STATISTICAL ANALYSIS PLAN

INCAGN 1949-101 / NCT02923349

A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCAGN01949 in Subjects With Advanced or Metastatic Solid Tumors

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Protocol Version:	**Original Protocol dated 07 JUN 2016**
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SAP Version:	**Original**
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This study is being conducted in compliance with good clinical practice, including the archiving of essential documents.

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LIST OF ABBREVIATIONS

Abbreviation	Term
[redacted]	[redacted]
AE	adverse event
AUC	area under the concentration-time curve
$AUC_{(0-\tau)}$	AUC from time zero (predose) to time of last observed quantifiable concentration within a subject across all treatments
CI	confidence interval
C_{max}	maximum observed concentration
C_{min}	minimum observed concentration
CR	complete response
CRF	case report form
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DLT	dose-limiting toxicity
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EOS	end of study
EOT	end of treatment
FAS	full analysis set
FDA	Food and Drug Administration
irAE	immune-related adverse event
JTc	corrected JT interval
KM	Kaplan-Meier
MedDRA	Medical Dictionary for Regulatory Activities
MNTD	maximum number of tolerated doses
MSI	microsatellite instability
MSKCC	Memorial Sloan Kettering Cancer Center
mRECIST	modified Response Evaluation Criteria in Solid Tumors
MTD	maximum tolerated dose
NCI	National Cancer Institute
NE	not evaluable
NSCLC	non–small cell lung cancer
ORR	objective response rate
PAD	pharmacologically active dose

Abbreviation	Term
PD	progressive disease
PD-1	programmed death-1
PD-L1	programmed death ligand-1
PFS	progression-free survival
PK	pharmacokinetic
PP	per protocol
PR	partial response
PT	preferred term
QTcF	QT interval corrected using the Fridericia formula
QRS	QRS is the combination of three of the graphical deflections on an ECG. It is usually the central and most visually obvious part of the tracing. It corresponds to the depolarization of the right and left ventricles of the human heart.
RCC	renal cell carcinoma
RECIST	Response Evaluation Criteria in Solid Tumors
RR	RR is the interval from the beginning of a QRS complex to the beginning of the next QRS complex
SAE	serious adverse event
SAP	Statistical Analysis Plan
SD	stable disease
SI	International System of Units
SOC	system organ class
t	time of last observed quantifiable concentration
TEAE	treatment-emergent adverse event
T_{max}	time of occurrence of C_{max}
WBC	white blood cell
WHO	World Health Organization

1. INTRODUCTION

This is a Phase 1/2, open-label, nonrandomized, multicenter, dose-escalation study. This study will be conducted in 2 parts. Part 1 will utilize a 3 + 3 design to determine the MTD or PAD for INCAGN01949 in subjects with advanced or metastatic solid tumors. Part 2 of the study will further evaluate the safety, tolerability, preliminary efficacy, PK, [redacted] of the recommended dose and schedule of INCAGN01949 in subjects with advanced or metastatic adenocarcinoma of the endometrium, ovarian cancer, RCC, melanoma, and NSCLC (squamous and nonsquamous). Section 1 of the Protocol provides a detailed description of the investigational product, target patient population, rationale for doses to be examined, and potential risks and benefits of treatment with INCAGN01949.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Study INCAGN 1949-101 Protocol. The scope of this plan includes the interim and final analyses that are planned and will be executed by the Department of Biostatistics or designee and the analyses of PK. [redacted].

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCAGN 1949-101 Protocol dated 07 JUN 2016 and CRFs approved 26 JUL 2016. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and CRF versions.

2.2. Study Objectives

2.2.1. Primary Objective

- To evaluate the safety, tolerability, and DLTs of INCAGN01949, and to define a MTD or PAD of INCAGN01949 in subjects with metastatic or advanced solid tumors.

2.2.2. Secondary Objectives

- To evaluate the PK of INCAGN01949 in subjects with advanced or metastatic solid tumors.
- To evaluate the preliminary efficacy of INCAGN01949 by assessing the ORR, DOR, PFS, and duration of disease control per RECIST v1.1 and mRECIST v1.1.

[redacted]

2.3. Study Endpoints

2.3.1. Primary Endpoint

- Safety and tolerability will be assessed by monitoring the frequency, duration, and severity of AEs.

2.3.2. Secondary Endpoints

- The PK of INCAGN01949, including C_{max}, T_{max}, C_{min}, and AUC_{0-t} for subjects in Parts 1 and 2 will be summarized.
- ORR, defined as the percentage of subjects having CR or PR, will be determined by investigator assessment of radiographic disease per RECIST v1.1 and mRECIST v1.1.
- DOR, defined as the time from earliest date of disease response (CR or PR) until earliest date of disease progression, will be determined by investigator assessment of radiographic disease per RECIST v1.1 and mRECIST v1.1, or death from any cause, if occurring sooner than progression.
- PFS, defined as the time from date of first dose of study drug until the earliest date of disease progression, as determined by investigator assessment of objective radiographic disease per RECIST v1.1 and mRECIST v1.1, or death from any cause if occurring sooner than progression.
- Duration of disease control (CR, PR, and SD), as measured from first report of SD or better until disease progression, will be determined by investigator assessment of radiographic disease per RECIST v1.1 and mRECIST v1.1, or death from any cause, if occurring sooner than progression.

