STATISTICAL ANALYSIS PLAN

STUDY NAME: BAROCCO

TRIAL CODE: IRFMN-OVA3-7289

EudraCT: 2016-003964-38

Best Approach in Resistant-Ovarian-Cancer with-Cediranib-Olaparib: an Italian multicenter randomized phase II study of weekly paclitaxel vs. Cediranib-Olaparib with continuous schedule vs. Cediranib-Olaparib with intermittent schedule in patients with platinum resistant high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer.

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This version of the *Statistical Analysis Plan* becomes effective on the date of final approval. If changes are made that affect the document's content or approach, a revised, complete document must be issued for re-approval by the roles of the approvers of the original document or their designated representatives. A description of those changes with revision number is noted in the revision log below:

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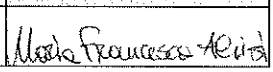
01	11/12/2017	Initial Document	Maria Francesca Alvisi	

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01		Initial Document		

Version	Date	Reason for issue/change	Approvers	Signature
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LIST OF ABBREVIATIONS

95%CI	95% confidence interval
CR	Complete Response
CSR	Clinical study report
e-CRF	Electronic- case record form
FACT-O	Functional Assessment of Cancer Therapy-Ovarian
HR	Hazard ratio
ICH	International Conference on Harmonization
ITT	Intent-to-treat
ORR	Overall response rate
OS	Overall survival
PFS	Progression free survival
PD	Progression of Disease
PP	Per-ptotocol
PR	Partial Response
PRO	Patient reported outcome
RECIST	Response Evaluation Criteria in Solid Tumours
SADR	Safety Adverse Drug Reaction
SAE	Serious Adverse Event
SD	Stable Disease
SE	Safety evaluable
SOC	System organ class
SUSAR	Suspected Unexpected Serious Adverse Reaction
WHO	World health organization

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1. INTRODUCTION

This document outlines the statistical methods for the analysis of data collected under Protocol No. IRFMN-OVA3-7289 and based on Version 1 of the Final Protocol dated 20/11/2017 and on the Final Version of the electronic- case record form (e-CRF) dated 11/10/2016.

The main objective of this document is to provide guidance for the production of the Clinical Study Report (CSR), including post-text tables, post-text listings (related to specific tables) and other listings (for all patients and all variables included in the Clinical Data Base).

2. GENERAL DESCRIPTION OF FINAL STUDY REPORT

The CSR of BAROCCO will fulfill all recommendations given in the guideline ICH topic E3 "Note for Guidance on Structure and Content of Clinical Study Report" (CPMP/ICH/137/95).

American English will be used for writing the CSR.

The core of the CSR will be written with Microsoft Word version 2016; all data summaries (tables) and listings will be prepared by using SAS Version 9.4.

The choice of the population(s) included in the table will depend on the considered variable.

2.1 Responsibilities

The CSR of the present study will be written by the statistician of the study. The structure of the CSR (see section 2.2 of this document) will be according to the guideline ICH topic E3.

2.2 Structure

The CSR will be divided in sections, titled and numbered as requested by the above mentioned guideline. The most relevant sections concerning study results are illustrated below.

Topics	Section
Disposition of Patients	10.1
Protocol Deviations	10.2
Data Sets Analyzed	11.1
Demographics & Other Baseline Characteristics	11.2
Measurements of Treatment Compliance	11.3
Efficacy Results	11.4
Adverse Events	12.2
Post-text Tables and Listings	14
Patient Data Listings	Appendix 16.2

2.3 Format

2.3.1 Text

All the pages of the CSR core (text) should contain the following information:

- Protocol identification;
- Page number;
- Specification of document version and date;

2.3.2 SAS Outputs

All tables and listings of the CSR will be generated by SAS version 9.4.

When not otherwise specified (in the SAS outputs), location indicators, percentages and standard deviations (SDs) will be rounded to the first decimal digit.

Dates will always be displayed as ddmmyyyy.

Format of SAS Outputs

As for the format of the SAS outputs (tables and listings), all the pages should contain the following information:

- Protocol identification;
- Specification of document version;
- Page number;
- Date when the output was generated;

Table/Listing Numbering and Naming of corresponding SAS programs

Patients Data Listings (for all patients and all variables included in the data base) will be included in Appendix 16.2 of the CSR.

Listings of all the individual patient data collected during the study will be included in Appendix 16.2 of the CSR (more details are given in Appendix 2 of this document).

Listings will be numbered as follows:

<Section>.<Listing Number>, where:

- *<Section>* is the number identifying the CSR section referencing the listing;
- *<Listing number>* indicates the sequence of the listings in each section.

The SAS program generating these listings will be named as

AL.<Section>.<Listing number>.sas, and the corresponding output as

AL.<Section>.<Listing number>.rtf, where

- *AL*= Appendix Listings;
- *<Section>* is the number identifying the CSR section referencing the listing;
- *<Listing number>* is the number indicating the listing sequence.

3. STUDY OBJECTIVES

This section is a draft of Section 8 of the CSR (see guideline ICH topic E3).

3.1 Efficacy objectives

3.1.1 Primary objective

The study primary objective is to compare the efficacy of Olaparib and Cediranib vs. weekly paclitaxel in terms of progression free survival (PFS) in platinum refractory or resistant recurrent ovarian cancer.

PFS is defined as the time from randomization to the date of first progression or death for any cause, whichever comes first.

Progression will be established as the objective radiological disease progression according to RECIST 1.1 or to clinical assessment.

3.1.2 Secondary objective

- Objective Response Rate (ORR), defined as the percentage of patients with an objective response as determined by RECIST 1.1
- PFS2 defined as time from randomization to second disease progression according to RECIST 1.1 or to clinical assessment, or death by any cause.
- Overall Survival (OS), defined for each patient as the time from randomization to the date of death for any cause.
- Quality of Life evaluated by the Functional Assessment of Cancer Therapy-Ovarian (FACT-O) questionnaire.

3.2 Safety objectives

The primary objective for safety is to compare the safety of Olaparib and Cediranib as intermittent vs. continuous regimen in terms of number of evacuations per day.

Secondary objectives are:

- Maximum toxicity grade experienced by each patient, for each toxicity, according to NCI-CTCAE v. 4.0;

- patients experiencing grade 3-4 toxicities for each toxicity;
- type, frequency and nature of SAEs;
- patients with at least a SAE;
- patients with at least a SADR;
- patients with at least a SUSAR.

3.3 Compliance endpoints

Compliance will be evaluated in terms of number of:

- administered cycles;
- reasons for discontinuation and treatment modification;
- dose intensity.

4. INVESTIGATIONAL PLAN

This section is a draft of Section 9 of the CSR (see guideline ICH topic E3). For further details refer to the study protocol.

4.1 General trial design

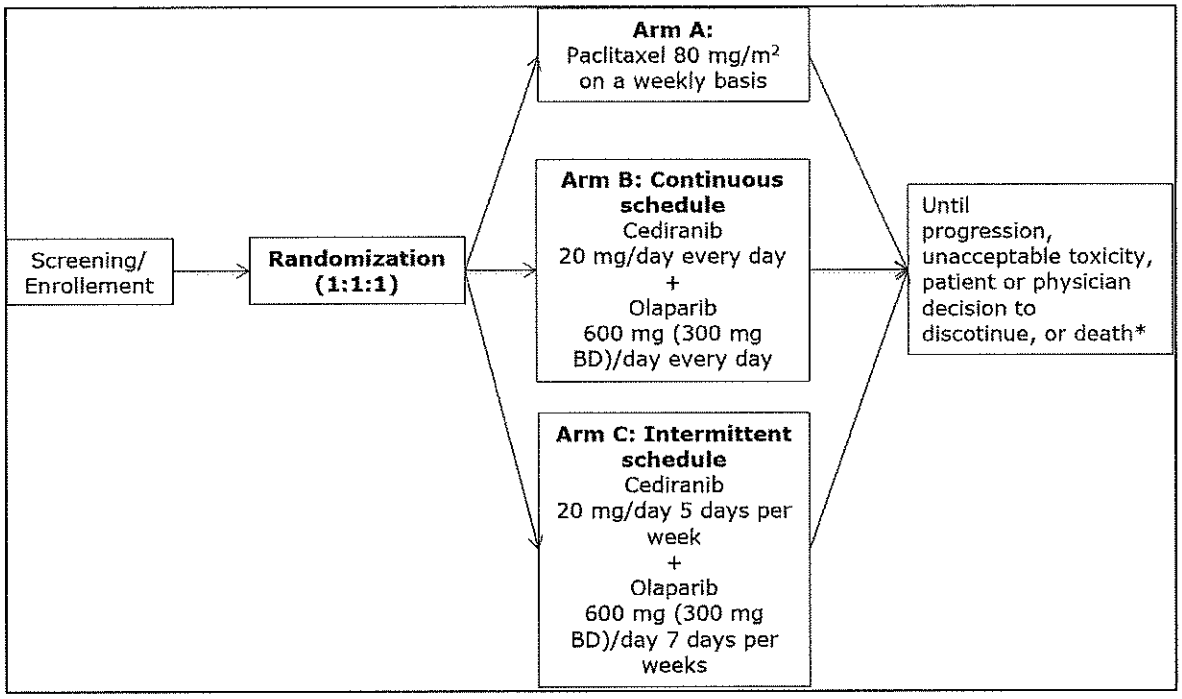
This is a Phase II, randomized, multi-center study with two experimental arms, Cediranib-Olaparib with continuous schedule and Cediranib-Olaparib with intermittent schedule. Weekly paclitaxel is the comparator arm, due to its known efficacy in platinum resistant/refractory disease.

