion Criteria Not Met
xxxxxx-xxxx	Version 1.0 (original)	INPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx-xxxx	Version 1.0 (original)	EXPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.1.2B Reasons for Screen Failure (Patients who Failed Screening in the Stage 2 PK Phase)

Listing 16.2.1.2D Reasons for Screen Failure (Patients who Failed Screening in the Stage 3 PK Phase)

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Listing 16.2.2A

Protocol Deviations for the PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment: < Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET>

Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS

[Programming Notes]

- Include only data that falls before first-dose Open-Label Extension Phase (i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase)

Repeat for:
Listing 16.2.2B Protocol Deviation for the PK Phase (Safety Population in the Stage 2 PK Phase)

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Listing 16.2.2C

Important Protocol Deviations for the Open-Label Extension Phase (Safety Population for Open-Label Extension Phase)

Treatment: <Extension (Stages 1 & 2): NIRAPARIB TABLET or NIRAPARIB CAPSULE; Extension (Stage 3): NIRAPARIB TABLET>

Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation	TESARO Classification [1]	GSK Classification [2]
					<<SIGNIFICANT/ IMPORTANT>>	<<IMPORTANT/NON-IMPORTANT>>

[1] For Stages 1 & 2, protocol deviation classification is done based on TESARO Protocol Deviation Management System only. GSK Classification will remain blank.
[2] For Stage 3, protocol deviation classification is done based on GSK Protocol Deviation Management System only. TESARO Classification will remain blank.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]

For Stage 3 Extension Phase, patients will receive NIRAPARIB TABLET formulation only.

For Stages 1 and 2 reporting, only TESARO Classifications will be populated, for Stage 3 – only GSK Classification will be populated.

Only include protocol deviation classed as Important.

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Listing 16.2.2.1D

Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population for Stage 3 PK Phase)

Treatment: <NIRAPARIB FASTED or NIRAPARIB FED>

Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]:

- Only include protocol deviation classed as Important.

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Listing 16.2.2.2D

GSK Protocol Deviations related to COVID-19 (Safety Population for Stage 3 PK Phase)

Treatment: <NIRAPARIB FASTED or NIRAPARIB FED>

Patient Number	Deviation Category	Description of Deviation	GSK Classification	Date
			<IMPORTANT/NOT-IMPORTANT>	

Note: * Patients with probable, suspected or confirmed COVID-19.
Note: This listing only includes COVID-19 related protocol deviations.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.3A

Study Populations for the PK Phase (All Patients Enrolled in the Stage 1 PK Phase)

Treatment: <TABLET/CAPSULE or CAPSULE/TABLET or SCREEN FAILURE>

Patient Number	PK Phase Safety (SAF) Population	Informed Consent Date	Randomization Date
	Y		

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.3B Study Populations for the PK Phase (All Patients Screened in the Stage 2 PK Phase)

- For Stage 2 PK, add column for BE Evaluable Population (Y/N).

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Listing 16.2.3C

Study Populations for the Open-Label Extension Phase (All Patients Enrolled in the Extension Phase)

Treatment: <NIRAPARIB TABLET or NIRAPARIB CAPSULE>

Patient Number	Extension Phase Safety (SAF) Population								
	Y								

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.3D

Study Populations for the PK Phase (All Patients Enrolled in the Stage 3 PK Phase)

Treatment: <FASTED/FED or FED/FASTED or SCREEN FAILURE>

Patient Number	PK Phase Safety (SAF) Population	FE Population	Informed Consent Date	Randomization Date
	Y	Y		
		N		

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.4.1A
Demographics (Safety Population in the Stage 1 PK Phase)

Study Treatment: <Stage 1 & 2: NOT DOSED or TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: NOT DOSED or FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Age (yrs)	Sex	Child-Bearing Potential	Ethnicity	Race	Height (cm)	Weight (kg)	BMI (kg/m^2)	ECOG Performance Status
					Other: specify				

ECOG = Eastern Cooperative Oncology Group: 0=Fully active, able to carry on all pre-disease performance without restriction
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.1B Demographics (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.1C Demographics (Safety Population in the Extension Phase)

Listing 16.2.4.1D Demographics (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.4.2A
Medical History (Safety Population in the Stage 1 PK Phase)

PK Phase Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	System Organ Class Preferred Term Medical Condition or Event	Start Date	Ongoing at Study Start?	Stop Date

Includes only patients with major medical conditions.