[redacted]

[redacted]

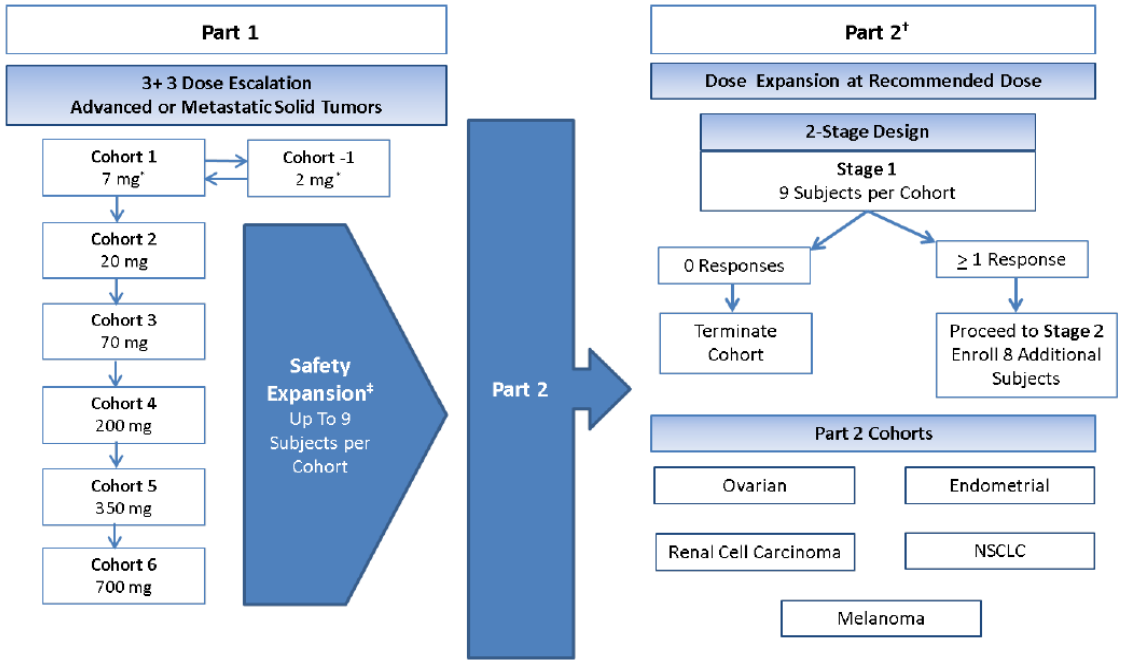
3. STUDY DESIGN

This is an open-label, nonrandomized, Phase 1/2 study to determine the safety and tolerability, define the MTD or PAD, and assess the preliminary efficacy of INCAGN01949 in subjects with advanced or metastatic solid tumors. Subjects will receive escalating doses of INCAGN01949 on Day 1 of each cycle. Part 1 of the study will begin with 14-day cycles; however, alternate dose administration schedules may also be explored depending on PK, [redacted] and safety results. The study will be conducted in 2 parts:

- **Part 1 – Dose Escalation and Safety Expansion** will determine the PAD, defined as a dose that provides a maximal biochemical effect, [redacted], and/or the MTD of INCAGN01949, including defining the optimal dose administration schedule and the MNTD.
- **Part 2 – Dose Expansion** will evaluate the recommended dose and administration schedule determined in Part 1 in subjects with select tumor types [redacted] including adenocarcinoma of endometrium, ovarian cancer, melanoma, NSCLC, and RCC.

See Figure 1 for overall study design.

Figure 1: Study Design



* If Cohort 1 (7 mg) ***exceeds*** the MTD, Cohort -1 (2 mg) may be tested and/or Cohort 1 (7 mg) will be tested at alternate dose schedules based on available safety, PK, [redacted] data. If an alternate schedule is tested and determined to be safe, re-escalation of INCAGN01949 will proceed as outlined above.

‡ The safety expansion cohorts may evaluate dose(s) and schedule(s) equivalent to or less than the highest dose levels determined to be safe or doses determined to be pharmacologically active. Alternate dose schedules may also be tested depending on PK, [redacted] and safety results.

†Subjects in Part 2 will receive the recommended dose determined in Part 1.

3.1. Dose Escalation and Expansion

3.1.1. Part 1 – Dose Escalation

The PAD is defined as a dose that provides a maximal biochemical effect, or an increase in biomarkers of immune activity.

A DLT will be defined as the occurrence of a toxicity, with the exception of events clearly associated with the underlying disease, disease progression, a concomitant medication, or comorbidity; the list of toxicities that will be designated as dose limiting toxicities are provided in Table 3 of the Protocol.

In Part 1 of the study, the MTD will be defined as 1 dose level below that at which ≥ one-third of subjects in a particular cohort have DLTs.

In Part 1, subjects with advanced or metastatic solid tumors who progressed after treatment with available therapies that are known to confer clinical benefit, who are intolerant to treatment, or refuse standard treatment will be enrolled.