All patients not previously tested for the presence of BRCA1-2 germline mutations will undergo BRCA test. However, both mutated and not mutated women will be included in the study protocol.

Randomization will use a biased-coin minimization procedure having as stratification factors BRCA1-2 genes status (mutated vs. wild-type vs. still unknown), prior chemotherapy (1-2 vs. ≥ 3 lines) and previous treatment with antiangiogenic drugs (yes vs. no). Patients will be randomized in a 1:1:1 ratio to the treatments as specified below:

ARM A: Paclitaxel 80 mg/mq every week.
ARM B: Cediranib 20 mg/day + Olaparib 600 mg / day (i.e. 300 mg BD) given every day.
ARM C: Cediranib 20 mg/day given 5 days per weeks + Olaparib 600 mg / day (i.e. 300 mg BD) given 7 days per weeks.

Figure 1. Study flow-chart



*For Arm A (weekly Paclitaxel): maximum 24 weeks.
BD:twice daily

Progression will be established as the radiological disease progression according to RECIST 1.1 or as clinical progression in case radiological evaluation is not feasible due to clinical condition.

All patients should have RECIST assessments until documented evidence of radiological progression in accordance with RECIST 1.1, irrespective of treatment decisions (i.e. RECIST follow up until progression even if a patient discontinues study treatment prior to progression and/or receives a subsequent therapy prior to progression).

Disease assessments will be scheduled every 8 weeks (+/- 1 week) from randomization for all treatment duration and every 12 weeks (+/- 1 week) thereafter.

4.2 **Sample size determination**

Assuming a median PFS in the control arm of 3.4 months (AURELIA trial control group), this study is designed to detect a HR of 0.51 that corresponds to an advantage in PFS median of 3.3 months. With one-sided 5% significance level and with at least 80% power, approximately 60 patients (55 events) for each comparison are estimated to be enrolled. Considering the two pre-planned comparisons (intermittent schedule vs Paclitaxel and continuous schedule vs Paclitaxel) a total of 90 eligible patients are needed. Taking into account a 10% of patients not evaluable for the primary endpoint, it will be necessary to enroll approximately 100 patients.

4.1 **Interim Analysis**

There are no formal interim analyses planned for this study.

5. DATA SUMMARIES AND STATISTICAL ANALYSIS

The following section is a draft of Sections 10.1 (Disposition of Patients), 10.2 (Protocol Deviations), 11 (Efficacy evaluation – see detailed sub-sections in paragraph 5.5 of the present document) and 12 (Safety evaluation – see detailed sub-sections in paragraph 5.6 of the present document) of the CSR (see also guideline ICH topic E3).

5.1 Definitions and conventions

5.1.1 Trial closure and data cut-off

The final analysis will be performed after reaching the PFS target number of events and after cleaning data in order to preserve the accurate frozen database.

5.1.2 Protocol violations and deviations

Major violations in the eligibility criteria, minor deviation and study conduction will be evaluated on a case by case basis in a pre-analysis meeting considering the following points:

1. Unfulfilled inclusion criteria

2. Subject enrollment and/or treatment in the presence of Exclusion Criteria

3. Treatment with unauthorized concomitant medication

4. Treatment regimen violations.

5.1.3 General Considerations

- Continuous variables will be described including number of observations, mean, standard deviation (SD), median, ranges (minimum and maximum) and number of missing values;
- Categorical variables will be described including the frequency and percentage of subjects in each category. In general, the denominator for

the percentage calculation should be the total number of subjects in the relevant analysis set, unless otherwise specified. Percentages are to be rounded to one decimal place;

- Response will be provided as the absolute and relative frequencies of patients with CR, PR, SD and PD according to RECIST. 95% CIs of response rate will be computed by means of exact binomial methods.
- Time-to-event variables (PFS, OS, PFS2) will be described with the Kaplan-Meier method. KM estimates for median and quartile event times, and event-free rates at selected times will be calculated. Cox regression model will be performed in order to evaluate the reduction of the risk in the differences in PFS, PFS2 and OS between arms, by including stratification variables and other clinical-biological features as covariates. Results will be presented as hazard ratios (HRs) and their 95% confidence intervals (95% CIs) unless otherwise specified.

5.1.4 Methods for Handling Withdrawals, Missing Data and Outliers

Missing values will be defined as not imputed, unless otherwise specified.

For time to event analysis calculate incomplete or missing dates of disease progression or death using the following approach:

- if the month and the year are reported, assign the 15th day of the month by default;
- if the entire date is unknown, assign the day following the last information available, in which the subject was known to be progression free or alive.

5.2 Analysis sets

The analysis sets described below will be considered for the analysis, as follows:

All Subjects Analysis Set: the All Subjects Analysis Set is defined as all participants who provided informed consent and were enrolled in the study. The listings of all variables will be based on the All Subjects Analysis Set.

Intent-to-Treat (ITT) Analysis Set: the ITT analysis set is defined as all randomized patients, without major violations of eligibility criteria. Patients will be analyzed according to randomization arm.

Major violations in the eligibility criteria will be evaluated on a case by case basis in a pre-analysis meeting in order to define the population.

Per-protocol (PP) Analysis Set: the PP analysis set is defined as all patients of the ITT analysis set, who received at least 4 weeks of treatment, unless they interrupted before for disease progression or death. Patients randomized to the control arm, receiving the experimental treatment and patients randomized to the experimental arm, receiving the control treatment will be excluded.

Safety 1 Analysis Set: the Safety 1 Analysis Set is defined as all patients included of the ITT Analysis Set, who were randomized to the two experimental arms, excluding patients who interrupted before 4 weeks, unless the interruption is due to diatrrhea. Patients randomized to the continue schedule (arm B), receiving the intermittent schedule (as arm C) and patients randomized to the intermittent schedule, receiving the continue schedule will be excluded.

Safety 2 Analysis Set: the Safety 2 Analysis Set is defined as all patients included of the ITT Analysis Set, who received at least one dose of study treatment, whether withdrawn prematurely or not. Patients will be considered in the treatment arm they actually received.

Overall Response Rate (ORR) Analysis Set: the ORR analysis set is defined as all patients included in the ITT analysis set, receiving at least one dose of study treatment and with at least one radiological assessment. Radiological assessment will be evaluated in accordance to RECIST criteria.

Compliance analysis set: the Compliance Analysis Set included all subjects of ITT analysis. Patients will be considered in the treatment arm they actually received. The Compliance Analysis Set is used for the compliance analyses.

Patient reported outcome (PRO) Analysis Set: the PRO Analysis Set includes all subjects of ITT analysis set with the evaluation of FACT-O questionaires.

5.3 Study-Population and Strata to be used

Tables will be created by strata (column) and applied to specific study population (patients/records contributing to table) according to the criteria described in the table below.

Table - Analysis sets and Strata to be applied

SECTION	TABLES	ANALYSIS SET	STRATA
ENROLMENT AND DISPOSITION OF PATIENTS	14.1.1.X	ALL RANDOMIZED PATIENTS	TREATMENT ARM
DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS	14.1.2.X	ITT	TREATMENT ARM
MEASUREMENT OF TREATMENT COMPLIANCE	14.2.1.X	COMPLIANCE	TREATMENT ARM
EFFICACY			TREATMENT ARM
Progression Free Survival	14.2.2.X	ITT AND PP	
Objective Response Rate	14.2.3.X	ORR	
Second Progression Free Survival	14.2.4.X	ITT AND PP	
Overall Survival	14.2.5.X	ITT AND PP	
Quality of Life	14.2.6.X	PRO	
SAFETY			
Primary Safety analyses (intermittent vs. continuous)	14.3.1.1	SAFETY 1	TREATMENT ARM (B VS. C)
Secondary Safety analyses	14.3.1.X	SAFETY 2	TREATMENT ARM

5.4 Enrollment and Disposition of Patients

5.4.1 Disposition of Subjects

A summary table will be provided showing the number of randomized patients, the number of withdrawn and the reasons for withdrawal for the overall population, grouped by study treatment.

Subject disposition will be described using the *All Subjects Analysis Set*.

Subject disposition is summarized in Appendix A,*Table 1* and listed by subject in Appendix B, *Listing 1*.

5.4.2 Inclusion and Exclusion Criteria

Inclusion and exclusion criteria will be described using the *All Subjects Analysis Set*.

Inclusion and exclusion criteria is listed by subject in Appendix B, *Listing 3* and *Listing 4*.

5.4.3 Protocol Violations and Deviations

A summary table will be provided showing the number and type of minor and major deviations for the overall population, grouped by study treatment.

Protocol deviations will be described using the *All Subjects Analysis Set*.

Protocol deviations are summarized in Appendix A, *Table 2* and listed by subject in Appendix B, *Listing 2*.

5.5 Efficacy evaluation

5.5.1 Data Sets Analyzed

Two summary tables will be provided showing:

- The total number of patients included in each analysis set for the overall population, grouped by study treatment.
- The number of patients by center included in each analysis set for the overall population, grouped by study treatment.

Data sets analyzed are summarized in Appendix A, *Table 3* and *Table 4*.

5.5.2 Demographics and other baseline characteristics

A summary table will be provided showing demographics and other patients' baseline characteristics for the overall population, grouped by study treatment.

