STATISTICAL ANALYSIS PLAN

Phase 1b Dose-Finding Study of Niraparib, TSR-022, Bevacizumab, and Platinum-Based Doublet Chemotherapy in Combination With TSR-042 in Patients With Advanced or Metastatic Cancer

Protocol Number:	3000-01-002
Protocol Version and Date:	v3.0 August 15, 2018 v2.0 November 15, 2017 (Amendment 1) v1.0 July 07, 2017 (Original)
Study Drug Name:	Niraparib, TSR-042, TSR-022, carboplatin-paclitaxel, carboplatin-pemetrexed, carboplatin–nab-paclitaxel, and bevacizumab
Phase:	Phase 1b
Sponsor:	TESARO, Inc.
Analysis Plan Date:	18 SEP, 2020
Analysis Plan Version:	Version 1.0

SPONSOR SIGNATURE PAGE

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Sponsor:	TESARO, Inc. 1000 Winter Street Waltham MA 02451

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.

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ABBREVIATIONS

Abbreviation	Explanation
ADA	Anti-Drug Antibody
AE	Adverse Event
AESI	Adverse Event of Special Interest
ATC	Anatomical Therapeutic Chemical
AUC	Area Under the Plasma or Serum Concentration-Time Curve
BE	Biomarker Evaluation
BLQQ	Below the Limit of Quantitation
BMI	Body Mass Index
BOR	Best Overall Response
BRCA	Breast Cancer Gene
BRCAmut	BRCA Mutation
CBC	Complete Blood Count
CI	Confidence Interval
CL	Clearance After Intravenous Administration
CL/F	Clearance After Oral Administration
C_{max}	Maximum Observed Plasma or Serum Concentration
C_{min}	Minimum Observed Plasma or Serum Concentration
CR	Complete Response
CRF	Case Report Form
CTCAE	Common Terminology Criteria for Adverse Events
Ctrough	Trough plasma concentration
CV	Coefficient of Variation
DCR	Disease Control Rate
DLT	Dose Limiting Toxicity
DOR	Duration of Response
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronical Case Report Form
EOT	End of Treatment

FFPE	Formalin-Fixed Paraffin Embedded
FT3	Free Triiodothyronine
FT4	Free Thyroxine
gBRCAmut	Germline BRCA Mutation
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
ID	Identification
KM	Kaplan-Meier
Max	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
NE	Not Evaluated
NSCLC	Non-Small Cell Lung Cancer
ORR	Objective Response Rate
PD	Progressive Disease
PD-L1	Programmed Death-Ligand 1
PDV	Protocol Deviation
PFS	Progression-Free Survival
PK	Pharmacokinetic(S)
PO	Orally
PR	Partial Response
PT	Preferred Term
Q3W	Every 3 Weeks
Q6W	Every 6 Weeks
QTcF	Corrected QT Interval Calculated Using Fridericia's Formula
RECIST v1.1	Response Evaluation Criteria in Solid Tumors Version 1.1
Rel	Relative Study
RP2D	Recommended Phase 2 Dose
SAE	Serious Adverse Event
SD	Stable Disease
SOC	System Organ Class
STD	Standard Deviation

T3	Triiodothyronine
TEAE	Treatment-Emergent Adverse Event
TSH	Thyroid-Stimulating Hormone
uBOR	Unconfirmed Best Overall Response
uDCR	Unconfirmed Disease Control Rate
uDOR	Unconfirmed Duration of Response
uORR	Unconfirmed Objective Response Rate
Vz	Volume of Distribution After Intravenous Administration
Vz/F	Volume of Distribution After Oral Administration
WHO	World Health Organization
WHO-DD	World Health Organization Drug Dictionary

1 INTRODUCTION

This statistical analysis plan is designed to outline the statistical methods in evaluating the safety and preliminary efficacy of niraparib or niraparib/bevacizumab in combination with TSR-042 treatment and confirming the safety and tolerability of carboplatin-paclitaxel, carboplatin-paclitaxel/bevacizumab, carboplatin-pemetrexed and TSR-022/carboplatin-pemetrexed in combination with TSR-042 treatment in patients with advanced or metastatic cancer for TESARO study protocol 3000-01-002. Parts G, H and I specified in the study design were not initiated and therefore not included in this SAP.

This document has been prepared based on Study Protocol version 3.0 dated 15 August 2018 and Case Report Form (CRF) dated 12 JUN 2020. Details will be described in this analysis plan to ensure that the data listings, summary tables and figures which will be produced, and the statistical methodologies that will be used, are complete and appropriate to allow valid conclusions regarding the study objectives.

2 STUDY DESIGN OVERVIEW

2.1 Overall Study Design

This is a multicenter, open-label, 9-part Phase 1b study evaluating the safety and preliminary efficacy of niraparib or niraparib/bevacizumab in combination with TSR-042 treatment and confirming the safety and tolerability of carboplatin-paclitaxel, carboplatin-paclitaxel/bevacizumab, carboplatin-pemetrexed, TSR-022/carboplatin-pemetrexed, carboplatin-nab-paclitaxel, TSR-022/carboplatin-nab-paclitaxel, and TSR-022/carboplatin-paclitaxel in combination with TSR-042 treatment in patients with advanced or metastatic cancer.

- Part A (dose finding—TSR-042 and niraparib combination treatment): all comers, defined as patients with previously treated advanced or metastatic cancer
- Part B (safety and tolerability evaluation—TSR-042 and carboplatin-paclitaxel combination treatment): patients with advanced or metastatic cancer for which treatment with carboplatin and paclitaxel is indicated (e.g., including, but not limited to, non-small cell lung cancer [NSCLC], ovarian cancer, and cervical cancer)
- Part C (dose finding—TSR-042, niraparib and bevacizumab combination treatment): all comers, defined as patients with previously treated advanced or metastatic cancer
- Part D (safety and tolerability evaluation—TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment): in patients in whom carboplatin-paclitaxel and bevacizumab is considered a reasonable therapy
- Part E (safety and tolerability evaluation—TSR-042 and carboplatin-pemetrexed combination treatment): as first-line treatment in patients with advanced or metastatic non-squamous NSCLC
- Part F (safety and tolerability evaluation—TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment): as first-line treatment in patients with advanced or metastatic non-squamous NSCLC
- Part G (safety and tolerability evaluation—TSR-042 and carboplatin–nab-paclitaxel combination treatment): as first-line treatment in patients with advanced or metastatic NSCLC
- Part H (safety and tolerability evaluation—TSR-042, TSR-022, and carboplatin–nab-paclitaxel combination treatment): as first-line treatment in patients with advanced or metastatic NSCLC
- Part I (safety and tolerability evaluation—TSR-042, TSR-022, and carboplatin-paclitaxel combination treatment): as first-line treatment in patients with advanced or metastatic NSCLC

Part A will be a dose-finding evaluation conducted in all comers (12 to 24 patients) to determine the RP2D of niraparib in combination with TSR-042.

Part B will evaluate the safety and tolerability of TSR-042 and carboplatin-paclitaxel combination treatment in approximately 12 patients with advanced or metastatic cancer for which carboplatin-paclitaxel is indicated.

Part C will be a dose-finding evaluation conducted in all comers (6 to 24 patients) to determine the RP2D of niraparib and bevacizumab in combination with TSR-042.

Part D will evaluate the safety and tolerability of TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment in 6 to 12 patients in whom carboplatin-paclitaxel and bevacizumab combination treatment is considered a reasonable therapy.

Part E will evaluate the safety and tolerability of TSR-042 and carboplatin-pemetrexed combination treatment as first-line treatment in 6 to 12 patients with advanced or metastatic non-squamous NSCLC.

Part F will evaluate the safety and tolerability of TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment as first-line treatment in 6 to 24 patients with advanced or metastatic non-squamous NSCLC.

Part G will evaluate the safety and tolerability of TSR-042 and carboplatin – nab-paclitaxel combination treatment as first-line treatment in 6 to 12 patients with advanced or metastatic NSCLC.

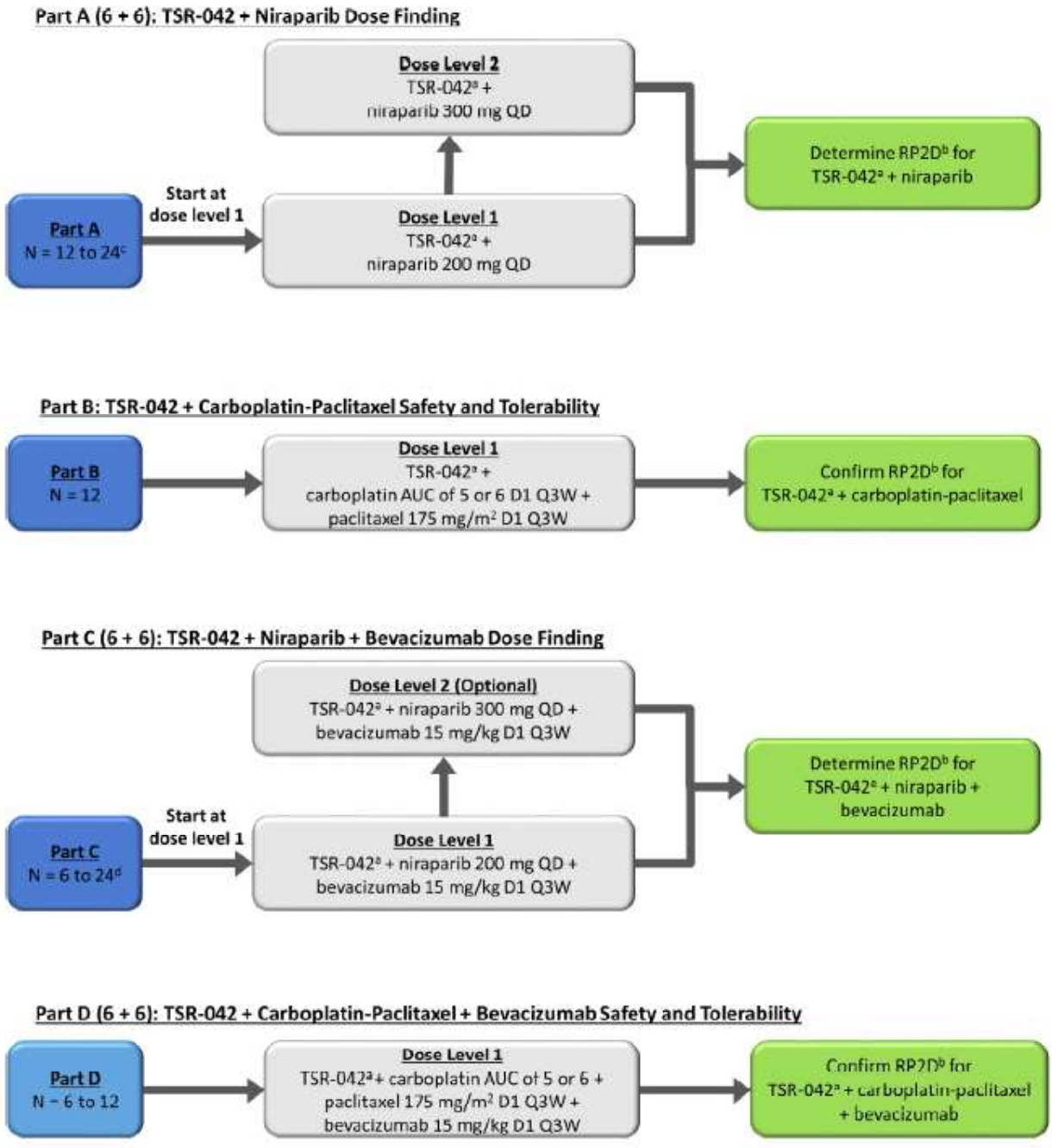
Part H will evaluate the safety and tolerability of TSR-042, TSR-022, and carboplatin – nab-paclitaxel combination treatment as first-line treatment in 6 to 24 patients with advanced or metastatic NSCLC.

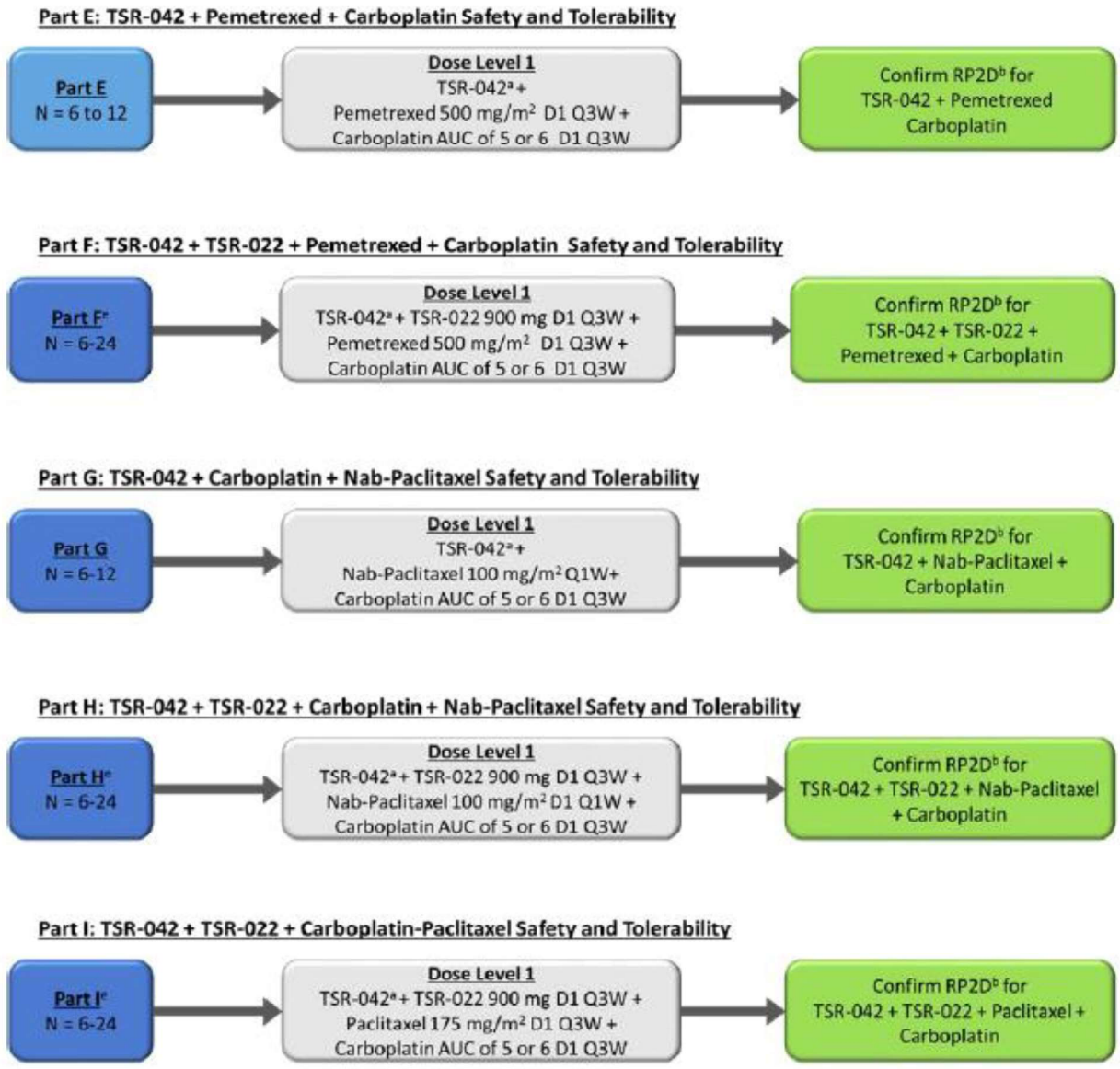
Part I will evaluate the safety and tolerability of TSR-042, TSR-022, and carboplatin-paclitaxel combination treatment as first-line treatment in 6 to 24 patients with advanced or metastatic NSCLC

Enrollment of patients into Parts A, B, D, E, G, and I will occur concurrently. Part C will be initiated after dose level 1 (niraparib 200 mg) in Part A is determined to be safe. Part F will be initiated after TSR-042 and carboplatin-pemetrexed combination treatment in Part E is determined to be safe. Part H will be initiated after TSR-042 and carboplatin–nab-paclitaxel combination treatment in Part G is determined to be safe.

The study design of nine parts is presented graphically in Figure 1. The study schedule of events for each part are be found in Table 17-34 in the protocol.

Figure 1: Study Design





Abbreviations: AE = adverse event; AUC = area under the plasma or serum concentration-time curve; D1 = Day 1; D21 = Day 21; DLT = dose-limiting toxicity; PK = pharmacokinetics; Q1W = every week; Q3W = every 3 weeks; Q6W = every 6 weeks; RP2D = recommended Phase 2 dose.

a In addition to receiving niraparib (Part A), carboplatin-paclitaxel (Part B), niraparib and bevacizumab (Part C), carboplatin-paclitaxel and bevacizumab (Part D), carboplatin-pemetrexed (Part E), carboplatin-pemetrexed and TSR-022 (Part F), carboplatin–nab-paclitaxel (Part G), TSR-022 and carboplatin–nab-paclitaxel (Part H), and TSR-022 and carboplatin-paclitaxel (Part I) at the specified regimen, all patients will be administered TSR-042 at 500 mg on Day 1 of every cycle (Q3W) for 4 cycles. Beginning on Day 1 of Cycle 5, TSR-042 will be administered to patients in Parts A, B, C, and D at 1,000 mg on Day 1 of every other cycle (Q6W) until the patient discontinues study treatment. Patients in Parts E, F, G, H, and I will continue to receive 500 mg on Day 1 of every cycle (Q3W) throughout the study.

b The RP2D for TSR-042 and niraparib combination treatment (Part A); TSR-042 and carboplatin-paclitaxel combination treatment (Part B); TSR-042, niraparib, and bevacizumab combination treatment (Part C); TSR-042, carboplatin-paclitaxel, and bevacizumab combination treatment (Part D); TSR-042 and carboplatin-pemetrexed (Part E); TSR-042, carboplatin-pemetrexed, and TSR-022 (Part F); TSR-042 and carboplatin–nab-paclitaxel (Part G); TSR-042, TSR-022, and carboplatin–

nab-paclitaxel (Part H); and TSR-042, TSR-022, and carboplatinpaclitaxel (Part I) will be determined or confirmed based on an evaluation of multiple endpoints, which may include the DLT rate in first and subsequent cycles of combination treatment, the rate of dose modifications for non-DLT AEs, the ability to manage toxicities, PK, niraparib dose intensity, and signs of clinical efficacy.

c 12 to 24 patients will be enrolled in Part A to determine the RP2D for TSR-042 and niraparib combination treatment.

d Initially, dose level 1 in Part C will enroll 6 to 12 patients to determine the RP2D for TSR-042, niraparib, and bevacizumab combination treatment. Dose level 2 is optional.

e 900 mg of TSR-022 is the highest dose tested in dose escalation in combination with TSR-042 that provides maximal pharmacodynamic effect; this dose may be lowered to dose level -1 (300 mg) if needed. Based on available safety information, the Sponsor may decide to test additional dose levels.

2.2 Sample Size

- Part A: approximately 12 to 24 patients will be enrolled.
- Part B: approximately 12 patients will be enrolled.
- Part C: approximately 6 to 24 patients may be enrolled.
- Part D: approximately 6 to 12 patients will be enrolled.
- Part E: approximately 6 to 12 patients will be enrolled.
- Part F: approximately 6 to 24 patients will be enrolled.
- Part G: approximately 6 to 12 patients will be enrolled.
- Part H: approximately 6 to 24 patients will be enrolled.
- Part I: approximately 6 to 24 patients will be enrolled.

2.3 Randomization and Blinding

This is an open-label Phase 1b study. Patients will not be randomized to study treatment.