Note: MedDRA version XX.X.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.2B Medical History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.2C Medical History (Safety Population in the Extension Phase)

Listing 16.2.4.2D Medical History (Safety Population in the Stage 3 PK Phase)

[Programming notes]

- For Stage 3, the latest available MedDRA version is to be used.

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Listing 16.2.4.3A
Prior Anti-Cancer Treatment (Safety Population in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Regimen Number	-Verbatim Term --Preferred Term	Reason for Administration	Best Response
			Other: specify	

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.3B Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.3C Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

Listing 16.2.4.3D Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.4.4A
Primary Cancer History (Safety Population in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Tumor Type	Date of First Diagnosis	Cancer Stage (Most Recent)	Number of Prior Lines of Therapy
	<Other: specify>			

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.4B Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.4C Primary Cancer History (Safety Population in the Extension Phase)

Listing 16.2.4.4D Primary Cancer History (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.4.5A
Prior/Concomitant Radiotherapy (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Site or Region	Date Started	Date Stopped	Total Grays	Prior/ Concomitant Flag

Note: Includes patients with prior or concomitant radiotherapy with respect to the PK Phase.
P=Prior (radiotherapy with start date earlier than the first dose date of study treatment)
C=Concomitant (radiotherapy occurring on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.4.5B Prior/Concomitant Radiotherapy (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.5C Prior/Concomitant Radiotherapy (Safety Population in the Extension Phase)

Listing 16.2.4.5D Prior/Concomitant Radiotherapy (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.1A
Prior and Concomitant Medications (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable
Patient Number = xxxxxx-xxxx

ATC/ Preferred Term/ Verbatim Term	Dose per Administration	Dose Unit	Frequency	Indication	Route of Administration	Start/ Stop Date	Ongoing	Prior/ Concomitant Flag	PK Dose 1	PK Dose 2
									YYYY-MM-DD	YYYY-MM-DD

Note: Includes patients with prior or concomitant medications taken during the PK Phase.
P=Prior medication only; C=Concomitant medication only; B=Both prior and concomitant medications.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.
- If ATC3 not available, use a footnote [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:
Listing 16.2.5.1B Prior and Concomitant Medications (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.1C Prior and Concomitant Medications (Safety Population in the Extension Phase)

Listing 16.2.5.1D Prior and Concomitant Medications (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.2A
Prior/Concomitant Procedures During PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Procedure Date	Rel Day [1]	Procedure	Results/Findings	AE/SAE?	Indication	Prior/Concomitant Flag
xxxxxx-xxxx							

[1] Relative to first dose during the PK Phase.
Note: Includes patients with prior or concomitant procedures during the PK Phase.
P=Prior (any procedure earlier than the first dose date of study treatment).
C=Concomitant (any procedure on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for
Listing 16.2.5.2B Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.2C Prior/Concomitant Procedures During the Extension Phase (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

- Footnote: [1] Relative to first dose during the Extension Phase.

Listing 16.2.5.2D Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.3A
Prior and Concomitant Transfusions (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Received Transfusion within 14 days of first dose or during study?	Type of Administration	Units	Transfusion Date	Rel Day [1]	Prior/ Concomitant Flag
		Other: specify				

[1] Relative to first dose during the PK Phase.
Note: Includes patients with prior or concomitant transfusions during the PK Phase.
P=Prior (any transfusion earlier than the first dose date of study treatment).
C=Concomitant (any transfusion on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.