Demographics and other patients' baseline characteristics will be described using the *ITT analysis set.*

Demographic and other baseline characteristics are summarized in Appendix A, *Table 5* and listed by subject in Appendix B, *Listing 6.*

A summary table will be provided showing tumor characteristics for the overall population, grouped by study treatment.

Tumor characteristics will be described using the *ITT analysis set.*

Tumor characteristics are summarized in Appendix A, *Table 6* and listed by subject in Appendix B, *Listing 7*.

A summary table will be provided showing previous therapies for the overall population, grouped by study treatment.

Previous therapies will be described using the *ITT analysis set*.

Previous therapies are summarized in Appendix A, *Table 7* and *Table 8* listed by subject in Appendix B, Listing 8.

5.5.3 Measurement of Treatment Compliance

Summary tables will be provided for the overall population and grouped by study treatment showing:

- the number of patients who never started or discontinued treatment
- the reasons for not starting the treatment
- the reasons for treatment interruption

- the number of completed cycles in subjects who discontinued treatment

- the dose intensity: which is defined as, for each agent separately, percent of dose received related to expected dose as following:

$$dose\ intensity = \frac{total\ dose\ received\ in\ mg/m^2}{expected\ dose\ in\ mg/m^2 \times total\ number\ of\ expected\ cycles}$$

Treatment compliance will be described using the *Compliance analysis set*.

Treatment compliance is summarized in Appendix A, *Table 9*, *Table 10*, *Table 11* and listed by subject in Appendix B, *Listing 9* and *Listing 10*.

5.5.4 Efficacy Results

5.5.4.1 Progression Free Survival

PFS will be analyzed using the *ITT Analysis Set* first, and as secondary analyses, PFS will be analysed on *PP Analysis Set*.

PFS is summarized in Appendix A, *Table 12* and ***Error! Reference source not found.***.

Cox Models (univariate and multivariate analysis) are presented in Appendix A, *Table 14* and *Table 15*.

Kaplan-Meier curves are presented in Appendix C, *Figure 2* and *Figure 3*.

Efficacy data is listed by subject in Appendix B, *Listing 11*.

5.5.4.2 Objective Response Rate

ORR will be analyzed using *ORR Analysis Set*.

ORR is summarized in Appendix A, *Table 16* and *Table 17.*

Efficacy data is listed by subject in Appendix B, Listing 13.

5.5.4.3 Second Progression Free Survival

PFS2 will be analyzed using the *ITT Analysis Set* first, and as secondary analyses, PFS2 will be analysed on *PP Analysis Set.*

PFS2 is summarized in Appendix A, *Table 18 and Table 19*.
Cox Models (univariate and multivariate analysis) are presented in Appendix A, *Table 20* and *Table 21*.
Kaplan-Meier curves are presented in Appendix C, *Figure 4* and *Figure 5*.
Efficacy data is listed by subject in Appendix B, *Listing 12*.

5.5.4.4 Overall Survival

OS will be analyzed using the *ITT Analysis Set* first, and as secondary analyses, OS will be analysed on *PP Analysis Set*.

OS is summarized in Appendix A, *Table 22*, *Table 23*.

Cox Models (univariate and multivariate analysis) are presented in Appendix A, Table 24 and *Table 25.*
Kaplan-Meier curves are presented in Appendix C, *Figure 6 and Figure 7*.
Efficacy data is listed by subject in Appendix B, *Listing 11*.

5.5.4.5 Quality of Life

Quality of Life evaluated by the Functional Assessment of Cancer Therapy-Ovarian (FACT-O) questionnaire. Change scores in quality of life (i.e. differences from baseline to each visit) will be calculated and described at every visit and at the time of study discontinuation, for each domain and within each arm.

A mixed model will be performed in order to assess differences in quality of life scores among groups and the interaction between time and treatment.

PRO will be analyzed using the *PRO Analysis Set.*
FACT-O scores are summarized for four evaluation in *Table 26*: baseline (T0), after 4 weeks (T1), after 8 weeks (T2) and after 12 weeks (T3).

Changes from baseline are presented in *Table 27* and mixed models are reported in *Table 28*. PRO data is listed by subject in Appendix B, *Listing 15* and *Listing 16*. The scores for each subscale will be calculated according the scoring system of FACT-O.

5.6 **Safety Evaluation**

The primary endpoint for safety is the number of evacuations per day.

Secondary endpoints of safety are:

- the maximum toxicity grade experienced by each patient, for each toxicity, according to NCI-CTCAE v. 4.0;
- the number of patients experiencing grade 3-4 toxicity for each toxicity;
- type, frequency and nature of SAEs;
- patients with at least a SAE; patients with at least a SADR;
- patients with at least a SUSAR.

Adverse Events (AEs) will be coded using the MedDRA coding dictionary and graded using the NCI-CTCAE scale, version 4.0

The chi-squared test for trend will be used to compare the maximum grade for each type of adverse event by treatment arm.

The primary safety analyses will be done using the *Safety 1 Analyses set*. The secondary analyses will be conducted using the *Safety 2 Analysis set*.

5.6.1 Number of evacuations per day

The number of evacuations per day analysis will be conducted on the *Safety 1 analysis set* excluding patients who interrupted the treatment before 4 weeks, unless the interruption is due to diarrhea.

In case both arms will demonstrate the superiority over control arm in terms of PFS, the best schedule will be selected based on safety profile considering in particular the mean number of evacuations per day.

The difference on mean number of evacuations per day will be tested through a t-test test for two independent groups. If the normality assumptions cannot be assumed a non-parametrical test will be performed.

The mean number of evacuations per day will be presented in Appendix A, *Table 29*. Changes on mean number of evacuations per day will be presented in Appendix A, *Table 30* and Appendix B, *Listing 17*.
For each patient and for each type of adverse event, the worst degree ever suffered during treatment will be used for the analysis.

5.6.2 Treatment Tolerability

The maximum grades of each adverse event per subject will be used to analyze treatment tolerability.

Adverse events related to the study drugs according to the investigators judgment are summarized in Appendix A, *Table 31*. MedDRA terms will be used.

Treatment tolerability data is listed by subject in Appendix B, *Listing 18* and *Listing 19*.

5.6.3 Serious Adverse Events

The assessment of safety will be mainly based on adverse reactions (ARs) and the frequency and nature of SAEs and will be conducted on the *Safety 2 Analysis Set*.
SAEs will be summarized by presenting the number and percentage of patients having any SAE and having an SAE in each system organ class. Other information collected (e.g. severity or suspected relationship to study medication) will be listed as appropriate.

A summary table will be provided showing SAEs occurred during the study for the overall population, grouped by study treatment.

SAEs occurred during the study are summarized in Appendix A, *Table 32, Table 33, Table 34, Table 35 and Table 36.*

All SAEs will be listed by subject in Appendix B, *Listing 20* .

6. APPENDIX A: TABLES OF SECTION 14 OF THE CSR

Overall content of Section 14 of the CSR (see guideline ICH topic E3):

14.1 Demographic Data

14.2 Efficacy Data

14.3 Safety Data

14.3.1 Displays of Adverse Events

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

14.3.3 Narratives of Deaths, Other Serious and Significant Events

Table 1. Subjects Disposition – All Subjects Analysis Set *(table 14.1.1.1 CSR)*

	ARM A N (%)	ARM B N (%)	ARM C N (%)	Overall N (%)
Patients discontinued	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Main reason for discontinuation:				
Disease Progression	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Toxicity	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Death	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Subject refusal	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Medical decision	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Major violation	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Lost to follow-up	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Other	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects.

Table 2. Protocol Violations and Deviations – All Subjects Analysis Set *(table 14.1.1.2 CSR)*

Subject status Number of patients	**ARM A** **N=XX**	**ARM B** **N=XX**	**ARM C** **N=XX**	**Overall** **N=XX**
Any protocol violation such to exclude the subject from any analysis set:				
Violations of the eligibility criteria	XX	XX	XX	XX
Any minor protocol deviation:				
Description of 1 minor protocol violation / deviation	XX	XX	XX	XX
Description of 2 minor protocol violation / deviation	XX	XX	XX	XX
Description of 3 minor protocol violation / deviation	XX	XX	XX	XX
Description of 4 minor protocol violation / deviation	XX	XX	XX	XX

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 3. Data Analysis Sets – All Subjects Analysis Set *(table 14.1.1.3 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
All subjects analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Intent-to-treat analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Per Protocol analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Safety 1 analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Safety 2 analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Overall Response Rate analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Compliance analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Patients reported outcome analysis set - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; N: number of subjects

Table 4. Recruitment, Analysis set and Allocation to treatment per Study Centre *(table 14.1.1.4 CSR)*

Center - n	All Subjects set				ITT set				PP set				Safety 1 set				Safety 2 set				Compliance set				ORR set				PRO set		
	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C	All	ARM A	ARM B	ARM C
Centre 1	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Centre 2	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Centre 3	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Centre 4	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Centre 5	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Centre 6	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; n: number of subjects

Table 5. Demographic and Baseline Characteristics – ITT Analysis Set *(table 14.1.2.1 CSR)*

Number of patients – n (%)	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Age				
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)
Min – max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx
Performance status – n (%)				
0	XX (XX)	XX (XX)	XX (XX)	XX (XX)
1	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Missing	xx	xx	xx	xx
Weight (Kg)				
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)
Min – max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx
Height (cm)				
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)
Min – max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx
Race - n (%)				
Caucasian	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Black	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Asian	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Missing	XX (XX)	XX (XX)	XX (XX)	XX (XX)
BRCA 1 mutational status - n (%)				
Mutated	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Wild-type	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Number of patients – n (%)	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Unknown	xx	xx	xx	xx
Missing	xx	xx	xx	xx
BRCA 2 mutational status - n (%)				
Mutated	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Wild-type	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	xx	xx	xx	xx
Missing	xx	xx	xx	xx
CA-125 (U/mL)				
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)	XX.X (XX.X – XX-X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx
Relevant disease - n (%)				
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	xx	xx	xx	xx
Start of disease - n (%)				
Relevant diseases started before Barocco randomization	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Relevant diseases started after Barocco randomization	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	xx	xx	xx	xx
Dermatological apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visual apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Respiratory apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cardiovascular apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gastrointestinal apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Genitourinary apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Muscoloskeletal apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Endocrine apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Neurological apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Psychiatric apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Immunological apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Laboratory apparatus - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Number of patients – n (%)	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects;
SD: standard deviation. Q1 - Q3: First - third quartile. Min - Max: minimum - maximum values.