In the dose-escalation part of the study, a 3 + 3 design will be used to determine the MTD or PAD of INCAGN01949. A minimum of 3 evaluable subjects will be enrolled in each cohort beginning with Cohort 1 (7 mg; starting dose). There will be a waiting period of 48 hours between dose administration of the first subject and second subject of each dose cohort. The first 3 subjects enrolled within a cohort will be observed for a DLT observation period of 28 days

before the next cohort begins enrollment. The dose will be escalated if 0 of the first 3 evaluable subjects enrolled has a DLT. If 1 of the first 3 evaluable subjects enrolled has a DLT, then the cohort will be expanded to include 3 additional evaluable subjects, and if no DLT occurs in the additional 3 subjects, then the dose will be escalated. If a DLT occurs in one-third or more of the expanded cohort, then the MTD will be deemed to be exceeded, and the prior dose level will be considered the MTD. If only 3 subjects were treated at the MTD or PAD, then a minimum of 3 additional subjects will be enrolled before this dose is administered in Part 2 of the study.

If Cohort 1 (7 mg; starting dose) exceeds the MTD, the sponsor and investigators will consider dosing INCAGN01949 at 2 mg (Cohort -1), and/or investigate 7 mg at alternate dose schedules (eg, every 3-week administration), based on available safety, PK, [redacted] data. If an alternate schedule is tested and determined to be safe, re-escalation of INCAGN01949 will proceed according to Table 1.

Throughout the treatment period, if > 33% of subjects (a minimum of 6 subjects) experience a ≥ Grade 3 toxicity related to study drug after completing ≥ 4 cycles, then dose administration will be stopped, and the MNTD will be determined in conjunction with the investigators and sponsor based on all available safety data.

Additional subjects will be enrolled in a cohort to achieve the minimum of 3 evaluable subjects. Subjects who drop out for reasons other than a DLT (eg, events clearly associated with the underlying disease, disease progression, concomitant medication, or comorbidity) during the 28-day DLT observation period will be considered nonevaluable and will be replaced. Dose modifications should not be made during the DLT observation period without discussion with the medical monitor. Intrasubject dose escalation is not permitted; however, once the recommended dose and schedule have been determined, ongoing subjects in Part 1 may be permitted to escalate the dose to the recommended level with approval of the medical monitor. The cohorts and dose levels are shown in Table 1.

Table 1: INCAGN01949 Dose Levels and Cohort

Cohort	Dose of INCAGN01949[a]
-1	2 mg[b]
1 (starting dose)	**7 mg**
2	20 mg
3	70 mg
4	200 mg
5	350 mg
6	700 mg

[a] Additional dose schedules may be explored that would depend on PK, [redacted], and safety results.
[b] Subjects who require a dose reduction below 2 mg should be discontinued from study drug.

3.1.2. Part 1 – Safety Expansion

In order to evaluate additional [redacted] activity of INCAGN01949 and confirm the preliminary safety of the dose escalation cohorts, Part 1 of the study may include safety expansion cohorts evaluating doses and schedules equivalent to or lower than the highest dose

levels determined to be safe and/or doses determined to be pharmacologically active. The alternative dose administration schedules and fixed doses (equivalent to or less than the MTD determined during dose escalation) that may be explored during the safety expansion would depend on PK, [redacted], and safety results.

A maximum of 36 subjects will be enrolled into the Part 1 safety expansion, and each Part 1 safety expansion cohort will enroll up to 9 evaluable subjects. If < 3 of 9 evaluable subjects have a DLT, then the cohort will be deemed safe. If > 1 safety expansion cohort is deemed safe, then a recommended dose and schedule will be determined in conjunction with the investigators and sponsor based on all available safety, PK, [redacted] results. The safety expansion cohorts may be run in parallel to Part 2 and may be limited by the sponsor to subjects with specific tumor types to achieve a balance across cohorts.

3.1.3. Part 2 – Dose Expansion

Part 2 of the study will further evaluate the safety, tolerability, preliminary efficacy, PK, and pharmacologic activity of the recommended dose of INCAGN01949 in subjects with advanced or metastatic adenocarcinoma of the endometrium, melanoma, NSCLC (squamous and nonsquamous), and RCC. Each cohort will comprise an individual tumor type. A Simon 2-stage design (Simon 1989) will be utilized with a stopping rule to allow early termination of a particular cohort at the end of Stage 1 if there are insufficient responses observed. During Stage 1, 9 subjects will be enrolled; if no responses are observed in 16 weeks with 2 scans, then enrollment in the cohort will be terminated. If at least 1 response is observed, then 8 additional subjects will be enrolled into that cohort (Stage 2), for a maximum of 17 subjects per cohort.

Subjects will continue to receive INCAGN01949 until Protocol-defined withdrawal criteria are met. Continuous evaluation of toxicity events will be performed throughout enrollment in Part 2 of the study. If the cumulative incidence of DLTs occurs in > 33% of subjects after 6 subjects are observed for at least 28 days, further enrollment will be interrupted until the sponsor determines the appropriate course of action. All AEs, regardless of the time of occurrence on study, may be considered in determining the appropriate dose, schedule, and MNTD.

Toxicity will continue to be monitored throughout the treatment period. If > 33% of subjects (minimum of 6 subjects) experience a Grade ≥ 3 toxicity related to study drug after completing ≥ 4 cycles, then the MNTD will be determined in conjunction with the investigators and sponsor based on all available safety data. All AEs, regardless of the time of occurrence on study, may be considered in DLT determination decisions.

3.2. Randomization

Not applicable.

3.3. Control of Type I Error

All statistical analyses are exploratory in nature. Unless otherwise specified, all CIs provided will be at the 95% confidence level.