3 STUDY OBJECTIVES

3.1 Primary Objectives

3.1.1 Primary Objectives for Part A

- To evaluate DLTs of TSR-042 and niraparib combination treatment during the first cycle of treatment in patients with advanced or metastatic cancer and to establish a RP2D
- To evaluate the safety and tolerability of TSR-042 and niraparib combination treatment

3.1.2 Primary Objectives for Part B

- To evaluate DLTs of TSR-042 and carboplatin-paclitaxel combination treatment during the first cycle of treatment in patients with advanced or metastatic cancer and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042 and carboplatin-paclitaxel combination treatment

3.1.3 Primary Objectives for Part C

- To evaluate DLTs of TSR-042, niraparib, and bevacizumab combination treatment during the first cycle of treatment in patients with advanced or metastatic cancer and to establish an RP2D
- To evaluate the safety and tolerability of TSR-042, niraparib, and bevacizumab combination treatment

3.1.4 Primary Objectives for Part D

- To evaluate DLTs of TSR-042, carboplatin-paclitaxel, and bevacizumab combination treatment during the first cycle of treatment in patients in whom carboplatin-paclitaxel and bevacizumab combination treatment is a reasonable therapy, and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

3.1.5 Primary Objectives for Part E

- To evaluate DLTs of TSR-042 and carboplatin-pemetrexed combination treatment during the first cycle of treatment, as first-line treatment in patients with advanced or metastatic non-squamous NSCLC, and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042 and carboplatin-pemetrexed combination treatment

3.1.6 Primary Objectives for Part F

- To evaluate DLTs of TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment during the first cycle of treatment, as first-line treatment in patients with advanced or metastatic non-squamous NSCLC, and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment

3.1.7 Primary Objectives for Part G

- To evaluate DLTs of TSR-042 and carboplatin – nab-paclitaxel combination treatment during the first cycle of treatment, as first-line treatment in patients with advanced or metastatic NSCLC, and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042 and carboplatin – nab-paclitaxel combination treatment

3.1.8 Primary Objectives for Part H

- To evaluate DLTs of TSR-042, TSR-022, and carboplatin – nab-paclitaxel combination treatment during the first cycle of treatment, as first-line treatment in patients with advanced or metastatic NSCLC, and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042, TSR-022, and carboplatin – nab-paclitaxel combination treatment

3.1.9 Primary Objectives for Part I

- To evaluate DLTs of TSR-042, TSR-022, and carboplatin-paclitaxel combination treatment during the first cycle of treatment, as first-line treatment in patients with advanced or metastatic NSCLC, and to confirm an RP2D
- To evaluate the safety and tolerability of TSR-042, TSR-022, and carboplatinpaclitaxel combination treatment

3.2 Secondary Objectives

3.2.1 Secondary Objectives for Part A

- To evaluate measures of clinical benefit as assessed by the Investigators, including objective response rate (ORR), duration of response (DOR), disease control rate (DCR), and PFS by Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)
- To evaluate the PK of niraparib, its major metabolite M1, and TSR-042 during TSR-042 and niraparib combination treatment
- To evaluate ADAs of TSR-042 during TSR-042 and niraparib combination treatment

3.2.2 Secondary Objectives for Part B

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 during TSR-042 and carboplatin-paclitaxel combination treatment
- To evaluate ADAs of TSR-042 during TSR-042 and carboplatin-paclitaxel combination treatment

3.2.3 Secondary Objectives for Part C

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of niraparib, its major metabolite M1, and TSR-042 during TSR-042, niraparib and bevacizumab combination treatment
- To evaluate ADAs of TSR-042 during TSR-042, niraparib and bevacizumab combination treatment

3.2.4 Secondary Objectives for Part D

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 during TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
- To evaluate ADAs of TSR-042 during TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

3.2.5 Secondary Objectives for Part E

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 during TSR-042 and carboplatin-pemetrexed combination treatment

- To evaluate ADAs of TSR-042 during TSR-042 and carboplatin-pemetrexed combination treatment

3.2.6 Secondary Objectives for Part F

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 and TSR-022 during TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment
- To evaluate ADAs of TSR-042 and TSR-022 during TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment

3.2.7 Secondary Objectives for Part G

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 during TSR-042 and carboplatin – nab-paclitaxel combination treatment
- To evaluate ADAs of TSR-042 during TSR-042 and carboplatin – nab-paclitaxel combination treatment

3.2.8 Secondary Objectives for Part H

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 and TSR-022 during TSR-042, TSR-022, and carboplatin – nab-paclitaxel combination treatment
- To evaluate ADAs of TSR-042 and TSR-022 during TSR-042, TSR-022, and carboplatin – nab-paclitaxel combination treatment

3.2.9 Secondary Objectives for Part I

- To evaluate measures of clinical benefit as assessed by the Investigators, including ORR, DOR, DCR, and PFS by RECIST v1.1
- To evaluate the PK of TSR-042 and TSR-022 during TSR-042, TSR-022, and carboplatin-paclitaxel combination treatment
- To evaluate ADAs of TSR-042 and TSR-022 during TSR-042, TSR-022, and carboplatin-paclitaxel combination treatment

3.3 Exploratory Objectives

3.3.1 Exploratory Objectives for Part A

- To explore biomarkers that may be predictive of benefit from TSR-042 and niraparib combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042 and niraparib combination treatment and correlate with clinical benefit

3.3.2 Exploratory Objectives for Part B

- To explore biomarkers that may be predictive of benefit from TSR-042 and carboplatin-paclitaxel combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042 and carboplatin-paclitaxel combination treatment and correlate with clinical benefit

3.3.3 Exploratory Objectives for Part C

- To explore biomarkers that may be predictive of benefit from TSR-042, niraparib and bevacizumab combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042, niraparib and bevacizumab combination treatment and correlate with clinical benefit

3.3.4 Exploratory Objectives for Part D

- To explore biomarkers that may be predictive of benefit from TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment and correlate with clinical benefit

3.3.5 Exploratory Objectives for Part E

- To explore biomarkers that may be predictive of benefit from TSR-042 and carboplatin-pemetrexed combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042 and carboplatin-pemetrexed combination treatment and correlate with clinical benefit

3.3.6 Exploratory Objectives for Part F

- To explore biomarkers that may be predictive of benefit from TSR-042, TSR-022, and carboplatin-pemetrexed combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042, TSR-022, and carboplatin-pemetrexed treatment and correlate with clinical benefit

3.3.7 Exploratory Objectives for Part G

- To explore biomarkers that may be predictive of benefit from TSR-042 and carboplatin-nab-paclitaxel combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042 and carboplatin-nab-paclitaxel combination treatment and correlate with clinical benefit

3.3.8 Exploratory Objectives for Part H

- To explore biomarkers that may be predictive of benefit from TSR-042, TSR-022, and carboplatin-nab-paclitaxel combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042, TSR-022, and carboplatin-nab-paclitaxel treatment and correlate with clinical benefit

3.3.9 Exploratory Objectives for Part I

- To explore biomarkers that may be predictive of benefit from TSR-042, TSR-022, and carboplatin-paclitaxel combination treatment based on the pretreatment biomarker profile
- To explore changes in biomarkers (e.g., immune cells and immune proteins) in the blood following TSR-042, TSR-022, and carboplatin-paclitaxel treatment and correlate with clinical benefit

4 STUDY ENDPOINTS AND EVALUATIONS

4.1 Safety Endpoints and Evaluations

The safety evaluations include:

- Dose-limiting toxicities (DLTs)
- Treatment emergent adverse events (TEAEs)
- Adverse Events of Special Interest (AESI)
- Clinical laboratory assessments
  - Hematology (CBC)
  - Serum chemistry
  - Coagulation factors
  - Serum/urine pregnancy testing
  - Urinalysis
  - Thyroid function including TSH, T3 or FT3, and FT4 or equivalent
- Physical examination findings
- Vital signs including height (at screening only) and weight
- ECOG performance status
- ECG
- Concomitant medications

4.2 Efficacy Endpoints and Evaluations

For each part, tumor response to treatment will be evaluated according to RECIST v1.1 per Investigation assessment.

The efficacy endpoints include:

- ORR (confirmed)
- DOR (confirmed)
- DCR (confirmed)
- PFS

The definition of ORR, DOR, DCR and PFS is described in Section 8.5.

4.3 Pharmacokinetics Endpoints and Evaluations

Plasma and serum samples for PK determination will be collected from all patients. For Part A and Part C, plasma will be analyzed using liquid chromatography with mass spectrometry detection for niraparib and its major metabolite M1. The serum will be analyzed for TSR-042 using enzyme-linked immunosorbent assay (ELISA). For Part B, Part D, and Part E to Part I serum samples will be analyzed for TSR-042 and TSR-022 using ELISA. The plasma samples will be analyzed for

carboplatin using inductively coupled plasma mass spectrometry, and for paclitaxel and pemetrexed using liquid chromatography tandem-mass spectrometry, if appropriate.

The plasma and serum PK parameters based on concentration-time data will be evaluated by non-compartmental analysis using WinNonlin version 6.2.1 or higher.

PK evaluations include:

- Plasma or serum concentrations
- PK parameters listed in Table 1 (but not limited to)

Table 1: PK Parameters

PK Parameter	Definition
AUC	Area under the plasma or serum concentration
AUCss	Area under the plasma or serum concentration at steady state
Cmin	Minimum observed plasma or serum concentration
Cmin, ss	Minimum observed plasma or serum concentration at steady state
Cmax	Maximum observed plasma or serum concentration
Cmax, ss	Maximum observed plasma or serum concentration at steady state
CL/F	Clearance after oral administration
CL	Clearance after IV administration
Vz/F	Volume of distribution after oral administration
Vz	Volume of distribution after IV administration

4.4 Immunogenicity Endpoints and Evaluations

Serum samples for the determination of TSR-042 and TRS-022 ADAs will be the same blood collections as those for the TSR-042 and TSR-022 PK assessments. ADAs will be analyzed in a tiered approach using electrochemiluminescence (i.e., screening, confirmation, titer, and neutralizing antibody assay). Minimally, ADAs will be analyzed in predose samples from all cycles collected; additional samples for ADA determination will be collected upon treatment discontinuation at a post-treatment and safety follow-up visit (i.e., approximately 90 days after the last dose of TSR-042 and TSR-022).

4.5 Biomarker Evaluations

FFPE tumor archival tissue samples (mandatory (if available) for Parts F, H and I, optional for Parts A, B, C, D, E and G) and blood samples will be assessed for biomarkers that may correlate with clinical benefits from study treatments include, but not limited to,

- Germline *BRCA* mutation (g*BRCA*mut)
- Homologous recombination deficiency (HRD) status
- Phenotype and molecular profile of circulating immune cells
- Expression of PD-L1 on tumor cells
- Circulating cytokines or chemokines prior to and during treatment

4.6 Other Evaluations

- Demographics and baseline characteristics
- Medical history including prior blood disorders history
- Prior anticancer treatment
  - Prior anticancer treatment for primary cancer
  - Previous radiotherapy
  - Previous cancer related surgery
- Previous and concomitant medications/procedures
  - Prior non-anticancer medications
  - Concomitant medications
  - Pemetrexed supplemental medications
  - Concomitant procedures
  - Prior and concomitant transfusions and growth factors
- HBsAg and HCV ribonucleic acid testing at baseline
- Subsequent anticancer treatment for primary cancer

5 DEFINITIONS AND CONVENTIONS FOR DATA HANDLING

5.1 Definition of Baseline

For all evaluations unless otherwise noted, baseline is defined as the most recent non-missing measurement prior to or on the first administration of study drug. Baseline can be the same date as first dose, given the measurement is expected prior to first dose when only date information is available.

5.2 First Dose Date of Study Treatment

The first dose date of study treatment is defined as the earliest dose date of study drugs in the treatment regimen.

5.3 Definition of Treatment Period

Treatment period is defined as the (Minimum (start date of new anti-cancer therapy, last dose of study treatment + 90) – First Dose date of study treatment)+1 .

5.4 Definition of Relative Study Days

Unless otherwise noted, relative study days (Rel Days) of an evaluation are defined as number of days relative to the first dose date of study drug which is designated as Day 1, and the preceding day is Day -1, the day before that is Day -2, etc.

Relative study days are calculated as following:

- If an evaluation date is before first dose date of study drug, then

  Relative study days = first dose date of study drug - an evaluation date

- If an evaluation date is on or after first dose date of study drug, then

  Relative study days = first dose date of study drug - an evaluation date + 1

Relative study days take negative values if evaluation date occurs prior to first dose date and take positive values if evaluation date occurs on or after first dose date of study drug.

5.5 Analysis Visit Window

For safety parameters as described in Section 4.1 excluding clinical laboratory data, measurements collected from unscheduled visits will not be included in the by-visit summary tables but will be included in the listings. Early termination visits for safety measurements will not be mapped to any scheduled post-baseline visit but will be used as the last assessment during treatment period.

5.6 Safety Data Handling

For all safety data, only observed data will be used for analyses, and missing data will not be imputed.

5.6.1 Handling of Unscheduled ECG Measurements

Unscheduled ECG measurements will not be used in computing the descriptive statistics for change from baseline at each post-baseline time point. However, they will be used in assessing the minimum and maximum of all visits and in the analysis of notable post-baseline abnormal ECG results.

5.6.2 Handling of Partial Dates for AEs

When determining the treatment emergent AE, 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 dose date. In this case, the onset date will be assumed to be the first date of 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 study treatment. In this case, the event onset will be coded to the day of treatment to conservatively report the event as treatment-emergent.
- A missing onset date will be coded as the day of 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.
- 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.

5.6.3 Handling of Partial Dates for Medications

Incomplete prior/concomitant medication dates will be imputed as follows:

Start Date:

- If the medication start date is missing completely, then the medication start date will be imputed as the first dose date of study treatment.
- If imputed start date greater than stop date and prior to first dose, then will be imputed as stop date
- If the day of medication start date is missing, but the month and year are equal to the first dose date of study treatment, then the medication start date will be replaced by the first dose date of study treatment.
- If both the day and month of medication start date are missing but the start year is equal to the first dose date of study treatment, then the medication date will be replaced by the first dose date of study treatment.

- In all other cases the missing medication day or missing medication month will be replaced by 1.

Stop Date:

- Incomplete stop date will be replaced by the last day of the month (if day is missing only), if not resulting in a date later than the date of patient's death. In the latter case the date of death will be used to impute the incomplete stop date.
- If 'day' and 'month' are missing, and 'year' is not missing, then impute as December 31st (or date of study discontinuation/completion if earlier than December 31st).

In all other cases the incomplete medication stop date will not be imputed.

5.6.4 Handling of Partial Dates for Disease History

Incomplete dates for disease history (e.g. initial diagnosis date; date of documented, locally advanced, metastatic disease diagnosis; date of treatment initiation) will be imputed as follows:

- If the day is missing, it will be imputed to the 1st day of the month.
- If both day and month are missing, the month and day will be imputed as January 1st. If the date is completely missing, no imputation will be performed.

5.6.5 Handling of Partial Dates for Progression in Prior Treatment

Incomplete dates for progression in prior treatment will be imputed as follows:

1. If progression date is partial missing day only, use imputed progression date (imputing missing day = 15th)

2. If progression date is partial missing both day and month, do the following:

a. if next regimen start date is not missing/partial AND year (next regimen start date) = year of progression, progression date= next regimen start date

b. if next regimen start date is not missing/partial, and year (next regimen start date) > year of progression, progression date= 15 Dec (year of progression)

3. Else if progression date = missing and next regimen start date is not missing/partial, PD date= Next regimen start date

4. Else, progression date = current regimen end date

6 PLANNED ANALYSIS

6.1 Changes from Planned Analyses in the Protocol

In order to capture immune-related adverse events that occur long after the completion of immunotherapy treatment, analyses of AEs will be performed for those events that are considered treatment-emergent where treatment-emergent is defined as any AE with onset beginning at the day of first administration of study treatment throughout the treatment period until 90 days after the last dose of study treatment, instead of 30 days after the last dose of study treatment as specified in the protocol.

Parts G, H and I as defined in the protocol is not included in the analysis as these parts were not initiated.

Data from parts E and F will be only listed due to small sample size.

6.2 Interim Analysis

A 2-stage 6 + 6 scheme is used for dose finding in Part A and Part C. Part C will be initiated after dose level 1 (niraparib 200 mg) if Part A is determined to be safe. Part F will be initiated after TSR-042 and carboplatin-pemetrexed combination treatment in Part E is determined to be safe. Part H will be initiated after TSR-042 and carboplatin-nab-paclitaxel combination treatment in Part G is determined to be safe.

So, interim safety will be evaluated after completion of dose level 1 for Part A, and then for Part C. Safety will also be evaluated after completion of Part E and G.

Similarly, preliminary safety will be evaluated after completion of dose level 2 in Part A before the start of dose level 2 study in Part C, after completion of Part E before starting Part F, and after completion of Part G before starting Part H.

6.3 Final Analyses and Reporting

All final planned analyses per protocol and this analysis plan will be performed only after database freeze.

7 ANALYSIS POPULATIONS AND APPLICATIONS

7.1 All Patients Population

All Patients Population includes all patients who sign an informed consent form.

7.2 Safety Population

Safety Population includes all patients who receive any amount of study drug.

All safety endpoints will be assessed in the safety population, except DLT assessment which will include only those patients completing the first cycle of therapy, unless the patient discontinued study treatment due to a DLT.

7.3 Application of Analysis Populations

Unless otherwise noted, the analysis populations that will be used for creating the summary table(s) of each type is provided in Table 2Table 2. Populations used for listing can be found in Section 9 **(Planned Statistical Tables, Figures and Listings).**

Table 2: Application of Populations on Tables and Figures

Type	All	Safety
Enrollment	X	X
Disposition		X
Demographics and baseline characteristics		X
Protocol deviations		X
Medical and disease history		X
Prior therapies/surgeries		X
Prior and concomitant medications or procedures		X
Efficacy evaluations		X
Safety evaluations		X
Treatment exposure		X

8 STATISTICAL CONSIDERATIONS

All analyses described in this plan are considered a priori analyses in that they have been defined prior to freezing the database. All other analyses, if any, designed subsequently to locking the database, will be considered post hoc analyses and will be described as exploratory analyses in the Clinical Study Report.

All summaries and statistical analysis will be performed by SAS v9.4 or later.

8.1 General Statistical Procedures

Frequency distributions for categorical variables will be provided as number of patients with a response in the category and the percentages of the total number of patients in that column. Percentages will be based on number of patients in the given population as noted. Percentages will be reported to one decimal place.

A 2-sided 90% exact binomial (Clopper-Pearson) confidence interval (CI) for categorical variables without multiplicity adjustment will be provided where appropriate for efficacy analysis.

The descriptive statistics for continuous variables will be number of patients, mean, standard deviation (STD), median, minimum (Min) and maximum (Max). Mean and median will be reported to 1 more decimal place than the raw data, while the standard deviation (STD) will be reported to 2 more decimal places than the raw data. Minimum and maximum will be reported the same as the original data.

Time-to-event analyses will be performed using Kaplan-Meier methods.

Otherwise stated, all statistical summary will be performed for Part A, B, C & D.

Listings will be ordered by study Part, patient ID and visit for available data unless otherwise specified in the text. Listings that contain an evaluation date will also contain relative study day (Rel days) which is defined as number of days relative to the first dose date of study drug (see Section 5.2 for details).

Analysis visit windows and safety data handling (partial dates of AEs and medications) are described in Section 5.5 to Section 5.6.

TSR-042 is fixed dose regimen (i.e. 4 x 500 mg Q3W followed by 1000 mg Q6W), the data will be summarized by patient ID and visit without distinguishing TSR-042 dose levels.

8.2 Enrollment and Disposition

8.2.1 Patients Enrollment

Patients enrollment will be summarized for all patients, and safety population. The number of patients in each analysis population will be presented for PartsA -D

Enrollment information will be provided in a data listing for All Patients Population and safety population.

8.2.2 Patients Disposition

In this study, each part consists a combination of several study drugs. The Treatment regimen is considered discontinued if patients discontinued all study drugs in the regimen.

Patients' discontinuation from treatment and primary reasons will be tabulated by study drug using Safety Population.

Patients' discontinuation from study and primary reasons will be tabulated for Safety Population.

Discontinued patients from treatment and from study will be provided in a data listing for Safety Population.

8.2.3 Protocol Deviations

Important or significant protocol deviations (PDVs) will be assessed by TESARO and GSK personnel following Protocol Deviation Guideline outlined in Clinical Management Plan.

- A PDV is classified as important if there is the potential to impact the completeness, accuracy, and/or reliability of the study data, or affect a patient's rights, safety, or well-being.
- A PDV is classified as significant if it is confirmed to adversely impact the completeness, accuracy, and/or reliability of the study data, or affect a patient's rights, safety, or well-being.

If a reported PDV does not meet classification criteria for importance or significance, the PDV will be reported as a protocol deviation without a classification.

All PDVs will be identified and finalized prior to database freeze

Number and percentage of patients with a significant or important PDV will be tabulated by type of deviation for Safety Population.

All protocol deviations will be listed for Safety Population.