Table 6. Tumour Characteristics – ITT Analysis Set *(table 14.1.2.2 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Time from diagnosis (years)				
Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min – max	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X
Missing	xx	xx	xx	xx
Primary Site - n (%)				
Ovary	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Fallopian	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Peritoneal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	xx	xx	xx	xx
F.I.G.O. Stage - n (%)				
IA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IIIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IB	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IIB	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IIIB	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IC	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IIC	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IIIC	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IV	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	xx	xx	xx	xx
Missing	xx	xx	xx	xx
Histological Type - n (%)				
Serous	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Endometroid	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Mixed	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unspecified	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Mucinous	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Clear Cell	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Transitional	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unspecified	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX	XX	XX	XX

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Size of residual disease after primary surgery - n (%)				
<=1cm	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
>1cm	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	xx	xx	xx	xx
Missing	xx	xx	xx	xx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects.
SD: standard deviation. Q1 - Q3: First - third quartile. Min - Max: minimum - maximum values.

Table 7. Previous therapies – ITT Analysis Set *(table 14.1.2.3 CSR)*

		ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
	Previous Chemotherapies lines - n (%)				
	Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
	Min - Max	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X
	Missing	xx	xx	xx	xx
	Previous Chemotherapies lines - n (%)				
	1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Last line before Barocco - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Previuos treatment with antiangiogenic drugs - n (%)				
	No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previuos chemotherapy lines - n (%)				
	Three or more lines	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Up to 2 lines	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Line 1	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
Line 2	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
Line 3	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
Line 4	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
Line 5	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
Line 6	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX

Line 7	**Number of patients - n (%)**	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Previous Chemotherapies - n (%)				
	Monotherapy with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Associations with PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Monotherapy without PLATIN	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX
	Maintenance therapy type - n (%)				
	Bevacizumab	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No Maintenance therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX	XX	XX	XX

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 8. Previous therapies – Last Platinum free interval– ITT Analysis Set *(table 14.1.2.4 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Number of patients – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Last Platinum Free interval (months)				
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X-XX.X)	XX.X (XX.X-XX.X)	XX.X (XX.X-XX.X)	XX.X (XX.X-XX.X)
Min – max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	XX	XX	XX	XX
Time from last chemotherapy to first dose (months)				
Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X
Missing	xx	xx	xx	xx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 9. Treatment Compliance – ITT Analysis Set *(table 14.2.1.1 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Never started – n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Missing	xx	xx	xx	xx
Reasons:				
Disease Progression	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Adverse Event	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Intercurrent illness of sufficient severity	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Deterioration of clinical conditions	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Other Primary tumor occurrence	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Consent withdrawn	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Patient refusal	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Lost at follow-up	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Death	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Other	xx	xx	xx	xx
Missing	xx	xx	xx	xx
Treatment discontinued – n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Missing	xx	xx	xx	xx
Reasons for discontinuation:				
For ARM A – treatment completed	XX (xx.x)			
Disease Progression	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Adverse Event	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Intercurrent illness of sufficient severity	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Deterioration of clinical conditions	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Other Primary tumor occurrence	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Consent withdrawn	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Patient refusal	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Lost at follow-up	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Death	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Other	xx	xx	xx	xx
Missing	xx	xx	xx	xx
Treatment completed – n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Missing	xx	xx	xx	xx
Treatment ongoing – n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Missing	xx	xx	xx	xx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 10. Number of completed cycles in subjects who have discontinued the treatment – Compliance Analysis Set *(table 14.2.1.2 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Number of patients – n (%)				
Number of cycles				
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X-XX.X)	XX.X (XX.X-XX.X)	XX.X (XX.X-XX.X)	XX.X (XX.X-XX.X)
Min – max	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X	XX.X-XX.X
Number of cycles - n (%)				
≥1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥5	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥6	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥7		XX (XX.X)	XX (XX.X)	XX (XX.X)
≥8		XX (XX.X)	XX (XX.X)	XX (XX.X)
≥9		XX (XX.X)	XX (XX.X)	XX (XX.X)
≥10		XX (XX.X)	XX (XX.X)	XX (XX.X)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; SD: standard deviation. Q1 - Q3: First - third quartile. Min - Max: minimum - maximum values.

Table 11. Dose intensity– Compliance Analysis Set *(table 14.2.1.3 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Number of patients – n (%)				
Paclitaxel				
Mean (SD)	XX.X (XX.X)			XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)			XX.X (XX.X - XX.X)
Min – max	XX.X – XX.X			XX.X – XX.X
Missing	xx			xx
Cediranib				
Mean (SD)		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)		XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min – max		XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing		xx	xx	xx

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Olaparib				
Mean (SD)		XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)		XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min – max		XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing		xx	xx	xx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; SD: standard deviation. Q1 - Q3: First - third quartile. Min - Max: minimum - maximum values.

Table 12. Progression Free Survival – ITT Analysis Set *(table 14.2.2.1 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Censored - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Site of progression - n (%)				
Single site	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Multiple site	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX	XX	XX	XX
Radiological progression for - n (%)				
no radiological progression	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for NTL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL and NTL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL and NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for NTL and NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL, NTL and NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression or death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Kaplan-Meier estimate of PFS (months)				

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartiles	XX.X	XX.X	XX.X	XX.X
Hazard ratio (Arm B vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx
Hazard ratio (Arm C vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; CI: Confidence Interval.

Table 13. Progression Free Survival – PP Analysis Set *(table 14.2.2.2 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Censored - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Site of progression - n (%)				
Single site	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Multiple site	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX	XX	XX	XX
Radiological progression for - n (%)				
no radiological progression	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for NTL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL and NTL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL and NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for NTL and NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
radiological progression for TL, NTL and NL	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression or death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Kaplan-Meier estimate of PFS (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
3rd quartiles	XX.X	XX.X	XX.X	XX.X
Hazard ratio (Arm B vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx
Hazard ratio (Arm C vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; CI: Confidence Interval.

Table 14. Progression Free Survival – Cox models - ITT Analysis Set *(table 14.2.2.3 CSR)*

	Univariate Analysis - PFS				Multivariate Analysis - PFS			
	HR	95% CI		p-value	HR	95% CI		p-value
Covariate 1	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 2	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 3	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate n	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx

Table 15. Progression Free Survival – Cox models - PP Analysis Set *(table 14.2.2.4 CSR)*

	Univariate Analysis - PFS				Multivariate Analysis - PFS			
	HR	95% CI		p-value	HR	95% CI		p-value
Covariate 1	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 2	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 3	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate n	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx

Table 16. Response to treatment – ORR Analysis Set *(table 14.2.3.1 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX
Response – n (%)			
CR	XX.X (xx.x)	XX.X (xx.x)	XX.X (xx.x)
PR	XX.X (xx.x)	XX.X (xx.x)	XX.X (xx.x)
SD	XX.X (xx.x)	XX.X (xx.x)	XX.X (xx.x)
PD	XX.X (xx.x)	XX.X (xx.x)	XX.X (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 17. Objective response rate – ORR Analysis Set *(table 14.2.3.2 CSR)*

Response rate	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX	Chi-squared Test
CR+PR - n (%)	XX.X (xx.x)	XX.X (xx.x)	XX.X (xx.x)	XX.X (xx.x)	Chi= xx.x
[95% CI]	[xx.x - xx.x]	[xx.x - xx.x]	[xx.x - xx.x]		Df=xx
SD + PD - n (%)	*XX.X (xx.x)*	*XX.X (xx.x)*	XX.X (xx.x)	XX.X (xx.x)	P-value= x.xxx
[95% CI]	[xx.x - xx.x]	[xx.x - xx.x]	[xx.x - xx.x]		

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; CI: Confidence Interval.

Table 18. Second Progression Free Survival – ITT Analysis Set *(table 14.2.4.1 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Censored - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression or death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Kaplan-Meier estimate of PFS (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartiles	XX.X	XX.X	XX.X	XX.X
Hazard ratio (Arm B vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx
Hazard ratio (Arm C vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; CI: Confidence Interval.

Table 19. Second Progression Free Survival – PP Analysis Set *(table 14.2.4.2 CSR)*

	ARM A N=XX	**ARM B N=XX**	**ARM C N=XX**	**Overall N=XX**
Censored - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progression or death - n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Kaplan-Meier estimate of PFS (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartiles	XX.X	XX.X	XX.X	XX.X
Hazard ratio (Arm B vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx
Hazard ratio (Arm C vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects; CI: Confidence Interval.