3.4. Sample Size Considerations

3.4.1. Sample Size in Part 1

The primary objective of Part 1 of the study is to determine the PAD or the MTD of INCAGN01949. The total number of subjects will depend on the number of dose levels tested before the MTD or PAD is established. Approximately 18 to 36 subjects (6 subjects per dose level for 6 dose levels) will be included based on the dose escalation. Dose escalation will follow the 3 + 3 design algorithm. Based on this algorithm, a minimum of 3 evaluable subjects will be enrolled in each cohort beginning with Cohort 1 (7 mg; starting dose) and a maximum of 6 evaluable subjects for each cohort. The probability of declaring a dose cohort as safe for various DLT rates in the 3 + 3 and the safety expansion is summarized in Table 2.

Table 2: Probability of Dose Escalation by DLT Rate for 3 + 3 Design and Safety Expansion

True DLT Rate	Probability of Declaring Dose Cohort as Safe	
	3 + 3 Design	In Both 3 + 3 Design and Safety Expansion
10%	90.6%	85.8%
20%	70.9%	52.3%
30%	49.4%	22.9%
40%	30.9%	7.2%
50%	17.2%	1.5%
60%	8.2%	0.2%

For example, if the true DLT rate is 50% at a given dose level, there is a 17.2% chance that the dose would be escalated. Further, if the true DLT rate is 20%, there is a 70.9% chance that the dose would be escalated. If the MTD is not determined at the highest dose level tested during the study, then the MTD is at or above the highest dose level. The MTD is below the lowest dose level of INCAGN01949 if Cohort 1 is not well-tolerated. The PAD may be used in lieu of the MTD and/or prescribed doses may need to be altered in order to determine the MTD.

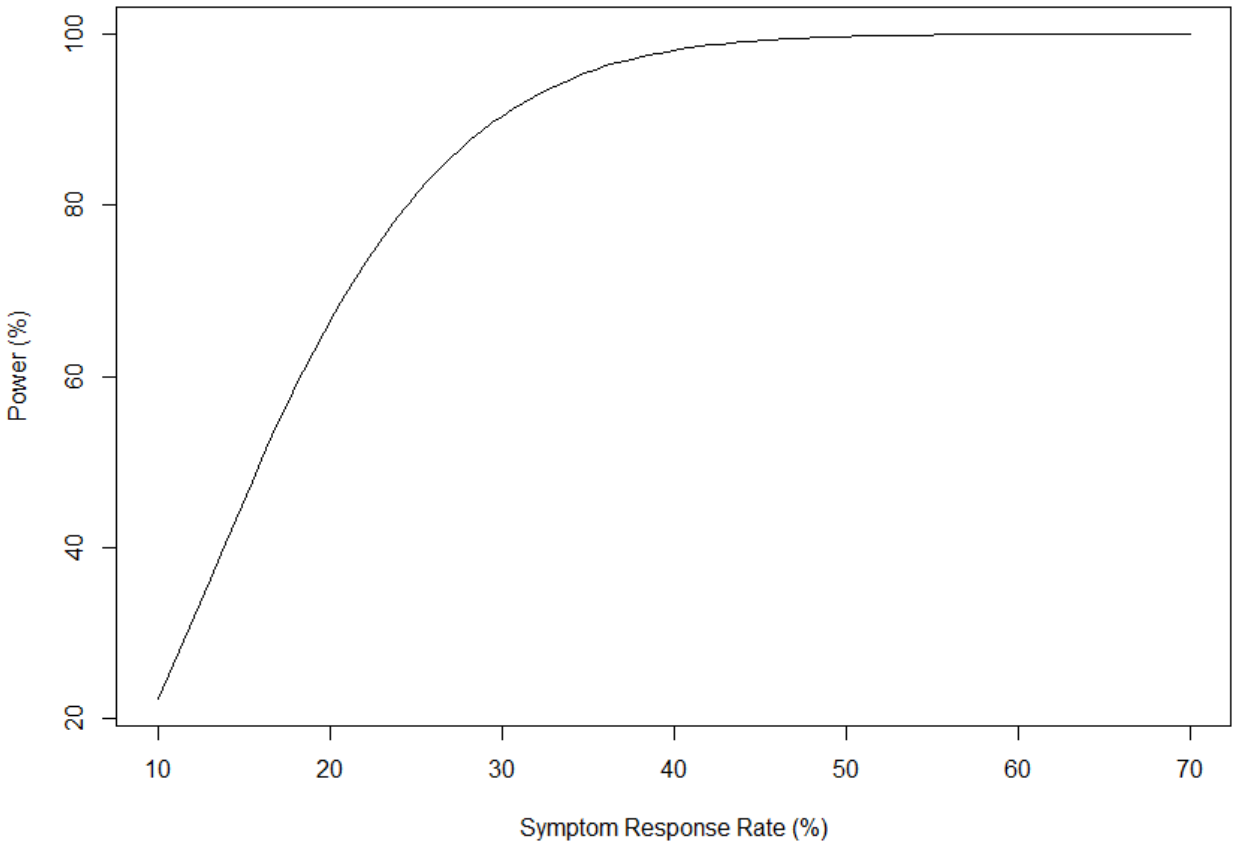
Part 1 of the study may also include safety expansion cohorts evaluating doses and schedules equivalent to or lower than the highest dose levels determined to be safe and/or doses determined to be pharmacologically active. Each safety expansion cohort will enroll 9 evaluable subjects (up to 36 subjects). If < 3 of 9 evaluable subjects experience a DLT, the cohort will be deemed safe. If more than 1 safety expansion cohort is deemed safe, then the recommended dose will be determined in conjunction with the investigators and sponsor based on all available safety, PK, [redacted] results.