8.3 Demographics and Baseline Characteristics

8.3.1 Demographics, Baseline and Disease Characteristics

Demographic and baseline (see Section 5.1 for baseline definition) characteristics will be tabulated using descriptive statistics for Safety Population for each part. The following variables will be included in the tables:

- The demographic data are:
  - Age (years) as (date of screening - date of birth) / 365.25 if date of birth is reported, or age as reported on the eCRF will be used
  - Age category (18 to < 65, 65 to < 74; and ≥ 75)
  - Sex
  - Race
  - Ethnicity
- Baseline characteristics include:
  - Height (cm)
  - Weight (kg)
  - BMI (body mass index, kg/m^2, calculated as weight (kg) / height $(m)^2$)
  - BSA (m^2, calculated as $([\text{height (cm)} \times \text{weight (kg)}] / 3600)^{0.5}$)
  - ECOG performance status
- Primary Cancer History include:
  - Primary tumor site at first diagnosis
  - Cancer stage at first and most recent diagnosis
  - Time from first diagnosis to the date of first dose of study treatment (months), calculated as (date of first dose of the treatment – date of first diagnosis)/30.4375

Conversions for height and weight are as follows:

Height (cm) = Height (inches) x 2.54
Weight (kg) = Weight (lb) x 0.4536

Demographics, baseline characteristics and primary cancer history will be listed for Safety Population.

8.3.2 Medical History

The medical history will be coded using version 23.0 of Medical Dictionary for Regulatory Activities (MedDRA) dictionary.

The frequency count and percentage of patients experiencing any medical conditions will be tabulated by system organ classifications (SOC) and preferred term (PT) of MedDRA for Safety

Population. If a PT or SOC was reported more than once for a patient, the patient would only be counted once in the incidence for that SOC or PT.

Patients' history of blood disorder will be summarized by count and percentage for Safety Population.

A data listing of medical history and prior blood disorders history will be provided for Safety Population.

8.3.3 Prior Anticancer Treatment

Prior anticancer treatment will be tabulated for each Part and overall for Safety Population. The following variables will be included in the tables:

- Number of regimens
- Reason for administration of last treatment
- Reason for discontinuation of last treatment
- Time from end of last treatment to the date of first dose of study treatment (months), defined as (date of first dose of the treatment – stop date of last treatment)/30.4375
- Best response during last treatment
- Any surgeries related to cancer
- Any radiotherapy prior to informed consent

Prior anticancer treatment for primary cancer, prior and concomitant radiotherapy, and previous surgery history will be provided for Safety Population.

8.3.4 Prior and Concomitant Medication/Procedures

All medications as documented by the investigator will be coded using Anatomical Therapeutic Chemical (ATC) classification based on the World Health Organization (WHO) Drug Dictionary (WHO-DD Sept 2018).

Prior non-anticancer medications are defined as any medications, other than study drugs, medications for cancer treatment and pre-medications for study treatment, which ended prior to the first dose date of study treatment.

Concomitant medications are medications other than study treatments, being taken on or after the initial study treatment dosing date through 90 days after the last dose or until the start of subsequent antitumor therapy.

The count and percentage of patients who took prior and concomitant medications will be provided by WHO Drug ATC level 3 and preferred term (PT) for Safety Population. For the summary tables, if a patient has taken a prior or concomitant medication more than once, the patient will be counted only once for the medication.

Patients' prior transfusion and growth factor will be summarized by count and percentage.

Prior and concomitant medication, pemetrexed supplemental medications, concomitant procedures, prior and concomitant transfusions and growth factors will be listed for Safety Population.

8.3.5 HBsAg and HCV Ribonucleic Acid Testing at Baseline

The testing results will be listed for Safety Population.

8.4 Safety Analysis

8.4.1 Adverse Events

AEs will be coded using MedDRA v23.0 and will be classified by SOC and PT of MedDRA. Severity of AEs will be assessed by investigators according to CTCAE (v4.03).

A treatment-emergent AE (TEAE) will be defined as any new AE that begins, or any preexisting condition that worsens in severity during the treatment period (see Section 5.3 for definition of treatment period).

TEAEs are classified as Related or Unrelated to study drugs by the Investigator. Any TEAEs for which the relationship to study drug is missing will be considered as related to study drugs.

The following types of summaries will be provided by study drug. The summary will be sorted by decreasing frequency of PT (number of patients in total) within SOC which is sorted alphabetically.

- Overview of TEAEs
- DLT by SOC and PT
- TEAEs by SOC and PT
- TEAEs by PT in decreasing frequency
- Immune Related TEAE by PT
  - Preferred term and SOC for Immune Related Adverse events are defined in APPENDIX
  - Immune Related TEAE by PT will summarize incidence of Grade 2 and above events as overall, TSR-042 related events, Grade 3 and above events, TSR-042 related Grade 3 and above, SAE, TSR-042 related SAE and events leading to TSR-042 discontinuation

- Drug-Related TEAEs by PT in descending frequency
  - Niraparib-related TEAEs by PT in descending frequency
  - TSR-042-related TEAEs by PT in descending frequency

  - TSR-022-related TEAEs by PT in descending frequency
  - Bevacizumab-related TEAEs by PT in descending frequency
  - Carboplatin-related TEAEs by PT in descending frequency
  - Paclitaxel -related TEAEs by PT in descending frequency
- Drug-related TEAEs by SOC and PT
  - Niraparib-related TEAEs by SOC and PT
  - TSR-042-related TEAEs by SOC and PT
  - TSR-022-related TEAEs by SOC and PT
  - Bevacizumab-related TEAEs by SOC and PT
  - Carboplatin-related TEAEs by SOC and PT
  - Paclitaxel -related TEAEs by SOC and PT
- TEAEs by SOC, PT and Maximum CTCAE toxicity grade ≥ 3
- Drug-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
  - Niraparib-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
  - TSR-042-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
  - TSR-022-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
  - Bevacizumab-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
  - Carboplatin-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
  - Paclitaxel-related TEAEs by SOC, PT and Maximum CTCAE grade ≥ 3
- Serious AEs by SOC and PT
- Drug-related serious AEs by SOC and PT
  - Niraparib-related Serious AEs by SOC and PT
  - TSR-042-related Serious AEs by SOC and PT
  - TSR-022-related Serious AEs by SOC and PT
  - Bevacizumab-related Serious AEs by SOC and PT
  - Carboplatin-related Serious AEs by SOC and PT
  - Paclitaxel -related Serious AEs by SOC and PT
- TEAEs leading to study drug discontinuation by SOC and PT
  - TEAEs leading to niraparib discontinuation
  - TEAEs leading to TSR-042 discontinuation
  - TEAEs leading to TSR-022 discontinuation
  - TEAEs leading to bevacizumab discontinuation
  - TEAEs leading to carboplatin discontinuation
  - TEAEs leading to paclitaxel discontinuation
- Drug-related TEAEs leading to study drug discontinuation by SOC and PT
  - Drug-related TEAEs leading to niraparib discontinuation
  - Drug-related TEAEs leading to TSR-042 discontinuation
  - Drug-related TEAEs leading to TSR-022 discontinuation
  - Drug-related TEAEs leading to bevacizumab discontinuation

  - Drug-related TEAEs leading to carboplatin discontinuation
  - Drug-related TEAEs leading to paclitaxel discontinuation
- TEAEs leading to niraparib reduction or interruption by SOC and PT
- TEAEs leading to study drug interruption by SOC and PT
  - TEAEs leading to TSR-042 interruption
  - TEAEs leading to TSR-022 interruption
  - TEAEs leading to bevacizumab interruption
  - TEAEs leading to carboplatin interruption
  - TEAEs leading to paclitaxel interruption
- AEs of special interest (AESIs) by SOC and PT
- Death and primary reasons causing death

If a SOC or PT was reported more than once for a patient, the patient would only be counted once in the incidence for that SOC or PT.

In tabulation by severity (i.e., CTCAE grade),

- For a given preferred term, only the most severe preferred term for each patient will be included.
- For a given system organ class, only the most severe system organ class for each patient will be included.

The following tables presented as listings will be provided:

- Deaths
- Serious AEs
- TEAEs leading to drug reduction or interruption.
- TEAEs leading to treatment discontinuation

COVID19 assessments and symptom assessments for subjects with COVID19 Adverse events will be listed.
AEs will be listed for All Safety Population.

8.4.2 Study Drug Exposure

Study drug will be summarized using descriptive statistics for Safety Population including:

- Duration of drug exposure
- Number of treatment cycles (Cycle1, Cycle 2, etc.)
- Actual dose intensity (exclude Carboplatin)
- Relative dose intensity (exclude Carboplatin)
- Number of patients with dose interruptions

- Number of patients with Niraparib dose reduction

Duration of exposure and dose intensity will be calculated as described in

Table 3 for each drug. Dose intensity for Carboplatin will not be included due to unit conversion issue between AUC and mg/m^2.

For each study treatment, swimmer plots displaying the duration of treatment for each patient will be presented by including indicators:

- Primary tumor type
- Treatment status (ongoing or discontinued)
- Response at each tumor assessment

Details of study treatment exposure will be listed for Safety Population.

Table 3: Extent of Study Drug Exposure

Parameter	Niraparib	TSR-042	TSR-022	Paclitaxel	Bevacizumab	Carboplatin
Dosing schedule per protocol	Dose level 1: 200mg daily Dose level2: 300mg daily	***Part A to D*:** 500mg Q3W for first 4 cycles, 1,000mg Q6W on and after Day 1 Cycle 5 ***Part E to I:*** 500mg Q3W	Dose level 1: 900mg Q3W Dose level -1: 300mg Q3W	175mg/m^2 Q3W	15mg/kg Q3W	AUC of 5 or 6 Q3W
Intended dose (unit)	(mg/day) Dose level 1: 200/1 Dose level2: 300/1	(mg/day) ***Part A to D:*** First 4 Cycles: 500/21 On and after Cycle 5: 1000/42 ***Part E to I:*** 500/21	(mg/day) 900/21	(mg/m^2 /day) 175/21	(mg/kg /day) 15/21	
Duration of Treatment (unit)	(day) Last dose date - Start dose date +1	(day) ***Part A to Part D:*** First 4 cycles: Last dose date prior to cycle 5 – Start dose date + 21 After cycle 5: Last dose date – First Dose Date at or after Cycle 5 + 42	(day) Last dose date - Start dose date +21	(day) Last dose date - Start dose date + 21	(day) Last dose date - Start dose date + 21	(day) Last dose date - Start dose date + 21

Parameter	Niraparib	TSR-042	TSR-022	Paclitaxel	Bevacizumab	Carboplatin
		Part E to Part F: Last dose date prior to cycle 5 – Start dose date + 21 *Note:* First 4 cycles: Last dose date prior to cycle 5 – Start dose date + 21. If the subject died less than 21 days after last dose date then duration = death date – start dose date +1. After cycle 5: Last dose date – First Dose Date at or after Cycle 5 + 42. If the subject died less than 42 days after last dose date then duration = death date – start dose date + 1.				
Actual Cumulative Dose (unit)	(mg)	(mg)	(mg)	(mg/m²)	(mg/kg)	
	Sum of the doses administered to a patient during the treatment period [1] For Niraparib**, t**he sum of the doses consumed (mg) is the total number of capsules consumed multiplying by 100 mg. The total number of capsules consumed is the sum of the number of capsules dispensed less the sum of the number of capsules returned by the patient during the study. Unused capsules not returned will be assumed to have been consumed. [2] For TSR-042, it is calculated separately for the first 4 cycles and cycles after cycle 5 for Part A to Part D. Note: Cycles that do not have kits actual cumulative dose will be calculated by the duration of the drug taken.					
	(mg/day)	(mg/day)	(mg/day)	(mg/m^2 /day)	(mg/kg/day)	

Parameter	Niraparib	TSR-042	TSR-022	Paclitaxel	Bevacizumab	Carboplatin
Actual Dose Intensity (unit)	Actual Cumulative Dose / Duration of treatment For TSR-042, calculated separately for the first 4 cycles and cycles at or after cycle 5 for Part A to Part D.					
Relative Dose Intensity (%)	Actual Dose Intensity/Intended Dose For TSR-042, calculated separately for the first 4 cycles and cycles at or after cycle 5 for Part A to Part D.					

8.4.3 Clinical Laboratory Tests

All laboratory parameters collected at each center's local laboratory will be normalized by converting values in original units to values in SI units and classified as normal, low, or high based on normal ranges supplied by the local laboratories and upon employing standardization.

For hematology, coagulation, serum chemistry and thyroid function laboratory parameters which are normalized in SI units, descriptive summary tables for observed values and changes from baseline will be provided by visit for Safety Population.

The laboratory test results will be categorized according to NCI CTCAE v4.03 toxicity grades. Shift tables from baseline toxicity to maximum post-baseline toxicity grade will be provided for Alkaline phosphatase increased, Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood bilirubin increased, Hypoalbuminemia, Creatinine increased, Hypocalcemia, Hypercalcemia,Hypomagnesemia, Hypermagnesemia,Hypokalemia, Hyperkalemia, Hyponatremia, Hypernatremia, Anemia,White blood cell decreased, Platelet count decreased, Lymphocyte count decreased, Neutrophil count decreased applicable hematology and chemistry laboratory parameter in Safety Population.

Continous urinalysis laboratory parameters at each visit will be summarized using descriptive statistics. The categorical urinalysis parameters will be summarized using frequency table.

Summary of liver function tests will include the following categories. The number and percentage of patients with each of the following during the treatment period will be summarized by treatment group: Patients with maximum elevations in categories of < 3xULN, ≥3xULN to <5xULN, ≥ 5xULN to <10xULN, ≥10xULN to <20xULN, and ≥20xULN under treatment

  - AST and ALT, separately
  - Any combinations of elevation categories under treatment of either ALT or AST

- Patient with normal values at baseline and any maximum elevations of TBL under treatment <1.5xULN, ≥1.5xULN to <2xULN, ≥2x ULN
- Patients with normal values at baseline and any maximum elevations of ALP under treatment <1.5xULN, ≥1.5xULN to <2xULN, ≥2x ULN
- Concurrent ALT ⩾ 3×ULN and TBL ⩾ 2×ULN Concurrent AST ⩾ 3×ULN and TBL ⩾ 2×ULNConcurrent (ALT or AST) ⩾ 3×ULN and TBL ⩾ 2×ULN
- Concurrent (ALT or AST) ⩾ 3×ULN and TBL ⩾ 2×ULN and ALP ⩾ 2×ULN
- Potential Hy's law: Concurrent (ALT or AST) ⩾ 3×ULN and TBL ⩾ 2×ULN and ALP < 2×ULN

Concurrent measurements are defined as measurements that occur on the same date.

Separate listings will be provided for all laboratory tests including pregnancy testing for Safety Population.

In general, all by visit summaries of clinical laboratory parameters will only be summarized up to and including month 6 and at the treatment discontinuation visit. The maximum and minimum calculations will use all post-baseline data, including any unscheduled assessments.

Unscheduled measurements will not be used in computing the descriptive statistics for change from baseline at each post-baseline time point. However, they will be used in assessing the minimum and maximum of all visits and in the analysis of notable post-baseline results (for example shift tables).

8.4.4 Vital Signs

A patient-detailed listing of vital signs (including systolic and diastolic blood pressure (mmHg), pulse (bmp), temperature (ºC)), height (cm) and weight (kg)) will be provided for Safety Population.

Conversion of temperature is as following:

Temperature (ºC) = (Temperature (ºF) – 32) x 5/9

8.4.5 Physical Examination Findings

Physical examination will be listed for Safety Population.

8.4.6 ECOG performance status

The ECOG shift from baseline score to worst (highest) post-baseline score during the on-treatment period will be summarized for Safety Population.

Listings will be provided for Safety Population.

8.4.7 Electrocardiogram (ECG)

The following analyses will be performed on Safety Population for each applicable ECG parameters (HR, RR, PR, QRS, QT and QTcF) measured during the on-treatment period (see Section 5.3 for definition).

- For each of continuous ECG parameters, descriptive statistics at baseline, at each post-baseline time point and changes from baseline at each post-baseline time point. If there are multiple measurements at a time point, the average of the replicate measurements should be taken at each time point.
- Frequency (number and percentage) of patients with notable ECG values according to the following categories:
  - QTcF increase from baseline > 30 ms, > 60 ms

- QTcF > 450 ms, > 480 ms, > 500 ms
- HR ≤ 50 bpm and decrease from baseline ≥ 20 bpm
- HR ≥ 120 bpm and increase from baseline ≥ 20 bpm
- PR ≥ 220 ms and increase from baseline ≥ 20 ms
- QRS ≥ 120 ms

Patients with notable ECG interval values and qualitative ECG abnormalities will be listed for each patient and time point and the corresponding notable values and abnormality findings will be included in the listings.

Listing will be presented for Safety Population.

8.5 Efficacy Analysis

RECIST v1.1 will be used by the Investigator as the primary measure for assessment of tumor response, date of disease progression. Tumor response assessment is performed every 12 weeks (84 ± 10 days) from the date of the first dose of study treatment until progression while on study treatment, independent of cycle delays or dose interruptions, or at any time when progression of disease is suspected.

The following plots will be provided for Safety Population:

- Spider plots, displaying the percent change from baseline over the period of subject evaluation.
- Waterfall plots, displaying the best percentage change from baseline in the sum of the diameter of all target lesions for each patient with measurable disease at baseline and at least one valid post-baseline assessment.

Detailed tumor time-point response will be listed for Safety Population.

8.5.1 Best Overall Response when confirmation is required

To confirm CR or PR response, tumor imaging may be performed at the earliest 4 weeks after the first indication of response or at the next scheduled scan (i.e., 12 weeks later), whichever is clinically indicated. Tumor imaging for confirmation of response occurred less than 4 weeks after the first indication of response of CR or PR may be used for clinical decision, but it will NOT be used for determination of BOR

Table 4

Overall response first time point	Overall response subsequent time point	Best overall response
CR	CR	CR
CR	PR	SD provided minimum criteria* for SD duration met, otherwise, PD
CR	SD	SD provided minimum criteria* for SD duration met, otherwise, PD
CR	PD	SD provided minimum criteria* for SD duration met, otherwise, PD
CR	NE	SD provided minimum criteria* for SD duration met, otherwise, NE
PR	CR	PR
PR	PR	PR
PR	SD	SD
PR	PD	SD provided minimum criteria* for SD duration met, otherwise, PD
PR	NE	SD provided minimum criteria* for SD duration met, otherwise, NE
NE	NE	NE

* The minimum criteria SD duration for this study is defined as 12 weeks minus 10 days (12 x 7 – 10 =74 days) from date of first dose of study treatment.

Abbreviation: CR = complete response; PR = partial response; SD = stable disease; PD=Progressive disease; NE=Not eveluated

8.5.2 Objective Response Rate

Confirmed ORR is defined as the proportion of patients who have achieved confirmed BOR of CR or PR, evaluated using RECIST v1.1 based on Investigator assessment.

Confirmed ORR will be summarized by count and percentage for Safety Population.

8.5.3 Duration of Response

DOR is defined as the time from first documentation of overall response leading to a confirmed CR or PR until the time of first documentation of disease progression by RECIST v1.1 or death by any cause.

DOR will be calculated only for patients who responded to the study treatment using the censoring rules specified in Table.

DOR in months is defined as

- (Date of Event or Censoring – Date of first confirmed CR or PR + 1)/30.4375

Due to a small sample size in each Part, DOR will be listed only.

Table 5: Censoring Rules Used for DOR Analysis

Situation	Date of Event or Censoring	Outcome
Start of subsequent anti-cancer therapy without a prior documented progression or death	Date of last evaluable radiologic tumor assessment prior to or on the date of initiation of the subsequent anti-cancer therapy	Censored
No documented radiologic progression and no subsequent anti-cancer therapy started	Date of last evaluable radiologic tumor assessment	Censored
Documented radiologic progression or death after two or more consecutive missing radiologic assessments	Date of last evaluable radiologic tumor assessment before the missed tumor assessments	Censored
Documented radiologic progression or death	Earliest date of documented radiologic progression or death	Event

Table 6: Assessment window to be considered for missing visit information in tumor data is given below

Target day	Analysis window		Analysis Visit
	Start day	End day	
60	1	73	Unscheduled 2.01
70	1	73	Unscheduled 2.02
83	74	94	Week 12
95	95	157	Unscheduled 12.01
170	158	178	Week 24

8.5.4 Disease Control Rate

Confirmed DCR is defined as the proportion of patients who have achieved confirmed BOR of CR, PR, or stable disease (SD) per RECIST v1.1.

Confirmed DCR will be summarized using frequency tables for Safety Population.