Table 20. Second Progression Free Survival – Cox models - ITT Analysis Set *(table 14.2.4.3 CSR)*

	Univariate Analysis – PFS 2				Multivariate Analysis – PFS 2			
	HR	95% CI		p-value	HR	95% CI		p-value
Covariate 1	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 2	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 3	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate n	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx

Table 21. Second Progression Free Survival – Cox models - PP Analysis Set *(table 14.2.4.4 CSR)*

	Univariate Analysis – PFS 2				Multivariate Analysis – PFS 2			
	HR	95% CI		p-value	HR	95% CI		p-value
Covariate 1	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 2	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 3	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate n	xx.x	xx.x	x.xxx	x.xxx	xx.x	xx.x	xx.x	x.xxx

Table 22. Overall Survival – ITT Analysis Set (table 14.2.5.1 CSR)

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Follow-up estimate (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartile	XX.X	XX.X	XX.X	XX.X
Censored - n (%)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X
Death - n (%)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X
Cause of death - n (%)				
Disease- related	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX
Other	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX
Unknown	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX
Kaplan-Meier estimate of OS (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartiles	XX.X	XX.X	XX.X	XX.X
Hazard ratio (Arm B vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx
Hazard ratio (Arm C vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 23. Overall Survival – PP Analysis Set *(table 14.2.5.2 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Follow-up estimate (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartile	XX.X	XX.X	XX.X	XX.X
Censored - n (%)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X
Death - n (%)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X
Kaplan-Meier estimate of OS (months)				
1st quartile	XX.X	XX.X	XX.X	XX.X
Median	XX.X	XX.X	XX.X	XX.X
3rd quartiles	XX.X	XX.X	XX.X	XX.X
Cause of death - n (%)				
Disease- related	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX
Other	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX
Unknown	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX
Hazard ratio (Arm B vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx
Hazard ratio (Arm C vs. A) [95% CI]				XX.X [XX.X - XX.X]
P-value				x.xxx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 24. Overall Survival – Cox models - ITT Analysis Set *(table 14.2.5.3 CSR)*

	Univariate Analysis - OS				Multivariate Analysis - OS			
	HR	**95% CI**		**p-value**	**HR**	**95% CI**		**p-value**
Covariate 1	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 2	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 3	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate n	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx

Table 25. Overall Survival – Cox models - PP Analysis Set *(table 14.2.5.4 CSR)*

	Univariate Analysis - OS				Multivariate Analysis - OS			
	HR	**95% CI**		**p-value**	**HR**	**95% CI**		**p-value**
Covariate 1	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 2	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate 3	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx
Covariate n	xx.x	xx.x	xx.x	x.xxx	xx.x	xx.x	xx.x	x.xxx

Table 26. Quality of life - PRO Analysis Set *(table 14.2.6.1 CSR)*

	ARM A				ARM B				ARM C				Overall			
FACT-O scores	**T0**	**T1**	**T2**	**T3**	**T0**	**T1**	**T2**	**T3**	**T0**	**T1**	**T2**	**T3**	**T0**	**T1**	**T2**	**T3**
Number of patients - N (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
FACT-O - TOI																
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Physical Well-being																
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X

Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Social Well-being																
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Emotional Well-being																
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X

Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Functional Well-being																
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Ovarian Cancer Symptom scales																
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 27. Quality of life - Change from baseline - PRO Analysis Set *(table 14.2.6.2 CSR)*

FACT-O differences from baseline (T0)	ARM A			ARM B			ARM C			Overall		
	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0
Number of patients - N (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX	XX	XX
Trial Outcome Index (TOI)												
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Physical Well-being												
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)

FACT-O differences from baseline (T0)	ARM A			ARM B			ARM C			Overall		
	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Social Well-being												
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Emotional Well-being												
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)

FACT-O differences from baseline (T0)	ARM A			ARM B			ARM C			Overall		
	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Functional Well-being												
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Ovarian Cancer Symptom scales												

FACT-O differences from baseline (T0)	ARM A			ARM B			ARM C			Overall		
	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0	T1-T0	T2-T0	T3-T0
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

Legend: ARM A: Paclitaxel, ARM B: Cediranib+Olaparib Continuous schedule, ARM C: Cediranib+Olaparib Intermittent schedule, N: number of subjects,SD: stadard deviation, Q1-Q3: First -third quartile, Min-Max: minimum - maximum values, T0: Time 0 (Baseline), T1: after 4 weeks, T2: after 8 weeks, T3: after 12 weeks.

Table 28. Quality of life – Mixed model for differences from baseline - PRO Analysis Set *(table 14.2.6.3 CSR)*

FACT-O scores	Effect	Estimate [95% CI]	P-value
Trial outcome index (TOI)	Intercept	XX [XX.XX-XX-XX]	x.xxx
	Treatment	XX [XX.XX-XX-XX]	x.xxx
	Time	XX [XX.XX-XX-XX]	x.xxx
	Interation	XX [XX.XX-XX-XX]	x.xxx
Physical Well-being	Intercept	XX [XX.XX-XX-XX]	x.xxx
	Treatment	XX [XX.XX-XX-XX]	x.xxx
	Time	XX [XX.XX-XX-XX]	x.xxx
	Interation	XX [XX.XX-XX-XX]	x.xxx
Social Well-being	Intercept	XX [XX.XX-XX-XX]	x.xxx
	Treatment	XX [XX.XX-XX-XX]	x.xxx
	Time	XX [XX.XX-XX-XX]	x.xxx
	Interation	XX [XX.XX-XX-XX]	x.xxx
Emotional Well-being	Intercept	XX [XX.XX-XX-XX]	x.xxx
	Treatment	XX [XX.XX-XX-XX]	x.xxx
	Time	XX [XX.XX-XX-XX]	x.xxx
	Interation	XX [XX.XX-XX-XX]	x.xxx
Functional Well-being	Intercept	XX [XX.XX-XX-XX]	x.xxx
	Treatment	XX [XX.XX-XX-XX]	x.xxx
	Time	XX [XX.XX-XX-XX]	x.xxx
	Interation	XX [XX.XX-XX-XX]	x.xxx
Ovarian Cancer Symptom scales	Intercept	XX [XX.XX-XX-XX]	x.xxx
	Treatment	XX [XX.XX-XX-XX]	x.xxx
	Time	XX [XX.XX-XX-XX]	x.xxx
	Interation	XX [XX.XX-XX-XX]	x.xxx

Legend: ARM A: Paclitaxel, ARM B: Cediranib+Olaparib Continuous schedule, ARM C: Cediranib+Olaparib Intermittent schedule, N: number of subjects.

Table 29. Number of evacuations per day – Safety 1 Analysis Set *(table 14.3.1.1 CSR)*

	ARM B N=7	ARM C N=8	OVERALL N=15
Number of daily stools at baseline			
1	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX	XX	XX
Total number of evacuations			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 1			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 2			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 3			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)

	ARM B N=7	ARM C N=8	OVERALL N=15
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 4			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 5			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 6			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 7			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)

	ARM B N=7	ARM C N=8	OVERALL N=15
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 8			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 9			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Total number of evacuations in cycle 10			
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median (Q1 - Q3)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)	XX.X (XX.X - XX.X)
Min - Max	XX.X – XX.X	XX.X – XX.X	XX.X – XX.X
Missing	xx	xx	xx
Worst experienced grade of diarrhea according to NCI-CTCAE			
0	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
1	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
2	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)

	ARM B N=7	ARM C N=8	OVERALL N=15
3	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Missing	xx	xx	xx

Legend: ARM B: Cediranib+Olaparib Continuous schedule, ARM C: Cediranib+Olaparib Intermittent schedule, N: number of subjects, SD: stadard deviation, Q1-Q3: First -third quartile, Min-Max: minimum - maximum values.

Table 30. Change of evacuations per day – Safety 1 Analysis Set *(table 14.3.1.2 CSR)*

Number of evacuations per day	**ARM B N=XX**	**ARM C N=XX**	***T-test* p-value**
Score	**Mean (SD)**	**Mean (SD)**	
Number of evacuations per day	XX (xx.x)	*XX (xx.x)*	x.xxx

Legend: ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: total number of subjects

Table 31. Adverse reactions – Safety 2 Analysis Set *(table 14.3.1.3 CSR)*

	Arm	G1 n (%)	G2 n (%)	G3 n (%)	G4 n (%)	G3+G4 n (%)	Chi-squared for trend
OVERALL	**ARM A**	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	x.xxx
	ARM B	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
	ARM C	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
SOC1	**ARM A**	**xx (xx)**	**xx (xx)**	**xx (xx)**	**xx (xx)**	**xx (xx)**	**x.xxx**
	ARM B	**xx (xx)**	**xx (xx)**	**xx (xx)**	**xx (xx)**	**xx (xx)**	
	ARM C	**xx (xx)**	**xx (xx)**	**xx (xx)**	**xx (xx)**	**xx (xx)**	
PREFERRED TERM1	ARM A	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	x.xxx
	ARM B	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
	ARM C	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
PREFERRED TERM2	ARM A	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	x.xxx
	ARM B	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
	ARM C	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
PREFERRED TERMn	ARM A	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	x.xxx
	ARM B	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
	ARM C	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
SOCn	ARM A	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	**x.xxx**
	ARM B	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
	ARM C	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
PREFERRED TERMn	ARM A	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	x.xxx