3.4.2. Sample Size in Part 2

Part 2 of the study will further evaluate the safety, tolerability, preliminary efficacy, PK, and pharmacologic activity of the recommended dose of INCAGN01949. The sample size for each tumor type will be guided by the Simon 2-stage design (Simon 1989). Let $P_0 = 5\%$ denote a clinically insignificant response rate for all tumor types. In order to determine whether the target response rate (25%) is likely, an initial number of evaluable subjects (9 subjects) treated at the

MTD or PAD and schedule of INCAGN01949 will be enrolled in a cohort (Stage 1). If there is no response for the cohort, it will be concluded that the true response rate is unlikely to be greater than or equal to the target rate, and no more subjects will be enrolled in that tumor type in Stage 2. Due to replacement of subjects for biopsy analysis, additional subjects may be enrolled for the biopsy evaluable population; however, the first 9 evaluable subjects in each cohort will be used for early stopping at Stage 1. In the tumor types in which at least 1 response among the Stage 1 subjects is observed, 8 additional evaluable subjects will be treated in Stage 2 to estimate the response rate. At the end of Stage 2, if ≤ 2 subjects have responded among the evaluable subjects, the drug will be declared nonpromising for that tumor type. In other words, after the study is finished, if there is a sufficient number of responses in the 2 stages combined, the study compound is considered promising; otherwise it is considered nonpromising. The detailed calculation is based on a 1-sided Type I error of 0.05 and power of 80% for each of the tumor types. Figure 2 shows the power to reject the null hypothesis for various response rates.

Figure 2: Power and Type I Error for Simon 2-Stage Design for Various Response Rates



4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date that the first dose of study drug (INCAGN01949) is administered to the subjects.

4.1.2. Study Day

If a visit/reporting date is on or after Day 1, then the study day at the visit/reporting date will be calculated as

Day # = (Visit/Reporting Date – Day 1 date + 1).

If the visit/reporting date is before Day 1, then the study day at the visit/reporting date will be calculated as

Day # = (Visit/Reporting Date – Day 1 date).

A study day of -1 indicates 1 day before Day 1.

4.1.3. Baseline Value

Baseline is the last nonmissing measurement obtained before the first administration of INCAGN01949.

When scheduled assessments and unscheduled assessments occur on the same day and time of the assessment or time of first dose is not available, use the following convention to determine baseline:

- If both a scheduled and an unscheduled visit are available on the day of the first dose and the time is missing, use the scheduled assessment as baseline.
- If all scheduled assessments are missing on the day of the first dose and an unscheduled assessment is available, use the unscheduled assessment as baseline.

4.1.4. Handling of Missing and Incomplete Data

In general, values for missing data will not be imputed unless methods for handling missing data are specified in this section or relevant sections.

Partial disease/cancer diagnosis date will be handled as follows:

- If only the day is missing, then the imputed day will be the first of the month.
- If both the month and day are missing, then the imputed day and month will be 01 JAN.
- No imputation will be done if the date is completely missing.

Missing or partial date of last dose will be handled as follows:

- If only the day is missing, then the imputed date of the last dose will be the earlier date of the first day of the month or the date that the subject discontinued treatment.
- Otherwise, the date that the subject discontinued treatment will be used as the date of the last dose.

For relevant efficacy endpoints, partial death date will be imputed as follows:

- If mmyyyy for the last contact date = mmyyyy for the death date, then the death date will be set to the day after the last contact date.
- If mmyyyy for the last contact date < mmyyyy for the death date, then the death date will be set to the first day of the death month.
- Otherwise, the partial death date will not be imputed.

For prior and concomitant medications:

The start/stop dates recorded in the CRF by the investigator and his or her research staff will be used to identify when a concomitant medication was taken during the study. Any missing start date must be queried for resolution. Unresolved missing start dates will be handled as follows:

- If the date is completely missing, the medication will be considered both prior and concomitant.
- If only the day is missing, and the last day of the month is before the first dose date on Day 1, then the concomitant medication will be considered as starting before Day 1, and the incomplete date will be imputed as the last day of the month.
- If only the day is missing, and the first day of the month is after the first dose date on Day 1, then the concomitant medication will be considered as starting after Day 1, and the incomplete date will be imputed as the first day of the month.
- If only the day is missing, and the month is equal to the month of the first dose date on Day 1, then the incomplete date will be imputed as the first day of the month.
- If both the month and day are missing, and the last day of the year is before the first dose date on Day 1, then the concomitant medication will be considered as starting before Day 1, and the incomplete date will be imputed as if it is the last day of the year. Otherwise, the incomplete date will be imputed as if it is the first day of the year.

4.1.5. Cycle Length and Duration

Cycle 1 Day 1 is the day that the first dose of study drug is administered. Scheduled cycle length is 14 days. Actual Day 1 of subsequent cycles will correspond with the first day of administration of INCAGN01949 in that cycle; thus, treatment cycles may become out of sync with the originally planned schedule and cycle length may be different from 14 days. The date of the Day 1 of subsequent cycles recorded on CRF will be used as the Day 1 of the subsequent cycles.

Note that there leaves flexibility to test different dosing schedules of INCAGN01949 based on evolving PK [redacted] data. The SAP does not specify all of the dosing schedule possibilities.