Repeat for:
Listing 16.2.5.3B Prior and Concomitant Transfusions (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.3C Prior and Concomitant Transfusions (Safety Population in the Extension Phase)

Listing 16.2.5.3D Prior and Concomitant Transfusions (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.4A
Prior and Concomitant Growth Factors (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Received growth factor within 14 days of first dose or during study?	Type of Administration	Dose	Unit	Administration Date	Prior/ Concomitant Flag
		Other: specify		Other: specify		

Note: Includes patients with prior or concomitant growth factors during the PK Phase.
P=Prior (any growth factor earlier than the first dose date of study treatment).
C=Concomitant (any growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.

Repeat for:
Listing 16.2.5.4B Prior and Concomitant Growth Factors (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.4C Prior and Concomitant Growth Factors (Safety Population in the Extension Phase)

Listing 16.2.5.4D Prior and Concomitant Growth Factors (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.5.5A
Study Treatment (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET>

Patient Number	Visit	Formulation	Date:Time of Administration (Rel Day [1])	Full Dose Taken?	If No, how much consumed?	Reason for Change	Bottle Number	Fast 8 hrs prior to administration?	Vomit within 8 hours of dose?

[1] Relative to first dose during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.5.5B Study Treatment (Safety Population in the Stage 2 PK Phase)

[For Stage 2 PK Phase]

- Modify label for Vomiting Question, 'Vomit within specified time of dose'.
- Add column for Nausea Question, 'Nausea within specified time of dose'.

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Listing 16.2.5.5C
Study Treatment (Safety Population in the Extension Phase)

TREATMENT: <NIRAPARIB TABLET or NIRAPARIB CAPSULE>

Patient Number	Visit	Dose Prescribed (mg)	Start Date (Rel Day [1])/ Stop Date (Rel Day [1])	Was Full Dose Taken?	Action Taken	Reason for Modification	Bottle number Dispensed	Bottle Number Returned	Tablets Remaining
				No		Other <specify reason>			

[1] Relative to first dose during the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.5D
Study Treatment (Safety Population in the Stage 3 PK Phase)

Treatment Sequence: <FASTED/FED or <FED/FASTED>

Patient Number	Visit	Fasted or Fed State	Date:Time of Administration (Rel Day [1])	Bottle Number	Fast 10 hrs prior to administration?	Vomit within protocol specified hours from dose?	Fast for minimum of 4 hours post dose?

[1] Relative to first dose during the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.6B
Subsequent Anti-Cancer Therapy (Safety Population in the Stage 2 PK Phase)

Treatment Sequence: TABLET/CAPSULE or CAPSULE/TABLET

Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]	

[1] Relative to first dose during the PK Phase.
Note: Includes only patients with subsequent anti-cancer therapy recorded for patients who do not continue to Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.6C
Subsequent Anti-Cancer Therapy (Safety Population in the Extension Phase)

Treatment: <NIRAPARIB TABLET or NIRAPARIB CAPSULE>

Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]	

[1] Relative to first dose during the Extension Phase.
Note: Includes only patients with subsequent anti-cancer therapy recorded.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.5.6D
Meal Status (Safety Population in the Stage 3 PK Phase)

Treatment Sequence: <FASTED/FED or <FED/FASTED>

Patient Number	Visit	Meal Start Date	Meal Start Time	Meal End Time	% of Meal Consumed

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.6.1C
Investigator Assessment of Response (Safety Population in the Extension Phase)

TREATMENT: <NIRAPARIB TABLET or NIRAPARIB CAPSULE>

Patient Number	Visit	Date	Rel Day [1]	Overall Response					
				NE: <Reason>					

[1] Relative to first dose during the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