8.5.5 Progression Free Survival

PFS is defined as the time from the date of the first dose of study treatment to the earlier date of assessment of progression, or death by any cause in the absence of progression by RECIST v1.1.

PFS in months will be calculated as following using the censoring rules specified in Table :

- (Earlier Date of Event or Censoring – First dose date of study treatment + 1) / 30.4375

The Kaplan-Meier (KM) method will be used to estimate the distribution of PFS for Safety Population including the number and percentage of events, number and percentage of censored patients, and the 25th, 50th, and 75th percentiles of times-to-event with 95% CIs. Survival risks at 6 and 12 months will be provided if applicable.

A KM plot will be provided to graphically present the PFS.

Table 7: Censoring Rules Used for PFS Analysis

Situation	**Date of Event or Censoring**	**Outcome**

No baseline tumor assessments	First dose date	Censored
No post-baseline tumor assessments and no death	First dose date	Censored
Start of subsequent anti-cancer therapy prior to a documented radiologic progression or death	Date of last evaluable radiologic tumor assessment prior to or on the date of initiation of the subsequent anti-cancer therapy	Censored
No documented radiologic progression, no subsequent anti-cancer therapy started, and no death	Date of last evaluable radiologic tumor assessment	Censored
Documented radiologic progression or death after two or more consecutive missing radiologic assessments	Date of last evaluable radiologic tumor assessment before the missed tumor assessments	Censored
Documented radiologic progression or death	Earliest date of documented radiologic progression or death	Event

9 APPENDIX: Immune Related Adverse Events

Immune Related Adverse Events – Preferred Term(irAE_PT)	Immune Related Adverse Events- System Organ Class(irAE_SOC)
Pneumonitis	Immune-mediated Pulmonary
Sarcoidosis	Immune-mediated Pulmonary
Colitis	Immune-mediated Gastrointestinal
Diarrhoea	Immune-mediated Gastrointestinal
Gastroenteritis	Immune-mediated Gastrointestinal
Enteritis	Immune-mediated Gastrointestinal
Gastritis	Immune-mediated Gastrointestinal
Duodenitis	Immune-mediated Gastrointestinal
Autoimmune hepatitis	Immune-mediated hepatic
Hepatitis	Immune-mediated hepatic
Hepatitis toxic	Immune-mediated hepatic
Liver injury	Immune-mediated hepatic
Transaminases increased	Immune-mediated hepatic
Aspartate aminotransferase increased	Immune-mediated hepatic
Alanine aminotransferase increased	Immune-mediated hepatic
Blood bilirubin increased	Immune-mediated hepatic
Hyperbilirubinaemia	Immune-mediated hepatic
Hepatic enzyme increased	Immune-mediated hepatic
Hyperthyroidism	Immune-mediated endocrinopathies
Hypothyroidism	Immune-mediated endocrinopathies

Thyroid disorder	Immune-mediated endocrinopathies
Thyroiditis	Immune-mediated endocrinopathies
Hypophysitis	Immune-mediated endocrinopathies
Hypopituitarism	Immune-mediated endocrinopathies
Adrenal insufficiency	Immune-mediated endocrinopathies
Secondary adrenocortical insufficiency	Immune-mediated endocrinopathies
Type 1 diabetes mellitus	Immune-mediated endocrinopathies
Diabetic ketoacidosis	Immune-mediated endocrinopathies
Hyperglycaemia	Immune-mediated endocrinopathies
Nephritis	Immune-mediated renal
Renal impairment	Immune-mediated renal
Blood creatinine increased	Immune-mediated renal
Rash	Immune-mediated skin adverse reactions
Rash maculo-papular	Immune-mediated skin adverse reactions
Rash macular	Immune-mediated skin adverse reactions
Rash erythematous	Immune-mediated skin adverse reactions
Rash papular	Immune-mediated skin adverse reactions
Rash pruritic	Immune-mediated skin adverse reactions
Rash pustular	Immune-mediated skin adverse reactions
Erythema	Immune-mediated skin adverse reactions
Exfoliative rash	Immune-mediated skin adverse reactions
Dermatitis exfoliative	Immune-mediated skin adverse reactions
Autoimmune dermatitis	Immune-mediated skin adverse reactions
Pemphigoid	Immune-mediated skin adverse reactions

Vitiligo	Immune-mediated skin adverse reactions
Pruritus	Immune-mediated skin adverse reactions
Stevens-Johnson syndrome	Immune-mediated skin adverse reactions
Toxic epidermal necrolysis	Immune-mediated skin adverse reactions
Pancreatitis	Immune-mediated pancreatitis
Pancreatitis acute	Immune-mediated pancreatitis
Autoimmune pancreatitis	Immune-mediated pancreatitis
Amylase increased	Immune-mediated pancreatitis
Lipase increased	Immune-mediated pancreatitis
Aplastic anaemia	Immune-mediated hematologic
Autoimmune haemolytic Anaemia	Immune-mediated hematologic
Haemolytic anaemia	Immune-mediated hematologic
Arthritis	Immune-mediated musculoskeletal
Myositis	Immune-mediated musculoskeletal
Polymyalgia rheumatica	Immune-mediated musculoskeletal
Rhabdomyolysis	Immune-mediated musculoskeletal
Autoimmune neuropathy	Immune-mediated nervous system
Polyneuropathy	Immune-mediated nervous system
Neuropathy peripheral	Immune-mediated nervous system
Peripheral sensory neuropathy	Immune-mediated nervous system
Hypoaesthesia	Immune-mediated nervous system
Paraesthesia	Immune-mediated nervous system
Facial paresis	Immune-mediated nervous system
Dysaesthesia	Immune-mediated nervous system

Demyelination	Immune-mediated nervous system
Myelitis	Immune-mediated nervous system
Encephalitis autoimmune	Immune-mediated nervous system
Seizure	Immune-mediated nervous system
Guillain-Barre syndrome	Immune-mediated nervous system
Motor dysfunction	Immune-mediated nervous system
Myasthenia gravis	Immune-mediated nervous system
Myasthenic syndrome	Immune-mediated nervous system
Iridocyclitis	Immune mediated Ocular
Uveitis	Immune mediated Ocular
Iritis	Immune mediated Ocular
Myocarditis	Immune-mediated cardiovascular
Vasculitis	Immune-mediated cardiovascular
Pericarditis	Immune-mediated cardiovascular
Hypersensitivity	Hypersensitivity
Infusion related reaction	Hypersensitivity
Anaphylactic reaction	Hypersensitivity
Drug hypersensitivity	Hypersensitivity
Type I hypersensitivity	Hypersensitivity
Haemophagocytic lymphohistiocytosis	Immune-mediated Others
Histiocytosis	Immune-mediated Others
Histiocytic necrotising lymphadenitis	Immune-mediated Others
Systemic inflammatory response syndrome	Immune-mediated Others
Vogt-Koyanagi-Harada disease	Immune-mediated Others

10 PLANNED STATISTICAL TABLES, FIGURES AND LISTINGS

Programming Specifications

1. add following footnotes for corresponsing Part(s) included in the summary.
   Part A-200: TSR-042 and niraparib (200mg) combination treatment
   Part A-300: TSR-042 and niraparib (300mg) combination treatment
   Part A: TSR-042 and niraparib (300mg/900mg) combination treatment
   Part B: TSR-042 and carboplatin-paclitaxel combination treatment
   Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
   Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
   Part C: TSR-042, niraparib (200mg/300mg) and bevacizumab combination treatment
   Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
   Part E: TSR-042 and carboplatin-pemetrexed combination treatment
   Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
   Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment
   Part F: TSR-042, TSR-022 (300mg/900mg) and carboplatin-pemetrexed combination treatment
2. Summary tables for adverse events (AEs) will be sorted by decreasing total number of patients of preferred term (PT) within system organ class (SOC) which is sorted alphabetically.
3. Listing will be sorted by Part, patient ID and visit.
4. Date is presented as MMDDYYY and time is presented as HH:MM:SS.

TABLE OF CONTENTS

Table 14.1.1
Overview of Patients Enrollment

Treatment	Statistics	All Patients Population	Safety Population
Not Dosed	n	xx	xx
Part A	n	xx	xx
Part A-200	n	xx	xx
Part A-300	n	xx	xx
Part B	n	xx	xx
Part C	n	xx	xx
Part C-200	n	xx	xx
Part C-300	n	xx	xx
Part D	n	xx	xx
Part E	n	xx	xx
Part F	n	xx	xx
Part F-300	n	xx	xx
Part F-900	n	xx	xx
Overall	n	xx	xx

Source: Listing 16.2.1.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Table 14.1.2.1
Patients Disposition for Part A (Safety Population)

Parameter	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Discontinued from Study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuations from Study				
Withdrawal of consent	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator decision	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation from Niraparib				
Adverse event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient request	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation from TSR-042				
Adverse event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient request	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 16.2.1.2.1 Listing 16.2.1.2.2 Listing 16.2.1.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Table 14.1.2.2
Patients Disposition for Part B (Safety Population)

Parameter	Statistics	Part B (N=XX)
Discontinued from Study	n (%)	xx (xx.x)
Primary Reason for Discontinuations from Study		
Withdrawal of consent	n (%)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)
Death	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Investigator decision	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)
Discontinued from Carboplatin/Paclitaxel	n (%)	xx (xx.x)
Primary Reason for Discontinuation from carboplatin-paclitaxel		
Adverse event	n (%)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Patient request	n (%)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)
Discontinued from TSR-042	n (%)	xx (xx.x)
Primary Reason for Discontinuation from TSR-042		
Adverse event	n (%)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Patient request	n (%)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)

Source: Listing 16.2.1.2.2 Listing 16.2.1.2.4 Listing 16.2.1.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Table 14.1.2.3
Patients Disposition for Part C (Safety Population)

Parameter	Statistics	Part C-200 (N=XX)	Part C-300 (N=XX)	Overall (N=XX)
Discontinued from Study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuations from Study				
Withdrawal of consent	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator decision	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation from Niraparib				
Adverse event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient request	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation from TSR-042				
Adverse event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient request	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from Bevacizumab	n (%)	xx (xx.x)	xx (xx.x)	n (%)

Primary Reason for Discontinuation from Bevacizumab				
Adverse event	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Patient request	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Patient becomes pregnant	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Sponsor decision to terminate study	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Completed Course	n (%)	xx (xx.x)	xx (xx.x)	n (%)
Other	n (%)	xx (xx.x)	xx (xx.x)	n (%)

Source: Listing 16.2.1.2.1 Listing 16.2.1.2.2 Listing 16.2.1.2.3 Listing 16.2.1.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Table 14.1.2.4
Patients Disposition for Part D (Safety Population)

Parameter	Statistics	Part D (N=XX)
Discontinued from Study	n (%)	xx (xx.x)
Primary Reason for Discontinuations from Study		
Withdrawal of consent	n (%)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)
Death	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Investigator decision	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)
Discontinued from Carboplatin/Paclitaxel	n (%)	xx (xx.x)
Primary Reason for Discontinuation from Carboplatin-paclitaxel		
Adverse event	n (%)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Patient request	n (%)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)
Completed Course	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)
Discontinued from TSR-042	n (%)	xx (xx.x)
Primary Reason for Discontinuation from TSR-042		
Adverse event	n (%)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Patient request	n (%)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)
Other		
Discontinued from Bevacizumab	n (%)	xx (xx.x)
Primary Reason for Discontinuation from Bevacizumab		
Adverse event	n (%)	xx (xx.x)
Risk to patient as judged by investigator and/or sponsor	n (%)	xx (xx.x)

Severe noncompliance to protocol as judged by investigator and/or sponsor	n (%)	xx (xx.x)
Patient request	n (%)	xx (xx.x)
Patient becomes pregnancy	n (%)	xx (xx.x)
Sponsor decision to terminate study	n (%)	xx (xx.x)
Disease progression per RECIST 1.1	n (%)	xx (xx.x)
Disease progression based on clinical criteria by Investigator	n (%)	xx (xx.x)
Confirmed Complete Response, treated for at least 24 weeks with study treatment, and have at least 2 cycles beyond initial CR	n (%)	xx (xx.x)
Completed Course	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)

Source: Listing 16.2.1.2.2 Listing 16.2.1.2.3 Listing 16.2.1.2.4 Listing 16.2.1.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Table 14.1.3.1
Protocol Deviation by Category and Severity for Part A (Safety Population)

Parameter	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Patients with any Protocol Deviation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Important Deviation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
Significant Deviation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

Source: Listing 16.2.2

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat for Table 14.1.3.1 for

Table 14.1.3.2 Protocol Deviation by Category and Severity for Part B (Safety Population)

Table 14.1.3.3 Protocol Deviation by Category and Severity for Part C (Safety Population)

Table 14.1.3.4 Protocol Deviation by Category and Severity for Part D (Safety Population)

Table 14.1.4.1
Demographic Characteristics for Part A (Safety Population)

Characteristics	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Age (years)				
	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Age Category				
18-64	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
65-74	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Liver ≥ 75	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)
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)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race				
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	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)
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 16.2.4.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat for Table 14.1.4.1 for

Table 14.1.4.2 Demographic Characteristics for Part B (Safety Population)

Table 14.1.4.3 Demographic Characteristics for Part C (Safety Population)

Table 14.1.4.4 Demographic Characteristics for Part D (Safety Population)

Table 14.1.5.1
Baseline Characteristics for Part A (Safety Population)

Parameter	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Height (cm)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
BMI (kg/m²)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
BSA (m²)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	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)

Source: Listing 16.2.9 Listing 16.2.10
Note: BMI=Body Mass Index; BSA = Body Surface Area

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.1.5.1 for

Table 14.1.5.2 Baseline Characteristics for Part B (Safety Population)

Table 14.1.5.3 Baseline Characteristics for Part C (Safety Population)

Table 14.1.5.4 Baseline Characteristics for Part D (Safety Population)

Table 14.1.6.1
Primary Cancer History for Part A (Safety Population)

Parameter	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Primary tumor site at first diagnosis				
Brain	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Breast	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Cancer stage at first diagnosis				
Stage I	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage I A	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage I B	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage I C	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage II	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Stage III	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Stage IV	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Unknown	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Time from first diagnosis to first dose of study treatment (months) [1]	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Cancer stage at most recent diagnosis				
Stage I	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage II	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage III	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Stage IV	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Unknown	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

[1] Time from first diagnosis to first dose of study treatment (months) = (first dose date – first diagnosis date + 1)/30.4375
Source: Listing 16.2.4.11

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.1.6.1 for

Table 14.1.6.2 Primary Cancer History for Part B (Safety Population)

Table 14.1.6.3 Primary Cancer History for Part C (Safety Population)

Table 14.1.6.4 Primary Cancer History for Part D (Safety Population)

Table 14.1.7.1
Prior Anticancer Treatment for Primary Cancer for Part A (Safety Population)

Parameter	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Number of Prior Regimens	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Reason for administration of last treatment				
Neoadjuvant	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adjuvant	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Advanced/Metastatic	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Best Response during last treatment				
Complete Response (CR)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Partial Response (PR)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stable Disease (SD)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progressive Disease (PD)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Evaluable	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for discontinuation of last treatment				
Toxicity	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed planned courses	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time from end of last treatment to first dose of study treatment (months) [1]	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Prior Surgery Related to Cancer	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Radiotherapy Prior to Informed Content	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Time from end of last treatment to first dose of study treatment (months) = (first dose date - last date of last treatment + 1)/30.4375.
Source: Listing 16.2.4.3 Listing 16.2.4.4 Listing 16.2.4.10

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.1.7.1 for

Table 14.1.7.2 Prior Anticancer Treatment for Primary Cancer for Part B (Safety Population)

Table 14.1.7.3 Prior Anticancer Treatment for Primary Cancer for Part C (Safety Population)

Table 14.1.7.4 Prior Anticancer Treatment for Primary Cancer for Part D (Safety Population)

Table 14.1.8.1
Medical History by System Organ Class and Preferred Term for Part A (Safety Population)

System Organ Class Preferred Term	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
SOC 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…	…			
SOC 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
	…			

Note: Patients who report multiple occurrences of the same condition (preferred term) are included only once per SOC and preferred term
Source: Listing 16.2.4.2

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.1.8.1 for

Table 14.1.8.2 Medical History by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.1.8.3 Medical History by System Organ Class and Preferred Term for Part C (Safety Population)

Table 14.1.8.4 Medical History by System Organ Class and Preferred Term for Part D (Safety Population)

Table 14.1.9.1
Prior Blood Disorder for Part A (Safety Population)

Event Grade	Statistic	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Any blood disorder	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Thrombocytopenia	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leukopenia	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anemia	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neutropenia	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 14.2.4.9

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.1.9.1 for

Table 14.1.9.2 Prior Blood Disorder for Part B (Safety Population)

Table 14.1.9.3 Prior Blood Disorder for Part C (Safety Population)

Table 14.1.9.4 Prior Blood Disorder for Part D (Safety Population)

Table 14.1.10.1
Prior Transfusion and Growth Factor for Part A (Safety Population)

Administration Type	Statistic	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Transfusion	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Red Blood Cells	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Platelets	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Erythropoietin	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Others	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Growth Factor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Granulocyte colony stimulating factor granulocyte	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Macrophage colony stim factor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Others	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 16.2.4.6

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.1.10.1 for

Table 14.1.10.2 Prior Transfusion and Growth Factor for Part B (Safety Population)

Table 14.1.10.3 Prior Transfusion and Growth Factor for Part C (Safety Population)

Table 14.1.10.4 Prior Transfusion and Growth Factor for Part D (Safety Population)

Table 14.1.11.1.1
Prior Non-Anticancer Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part A (Safety Population)

ATC Level 3 Preferred Term	Statistic	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Any Prior Medications	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ATC Level 3				
PT1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PT3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…	…	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Source: Listing 16.2.5.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat for Table 14.1.11.1.1

Table 14.1.11.1.2 Prior Non-Anticancer Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part B (Safety Population)

Table 14.1.11.1.3 Prior Non-Anticancer Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part C (Safety Population)

Table 14.1.11.1.4 Prior Non-Anticancer Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part D (Safety Population)

Repeat for Table 14.1.11.1.1

Table 14.1.11.2.1 Concomitant Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part A (Safety Population)

Table 14.1.11.2.2 Concomitant Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part B (Safety Population)

Table 14.1.11.2.3 Concomitant Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part C (Safety Population)

Table 14.1.11.2.4 Concomitant Medication by Anatomical Therapeutic Chemical (ATC) and Preferred Term for Part D (Safety Population)

Table 14.2.1.1.1
Best Overall Response for Part A (Confirmed, Safety Population)

	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Best Overall Response by RECIST v1.1				
Confirmed Complete Response	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Confirmed Partial Response	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stable Disease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progressive Disease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Evaluable	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Objective Response Rate (ORR)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	90% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Duration of Response				
Median in Months (range)		x.x(xx.x, xx.x)	x.x(xx.x, xx.x)	x.x(xx.x, xx.x)
Response Ongoing	n (%)	xx	xx	xx
Disease Control Rate (DCR)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	90% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Objective Response is defined as overall response as confirmed complete response (CR) or partial response (PR)
CI: Confidence Interval. Response Ongoing: All responders who have not yet died or progressed (including clinical progression), denominator for percentage is number of responders.
Source: Listing 16.2.6.4 Listing 16.2.6.5.2

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.2.1.1.1 for

Table 14.2.1.1.2 Best Overall Response for Part B (Confirmed, SafetyPopulation)

Table 14.2.1.1.3 Best Overall Response for Part C (Confirmed, Safety Population)

Table 14.2.1.1.4 Best Overall Response for Part D (Confirmed, Safety Population)

Table 14.2.2.1
Progression Free Survival for Part A (Safety Population)

Assessment	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Number of Patients	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Censored Patients	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progression Free Survival (months)				
	25 Percentile	xx.x	xx.x	xx.x
	95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	50 Percentile	xx.x	xx.x	xx.x
	95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	75 Percentile	xx.x	xx.x	xx.x
	95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Survival Distribution Function (SDF)				
6 months	SDF	xx.x	xx.x	xx.x
	95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
12 months	SDF	xx.x	xx.x	xx.x
	95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Note: Progression Free Survival is defined as the date of first dose to the date of disease progression or death due to any cause, whichever occurs earlier.
CI: Confidence Interval
Source: Listing 16.2.6.4 Listing 16.2.6.5.2 Listing 16.2.6.16