4.2. Variable Definitions

4.2.1. Derived Variables

The following variable is provided on the CRF but also derived for analysis purposes. The MSKCC (Motzer et al 2004) criteria will be summarized for both investigator reported and derived data for RCC subjects.

4.2.1.1. MSKCC Criteria for Renal Cell Carcinoma Subjects

The MSKCC (Motzer et al 2004) score will be derived as a prognostic tool for RCC subjects enrolled in Parts 1 and 2. The calculation for the MSKCC score is provided below as the sum of 5 component "no" vs "yes" (0 vs 1) scores. For each component, subjects will have a score of 1 for each criterion they meet. An MSKCC total score of 0 indicates a prognosis of Good. A MSKCC total score of 1 to 2 indicates an Intermediate prognosis, and a total score of ≥ 3 indicates a Poor prognosis. The derivation of MSKCC will use screening data; if screening data is not available, then Cycle 1 Day 1 data will be used.

1. Time from diagnosis to systematic treatment < 1 year
2. Low hemoglobin
   - Men (normal): 13.5 to 17.5 g/dL
   - Women (normal): 12.0 to 15.5 g/dL
3. Calcium > 10 mg/dL (> 2.5 mmol/L)
4. Lactate dehydrogenase > 420 U/L
5. Performance status: Karnofsky < 80% or ECOG > 1

Missing dates for time of first systemic treatment will be handled according to rules for missing partial disease/cancer diagnosis date that are given in Section 4.1.4.

4.2.1.2. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCAGN01949.

Concomitant medication is defined as any nonstudy medication that is started accordingly:

- Before the date of first administration of INCAGN01949 and is ongoing throughout the study or ends on/after the date of first study drug administration.
- On/after the date of first administration INCAGN01949 and is ongoing or ends during the course of study drug.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first dose of INCAGN01949. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant medication.

For the purposes of analysis, all medications will be considered concomitant medications unless the medications can unequivocally be defined as not concomitant.

4.2.2. Variables to Be Derived Only If Not Provided on Case Report Form

The following variables will only be calculated if not reported on the CRF.

- Subject age will be calculated as the integer part of the number of years from date of birth to the date of signing the informed consent form, using the following formula:

  Age = integer part of (date of informed consent – date of birth + 1) / 365.25

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; Version 9 or later) will be used for the generation of all tables, graphs, and statistical analyses. Descriptive summaries for continuous variables will include, but not be limited to, the number of observations, mean, standard deviation, median, minimum, and maximum. Descriptive summaries for categorical variables will include the number and percentage of subjects in each category.

Interim analyses are planned for this study as defined in Section 9.

5.2. Treatment Groups

This is a Phase 1/2, open-label, nonrandomized, multicenter, dose-escalation study. Up to 7 doses will be tested. Data will be summarized overall and by treatment group. Treatment group is defined as the dose regimen initially assigned. Treatment cycles will begin every 14 days (± 3 days) but are flexible for different dose schedules based on emerging safety, PK, [redacted] data.

- 2 mg
- 7 mg
- 20 mg
- 70 mg
- 200 mg
- 350 mg
- 700 mg

5.3. Analysis Populations

5.3.1. Full Analysis Set Population

The FAS population includes all subjects enrolled in the study who received at least 1 dose of INCAGN01949. The FAS population will be used for the summary of demographics, baseline characteristics, subject disposition, safety, study drug administration, and analyses of all efficacy data.

5.3.2. Part 1 Full Analysis Set Population

The Part 1 FAS population includes all subjects in the FAS population enrolled in Part 1 of the study who received at least 1 dose of INCAGN01949.

5.3.3. Part 2 Full Analysis Set Population

The Part 2 FAS population includes all subjects in the FAS population enrolled in Part 2 of the study who received at least 1 dose of the MTD/PAD of INCAGN01949. Subjects tested in Part 1 (dose escalation and safety expansion) who are treated at the MTD/PAD and in Part 2, are of the same tumor type, and who meet inclusion/exclusion criteria used for the tumor type of interest in Part 2 will be combined for both safety and efficacy summary purposes.

Specific analysis populations to be used for evaluating the Simon 2-stage efficacy rules include the following subgroups:

- Part 2 FAS population subjects with adenocarcinoma of endometrium
- Part 2 FAS population subjects with melanoma
- Part 2 FAS population subjects with ovarian cancer
- Part 2 FAS population subjects with NSCLC
- Part 2 FAS population subjects with RCC

Table summaries, unless otherwise indicated, will be provided by tumor-specific cohort.

5.3.4. Per Protocol Population

Subjects in the FAS population who are considered to be sufficiently compliant with the Protocol comprise the PP population.

The following procedures will be performed to identify those subjects who are to be excluded from the PP population before the database lock:

- Clinical review of Protocol deviations/violations
- Clinical review of concomitant medications (prohibited medications) as defined in Section 5.6.3 of the Protocol.
- Clinical review of the dose administration and drug accountability listing.

5.3.5. Pharmacokinetic [redacted] Evaluable Populations

5.3.5.1. Pharmacokinetic Evaluable Population

The PK evaluable population will include all subjects who received at least 1 dose of INCAGN01949 and provided at least 1 postdose sample (1 PK measurement). The study pharmacokineticist will review data listings of study drug administration and sample records to identify subjects to be excluded from analyses of PK data.