	Arm	G1 n (%)	G2 n (%)	G3 n (%)	G4 n (%)	G3+G4 n (%)	Chi-squared for trend
	ARM B	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	
	ARM C	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	

Legend: ARM A: Paclitaxel, ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: total number of subjects

Table 32. Overview of Serious Adverse Events – Safety 2 Analysis Set *(table 14.3.1.4 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Number of patients – n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SAEs - n	XX	XX	XX	XX
Subjects with at least one SAE - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SADRs - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SUSARs - n (%)	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel, ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: total number of subjects

Table 33. Description of Serious Adverse Events (SAEs) – Safety 2 Analysis Set *(table 14.3.1.5 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Causal relationship - n (%)				
With only disease	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
With only Paclitaxel	XX (xx.x)			XX (xx.x)
With both disease and Paclitaxel	XX (xx.x)			XX (xx.x)
With only Olaparib		XX (xx.x)	XX (xx.x)	XX (xx.x)
With both disease and Olaparib		XX (xx.x)	XX (xx.x)	XX (xx.x)
With only Cediranib		XX (xx.x)	XX (xx.x)	XX (xx.x)
With both disease and Cediranib		XX (xx.x)	XX (xx.x)	XX (xx.x)
With disease, Olaparib and Cediranib		XX (xx.x)	XX (xx.x)	XX (xx.x)
Seriousness - n (%)				
Death	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Hospitalisation/Prolonged hospitalisation	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
Life-threatening	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Medically Significant	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Significant disability	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Congenital anomaly/birth defect	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Death	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 34. Description of Serious Adverse Events (SAEs) by MedDRA – Safety 2 Analysis Set *(table 14.3.1.6 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
SAEs by MEdDra System Organ Class (SOC) - n (%)				
SOC1	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SOC2	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SOCn	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SAEs by MEdDra Preferred Term (PT) - n (%)				
PT1	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
PT2	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
PTn	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 35. Description of Serious Adverse Drug Reactions (SADRs) - Safety 2 Analysis Set *(table 14.3.1.7 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
NCI/CTC grade - n (%)				
1 – Mild	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
2 – Moderate	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
3 – Severe	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
4 – Life-treatening	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
5 - Fatal	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Outcome - n (%)				
Resolved	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Resol. With sequelae	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Not resolved	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Fatal	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
Unknown	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

Table 36. Description of Serious Adverse Drug Reactions (SADRs) by MEdDra – Safety 2 Analysis Set *(table 14.3.1.8 CSR)*

	ARM A N=XX	ARM B N=XX	ARM C N=XX	Overall N=XX
SADRs (Serious Adverse Drug Reactions) - n (%)	XX	XX	XX	XX
SADRs by MEdDra System Organ Class (SOC) - n (%)				
SOC1	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SOC2	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SOCn	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
SAERs by MEdDra Preferred Term (PT) - n (%)				
PT1	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
PT2	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)
PTn	XX (xx.x)	XX (xx.x)	XX (xx.x)	XX (xx.x)

Legend: ARM A: Paclitaxel; ARM B: Cediranib+Olaparib Continuous schedule; ARM C: Cediranib+Olaparib Intermittent schedule; N: number of subjects

7. APPENDIX B: LISTINGS OF SECTION 16.2 OF THE CSR

Overall content of Appendix 16.2 of the CSR (see guideline ICH topic E3):

16.2.1 Discontinued patients

16.2.2 Protocol Deviations

16.2.3 Patients Excluded from the Efficacy Analysis

16.2.4 Demographic Data / Tumor characteristics

16.2.5 Compliance

16.2.6 Individual Efficacy Response Data

16.2.7 Adverse Events Listings (each patient)

Listing 1. Subject disposition (All subjects set) (listing 16.2.1.1)

Key	Age	Arm	Status	Reason for withdrawal	N cycles	N Fup	Lost to Fup

Listing 2. Protocol Deviations (listing 16.2.2.1)

Key	Age	Arm	Deviation	Deviation: specification

Listing 3. Inclusion criteria (All subjects set) (listing 16.2.2.2)

Key	Age	Arm	Inclusion 1 (yes/no)	Inclusion 2 (yes/no)	Inclusion 3 (yes/no)	Inclusion 4 (yes/no)	Inclusion 5 (yes/no)	Inclusion 6 (yes/no)	Inclusion n (yes/no)

Listing 4. Exclusion criteria (All subjects set) (listing 16.2.2.3)

Key	Age	Arm	Exclusion 1 (yes/no)	Exclusion 2 (yes/no)	Exclusion 3 (yes/no)	Exclusion 4 (yes/no)	Exclusion 5 (yes/no)	Exclusion 6 (yes/no)	Exclusion n (yes/no)

Listing 5. Patients inclusion in the analysis sets (All subjects set) (listing 16.2.3.1)

Key	Age	Arm	All subjects analysis set (yes/no/if no reason)	Intent-to-treat analysis set (yes/no/if no reason)	Per-protocol analysis set (yes/no/if no reason)	Safety analysis set (yes/no/if no reason)	Overall Response rate analysis set (yes/no/if no reason)	Compliance analysis set (yes/no/if no reason)	PRO analysis set (yes/no/if no reason)

Listing 6. Demographic and baseline characteristics (All subjects set) (listing 16.2.4.1)

Key	Age	Arm	Characteristic1	Characteristic n	Dataset

Listing 7. Tumor characteristics (All subjects set) (listing 16.2.4.2)

Key	Age	Arm	Characteristic1	Characteristic n	Dataset

Listing 8. Previous therapies (All subjects set) (listing 16.2.4.3)

Key	Age	Arm	Therapy 1	Therapy n	Dataset

Listing 9. Drug administration: dose administer per cycle (All subjects set) (listing 16.2.5.1)

Key	Age	Arm	Date	Dose Paclitaxel	Dose Cediranib	Dose Olaparib	Treatment modification (yes/no)	Time modification	Dose modification	Treatment not administered	Dataset

Listing 10. Treatment compliance (All subjects set) (listing 16.2.5.2)

Key	Age	Arm	Treatment	Treatment modification	N cycles	Reason for modification	Dose Intensity Paclitaxel	Dose Intensity Cediranib	Dose Intensity Olaparib	Dataset

Listing 11. Efficacy data (All subjects set) (listing 16.2.6.1)

Key	Age	Arm	Death	Date of death	Overall survival time (months)	Cause of death	Progression	Date of progression	Progression free survival time (months)	Dataset

Listing 12. Follow-up (All subjects set) (listing 16.2.6.2)

Key	Age	Arm	Death	Date of death	Overall survival time (months)	Cause of death	Second Progression	Date of second progression	Second Progression free survival time (months)	Dataset

Listing 13. Response to treatment (All subjects set) (listing 16.2.6.3)

Key	Age	Arm	Best response	Reason for no response	Response duration (months)	Event (progression/death/censored)	Dataset

Listing 14. Tumor assessment (All subjects set) (listing 16.2.6.4)

Key	Age	Arm	Evaluation (weeks)	date	Conclusion for target lesion	Conclusion for non-target lesion	Conclusion for new lesion	Overall evaluation	Dataset

Listing 15. Quality of life assessment: FACT-O scores (All subjects set) (listing 16.2.6.5)

Key	Age	Arm	Evaluation (weeks)	date	TOI	Physical well-being	Social well-being	Functional well-being	Emotional well-being	Additional concern	Dataset

Listing 16. Quality of life assessment: FACT-O items (All subjects set) (listing 16.2.6.6)

Key	Age	Arm	Evaluation (weeks)	date	Item 1	Item 2	Item 3	Item ...	Item 39	Dataset

Listing 17. Number of evacuation per day (All subjects set) (listing 16.2.7.1)

Key	Age	Arm	Evaluation (weeks)	date	Total number of evacuations	Number of days	Dose Loperamid	Number of days of Loperamid	Worst grade (NCI-CTCAE)	Dataset

Listing 18. Treatment tolerability- haematological toxicity (All subjects set) (listing 16.2.7.2)

Key	Age	Arm	Toxicity 1	Toxicity n	Dataset

Listing 19. Treatment tolerability- Non haematological toxicity (All subjects set) (listing 16.2.7.3)

Key	Age	Arm	Toxicity 1	Toxicity n	Dataset

Listing 20. Serious Adverse Events (listing 16.2.7.4)