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.2.2.1 for

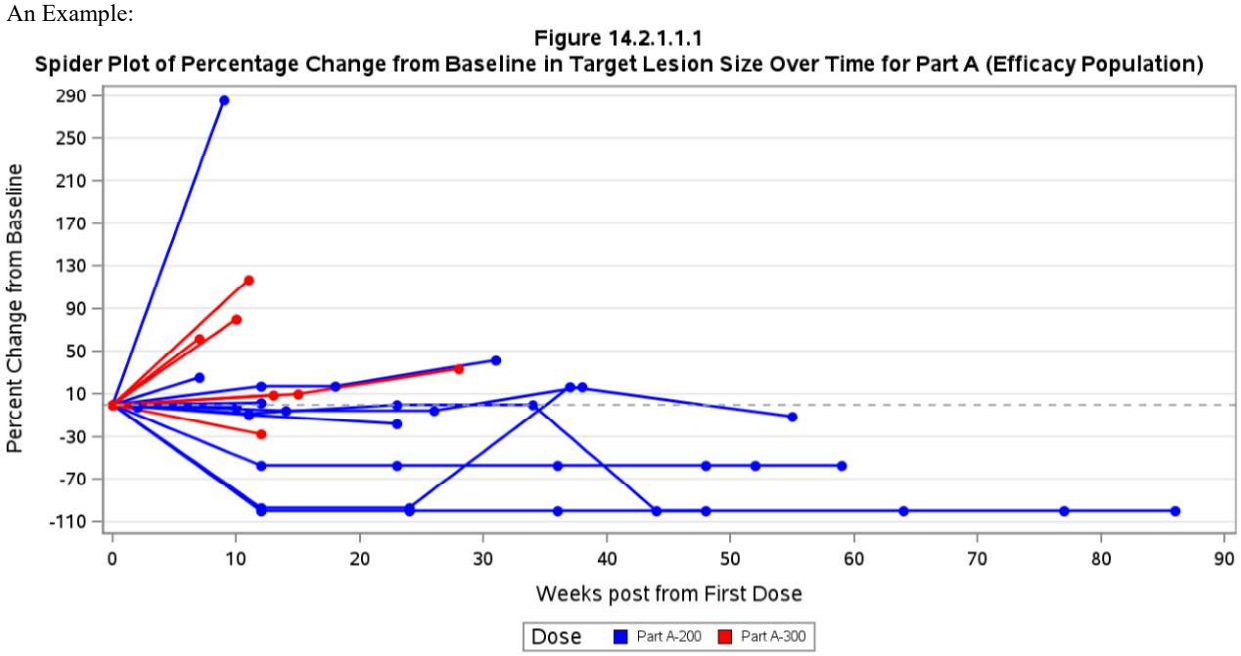
Table 14.2.2.2 Progression Free Survival for Part B (Safety Population)

Table 14.2.2.3 Progression Free Survival for Part C (Safety Population)

Table 14.2.2.4 Progression Free Survival for Part D (Safety Population)

Figure 14.2.1.1.1
Spider Plot of Percentage Change from Baseline in Target Lesion Size Over Time for Part A (Safety Population)

An Example:



Source: Listing 16.2.6.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Figure 14.2.1.1.1 for

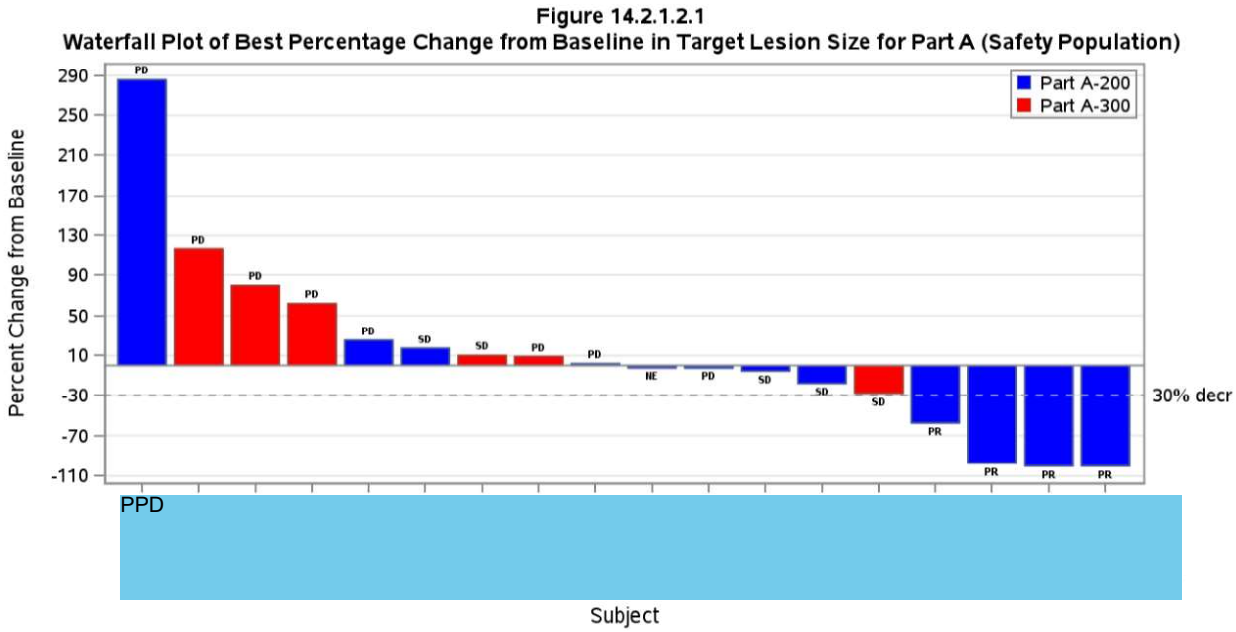
Figure 14.2.1.1.2 Spider Plot of Percentage Change from Baseline in Target Lesion Size Over Time for Part B (Safety Population)

Figure 14.2.1.1.3 Spider Plot of Percentage Change from Baseline in Target Lesion Size Over Time for Part C (SafetyPopulation)

Figure 14.2.1.1.4 Spider Plot of Percentage Change from Baseline in Target Lesion Size Over Time for Part D (Safety Population)

Figure 14.2.1.2.1
Waterfall Plot of Best Percentage Change from Baseline in Target Lesion Size for Part A (Safety Population)

An Example:



Source: Listing 16.2.6.1

Repeat for

Figure 14.2.1.2.2 Waterfall Plot of Best Percentage Change from Baseline in Target Lesion Size for Part B (Safety Population)

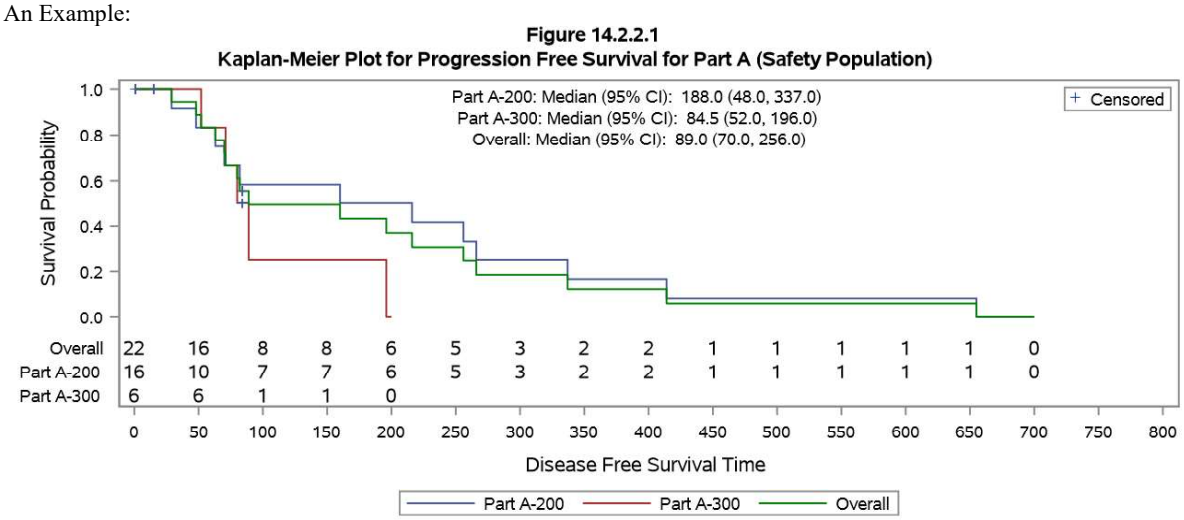
Figure 14.2.1.2.3 Waterfall Plot of Best Percentage Change from Baseline in Target Lesion Size for Part C (Safety Population)

Figure 14.2.1.2.4 Waterfall Plot of Best Percentage Change from Baseline in Target Lesion Size for Part D (Safety Population)

For programmer: add following footnotes as applicable to each output
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Figure 14.2.2.1
Kaplan-Meier Plot for Progression Free Survival for Part A (Safety Population)

An Example:



This is an example of KM plot with 90% CI. For Part A, KM plot includes PFS curve for Part A-200, Part A-300 and Part A overall. Do similar plot for Part C.
Source: Listing 16.2.6.4 Listing 16.2.6.5.1 Listing 16.2.6.5.2 Listing 16.2.6.16

PROGRAM NAME:
DATE: DDMMYYYY

Repeat for

Figure 14.2.2.2 Kaplan-Meier Plot for Progression Free Survival for Part B (Safety Population)

Figure 14.2.2.3 Kaplan-Meier Plot for Progression Free Survival for Part C (Safety Population)

Figure 14.2.2.4 Kaplan-Meier Plot for Progression Free Survival for Part D (Safety Population)

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Table 14.3.1.1.1
Overall Treatment Emergent Adverse Events Summary for Part A (Safety Population)

Characteristic	Statistic	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Treatment Emergent Adverse Event (TEAE)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dose-Limiting Toxicities (DLTs)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to both drugs	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to both drugs	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious AE (SAE)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related SAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to both drugs	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Dose Reduction/Interruption				
TEAE Leading to Niraparib Dose Reduction	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Niraparib Dose Interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to TSR-042 Infusion Interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to TSR-042 Infusion Delayed	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Treatment Discontinuation				
TEAEs Leading to Niraparib Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs Leading to TSR-042 Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Discontinuation of Both Drugs	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs Leading to Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Table 14.3.1.1.2
Overall Treatment Emergent Adverse Events Summary for Part B (Safety Population)

Characteristic	Statistic	Part B (N=XX)
Treatment Emergent Adverse Event (TEAE)	n (%)	xx (xx.x)
Dose-Limiting Toxicities (DLTs)	n (%)	xx (xx.x)
Related to TEAE	n (%)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)
Related to Carboplatin	n (%)	xx (xx.x)
Related to Paclitaxel	n (%)	xx (xx.x)
CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)
Related CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)
Related to Carboplatin	n (%)	xx (xx.x)
Related to Paclitaxel	n (%)	xx (xx.x)
Serious AE (SAE)	n (%)	xx (xx.x)
Related SAE	n (%)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)
Related to Carboplatin	n (%)	xx (xx.x)
Related to Paclitaxel	n (%)	xx (xx.x)
TEAE Leading to Infusion Interruption/Delayed		
TEAE Leading to TSR-042 Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to TSR-042 Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Carboplatin Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to Carboplatin Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Paclitaxel Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to Paclitaxel Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Treatment Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to TSR-042 Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Carboplatin Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Paclitaxel Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Death	n (%)	xx (xx.x)

Source: Listing 16.2.7.2

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Table 14.3.1.1.3
Overall Treatment Emergent Adverse Events Summary for Part C (Safety Population)

Characteristic	Statistic	Part C-200 (N=XX)	Part C-300 (N=XX)	Overall (N=XX)
Treatment Emergent Adverse Event (TEAE)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dose-Limiting Toxicities (DLTs)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Bevacizumab	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Bevacizumab	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious AE (SAE)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related SAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Niraparib	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related to Bevacizumab	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Dose Reduction/ Interruption				
TEAE Leading to Niraparib Dose Reduction	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Niraparib Dose Interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to TSR-042 Infusion Interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to TSR-042 Infusion Delayed	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Bevacizumab Infusion Interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Bevacizumab Infusion Delayed	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE Leading to Treatment Discontinuation				
TEAEs Leading to Niraparib Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs Leading to TSR-042 Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs Leading to Bevacizumab Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs Leading to Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 16.2.7.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Table 14.3.1.1.4
Overall Treatment Emergent Adverse Events Summary for Part D (Safety Population)

Characteristic	Statistic	Part D (N=XX)
Treatment Emergent Adverse Event (TEAE)	n (%)	xx (xx.x)
Dose-Limiting Toxicities (DLTs)	n (%)	xx (xx.x)
Related to TEAE	n (%)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)
Related to Carboplatin	n (%)	xx (xx.x)
Related to Paclitaxel	n (%)	xx (xx.x)
Related to Bevacizumab	n (%)	xx (xx.x)
CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)
Related CTCAE Grade ≥ 3 TEAE	n (%)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)
Related to Carboplatin	n (%)	xx (xx.x)
Related to Paclitaxel	n (%)	xx (xx.x)
Related to Bevacizumab	n (%)	xx (xx.x)
Serious AE (SAE)		
Related SAE	n (%)	xx (xx.x)
Related to TSR-042	n (%)	xx (xx.x)
Related to Carboplatin	n (%)	xx (xx.x)
Related to Paclitaxel	n (%)	xx (xx.x)
Related to Bevacizumab	n (%)	xx (xx.x)
TEAE Leading to Infusion Interruption/Delayed		
TEAE Leading to TSR-042 Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to TSR-042 Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Carboplatin Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to Carboplatin Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Paclitaxel Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to Paclitaxel Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Bevacizumab Infusion Interruption	n (%)	xx (xx.x)
TEAE Leading to Bevacizumab Infusion Delayed	n (%)	xx (xx.x)
TEAE Leading to Treatment Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to TSR-042 Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Carboplatin Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Paclitaxel Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Bevacizumab Discontinuation	n (%)	xx (xx.x)
TEAEs Leading to Death	n (%)	xx (xx.x)

Source: Listing 16.2.7.4

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Table 14.3.1.2.1
Dose-Limiting Toxicity by Preferred Term and Maximum CTCAE Toxicity Grade for Part A (Safety Population)

Preferred Term	Statistic	Maximum CTCAE Grades	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Any dose-limiting toxicity	n (%)		n (%)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	Grade 1	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 2	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	n (%)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade 1	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 2	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	n (%)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	n (%)	xx (xx.x)	xx (xx.x)

…

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.3.1.2.1 for

Table 14.3.1.2.2 Dose-Limiting Toxicity by Preferred Termand Maximum CTCAE Toxicity Grade for Part B (Safety Population)

Table 14.3.1.2.3 Dose-Limiting Toxicity by Preferred Termand Maximum CTCAE Toxicity Grade for Part C (Safety Population)

Table 14.3.1.2.4 Dose-Limiting Toxicity by Preferred Termand Maximum CTCAE Toxicity Grade for Part D (Safety Population)

Table 14.3.1.3.1
Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part A (Safety Population)

System Organ Class Preferred Term	Statistics	Part A - 200 (N=XX)	Part A - 300 (N=XX)	Overall (N=XX)
Any treatment emergent adverse event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
…				

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.3.1.3.1 for

Table 14.3.1.3.2 Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.3.1.3.3 Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part C (Safety Population)

Table 14.3.1.3.4 Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part D (Safety Population)

Table 14.3.1.4.1
Treatment Emergent Adverse Events by Preferred Term for Part A (Safety Population)

Preferred Term	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…			

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat for

Table 14.3.1.4.2 Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part B (Safety Population)

Table 14.3.1.4.3 Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part C (Safety Population)

Table 14.3.1.4.4 Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part D (Safety Population)

Table 14.3.1.5.1
Drug-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part A (Safety Population)

System Organ Class		Part A-200 (N=XX)		Part A-300 (N=XX)		Part A (N=XX)		
Preferred Term	Statistics	Related to Niraparib	Related to TSR-042	Related to Niraparib	Related to TSR-042	Related to Niraparib	Related to TSR-042	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…								
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…								
…								

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part A: TSR-042 and niraparib (200mg/300mg) combination treatment

Table 14.3.1.5.2
Drug-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part B Group (Safety Population)

System Organ Class Preferred Term	Statistics	Part B (N=XX) Related to TSR-042	 Related to Carboplatin	 Related to Paclitaxel	Overall (N=XX)
Any Treatment Emergent Adverse Events	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…				
…					

Source: Listing 16.2.7.2

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Table 14.3.1.5.3.1
Drug-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part C – Result 1 (Safety Population)

System Organ Class		Part C-200 (N=XX)			Part C-300 (N=XX)		
Preferred Term	Statistics	Related to Niraparib	Related to TSR-042	Related to Bevacizumab	Related to Niraparib	Related to TSR-042	Related to Bevacizumab
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…						
…							

Source: Listing 16.2.7.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Table 14.3.1.5.3.2
Drug-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part C - Result 2 (Safety Population)

System Organ Class Preferred Term	Statistics	Part C (N=XX) Related to Niraparib	 Related to TSR-042	 Related to Bevacizumab	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…				
…					

Source: Listing 16.2.7.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C: TSR-042, niraparib (200mg/300mg) and bevacizumab combination treatment

Table 14.3.1.5.4
Drug-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term for Part D (Safety Population)

System Organ Class		Part D (N=XX)				
Preferred Term	Statistics	Related to TSR-042	Related to Carboplatin	Related to Paclitaxel	Related to Bevacizumab	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…						
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…					
…						

Source: Listing 16.2.7.4

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Table 14.3.1.6.1
Drug-Related Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part A (Safety Population)

		Part A-200 (N=XX)		Part A-300 (N=XX)		Part A (n=XX)		
Preferred Term	Statistics	Related to Niraparib	Related to TSR-042	Related to Niraparib	Related to TSR-042	Related to Niraparib	Related to TSR-042	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…								

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part A: TSR-042 and niraparib (200mg/300mg) combination treatment

Table 14.3.1.6.2
Drug-Related Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part B (Safety Population)

		Part B (N=XX)			
Preferred Term	Statistic	Related to TSR-042	Related to Carboplatin	Related to Paclitaxel	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Source: Listing 16.2.7.2

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Table 14.3.1.6.3.1
Drug-Related Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part C – Result 1 (Safety Population)

		Part C-200 (N=XX)			Part C-300 (N=XX)		
Preferred Term	Statistic	Related to Niraparib	Related to TSR-042	Related to Bevacizumab	Related to Niraparib	Related to TSR-042	Related to Bevacizumab
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							

Source: Listing 16.2.7.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Table 14.3.1.6.3.2
Drug-Related Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part C – Result 2
(Safety Population)

		Part C (N=XX)			
Preferred Term	Statistic	Related to Niraparib	Related to TSR-042	Related to Bevacizumab	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Source: Listing 16.2.7.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C: TSR-042, niraparib (200mg/300mg) and bevacizumab combination treatment

Table 14.3.1.6.4
Drug-Related Treatment Emergent Adverse Events by Preferred Term in Decreasing Frequency for Part D (Safety Population)

		Part D (N=XX)				
Preferred Term	Statistic	Related to TSR-042	Related to Carboplatin	Related to Paclitaxel	Related to Bevacizumab	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…						

Source: Listing 16.2.7.4

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Table 14.3.1.7.1
Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE Toxicity Grade ≥ 3 for Part A (Safety Population)

System Organ Class Preferred Term	Statistics	Maximum CTCAE Grades	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)		xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					
SOC 2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…				
…					

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.3.1.7.1 for

Table 14.3.1.7.2 Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE Toxicity Grade ≥ 3 for Part B (Safety Population)

Table 14.3.1.7.3 Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE Toxicity Grade ≥ 3 for Part C (Safety Population)

Table 14.3.1.7.4 Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE Toxicity Grade ≥ 3 for Part D (Safety Population)

Table 14.3.1.8.1

Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE Toxicity Grade ≥ 3 for Part A (Safety Population)

System Organ Class		Maximum	Part A-200 (N=XX)		Part A-300 (N=XX)		Part A (N=XX)		
Preferred Term	Statistic	CTCAE Grades	Related to Niraparib	Related to TSR-042	Related to Niraparib	Related to TSR-042	Related to Niraparib	Related to TSR-042	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…								
SOC 2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…								
…									

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Table 14.3.1.8.2
Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE Toxicity Grade ≥ 3 for Part B (Safety Population)

System Organ Class			Part B (N=XX)			
Preferred Term	Statistic	Maximum CTCAE Grades	Related to TSR-042	Related to Carboplatin	Related to Paclitaxel	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…						
SOC 2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…					
…						

Source: Listing 16.2.7.2

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Table 14.3.1.8.3.1
Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE Toxicity Grade ≥ 3 for Part C – Result 1
(Safety Population)