[redacted]

[redacted]

[redacted]

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix A provides a list of data displays and sample data displays.

6.1. Baseline and Demographics, Physical Characteristics, and Disease History

6.1.1. Demographics

The following demographics will be summarized for the Part 1 FAS population by dose level and for the Part 2 FAS population by tumor type: age, sex, race, ethnicity, and ECOG performance status.

6.1.2. Baseline Disease Characteristics and Disease History

For each type of tumor, primary tumor histology, date of initial diagnosis, stage at initial diagnosis, current stage of disease, current site of disease, and tumor markers will be summarized for all subjects in the Part 1 FAS population by dose level and Part 2 FAS population by tumor type.

6.1.3. Prior Therapy

Number of prior systemic cancer therapy regimens and prior immunotherapy will be summarized for all subjects in the FAS population by dose level in Part 1 and by tumor type in Part 2. Regimen name, component drugs, start and stop date, purpose of the regimen, best response, reason for discontinuation, and date of relapse/progression will be listed by total number and by number of prior systematic cancer therapies taken for both advanced and metastatic disease.

Number of subjects who received prior radiation will be summarized for the FAS population. Radiotherapy type, body site, start and stop date, total dose, and best response will be listed.

Number of subjects who had prior surgery or surgical procedure for the malignancies under study will be summarized for the FAS population. Date and description of the surgery/procedure will be listed.

Number of subjects with prior immunotherapy and prior anti–PD-1/PD-L1 therapy will be summarized for the Part 1 FAS population by dose level and the Part 2 FAS population by tumor type. Prior immunotherapy type, start and stop date, total dose, and best response will be listed.

6.1.4. Medical History

For subjects in the Part 1 FAS population by dose level and Part 2 FAS population by tumor type, medical history will be summarized by assigned treatment group. This summation will include the number and percentage of subjects with significant medical history for each body system/organ class as documented on the CRF.

6.2. Disposition of Subjects

The number and percentage of subjects who were enrolled, treated, completed the study, discontinued study treatment with a primary reason for discontinuation, and discontinued from the study with a primary reason for withdrawal will be summarized for the subjects in the Part 1 FAS population by dose level and Part 2 FAS population by tumor type. The number of subjects enrolled by site will also be provided by treatment group.

6.3. Protocol Deviations and Violations

Protocol deviations and violations recorded on the CRF will be presented in the subject data listings.

6.4. Exposure

For subjects in the FAS population, exposure to INCAGN01949 will be summarized descriptively as the following:

- **Total number of infusions:** Total number of infusions per subject by the time of date cutoff will be the total number of infusions per subject with a nonzero dose of INCAGN01949.
- **Dose administered per cycle:** The actual dose administered (in mg) per cycle.
- **Total dose administered in mg/kg:** The total actual dose administered (in mg/kg) across cycles for each subject will be determined according to the following calculation:

  For an infusion i, let C_i be the concentration (in mg/mL) of INCAGN01949 and V_i be the total volume administered (in mL) reported on the INCAGN01949 dosing CRF; let W be the subject's baseline weight (in kg), and N be the total number of infusions

  Total dose administered (in mg/kg) = $\sum_{i=1}^{N} \frac{C_i \times V_i}{W}$.

- **Average dose in mg/kg:** The average dose (in mg/kg) will be the total dose administered (in mg/kg) divided by the total number of infusions.
- **Total dose administered in mg:** Total actual dose administered (in mg) across cycles for each subject will be determined according to the following calculation:

  For an infusion i, let C_i, V_i, and N be defined as above

  Total dose administered (in mg) $=\sum_{i=1}^{N} C_i \times V_i$.
- **Average dose in mg:** The average dose (in mg) will be the total dose administered (in mg) divided by the total number of infusions.

6.5. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary and summarized by WHO drug class and WHO drug term by dose level in the Part 1 FAS population and by tumor type in the Part 2 FAS population. Results will be summarized as number and percentage of subjects with prior and concomitant medications by PT and WHO drug class.

7. EFFICACY

Sample data displays are provided in Appendix A.

7.1. General Considerations

Efficacy endpoints of this study are secondary and include ORR, DOR, duration of disease control, and PFS by investigator assessment based on RECIST v1.1 and mRECIST v1.1.

7.2. Efficacy Hypotheses

Each Simon 2-stage design will test the null hypothesis that the true ORR is less than or equal to the clinically insignificant response rate 5% against the alternative hypothesis that the true ORR is equal to the target ORR of 25%.

7.3. Analysis of the Primary Efficacy Parameter

Not applicable.

7.4. Analysis of the Secondary Efficacy Parameter

7.4.1. Response Criteria

Overall disease status will be categorized using RECIST v1.1 and mRECIST v1.1. Subjects will have their overall response evaluated as CR, PR, SD, PD, or NE at each postbaseline radiological assessment based on changes in target lesions, nontarget lesions, and appearance of new lesions.

7.4.2. Objective Response Rates and Best Overall Response

A subject is defined as an objective responder if the subject has an overall response of CR or PR at any postbaseline visit before first PD. Objective responders will be assessed based on both RECIST v1.1 and mRECIST v1.1.

Objective response rate is defined as the proportion of subjects with objective responses. Objective response rate will be estimated with 95% CIs overall by cohort-specific tumor type. Confidence intervals will be calculated based on the method for Simon 2-stage CIs of response rates outlined in Koyama and Chen (Koyama and Chen 2008). Subjects who do not have sufficient baseline or on-study response assessment information to be adequately assessed for response status will be included in the denominators in the calculation of ORR.