Key	Age	Arm	Description	Relationship	Seriousness	Severity	Outcome

8. APPENDIX C: FIGURES TEMPLATE

Figure 2. Kaplan-Meier display of Progression Free Survival – *ITT* Analysis Set

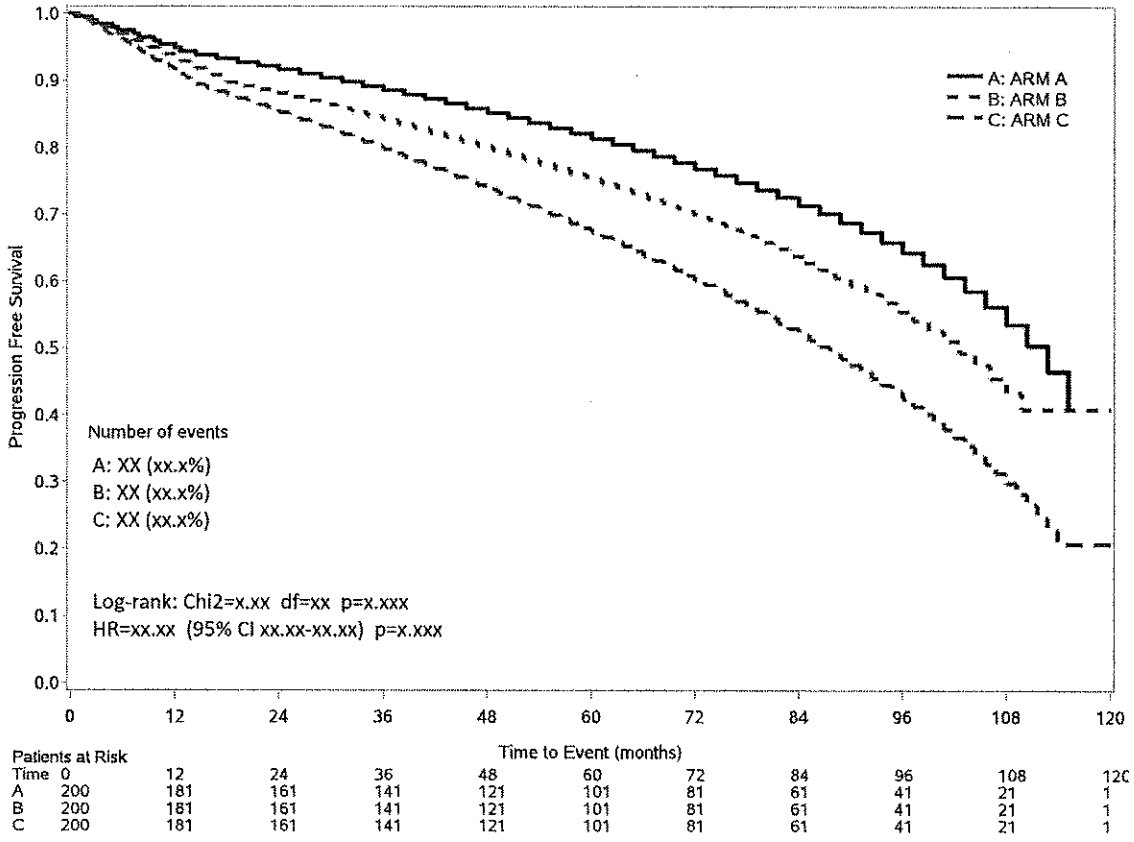
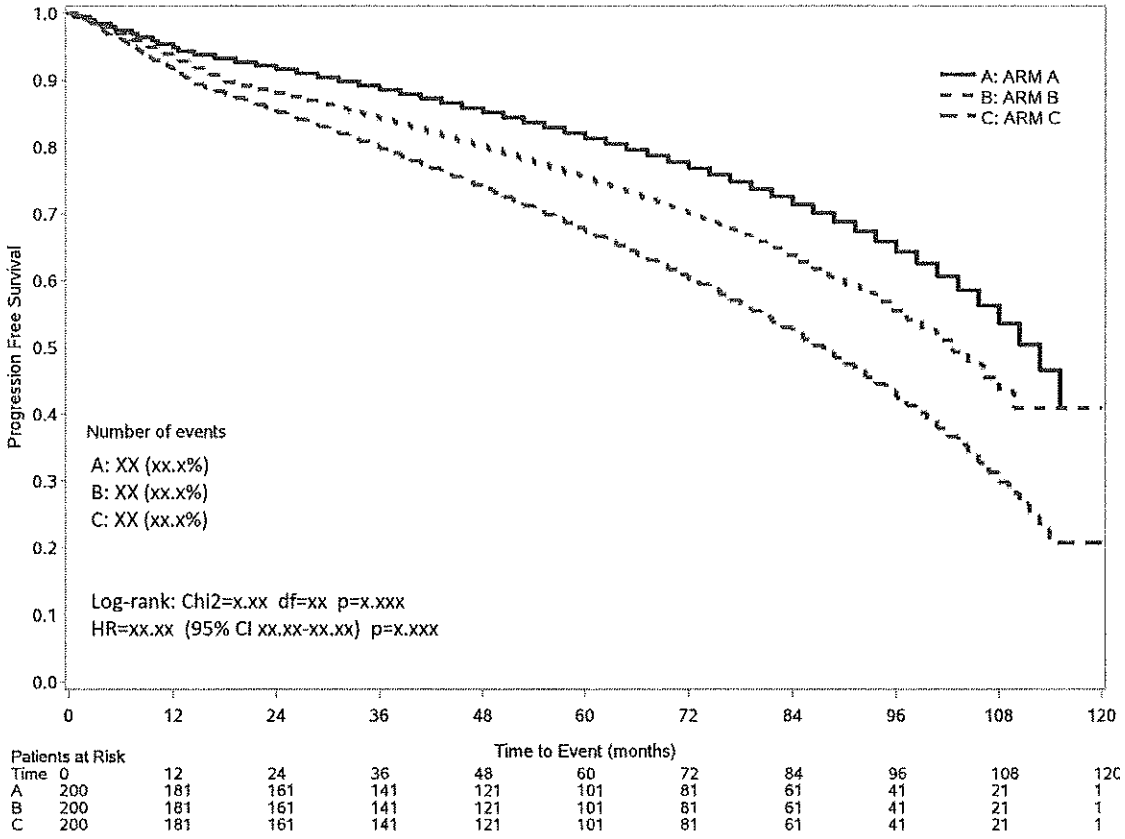


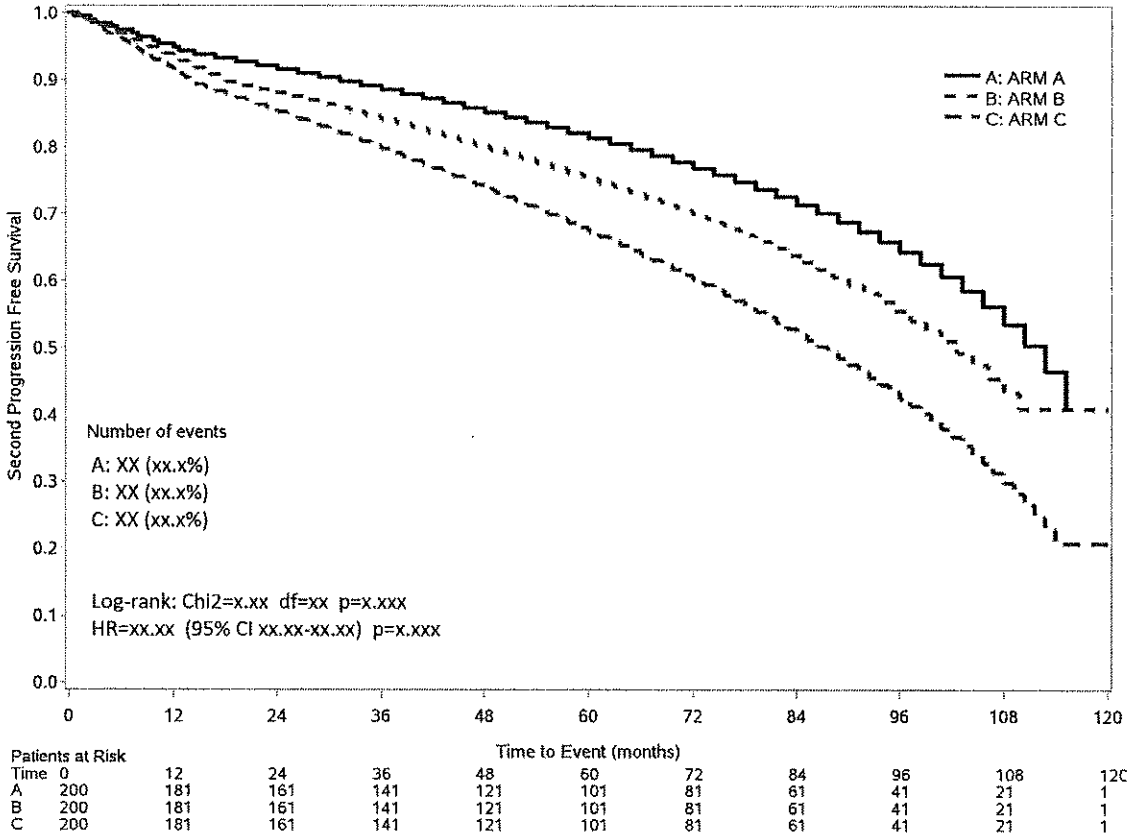
Figure 3. Kaplan-Meier display of Progression Free Survival – *PP* Analysis Set



Patients at Risk

Time	0	12	24	36	48	60	72	84	96	108	120
A	200	181	161	141	121	101	81	61	41	21	1
B	200	181	161	141	121	101	81	61	41	21	1
C	200	181	161	141	121	101	81	61	41	21	1