System Organ Class Preferred Term	Statistic	Maximum CTCAE Grades	Part C-200 (N=XX)			Part C-300 (N=XX)		
			Related to Niraparib	Related to TSR-042	Related to Bevacizumab	Related to Niraparib	Related to TSR-042	Related to Bevacizumab
Any Treatment Emergent Adverse Event	n (%)		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…								
SOC 2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…							
…								

Source: Listing 16.2.7.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Table 14.3.1.8.3.2
Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE Toxicity Grade ≥ 3 for Part C – Result 2 (Safety Population)

System Organ Class Preferred Term	Statistic	Maximum CTCAE Grades	Part C (N=XX) Related to Niraparib	 Related to TSR-042	 Related to Bevacizumab	 Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…						
SOC 2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…					
…						

Source: Listing 16.2.7.3

PROGRAM NAME:

DATE: DDMMYYYY

For programmer: add following footnotes
Part C: TSR-042, niraparib (200mg/300mg) and bevacizumab combination treatment

Table 14.3.1.8.4
Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE Toxicity Grade ≥ 3 for Part D (Safety Population)

System Organ Class Preferred Term	Statistic	Maximum CTCAE Grades	Part D (N=XX) Related to TSR-042	Related to Carboplatin	Related to Paclitaxel	Related to Bevacizumab	Overall (N=XX)
Any Treatment Emergent Adverse Event	n (%)		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							
SOC 2	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	…						

…

Source: Listing 16.2.7.4

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Repeat Table 14.3.1.3.1 for

Table 14.3.1.9.1 Serious AEs by System Organ Class and Preferred Term for Part A (Safety Population)

Table 14.3.1.9.2 Serious AEs by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.3.1.9.3 Serious AEs by System Organ Class and Preferred Term for Part C (Safety Population)

Table 14.3.1.9.4 Serious AEs by System Organ Class and Preferred Term for Part D (Safety Population)

Repeat Table 14.3.1.5.1 for

Table 14.3.1.10.1 Drug-Related Serious AEs by System Organ Class and Preferred Term for Part A (Safety Population)

Repeat Table 14.3.1.5.2 for

Table 14.3.1.10.2 Drug-Related Serious AEs by System Organ Class and Preferred Term for Part B (Safety Population)

Repeat Table 14.3.1.5.3.1 for

Table 14.3.1.10.3.1 Drug-Related Serious AEs by System Organ Class and Preferred Term for Part C – Result 1 (Safety Population)

Repeat Table 14.3.1.5.3.2 for

Table 14.3.1.10.3.2 Drug-Related Serious AEs by System Organ Class and Preferred Term for Part C – Result 2 (Safety Population)

Repeat Table 14.3.1.5.4 for

Table 14.3.1.10.4 Drug-Related Serious AEs by System Organ Class and Preferred Term for Part D (Safety Population)

Repeat Table 14.3.1.3.1 for

Table 14.3.1.11.1 Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part A (Safety Population)

Table 14.3.1.11.2 Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.3.1.11.3 Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part C (Safety Population)

Table 14.3.1.11.4 Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part D (Safety Population)

Repeat Table 14.3.1.5.1 for

Table 14.3.1.12.1 Drug-Related Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part A (Safety Population)

Repeat Table 14.3.1.5.2 for

Table 14.3.1.12.2 Drug-Related Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part B (Safety Population)

Repeat Table 14.3.1.5.3.1 for

Table 14.3.1.12.3.1 Drug-Related Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part C – Result 1 (Safety Population)

Repeat Table 14.3.1.5.3.2 for

Table 14.3.1.12.3.2 Drug-Related Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part C – Result 2 (Safety Population)

Repeat Table 14.3.1.5.4 for

Table 14.3.1.12.4 Drug-Related Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term for Part D (Safety Population)

Table 14.3.1.13.1.1
Treatment Emergent Adverse Events Leading to Niraparib Reduction/Interruption by System Organ Class and Preferred Term for Part A (Safety Population)

System Organ Class Preferred Term	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Any Reduction	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
…				
Any Interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
SOC 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
…				

Source: Listing 16.2.7.1

PROGRAM NAME:

DATE: DDMMYYYY

Repeat using proper drugs in the treatment for

Table 14.3.1.13.1.2 Treatment Emergent Adverse Events Leading to Niraparib Reduction/Interruption by System Organ Class and Preferred Term for Part C (Safety Population)

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Repeat Table 14.3.1.3.1 for

Table 14.3.1.13.2.1 Treatment Emergent Adverse Events Leading to TSR-042 Interruption by System Organ Class and Preferred Term for Part A (Safety Population)

Table 14.3.1.13.2.2 Treatment Emergent Adverse Events Leading to TSR-042 Interruption by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.3.1.13.2.3 Treatment Emergent Adverse Events Leading to TSR-042 Interruption by System Organ Class and Preferred Term for Part C (Safety Population)

Table 14.3.1.13.2.4 Treatment Emergent Adverse Events Leading to TSR-042 Interruption by System Organ Class and Preferred Term for Part D (Safety Population)

Repeat Table 14.3.1.3.1 for

Table 14.3.1.13.3.1 Treatment Emergent Adverse Events Leading to Carboplatin Interruption by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.3.1.13.3.2 Treatment Emergent Adverse Events Leading to Carboplatin Interruption by System Organ Class and Preferred Term for Part D (Safety Population)

Repeat Table 14.3.1.3.1 for

Table 14.3.1.13.4.1 Treatment Emergent Adverse Events Leading to Paclitaxel Interruption by System Organ Class and Preferred Term for Part B (Safety Population)

Table 14.3.1.13.4.2 Treatment Emergent Adverse Events Leading to Paclitaxel Interruption by System Organ Class and Preferred Term for Part D (Safety Population)

Table 14.3.1.13.5.1 Treatment Emergent Adverse Events Leading to Bevacizumab Interruption by System Organ Class and Preferred Term for Part C (Safety Population)

Table 14.3.1.13.5.2 Treatment Emergent Adverse Events Leading to Bevacizumab Interruption by System Organ Class and Preferred Term for Part D (Safety Population)

Table 14.3.1.14.1
Deaths in Part A (Safety Population)

Period	Statistic	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
During Treatment Period				
Deaths	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
Reasons for Death				
Disease Progression	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Follow-up Period				
Deaths	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for Death				
Disease Progression	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.3.1.14.1 for

Table 14.3.1.14.2 Deaths in Part B (Safety Population)

Table 14.3.1.14.3 Deaths in Part C (Safety Population)

Table 14.3.1.14.4 Deaths in Part D (Safety Population)

Table 14.3.1.15.1
Adverse Events of Special Interest by Preferred Term for Part A (Safety Population)

Adverse Event Special Interest Category Preferred Term	Statistic	TRT A-200 (N=XX)	TRT A-300 (N=XX)	Overall (N=XX)
Any Adverse Event of Special Interest	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
Category 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
…				

Source: Listing 16.2.7.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
TRT A-200: TSR-042 and niraparib (200mg) combination treatment
TRT A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat for

Table 14.3.1.15.2 Adverse Events of Special Interest by Preferred Term for Part B (Safety Population)

Table 14.3.1.15.3 Adverse Events of Special Interest by Preferred Term for Part C (Safety Population)

Table 14.3.1.15.4 Adverse Events of Special Interest by Preferred Term for Part D (Safety Population)

Table 14.3.1.16
Overall Summary of Immune Related Treatment Emergent Adverse Events by Preferred Term (Safety Population)

Preferred Term/ Treatment	Overall n(%)	TSR-042 Related n(%)	>=Grade3 n(%)	TSR-042 Related >=Grade3 n(%)	SAE n(%)	TSR-042 Related SAE n(%)	Leading to TSR-042 Discontinuation n(%)
Diarrhoea							
Part A-200 (N= 16)	0	0	0	0	0	0	0
Part A-300 (N= 6)	0	0	0	0	0	0	0
Part B (N= 14)	3(21.43)	0	0	0	0	0	0
Part C-200 (N= 6)	0	0	0	0	0	0	0
Part C-300 (N= 7)	1(14.29)	1(14.29)	1(14.29)	1(14.29)	0	0	0
Part D (N= 6)	3(50.00)	0	1(16.67)	0	0	0	0
Overall (N= 55)	7(12.73)	1(1.82)	2(3.64)	1(1.82)	0	0	0
Alanineaminotransferase increased							
Part A-200 (N= 16)	1(6.25)	1(6.25)	1(6.25)	1(6.25)	0	0	0
Part A-300 (N= 6)	0	0	0	0	0	0	0
Part B (N= 14)	2(14.29)	2(14.29)	2(14.29)	2(14.29)	0	0	2(14.29)
Part C-200 (N= 6)	1(16.67)	0	0	0	0	0	0
Part C-300 (N= 7)	1(14.29)	1(14.29)	1(14.29)	1(14.29)	0	0	0
Part D (N= 6)	1(16.67)	0	0	0	0	0	0
Overall (N= 55)	6(10.91)	4(7.27)	4(7.27)	4(7.27)	0	0	2(3.64)

Table 14.3.2.1
Patients with Adverse Events with Outcome of Death (Safety Analysis Set)

Part	Patient ID	Drugs	First Dose Date	Last Dose Date	Death Date	Death within 90 Days of Last Treatment	Cause of Death
					DDMMYYYY	Y/N	

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Table 14.3.2.2
Listing of Serious Adverse Events (Safety Population)

Part	Patient ID	System Organ Class/ Preferred Term/Verbatim Term	Start Date/Time (Rel Days [1])	Stop Date/Time	Severity	Relationship to Drug	Action Taken [2][3]	16.2.7.1
			DDMMYYYYTH H:MM:SS (days)					
Part A - 200								Y/N
Part A - 300				ongoing				
…								

[1] Rel Days are calculated as AE date minus first dose date (plus 1 day if AE date is on or after first dose date).
[2] N=Niraparib, T=TSR-042, C=Carboplatin, PC=Paclitacxel, B=Bevacizumab, PM=Pemetrexed, TT=TSR-022
[3] 1= Dose/Infusion Not Changed; 4= Drug/Infusion Interrupted; 5= Infusion Delayed; 6= Drug Withdrawn; 7= Not Applicable;
PROGRAM NAME:
DATE: DDMMYYYY

Repeat for

Table 14.3.2.3 Listing of Treatment Emergent Adverse Events Leading to Dose Interruption (Safety Population)

Table 14.3.2.4 Listing of Treatment Emergent Adverse Events Leading to Dose Modification (Safety Population)

Table 14.3.2.5 Listing of Treatment Emergent Adverse Events Leading to Discontinuation from Treatment (Safety Population)

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Table 14.3.4.1
Listing of Abnormal Laboratory Values (Safety Population)

Part	Patient ID	Age/Sex	Group	Visit	Visit Date (Rel Days [1])	Laboratory Test (Unit)	Measurement Date	Result	CTCAE Grade	Normal Range	Clinically Significant
			Chemistry	Baseline			DDMMYYYY			xx.xx, xx.xx	Y/N
				…							
			Hematology	Baseline							
				…							
			Coagulation	Baseline							
				…							
			Chemistry	Baseline							
				…							
			…								

[1] Rel Days are calculated as visit date minus first dose date (plus 1 day if visit date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

Repeat for

Table 14.3.4.2 Listing of Laboratory Values with CTCAE Toxicity Grade ≥ 3 (Safety Population)

Table 14.3.4.3 Listing of Clinically Significant Laboratory Values (Safety Population)

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Table 14.3.5.1
Extent of Exposure for Part A (Safety Population)

Study Drug Parameters	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Niraparib				
Duration of Exposure (days)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of Treatment Cycles				
1 Cycle	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Actual Cumulative Dose (mg)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Actual Dose Intensity (mg/day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Relative Dose Intensity (%)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of patients with dose interruptions	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Number of patients with dose reduction	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
TSR-042				
Duration of Treatment (day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of Treatment Cycles				
1 Cycle	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Actual Dose Intensity (mg/day)				
< 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

≥ 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Relative dose Intensity (%)				
< 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
≥ 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Source: Listing 16.2.5.4 Listing 16.2.5.5 Listing 16.2.5.6

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Table 14.3.5.2
Extent of Exposure for Part B (Safety Population)

Study Drug Parameters	Statistics	Part B (N=XX)
TSR-042		
Duration of Treatment (day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Actual Cumulative Dose (mg)		
< 5th Cycle	n	xx
	Mean(STD)	xx.x (xx.xx)
	Median	xx.x
	Min,Max	xx, xx
≥ 5th Cycle	n	xx
	Mean(STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Actual Dose Intensity (mg/day)		
< 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
≥ 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Relative dose Intensity (%)		
< 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
≥ 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)
Paclitaxel		
Duration of Treatment (day)	n	xx

	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Actual Dose Intensity (mg/m2/day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Relative dose Intensity (%)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)
Carboplatin		
Duration of Treatment (day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)

Source: Listing 16.2.5.6 Listing 16.2.5.7 Listing 16.2.5.8

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Table 14.3.5.3
Extent of Exposure for Part C (Safety Population)

Parameters	Statistics	Part C-200 (N=XX)	Part C-300 (N=XX)	Overall (N=XX)
Niraparib				
Duration of Exposure (day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of Treatment Cycles				
1 Cycle	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Actual Cumulative Dose (mg)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Actual Dose Intensity (mg/day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Relative Dose Intensity (%)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of patients with dose interruptions	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Number of patients with dose reduction	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

TSR-042				
Duration of Treatment (day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of Treatment Cycles				
1 Cycle	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Actual Cumulative Dose(mg)				
< 5th Cycle	n	xx	xx	n
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	Mean (STD)
	Median	xx.x	xx.x	Median
	Min, Max	xx, xx	xx, xx	Min, Max
≥ 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Actual Dose Intensity (mg/day)				
< 5th Cycle	n	xx	xx	n
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	Mean (STD)
	Median	xx.x	xx.x	Median
	Min, Max	xx, xx	xx, xx	Min, Max
≥ 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Relative dose Intensity (%)				
< 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

≥ 5th Cycle	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of patients with dose interruptions	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Bevacizumab				
Duration of Treatment (day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of Treatment Cycles				
1 Cycle	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
…				
Actual Cumulative Dose (mg)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Actual Dose Intensity (mg/kg/day)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Relative dose Intensity (%)	n	xx	xx	xx
	Mean (STD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Number of patients with dose interruptions	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Source: Listing 16.2.5.4 Listing 16.2.5.5 Listing 16.2.5.6

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Table 14.3.5.4
Extent of Exposure for Part D (Safety Population)

Parameters	Statistics	Part D (N=XX)
TSR-042		
Duration of Treatment (day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Actual Cumulative Dose(mg)		
< 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
≥ 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Actual Dose Intensity (mg/day)		
< 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
≥ 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Relative dose Intensity (%)		
< 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x

	Min, Max	xx, xx
≥ 5th Cycle	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)
Paclitaxel		
Duration of Treatment (day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Actual Cumulative Dose (mg)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Actual Dose Intensity (mg/m^2/day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Relative dose Intensity (%)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)
Carboplatin		

Duration of Treatment (day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)
Bevacizumab		
Duration of Treatment (day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of Treatment Cycles		
1 Cycle	n (%)	xxx (xx.x)
2 Cycles	n (%)	xxx (xx.x)
…		
Actual Cumulative Dose (mg)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Actual Dose Intensity (mg/kg/day)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Relative dose Intensity (%)	n	xx
	Mean (STD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Number of patients with Dose Interruptions	n (%)	xxx (xx.x)

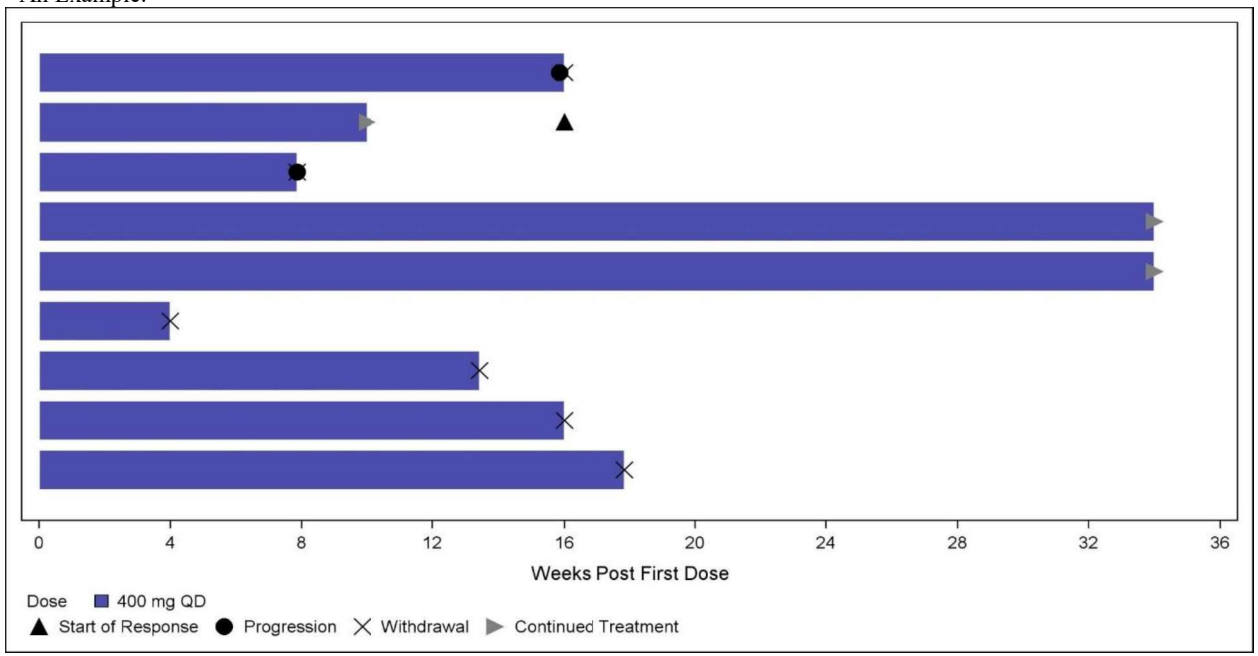
Source: Listing 16.2.5.6 Listing 16.2.5.7 Listing 16.2.5.8 Listing 16.2.5.11

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Figure 14.3.5.1
Swimmer Plot of Treatment Duration for Part A (Safety Population)

An Example:

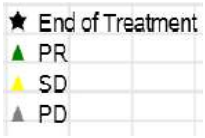


This is an example of swimmer plot. Add indicators to the plot: primary tumor type, treatment on-going or discontinued and response at each tumor assessment.
Source: Listing 16.2.6.1

PROGRAM NAME:
DATE: DDMMYYYY

Programming Notes for Programmers

Include subjid and dose level in Y-axis. Label should be Subject (Dose level)
Y-axis label should be “Duration of exposure (weeks)”

Include the following indicators 

in the figure
Legend should be placed in the bottom right corner of the figure

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Figure 14.3.5.1 for

Figure 14.3.5.2 Swimmer Plot of Treatment Duration for Part B (Safety Population)

Figure 14.3.5.3 Swimmer Plot of Treatment Duration for Part C (Safety Population)

Figure 14.3.5.4 Swimmer Plot of Treatment Duration for Part D (Safety Population)

Table 14.3.6.1.1
Summary of Actual and Change from Baseline Value for Hematology Parameters for Part A (Safety Population)

Parameter	Visit	Actual/Change	Statistics	PARTA-200 (N=16)	PART A-300 (N=6)	Overall (N=22)
Hemoglobin (g/L)	Baseline	Actual	n	16	6	22
			Mean (STD)	121.6 (13.36)	134.0 (8.72)	125.0 (13.32)
			Median	123.0	132.0	126.5
			Min, Max	93, 146	126, 151	93, 151
	CYCLE 1 DAY 8	Actual	n	16	5	21
			Mean (STD)	120.8 (12.87)	133.8 (7.95)	123.9 (13.01)
			Median	122.0	131.0	127.0
			Min, Max	100, 145	127, 147	100, 147
		Change	n	16	5	21
			Mean (STD)	-0.9 (6.70)	-0.4 (4.83)	-0.8 (6.20)
			Median	-1.0	-1.0	-1.0
			Min, Max	-9, 16	-6, 5	-9, 16
	CYCLE 1 DAY 15	Actual	n	13	6	19
			Mean (STD)	119.8 (12.77)	127.0 (7.18)	122.1 (11.60)
			Median	124.0	127.5	125.0
			Min, Max	93, 139	115, 137	93, 139
		Change	n	13	6	19
			Mean (STD)	-2.5 (9.32)	-7.0 (10.68)	-3.9 (9.71)
			Median	-5.0	-5.5	-5.0
			Min, Max	-18, 16	-23, 6	-23, 16