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Listing 16.2.7.1A
Adverse Events (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Dosing Period/ Niraparib Treatment	Adverse Event MedDRA Preferred Term System Organ Class	Start Date:Time (Rel Day [1]) End Date (Rel Day [1])	TEAE?	SAE/ Reason [2]	Severity	Action Taken on Study Treatment	Other Action Taken	Relation-ship	Outcome
	Period 1/ Capsule	XXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved
	Period 2/ Tablet	XXXXXXXXXXXXXXXX [P]XXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x] yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/ Resolved
	PK Safety FU									

[1] Relative to the date of first dose in PK Phase.
[2] Reason for SAE: 1 = Result in death; 2 = Life threatening; 3 = Result in persistent or significant disability/incapacity; 4 = Requires or prolongs hospitalization; 5 = Congenital abnormality/birth defect; 6 = Other medically important event.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.7.1B Adverse Events (Safety Population in the Stage 2 PK Phase)

[Add time for start date]
Listing 16.2.7.1C Adverse Events (Safety Population in the Extension Phase)

Listing 16.2.7.1D Adverse Events (Safety Population in the Stage 3 PK Phase)

[Programming Notes]

- Stage 3: Treatment Sequence will be Fasted/Fed and Fed/Fasted.
- Stage 3: Column 2: Dosing Period/Treatment – Treatment should be Niraparib FASTED or Niraparib FED.
- Extension Phase: Do not need column for Dosing Period/Treatment.
- Extension Phase: Do not need time with start/stop dates.
- Extension Phase: Footnote: [1] Relative to first dose during the Extension Phase.
- Extension Phase: Add column for Dose at Onset of AE.

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Listing 16.2.8.1.1A
Hematology Results in the PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Parameter (unit)	Visit	Rel Day [1]	Sample date/time	Result	Change from baseline	Normal range	Out of range flag	Clinically significant flag
					xx.x	xx.x	xx.x – xx.x		

[1] Relative to the date of first dose in the PK Phase.
Scheduled and unscheduled visits through the extension screening phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the extension screening phase are not included.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]:

- If required for readability, move 'Patient Number' into Header row after 'Treatment Sequence'.

Repeat for:
Listing 16.2.8.1.1B Hematology Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.1.1C Hematology Results (Safety Population in the Extension Phase)

Listing 16.2.8.1.1D Hematology Results Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

Listing 16.2.8.1.2A Chemistry Results (Safety Population in the Stage 1 PK Phase)

Listing 16.2.8.1.2B Chemistry Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.1.2C Chemistry Results (Safety Population in the Extension Phase)

Listing 16.2.8.1.2D Chemistry Results Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

Listing 16.2.8.1.3A Urinalysis Results (Safety Population in the Stage 1 PK Phase)

Listing 16.2.8.1.3B Urinalysis Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.1.3C Urinalysis Results (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

- Footnote: [1] Relative to first dose during the Extension Phase.

Listing 16.2.8.1.3D Urinalysis Results Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.8.1.4C

Liver Function Tests – Potential Hy's Law Cases (Safety Population in the Extension Phase)

TREATMENT: <NIRAPARIB TABLET or NIRAPARIB CAPSULE>

Patient Number	Visit	Sample Collection Date	Day [1]	Laboratory Analyte (result/xULN)			
				ALT (U/L)	AST (U/L)	Total Bilirubin (umol/L)	ALP (U/L)
		DDMMMYYYY		150/3.3	100/2.7	40/2.3	100/0.7

ALP=alkaline phosphatase. ALT=alanine aminotransferase. AST=aspartate aminotransferase. ULN=upper limit of normal.

[1] Relative to first dose during the Extension Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
Include all visits for any Patients with ALT or AST >3×ULN with bilirubin >2×ULN and ALP <2×ULN at any time in Extension Phase.