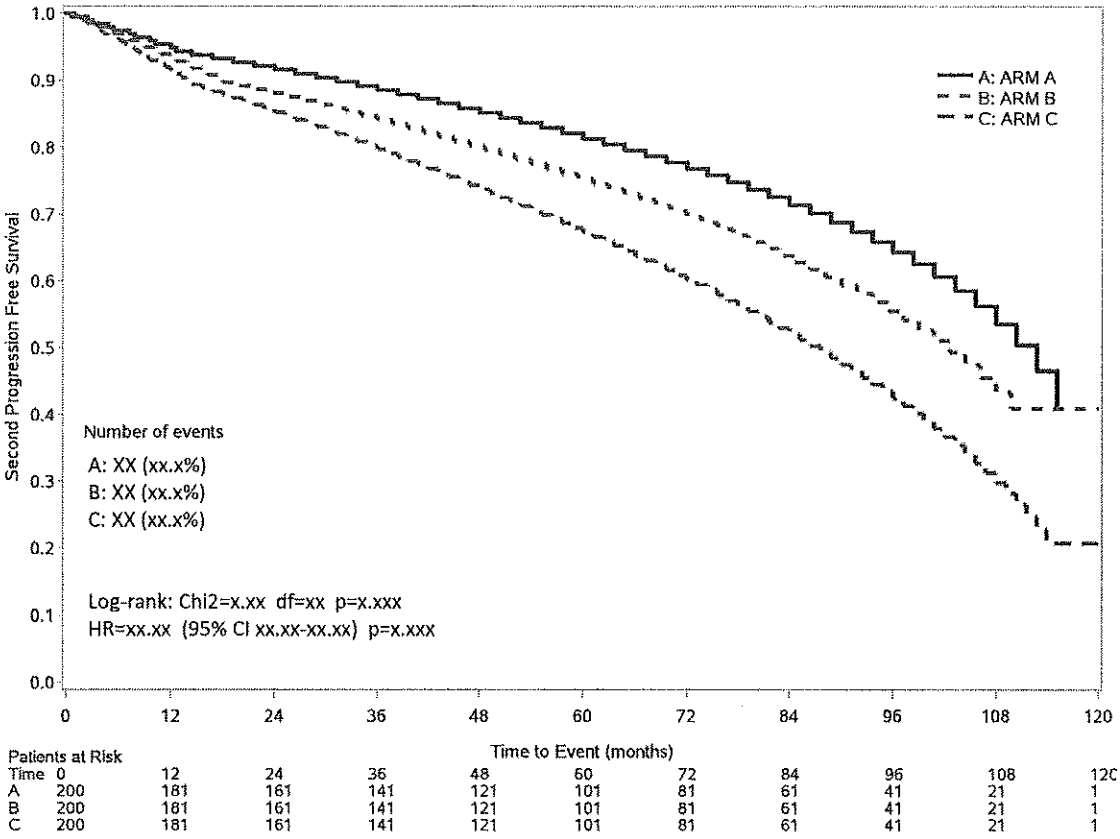
Figure 4. Kaplan-Meier display of Second Progression Free Survival – *ITT* Analysis Set



Patients at Risk

Time	0	12	24	36	48	60	72	84	96	108	120
A	200	181	161	141	121	101	81	61	41	21	1
B	200	181	161	141	121	101	81	61	41	21	1
C	200	181	161	141	121	101	81	61	41	21	1

Figure 5. Kaplan-Meier display of Second Progression Free Survival – *PP* Analysis Set



Patients at Risk

Time	0	12	24	36	48	60	72	84	96	108	120
A	200	181	161	141	121	101	81	61	41	21	1
B	200	181	161	141	121	101	81	61	41	21	1
C	200	181	161	141	121	101	81	61	41	21	1

Figure 6. Kaplan-Meier display of Overall Survival – *ITT* Analysis Set

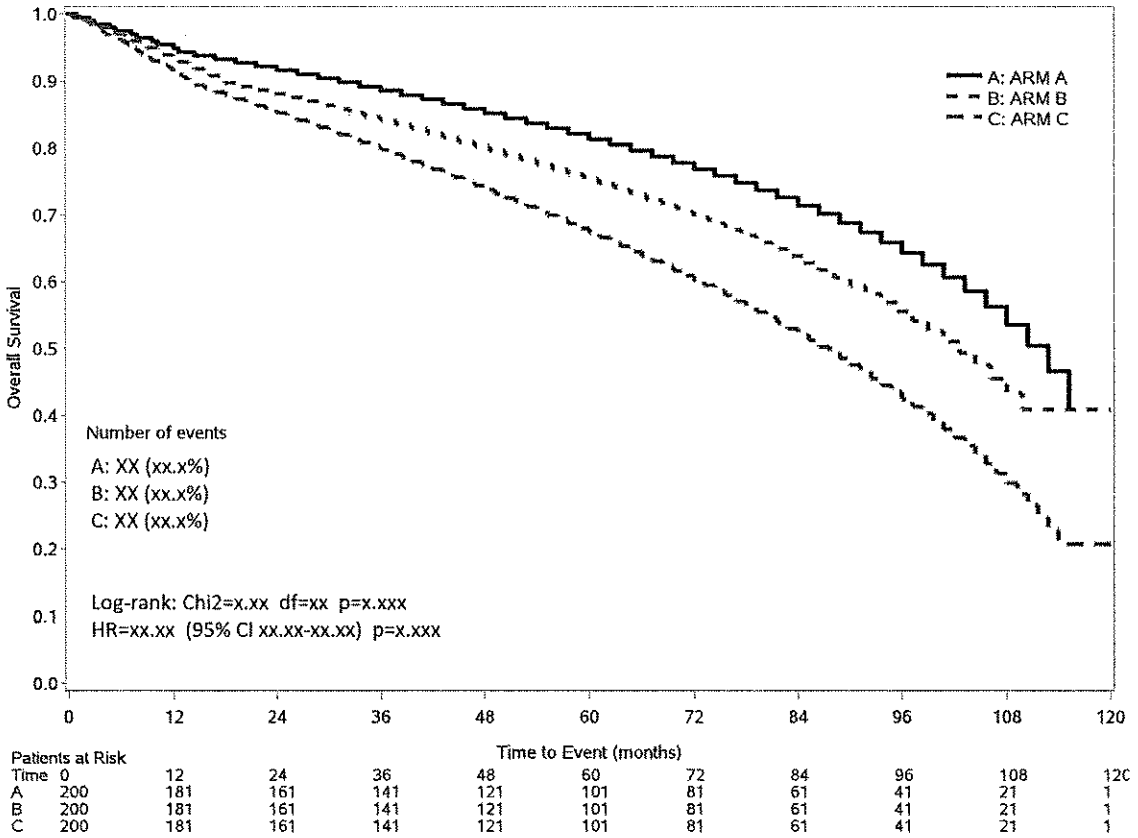
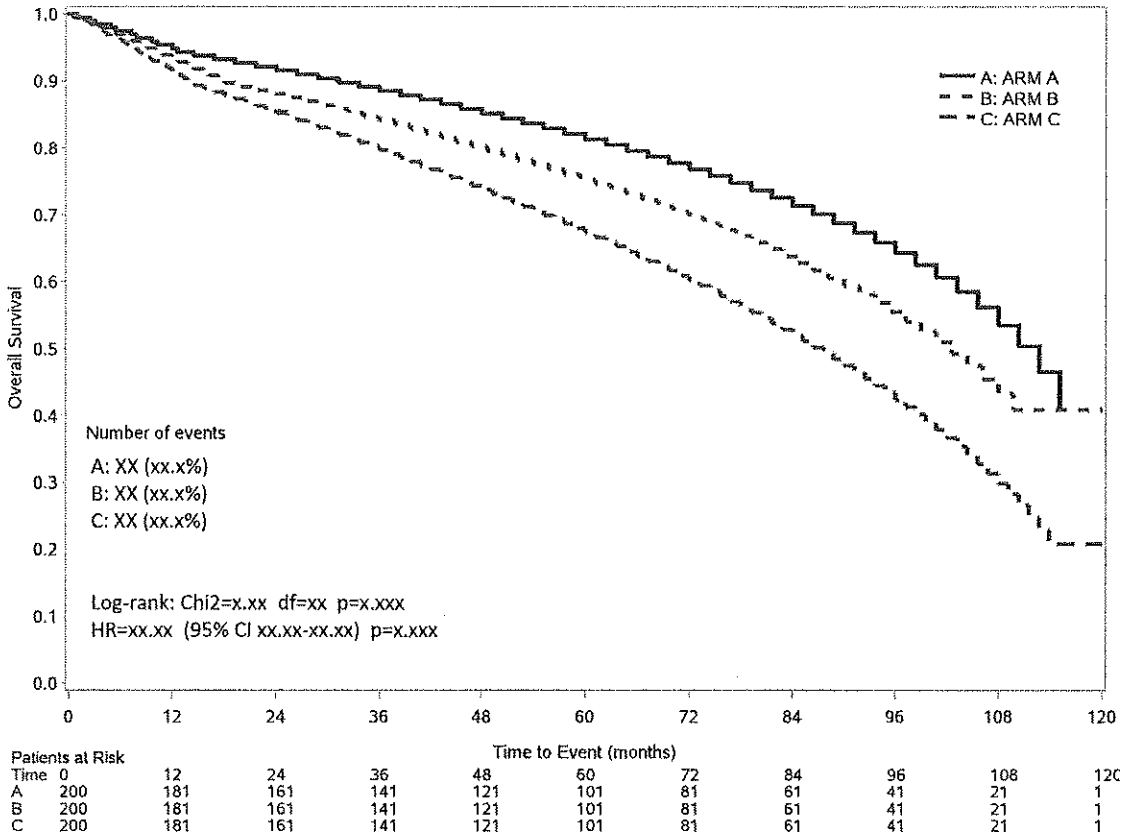


Figure 7. Kaplan-Meier display of Overall Survival – *PP* Analysis Set



Patients at Risk

Time	0	12	24	36	48	60	72	84	96	108	120
A	200	181	161	141	121	101	81	61	41	21	1
B	200	181	161	141	121	101	81	61	41	21	1
C	200	181	161	141	121	101	81	61	41	21	1