Repeat Table 14.3.6.1.1 for

Table 14.3.6.1.2 Summary of Actual and Change from Baseline Value for Hematology Parameters for Part B (Safety Population)

Table 14.3.6.1.3 Summary of Actual and Change from Baseline Value for Hematology Parameters for Part C (Safety Population)

Table 14.3.6.1.4 Summary of Actual and Change from Baseline Value for Hematology Parameters for Part D (Safety Population)

Repeat Table 14.3.6.1.1 for

Table 14.3.6.2.1 Summary of Actual and Change from Baseline Value for Chemistry Parameters for Part A (Safety Population)

Table 14.3.6.2.2 Summary of Actual and Change from Baseline Value for Chemistry Parameters for Part B (Safety Population)

Table 14.3.6.2.3 Summary of Actual and Change from Baseline Value for Chemistry Parameters for Part C (Safety Population)

Table 14.3.6.2.4 Summary of Actual and Change from Baseline Value for Chemistry Parameters for Part D (Safety Population)

Repeat Table 14.3.6.1.1 for

Table 14.3.6.3.1 Summary of Actual and Change from Baseline Value for Coagulation Parameters for Part A (Safety Population)

Table 14.3.6.3.2 Summary of Actual and Change from Baseline Value for Coagulation Parameters for Part B (Safety Population)

Table 14.3.6.3.3 Summary of Actual and Change from Baseline Value for Coagulation Parameters for Part C (Safety Population)

Table 14.3.6.3.4 Summary of Actual and Change from Baseline Value for Coagulation Parameters for Part D (Safety Population)

Repeat Table 14.3.6.1.1 for

Table 14.3.6.4.1 Summary of Actual and Change from Baseline Value for Thyroid Function Parameters for Part A (Safety Population)

Table 14.3.6.4.2 Summary of Actual and Change from Baseline Value for Thyroid Function Parameters for Part B (Safety Population)

Table 14.3.6.4.3 Summary of Actual and Change from Baseline Value for Thyroid Function Parameters for Part C (Safety Population)

Table 14.3.6.4.4 Summary of Actual and Change from Baseline Value for Thyroid Function Parameters for Part D (Safety Population)

Repeat Table 14.3.6.1.1 for

Table 14.3.7.1 Summary of Actual and Change from Baseline Value for ECG Continuous Parameters for Part A (Safety Population)

Table 14.3.7.2 Summary of Actual and Change from Baseline Value for ECG Continuous Parameters for Part B (Safety Population)

Table 14.3.7.3 Summary of Actual and Change from Baseline Value for ECG Continuous Parameters for Part C (Safety Population)

Table 14.3.7.4 Summary of Actual and Change from Baseline Value for ECG Continuous Parameters for Part D (Safety Population)

Programming Notes for programmers:

Add Timepoint column after Visit to capture the timepoints PREDOSE and 2 HOURS POST DOSE

Table 14.3.8.1.1
Shift of Hematology Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part A (Safety Population)

Hemoglobin
(Anemia)

			Post-Baseline Maximum CTCAE Grade							
Treatment Group	Statistics	Baseline CTCAE Grade	Missing	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Overall
Part A-200 (N=16)	n (%)	Missing	0	0	0	0	0	0	0	0
	n (%)	Grade 0	0	1 (6.3)	3 (18.8)	1 (6.3)	2 (12.5)	0	0	7 (43.8)
	n (%)	Grade 1	0	0	4 (25.0)	3 (18.8)	1 (6.3)	0	0	8 (50.0)
	n (%)	Grade 2	0	0	0	0	1 (6.3)	0	0	1 (6.3)
	n (%)	Grade 3	0	0	0	0	0	0	0	0
	n (%)	Grade 4	0	0	0	0	0	0	0	0
	n (%)	Overall	0	1 (6.3)	7 (43.8)	4 (25.0)	4 (25.0)	0	0	16 (100.0)
Part A-300 (N=6)	n (%)	Missing	0	0	0	0	0	0	0	0
	n (%)	Grade 0	0	1 (16.7)	0	2 (33.3)	0	0	0	3 (50.0)
	n (%)	Grade 1	0	0	2 (33.3)	1 (16.7)	0	0	0	3 (50.0)
	n (%)	Grade 2	0	0	0	0	0	0	0	0
	n (%)	Grade 3	0	0	0	0	0	0	0	0
	n (%)	Grade 4	0	0	0	0	0	0	0	0
	n (%)	Overall	0	1 (16.7)	2 (33.3)	3 (50.0)	0	0	0	6 (100.0)

…

Note: Percentages are based on number of patients who has grades present at both baseline and post-baseline in safety population for each study treatment.
Source: Listing 16.2.8.1

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat Table 14.3.8.1.1 for

Table 14.3.8.1.2 Shift of Hematology Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part B (Safety Population)

Table 14.3.8.1.3 Shift of Hematology Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part C (Safety Population)

Table 14.3.8.1.4 Shift of Hematology Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part D (Safety Population)

Repeat Table 14.3.8.1.1 for

Table 14.3.8.2.1 Shift of Chemistry Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part A (Safety Population)

Table 14.3.8.2.2 Shift of Chemistry Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part B (Safety Population)

Table 14.3.8.2.3 Shift of Chemistry Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part C (Safety Population)

Table 14.3.8.2.4 Shift of Chemistry Parameters from Baseline to Worst Post-Baseline Toxicity Grade for Part D (Safety Population)

Table 14.3.9.1.1
Summary of Post-Baseline Liver Function for Part A (Safety Population)

Maximum Elevation under treatment	Statistics	PART A-200 (N=16)	PART A-300 (N=6)	Overall (N=22)
ALT				
<3 x ULN	n(%)	15(93.8)	6(100.0)	21(95.5)
3 x ULN =<-- < 5 x ULN	n(%)	0	0	0
5 x ULN =<-- < 10 x ULN	n(%)	0	0	0
10 x ULN =<-- < 20 x ULN	n(%)	0	0	0
>= 20 x ULN	n(%)	1(6.3)	0	1(4.5)
AST				
<3 x ULN	n(%)	14(87.5)	5(83.3)	19(86.4)
3 x ULN =<-- < 5 x ULN	n(%)	1(6.3)	0	1(4.5)
5 x ULN =<-- < 10 x ULN	n(%)	0	1(16.7)	1(4.5)
10 x ULN =<-- < 20 x ULN	n(%)	0	0	0
>= 20 x ULN	n(%)	1(6.3)	0	1(4.5)
ALT or AST				
<3 x ULN	n(%)	13(81.3)	5(83.3)	18(81.8)
3 x ULN =<-- < 5 x ULN	n(%)	1(6.3)	0	1(4.5)
5 x ULN =<-- < 10 x ULN	n(%)	0	1(16.7)	1(4.5)
10 x ULN =<-- < 20 x ULN	n(%)	0	0	0
>= 20 x ULN	n(%)	1(6.3)	0	1(4.5)
Total Bilirubin Level (TBL)				
< 1.5 x ULN	n(%)	15(93.8)	5(83.3)	20(90.9)
1.5 x ULN =< -- < 2 x ULN	n(%)	1(6.3)	0	1(4.5)
>= 2 x ULN	n(%)	0	1(16.7)	1(4.5)
Alkaline Phosphatase (ALP)				
< 1.5 x ULN	n(%)	11(68.8)	4(66.7)	15(68.2)
1.5 x ULN =< -- < 2 x ULN	n(%)	0	0	0
>= 2 x ULN	n(%)	5(31.3)	2(33.3)	7(31.8)

```
Concurrent          ALT          >=3×ULN          and n(%)          0                 0                 0
TBL >=2×ULN

Concurrent          AST          >=3×ULN          and n(%)          0                 1( 16.7)          1(  4.5)
TBL >=2×ULN

Concurrent     (ALT     or     AST)     >=3×ULN     and n(%)          0                 1( 16.7)          1(  4.5)
TBL >=2×ULN

Concurrent     (ALT     or     AST)     >=3×ULN     and n(%)          0                 1( 16.7)          1(  4.5)
TBL >=2×ULN and ALP >= 2×ULN

Potential                  Hy's                  law: n(%)          0                 0                 0
Concurrent       (ALT       or       AST)       >=3×ULN
and TBL >=2×ULN and ALP <2×ULN
```

Repeat for

Table 14.3.9.1.2 Summary of Post-Baseline Liver Function for Part B (Safety Population)

Table 14.3.9.1.3 Summary of Post-Baseline Liver Function for Part C (Safety Population)

Table 14.3.9.1.4 Summary of Post-Baseline Liver Function for Part D (Safety Population)

Table 14.3.10.1.1
Shift of ECOG Performance Status from Baseline to Worst Post-Baseline Score for Part A (Safety Population)

			Worst Post-Baseline ECOG Score							
Part	Statistics	Baseline ECOG Score	0	1	2	3	4	5	Missing	Overall
Part A-200 (N=16)	n(%)	0	3(18.8)	4(25.0)	0	0	0	0	1(6.3)	8(50.0)
	n(%)	1	0	5(31.3)	1(6.3)	0	0	0	2(12.5)	8(50.0)
	n(%)	2	0	0	0	0	0	0	0	0
	n(%)	3	0	0	0	0	0	0	0	0
	n(%)	4	0	0	0	0	0	0	0	0
	n(%)	Overall	3(18.8)	9(56.3)	1(6.3)	0	0	0	3(18.8)	16(100.0)
Part A-300 (N=6)	n(%)	0	1(16.7)	1(16.7)	1(16.7)	0	0	0	0	3(50.0)
	n(%)	1	0	3(50.0)	0	0	0	0	0	3(50.0)
	n(%)	2	0	0	0	0	0	0	0	0
	n(%)	3	0	0	0	0	0	0	0	0
	n(%)	4	0	0	0	0	0	0	0	0
	n(%)	Overall	1(16.7)	4(66.7)	1(16.7)	0	0	0	0	6(100.0)
Overall (N=22)	n(%)	0	4(18.2)	5(22.7)	1(4.5)	0	0	0	1(4.5)	11(50.0)
	n(%)	1	0	8(36.4)	1(4.5)	0	0	0	2(9.1)	11(50.0)
	n(%)	2	0	0	0	0	0	0	0	0
	n(%)	3	0	0	0	0	0	0	0	0
	n(%)	4	0	0	0	0	0	0	0	0
	n(%)	Overall	4(18.2)	13(59.1)	2(9.1)	0	0	0	3(13.6)	22(100.0)

Repeat Table 14.3.10.1.1 for

Table 14.3.10.1.2 Shift of ECOG Performance Status from Baseline to Worst Post-Baseline Score for Part B (Safety Population)

Table 14.3.10.1.3 Shift of ECOG Performance Status from Baseline to Worst Post-Baseline Score for Part C (Safety Population)

Table 14.3.10.1.4 Shift of ECOG Performance Status from Baseline to Worst Post-Baseline Score for Part D (Safety Population)

Table 14.3.10.2.1
Notable ECG Values for Part A (Safety Population)

Visit	Parameter	Statistics	Part A-200 (N=XX)	Part A-300 (N=XX)	Overall (N=XX)
Cycle 1 Day 1	Number of Patients	n	xx	xx	
	QTcF increase from baseline				
	>30 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	>60 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	QTcF				
	> 450 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	> 480 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	> 500 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	HR				
	HR ≤ 50 bpm and decrease from baseline ≥ 20 bpm	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	HR ≥ 120 bpm and increase from baseline ≥ 20 bpm	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	PR				
	PR ≥ 220 ms and increase from baseline ≥ 20 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	QRS ≥ 120 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cycle 2 Day 1	Number of Patients	n	xx	xx	
	QTcF increase from baseline				
	>30 ms	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	…				
	…				
…					

Note: Percentage is calculated using the number of patients at visit as denominator
Source: Listing 16.2.12.2 Listing 16.2.12.3

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment

Repeat for

Table 14.3.10.2.2 Notable ECG Values for Part B (Safety Population)

Table 14.3.10.2.3 Notable ECG Values for Part C (Safety Population)

Table 14.3.10.2.4 Notable ECG Values for Part D (Safety Population)

Listing 16.2.1.1
Patient Enrollment (All Patients Population)

Part	Patient ID	AAP	SP	Informed Consent Date	Drug Received	Date of First Dose
Not Dosed	PPD	Y	N	PPD		
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
		Y	N			
Part A-200		Y	Y		TSR-042/Niraparib	PPD
		Y	Y		TSR-042/Niraparib	
		Y	Y		TSR-042/Niraparib	
		Y	Y		TSR-042/Niraparib	
		Y	Y		TSR-042/Niraparib	

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.1.2.1
Discontinuation of Treatment Niraparib (Safety Population)

Part	Patient ID	Date of Discontinuation	First Dose Date	Last Dose Date	Number of Days on Treatment [1]	Discontinuation Reasons	Other Reasons
			DDMMYYYY	DDMMYYYY			
Part A -200		DDMMYYYY					
Part A-300							
Part C-200							
Part C-300							
…							

[1] Days on treatment = Last dose date – first dose date + 1

PROGRAM NAME:
DATE: DDMMYYYY

Repeat using proper treatment and study drug for

Listing 16.2.1.2.2 Discontinuation of Treatment TSR-042 (Safety Population)

Listing 16.2.1.2.3 Discontinuation of Treatment Bevacizumab (Safety Population)

Listing 16.2.1.2.4 Discontinuation of Carboplatin-Paclitaxel (Safety Population)

Listing 16.2.1.2.5 Discontinuation of Treatment TSR-022 (Safety Population)

Listing 16.2.1.2.6 Discontinuation of Treatment Carboplatin (Safety Population)

Listing 16.2.1.2.7 Discontinuation of Treatment Pemetrexed (Safety Population)

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Listing 16.2.1.3
Discontinuation from Study (Safety Population)

Part	Patient ID	Discontinuation Date	Reasons for Discontinuation	Other Reasons for Discontinuation	Death Date	Cause of Death	Other Death Cause	Autopsy performed
Part A-200		DDMMYYYY	DDMMYYYY					Y/N
Part A-300								
Part B								
Part C-200								
Part C-300								
Part D								
…								
…								

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.2
Protocol Deviation by Category and Severity (All Patients Population)

Part	Patient ID	Date of Protocol Deviation	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation
Part A-200		DDMMYYYY			
Part A-300					
Part B					
Part C-200					
Part C-300					
Part D					
…					
…					

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.3
Patients Excluded Due to Eligibility (All Patients Population)

Patient ID	SAFFL	Initial Protocol Version	Current Protocol Version	Visit Date	Meet all Eligibility Criteria?	Failed Criteria	
						Criterion Type	Criterion Number
				DDMMYYYY	Y		
				DDMMYYYY	N	Exclusion	EXCL 5
				…			
				…			
				DDMMYYYY	N	Inclusion	INCL 1
				…			
				…			
				…			

PROGRAM NAME:
DATE: DDMMYYYY

Listing 16.2.4.1
Demographics (Safety Population)

Part	Patient ID	Age (Years)	Sex	Ethnicity	Race	Specify Other Race
Part A-200						
Part A-300						
Part B						
Part C-200						
Part C-300						
Part D						
…						

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.2
Medical History (Safety Population)

Part	Patient ID	Condition	System Organ Class/Preferred Term	Start date (Rel Days [1])	Condition Ongoing at Study Entry	Stop date
Part A-200				DDMMYYYY (days)	Y/N	DDMMYYYY
Part A-300				Unknown		Unknown
Part B						
Part C-200						
Part C-300						
Part D						
…						
…						

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.3
Surgical History (Safety Population)

Part	Patient ID	Major Surgeries Reported	Surgery	Surgery Date (Rel Days [1])	Cancer Related
Part A-200		Y/N		DDMMYYYY (days)	Y/N
Part A-300					
Part B					
Part C-200					
Part C-300					
Part D					
…					

[1] Rel Days are calculated as surgery date minus first dose date (plus 1 day if surgery date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.4
Previous Radiotherapy (Safety Population)

Part	Patient ID	Radiotherapy Prior to Informed Consent	Site or Region	Start Date (Rel Days [1])	End Date	Total Grays
Part A-200		Y/N		DDMMYYYY (days)	DDMMYYYY	
Part A-300						
Part B						
Part C-200						
Part C-300						
Part D						
…						

[1] Rel Days = first dose date - start date

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.5
Concomitant Radiotherapy (Safety Population)

Part	Patient ID	Was the site a target or non-target lesion?	Lesion Number	Start Date (Rel Days [1])	End Date	Total Grays
Part A-200		Y/N		DDMMYYYY (days)	DDMMYYYY	
Part A-300						
Part B						
Part C-200						
Part C-300						
Part D						
…						

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if radiotherapy start date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.6
Prior Transfusions and Growth Factors (Safety Population)

Part	Patient ID	Received Transfusions or Growth Factors	Type of Administration	Specify Other	Total Units	Start Date (Rel Days [1])	Stop Date
Part A-200		Y/N				DDMMYYYY (days)	DDMMYYYY
Part A-300							
Part B							
Part C-200							
Part C-300							
Part D							

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date).

PROGRAM NAME:

DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.7
Concomitant Transfusion (Safety Population)

Part	Patient ID	Transfusions within 14 days prior to first dose and/or during the study	Type of Administration	Specify Other	Total Units	Start Date (Rel Days [1])	End Date
						DDMMYYYY (days)	DDMM YYYY
Part A-200		Y/N					
Part A-300							
Part B							
Part C-200							
Part C-300							
Part D							

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.8
Concomitant Growth Factors (Safety Population)

Part	Patient ID	Growth factor given within 14 days prior to first dose and/or during the study	Type of Administration	Specify Other	Dose	Units	Start Date (Rel Days [1])	End Date
Part A-200 Part A-300 Part B Part C-200 Part C-300 Part D		Y/N					DDMMYYYY (days)	DDMMYYYY

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.9
Prior Blood Disorders (Safety Population)

Part	Patient ID	Prior History of Thrombocytopenia, Leukopenia, Anemia or Neutropenia	Event	CTCAE Grade	Start Date (Rel Days [1])	End Date
Part A-200		Y/N			DDMMYYYY (days)	DDMMYYYY
Part A-300						
Part B						
Part C-200						
Part C-300						
Part D						

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.10
Prior Anticancer Treatment for Primary Cancer (Safety Population)

Part	Patient ID	Regimen Number	Agent Name	Specify Other	Start Date	End Date	Best Response	SDate of Progression or Recurrence	Reason for Discontinuation	Specify if Toxicity or Other
					DDMM YYYY					
Part A-200										
Part A-300										
Part B										
Part C-200										
Part C-300										
Part D										

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.11
Primary Cancer History (Safety Population)

Part	Patient ID	Date of First Diagnosis (Rel Days [1])	Tumor Site at First Diagnosis	Cancer Stage First Diagnosis	Tumor Site Most Recent Diagnosis	Cancer Stage Most Recent Diagnosis
Part A-200		DDMMYYYY				
Part A-300						
Part B						
Part C-200						
Part C-300						
Part D						

[1] Rel Days are calculated as first diagnosis date minus first dose date (plus 1 day if first diagnosis date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.4.12
HBsAg and HCV Testing at Baseline (Safety Population)

Part	Patient ID	Test Name	Test Date (Rel Days [1])	HBsAg	HCV
			DDMMYYYY (days)		
Part A-200					
Part A-300					
Part B					
Part C-200					
Part C-300					
Part D					

[1] Rel Days are calculated as test date minus first dose date (plus 1 day if test date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.5.1
Prior and Concomitant Medication/Therapy (Safety Population)

Part	Patient ID	ATC/Generic Name/Verbatim Name	Non-Anticancer Y/N	Indication	Dose per administration	Dose Unit	Frequency	Route of Administration	Start Date (Rel Days [1])	End Date	Ongoing
Part A-200											Y/N
Part A-300											
Part B											
Part C-200											

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date)

PROGRAM NAME:

DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment

Part A-300: TSR-042 and niraparib (300mg) combination treatment

Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment

Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Part E: TSR-042 and carboplatin-pemetrexed combination treatment

Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment

Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.5.2
Concomitant Procedures (Safety Population)

Part	Patient ID	Procedure Performed	Start Date (Rel Days [1])	Procedure	Results/Findings	AE/SAE	Indication
Part A-200		Y/N					
Part A-300							
Part B							
Part C-200							
Part C-300							
Part D							

[1] Rel Days are calculated as procedure date minus first dose date (plus 1 day if procedure date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.5.3
Niraparib First Dose (Safety Population)