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Listing 16.2.8.2A
Vital Signs (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Visit	Assessment Date	Rel Day [1]	Height (cm)	Weight (kg)	Temperature (°C)	Pulse (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)

[1] Relative to the date of first dose in the PK Phase.
Data is listed only when the vital sign assessment was performed.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.2B Vital Signs (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.2C Vital Signs (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

- Footnote: [1] Relative to first dose during the Extension Phase

Listing 16.2.8.2D Vital Signs Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.8.3A
ECG Results (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Visit	Date	Rel Day [1]	ECG Interpretation

[1] Relative to the date of first dose in the PK Phase.
NCS = Not Clinically Significant, CS = Clinically Significant.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.3B ECG Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.3C ECG Results (Safety Population in the Extension Phase)

Listing 16.2.8.3D ECG Results (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase Tables]:

- Footnote: [1] Relative to first dose during the Extension Phase

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Listing 16.2.8.4A
ECOG Performance Status (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Visit	Assessment Date	Rel Day [1]	Performance Status

[1] Relative to the date of first dose in the PK Phase. Data is listed only when the ECOG Performance Status assessment was performed.
ECOG = Eastern Cooperative Oncology Group:
0=Fully active, able to carry on all pre-disease performance without restriction
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.4B ECOG Performance Status (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.4C ECOG Performance Status (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

- Footnote: [1] Relative to first dose during the Extension Phase

Listing 16.2.8.4D ECOG Performance Status Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.8.5A
Baseline Physical Examination Findings (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Visit	Date Performed	Rel Day [1]	Body System	Status	Abnormality Description

[1] Relative to the date of first dose in the PK Phase.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.5B Baseline Physical Examination Findings (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.5C Baseline Physical Examination Findings (Safety Population in the Extension Phase)

Listing 16.2.8.5D Baseline Physical Examination Findings (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase Tables]:

- Footnote: [1] Relative to first dose during the Extension Phase.

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Listing 16.2.8.6A
Pregnancy Test (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Visit	Was Pregnancy Test Performed?	Date of Test	Rel Day [1]	Type	Result

[1] Relative to the date of first dose in the PK Phase.
Scheduled and unscheduled visits through the Extension Screening Phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the Extension Screening Phase are not included.

Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:
Listing 16.2.8.6B Pregnancy Test (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.6C Pregnancy Test (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

- Footnote: [1] Relative to first dose during the Extension Phase

Listing 16.2.8.6D Pregnancy Test (Safety Population in the Stage 3 PK Phase)

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Listing 16.2.9.2D
Listing of COVID-19 Assessments and Symptom Assessments for Patients with COVID-19 Adverse Events
(Safety Population in the Stage 3 PK Phase)

Treatment Sequence: <Stage 3: Period 1: FASTED or FED; Period 2: FASTED or FED>

Patient Number	Treatment Period (State)	Adverse Event	AE Start Date	COVID-19 Case Diagnosis [1]	COVID-19 Test Performed/ Test Date/ Results	Assessments and Symptom Assessments	Result
xxxx	1 (FASTED)	Coronavirus infection	2020-04-16	Suspected	Yes/ 2020-04-17/ Indeterminate	Travel to Location with Community Transmission [2]	No
						Visited Health Care Facility [2]	No
						Contact with COVID-19 Confirmed/Probable Case [2]	Unknown
						Medication Taken to Treat COVID-19	Yes
						Fever	Yes
						Cough	Yes
						Shortness of Breath	Yes
						Sore Throat	No
						Loss of Appetite	No
						Nausea	No
						Vomiting	No
						Diarrhea	No
						Abdominal Pain	No
						Fatigue	No
						Loss of Smell	No
						Loss of Taste	No
						Asymptomatic	No
						Home Quarantined/Isolated	Unknown
	2 (FED)					...	

AE=Adverse event.
[1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.
[2] Within 14 days prior to symptom onset.

Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]
The COVID-19 AE terms include: Asymptomatic COVID-19, Coronavirus infection, COVID-19, COVID-19 pneumonia, Suspected COVID-19.
Note that the number of COVID-19 AE terms may change.