Part	Patient ID	Taken at C1D1	Dose date	Time	Kit Number Assigned	No. of Pills dispensed	Dose prescribed (mg)	Full Dose Consumed	Dose Consumed (mg)	Reason Not Consumed
Part A-200		Y/N	DDMMYYYY	HH:MM:SS						
Part A-300										
Part C-200										
Part C-300										

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Listing 16.2.5.4
Niraparib Dose Modification (Safety Population)

Part	Patient ID	Dose Modified or Missed	Start date (Rel Days [1])	Stop date	No. of Pills Not Taken	Action Taken	Dose	Unit	Reason for Modification	Other Reason for Modification
A-200 A-300 C-200 C-300		Y/N	DDMMYYYY (days)							

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Listing 16.2.5.5
Niraparib Administration (Safety Population)

			At this Cycle												
Part	Patient ID	Visit	Niraparib Kit Return	Kit Returned	No. Pills Remain	Niraparib Dose Given	Kit Disp.	No. Pills Disp.	Dose Prescribed (mg)	Date Administered (Rel Days [1])	Dose	Time Dose Administered	Full Dose Consumed	Dose Consumed (mg)	Reason for Modification
A-200	PPD	C2D1	Y	P1000041	30	Y	P1000043	72	200	PPD	(22)	10:26	Y	200	
A-200		C3D1	Y	P1000043	32	Y	P1000044	72	200		(43)	13:05	Y	200	
A-200		C4D1	Y	P1000044	30	Y	P1000061	72	200		(64)	11:53	Y	200	
A-200		C5D1	Y	P1000061	30	Y	P1000062	72	200		(85)	12:37	Y	200	
A-200		C6D1	Y	P1000062	32	Y	P1000063	72	200		(107)	11:26	Y	200	

…

[1] Rel Days are calculated as administration date minus first dose date (plus 1 day if administration date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Listing 16.2.5.6
TSR-042 Administration (Safety Population)

Part	Patient ID	Visit	Infusion Given/ Reason	Intended Total Dose (mg)	Delayed More Than 3 Days/ Reason	Date of Infusion (Rel Days [1])	Start Time	Infusion Interrupted/ Reason	Interrupted Infusion Restarted	Restarted Infusion Completed/ Reason	End Date Time	Total Dose Infused (mg)	Total Volume Administered (mL)	Total Volume Left (mL)
A-200	PPD	C1D1	Y	500	N	PPD (1)	10:55	N			11:25	500	100	0
A-200		C2D1	Y	500	N	(22)	09:55	N			10:25	500	100	0
A-200		C3D1	Y	500	N	(43)	12:31	N			13:02	500	100	0
A-200		C4D1	Y	500	N	(64)	11:20	N			11:52	500	100	0
A-200		C5D1	Y	1000	N	(85)	11:44	N			12:18	1000	100	0

[1] Rel Days are calculated as infusion date minus first dose date (plus 1 day if infusion date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.5.7
Carboplatin Administration (Safety Population)

Part	Patient ID	Visit	Infusion Given/ Reason	Intended Dose Level (AUC)	Delayed More Than 3 Days/ Reason	Date of Infusion (Rel Days [1])	Start Time	Infusion Interrupted/ Reason	Interrupted Infusion Restarted	Restarted Infusion Completed/ Reason	End Time of Infusion	Total Dose Infused (mg)	Total Volume to be Administered (mL)	Total Volume Left (mL)
B	PPD	C1D1	Y	413	N	PPD (1)	09:55	N			10:55	413	541	0
B		C2D1	Y	403	N	PPD (22)	11:15	N			12:15	403	540	0
B		C3D1	Y	403	N	PPD (43)	12:15	N			13:15	403	540	0
B		C4D1	Y	403	Y/OTHER-SCHEDULING CONFLICT	PPD (75)	14:46	N			15:46	403	540	0

[1] Rel Days are calculated as infusion date minus first dose date (plus 1 day if infusion date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.5.8
Paclitaxel Administration (Safety Population)

Part	Patient ID	Visit	Infusion Given/ Reason	Body Surface Area (m2)	Intended Total Dose (mg)	Delayed More Than 3 Days/ Reason	Date of Infusion (Rel Days [1])	Start Time	Infusion Completed	Infusion Interrupted / Reason	Interrupted Infusion Restarted	Restarted Infusion Completed / Reason	End Time	Total Dose Infused (mg)	Total Volume Administered (mL)	Total Volume Left (mL)
B	PPD	C1D1	Y	2.09	364	N	PPD (1)	11:00	Y	N			14:00	364	560	0
B		C2D1	Y	2.06	360	N	PPD (22)	12:30	Y	N			15:30	360	560	0
B		C3D1	Y	2.04	360	N	PPD (43)	13:50	Y	N			16:50	360	560	0
B		C4D1	Y	2.07	355	Y/OTHER-SCHEDULING CONFLICT	PPD (75)	11:45	Y	N			14:45	355	559	0

…

[1] Rel Days are calculated as infusion date minus first dose date (plus 1 day if infusion date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

Repeat for

Listing 16.2.5.9 Pemetrexed Administration (Safety Population)

For programmer: add following footnotes
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Listing 16.2.5.11
Bevacizumab Administration (Safety Population)

Part	Patient ID	Visit	Infusion Given (15mg/kg)/ Reason	Intended Total Dose (mg)	Delayed More Than 3 Days/ Reason	Date of Infusion (Rel Days [1])	Start Time	Infusion Interrupted /Reason	Interrupted Infusion Restarted	Restarted Infusion Completed/ Reason	End Time	Total Dose Infused (mg)	Total Volume to be Administered (mL)	Total Volume Left (mL)
C-200	PPD	C1D1	Y	1274	N	PPD (1)	10:28	N			12:03	1274	100	0
C-200		C2D1	Y	1203	N	PPD (22)	10:40	N			11:34	1203	100	0
C-200		C3D1	Y	1172	N	PPD (43)	11:10	N			11:38	1172	100	0

[1] Rel Days are calculated as infusion date minus first dose date (plus 1 day if infusion date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Listing 16.2.5.12
TSR-022 Administration (Safety Population)

…

Part	Patient ID	Visit	Infusion Given/ Reason	Intended Total Dose (mg)	Delayed More Than 3 Days/ Reason	Date of Infusion (Rel Days [1])	Start Time	Infusion Interrupted/Reason	Interrupted Infusion Restarted	Restarted Infusion Completed/Reason	End Date Time	Total Dose Infused (mg)	Total Volume Administered (mL)	Total Volume Left (mL)
F-900	PPD	C1D1	Y	900	N	PPD (1)	10:14	N			10:44	900	250	0
F-900		C2D1	Y	900	N	PPD (22)	11:23	N			11:53	900	250	0
F-900		C3D1	Y	900	N	PPD (42)	11:31	N			12:01	900	250	0
F-900		C4D1	Y	900	N	PPD (64)	11:07	N			11:37	900	250	0
F-900		C5D1	Y	900	N	PPD (85)	11:38	N			12:08	684	250	60

…

[1] Rel Days are calculated as infusion date minus first dose date (plus 1 day if infusion date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Part	Patient ID	Did the subject receive at least 5 doses (350 to 1,000 µg oral) of folic acid during the week preceding the first dose of Pemetrexed?	Did the subject receive the dose (1,000 µg intramuscular injection) of Vitamin B-12 during the week preceding the first dose of Pemetrexed?
Part E			
Part F-300			
Part F-900			
…			
…			

PROGRAM NAME:
DATE: DDMMYYYY

Listing 16.2.5.14
Pemetrexed Supplemental Medications (Safety Population)

Part	Patient ID	Name of Medication	Indication	Dose per administration	Frequency	Route of Administration	Start Date	Ongoing?	End Date
Part E					Specify other		unknonw	Y/N	
Part F-300									
Part F-900									
…									
…									

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.6.1
Tumor Target Lesion Assessment (Safety Population)

Part	Patient ID	Visit	Any Target Lesions	Lesion Number	Site	Region for Lymph Node	Date of Scan/Assessment (Rel Days [1])	Method	Lesion Measurement	Lesion Status
					Specify if other Site	Specify Other	DDMMYYYY (days)			
Part A-200			Y/N							
Part A-300										
Part B							Not Done			
Part C-200										
Part C-300										
Part D										
…										

[1] Rel Days are calculated as assessment date minus first dose date (plus 1 day if assessment date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.6.2
Tumor Non-Target Lesion Assessment (Safety Population)

Part	Patient ID	Visit	Any Non-Target Lesions	Lesion Number	Site	Region for Lymph Node-Other	Date of Scan/Assessment (Rel Days [1])	Method	Lesion Status
					Specify region for lymph node				
Part A-200			Y/N				DDMMYYYY (days)		
Part A-300									
Part B									
…									

[1] Rel Days are calculated as assessment date minus first dose date (plus 1 day if assessment date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.6.3
New Lesion Assessment (Safety Population)

Part	Patient ID	Visit	Any New Lesions	Lesion Number	Site	Region for Lymph Node-Other	Evaluation Date (Rel Days [1])	Method	Status
Part A-200 Part A-300 Part B			Y/N		Specify region for lymph node		DDMMYYYY (days)		

…

[1] Rel Days are calculated as assessment date minus first dose date (plus 1 day if assessment date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.6.4
Tumor Response Assessments by RECIST v1.1 (Safety Population)

Part Patient ID	Visit	Date of Radiological Scan/Asmnt. (Rel Days [1])	Target Lesion(s) Respon-se	Sum of Diameters of all target lesions (mm)	New Lesion	Sum of Diameters of all target lesions (mm) Change from baseline (mm)	Sum of Diameters of all target lesions (mm) % Change from baseline (%)	Change from smallest sum on study of all measurable lesions (mm)	% Change from Smallest (%)	Non-Target Lesion(s) Response	Overall Respon-se
Part A-200 PPD	SCREENING	PPD (-6)		43.0	N						
		(81)	CR	0.0	N	-43.0	-100.0	0.0		Non-CR/Non-PD	PR
		(166)	CR	0.0	N	-43.0	-100.0	0.0		Non-CR/Non-PD	PR
		(250)	CR	0.0	N	-43.0	-100.0	0.0		Non-CR/Non-PD	PR
		(337)	CR	0.0	Y	-43.0	-100.0	0.0		UNEQUIVOCAL PD	PD
Part A-200 PPD	SCREENING	(-11)		46.0	N						
		(15)	SD	45.0	N	-1.0	-2.2	0.0	0.0	Not Applicable	SD

[1] Rel Days are calculated as assessment date minus first dose date (plus 1 day if assessment date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment

Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.6.5.2
Confirmed Best Overall Response and Duration of Response (RECIST v1.1) and Survival (Safety Population)

Part	Patient ID	Best Overall Response	Date of First CR/PR (Rel Days [1])	Duration of Response	Disease Progression	Date of PD (Rel Days [1])	Death	Date of Death (Rel Days [1])	Date of Last Contact (Rel Days [1])
Part A-200		CR	YYYY-MM-DD (days)		Yes/No	YYYY-MM-DD (days)	Yes/No	YYYY-MM-DD (days)	YYYY-MM-DD (days)
Part A-300		PR							
Part B		SD							
Part C-200		PD							
Part C-300		NE							
Part D									

[1] Relative to the date of first dose

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.6.16
Survival Assessment (Safety Population)

Part	Patient ID	First Dose Date	Current Patient Status	Date of Contact (Rel Days [1])	New Malignancy Reported	Diagnosis of New Malignancy
Part A-200		DDMMYYYY		DDMMYYYY (days)	Y/N	
Part A-300					Not Reported /Unknown	
Part B						
Part C-200						
Part C-300						
Part D						
…						

[1] Rel Days are calculated as contact date minus first dose date (plus 1 day if contact date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.7.1
Adverse Events for Part A (Safety Population)

Part	Patient ID	System Organ Class/ Preferred Term/Verbatim Term	Start Date/Time (Rel Days [1])	Stop Date/Time	CTCAE Grade	TEAE/SAE	SAE Due to [2]	Relationship to Drug	Action Taken [3] [4] /Outcome [5]	Trt. or Medication given	AESI/ DLT
			DDMMYYYYTHH:MM:SS (days)			Y/N		Niraparib	Other Action Taken	Y/N	Y/N
Part A-200											
Part A-300				ongoing				TSR-042			

[1] Rel Days are calculated as AE date minus first dose date (plus 1 day if AE date is on or after first dose date).
[2] 1=Death, 2=Life Threatening, 3=Requires inpatient hospitalization or prolongation of existing hospitalization, 4=Persistent or Significant Disability or Incapacity,5=Congenital Anomaly or Birth Defect, 6=Other Medically Important Event
[3] N=Niraparib, T=TSR-042
[4] 1= Dose/Infusion Not Changed; 3= Dose Reduced; 4= Drug/Infusion Interrupted; 5= Infusion Delayed; 6= Drug Withdrawn; 7= Not Applicable;
[5] 2= Not Recovered/Not Resolved; 3= Recovered/Resolved; 4= Recovered/Resolved With Sequelae; 5= Recovering/Resolving; 6= Unknown;

PROGRAM NAME:
DATE: DDMMYYYY

Repeat for

Listing 16.2.7.2 Adverse Events for Part B (Safety Population)

Listing 16.2.7.3 Adverse Events for Part C (Safety Population)

Listing 16.2.7.4 Adverse Events for Part D (Safety Population)

Listing 16.2.7.5 Adverse Events for Part E (Safety Population)

Listing 16.2.7.6 Adverse Events for Part F (Safety Population)

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.8.1
Hematology Results (Safety Population)

Part	Patient ID	Visit	Date of Lab (Rel Days [1])	Parameter	Result	Unit	Change from Baseline	Normal Range	Out of Range Flag	Clinically Significant
Part A-200			DDMMYYYY (days)							
Part A-300										
Part B										
Part C-200										
Part C-300										
Part D										

[1] Rel Days are calculated as lab date minus first dose date (plus 1 day if lab date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

Repeat for

Listing 16.2.8.2 Chemistry Results (Safety Population)

Listing 16.2.8.3 Coagulation Results (Safety Population)

Listing 16.2.8.4 Serum tumor markers (Safety Population)

Listing 16.2.8.5 Thyroid Function Results (Safety Population)

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment

Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.8.6
Pregnancy Test (Safety Population)

Part	Patient ID	Visit	Test Performed	Test Date (Rel Days [1])	Test Type	Test Result
Part A-200			Y/N	DDMMMYYYY (days)	Serum	Positive
Part A-300					Urine	Negative
Part B						
Part C-200						
Part D						

…

[1] Rel Days are calculated as test date minus first dose date (plus 1 day if test date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.8.7
Urinalysis Results (Safety Population)

Part	Patient ID	Visit	Lab Date (Rel Days [1])	Parameter	Result
Part A-200			DDMMYYYY (days)	Glucose	
Part A-300				Ketones	
Part B					
Part C-200					
Part D					
…					
…					

[1] Rel Days are calculated as lab date minus first dose date (plus 1 day if lab date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.9
Vital Signs (Safety Population)

Part	Patient ID	Visit	Assessment Date (Rel Days [1])	Height (cm)	Weight (kg)	Temperature (°C)	Pulse (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
Part A-200			DDMMYYYY (days)						
Part A-300									
Part B									
Part C-200									
Part D									
…									

[1] Rel Days are calculated as assessment date minus first dose date (plus 1 day if assessment date is on or after first dose date).

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment
Part G: TSR-042 and carboplatin-nab-paclitaxel combination treatment
Part H-300: TSR-042, TSR-022 (300mg) and carboplatin-nab-paclitaxel combination treatment
Part H-900: TSR-042, TSR-022 (900mg) and carboplatin-nab-paclitaxel combination treatment
Part I-300: TSR-042, TSR-022 (300mg) and carboplatin-paclitaxe combination treatment
Part I-900: TSR-042, TSR-022 (900mg) and carboplatin-paclitaxe combination treatment

Listing 16.2.10
ECOG Performance Status (Safety Population)

Part	Patient ID	Visit	ECOG Performance Status Collected	Performance Date (Rel Days [1])	Performance Status
Part A-200			Y/N	DDMMYYYY (days)	
Part A-300					
Part B					
Part C-200					
Part C-300					
Part D					
…					

[1] Rel Days are calculated as ECOG performance date minus first dose date (plus 1 day if ECOG performance date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.11
Physical Examination Findings (Safety Population)

Part	Patient ID	Visit	Date of Examination (Rel Days [1])	Body System Examined	Examination Result	Description of Abnormal Findings	Symptom Directed Physical Exam Performed
Part A-200			DDMMYYYY (days)				Y/N
Part A-300							
Part B							
Part C-200							
Part C-300							
Part D							

[1] Rel Days are calculated as exam date minus first dose date (plus 1 day if exam date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.12.1
ECG - Pre-Post Niraparib Dose (Safety Population)

Part	Patient ID	Visit	ECG Performed	ECG Date and Time (Rel Days [1])	ECG Timepoint	ECG Test (Unit)	ECG Result	ECG Interpretation
				YYYY-MM-DDTHH:MM				
Part A-200			Y/N	(days)				
Part A-300								
Part B								
Part C-200								
Part C-300								
Part D								

…

PROGRAM NAME:

DATE: DDMMYYYY

For programmer: add following footnotes

Part A-200: TSR-042 and niraparib (200mg) combination treatment

Part A-300: TSR-042 and niraparib (300mg) combination treatment

Part B: TSR-042 and carboplatin-paclitaxel combination treatment

Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment

Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment

Part E: TSR-042 and carboplatin-pemetrexed combination treatment

Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment

Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.12.2
ECG (Safety Population)

Part	Patient ID	Visit	ECG Performed	ECG Date and Time (Rel Days [1])	Position of the Subject	ECG Test (Unit)	ECG Result	ECG Interpretation
				YYYY-MM-DDTHH:MM				
Part A-200			Y/N	(days)				
Part A-300								
Part B								
Part C-200								
Part C-300								
Part D								

…

PROGRAM NAME:

DATE: DDMMYYYY

Repeat for

Listing 16.2.12.3 Notable ECG (Safety Population)

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment

Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.13
Subsequent Anticancer Treatment for Primary Cancer (Safety Population)

Part	Patient ID	Any Subsequent Anticancer Therapy	Regimen Number	Agent Name	Reason for administration	Start Date (Rel Days [1])	End Date	Best Response	Date of Progression or Recurrence	Reason for discontinuation
Part A-200 Part A-300 Part B Part C-200 Part C-300 Part D		Y/N		Specify Other Agent Name	Other/Specify	DDMMYYYY Y (days)	DDMMY YYYY Ongoing			Specify if Toxicity or Other

[1] Rel Days are calculated as start date minus first dose date (plus 1 day if start date is on or after first dose date)

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes
Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment

Listing 16.2.14
Listing of COVID19 Assessments and Symptom Assessments for Subjects with COVID19 Adverse Events

Site Id.:
PPD

Treatment	Unique Subject Id./ Subject Id.	Adverse Event	AE Start Date	COVID-19 Case Diagnosis [1]	COVID-19 Test Performed/ Test Date/ Results	Assessments and Symptom Assessments	Result
Part A-200	PPD	Coronavirus infection	PPD	Suspected	Y/ PPD / Indeterminate	Travel to Location with Community Transmission [2]	N
						Visited Health Care Facility [2]	N
						Contact with COVID-19 Confirmed/Probable Case [2]	Unknown
						Medication Taken to Treat COVID-19	Y
						Fever	Y
						Cough	Y
						Shortness of Breath	Y
						Sore Throat	N
						Loss of Appetite	N
						Nausea	N
						Vomiting	N
						Diarrhea	N

Abdominal Pain	N
Fatigue	N
Loss of Smell	N
Loss of Taste	N
Asymptomatic	N
Home Quarantined/Isolated	Unknown

PROGRAM NAME:
DATE: DDMMYYYY

For programmer: add following footnotes as applicable

Part A-200: TSR-042 and niraparib (200mg) combination treatment
Part A-300: TSR-042 and niraparib (300mg) combination treatment
Part B: TSR-042 and carboplatin-paclitaxel combination treatment
Part C-200: TSR-042, niraparib (200mg) and bevacizumab combination treatment
Part C-300: TSR-042, niraparib (300mg) and bevacizumab combination treatment
Part D: TSR-042, carboplatin-paclitaxel and bevacizumab combination treatment
Part E: TSR-042 and carboplatin-pemetrexed combination treatment
Part F-300: TSR-042, TSR-022 (300mg) and carboplatin-pemetrexed combination treatment
Part F-900: TSR-042, TSR-022 (900mg) and carboplatin-pemetrexed combination treatment