7.4.2.1. Objective Response Rate by RECIST v1.1

Under RECIST v1.1, the best overall response is determined on subject level using the highest overall response achieved postbaseline before and including the first PD, in the order of CR, PR, SD, PD, and NE. Responses of CR, PR, or SD after the first assessment of PD will not be considered. In the case of SD, measurements must meet the SD criteria at least after the date of first dose at a minimum of 49 (56-57) days. Subjects who fail to meet this criterion will have best overall response of PD if the next available assessment indicated PD or NE if there is no additional assessment available.

For subjects with measurable disease at baseline, the RECIST v1.1 assessment criteria presented in Table 3 can be used to determine the overall disease status at a given timepoint based on the target lesion, nontarget lesion, and new lesion assessment.

Table 3: RECIST Evaluation Criteria for Overall Response: Measurable Disease at Baseline

Target Lesions	Nontarget Lesions	New Lesions	Overall Response
CR	CR	No	CR
CR	Non-CR/non-PD	No	PR
CR	NE	No	PR
PR	Non-PD or NE	No	PR
SD	Non-PD or NE	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

7.4.2.2. Objective Response Rate by mRECIST v1.1

The mRECIST v1.1 instrument was adapted from RECIST v1.1 to include criteria that accounts for new lesions that can occur in immuno-oncology subjects before the occurrence of an SD, PR, or CR. Under mRECIST v1.1, if radiologic imaging shows PD, tumor assessment should be

repeated at a minimum of 4 weeks but not more than 6 weeks later to confirm the progression. If there is no second PD tumor assessment in the 4- to 6-week follow-up time, the PD will be defined as unconfirmed. Table 4 lists the scenarios that can occur after an unconfirmed PD in at least 4 weeks and no more than 6 weeks, and provides rules for determining whether or not the unconfirmed PD will be counted as an event in the corresponding scenario.

Table 4: Rules for Determining PD Event Status After an Unconfirmed PD

Event Occurring After Unconfirmed PD in the Confirmation Window (4-6 Weeks)	PD Event Status
Subject had EOS/EOT or started new anticancer therapy.	PD will be confirmed as a PD.
Subject had a confirmed PD.	PD will be confirmed as a PD.
Subject had an CR, PR, SD, or NE.	PD will not be considered as a PD and counted as corresponding CR, PR, SD, or NE for the second timepoint only.

7.4.3. Subgroup Analyses of Objective Response Rates

Subgroups will be formed based on the following subject characteristics and baseline variables for those subjects whose data are available.

- PD-L1 expression within tumor type: high versus negative/low
- Prior treatment with an anti–PD-1/PD-L1 therapy within tumor type: Yes/No
- Number of prior therapies for advanced and metastatic disease within tumor type
- Subjects with > 1 postbaseline scan within tumor type
- Tumor-type disease characteristics including the following:
  - Endometrium – MSI status (high, low, stable, unknown)
  - Ovarian – Histology and BRCA status
  - Melanoma – BRAF mutation status (mutated, wild-type, unknown), PD-L1 status (positive or negative)
  - NSCLC – Histology (squamous or nonsquamous), PD-L1 status (positive or negative)
  - RCC – MSKCC score (Poor, Intermediate, Good), PD-L1 status (positive or negative)

7.4.4. Duration of Response

Duration of response will be assessed with RECIST v1.1 and mRECIST v1.1 criteria.

Censoring of DOR will follow the same algorithm as the censoring of PFS. Kaplan-Meier curves for DOR will be presented by cohort-specific tumor types. The KM estimate of median DOR will be presented with its 95% CI. The 95% CI will be calculated using Brookmeyer and

Crowley's method (Brookmeyer and Crowley 1982). A swim plot for DOR will be generated under both RECIST v1.1 and mRECIST v1.1 criteria.

7.4.4.1. Duration of Response by RECIST v1.1

Under RECIST v1.1, for objective responders, DOR is defined as the time from the first overall response contributing to an objective response (CR or PR) to the earlier of the subject's death from any cause or first assessment of PD.

7.4.4.2. Duration of Response by mRECIST v1.1

Under mRECIST v1.1, for objective responders, DOR is the time from the first overall response contributing to an objective response (CR or PR) to the earlier of the subject's death from any cause or first confirmed assessment of PD. Note that the criteria for the assessment of PD in DOR are the same with ORR, which are presented in Section 7.4.2.2.

7.4.5. Duration of Disease Control

Duration of disease control (CR, PR, and SD) is defined as the time from the first report of SD or better until disease progression or death from any cause, if occurring sooner than progression, as determined by investigator assessment of radiographic disease per RECIST v1.1 and mRECIST v1.1. Note that the criteria for the assessment of PD in duration of disease control are the same with ORR, which are presented in Section 7.4.2.2.

The duration of disease control will be estimated with 95% CIs overall and by treatment group. Confidence intervals will be calculated based on the exact method for binomial distributions. Swim plots for duration of disease control will be generated separately for RECIST v1.1 and mRECIST v1.1 criteria.

Subjects who do not have sufficient baseline or on-study response assessment information to be adequately assessed for response status will be included in the denominators in the calculation of rate of disease control.

7.4.6. Largest Percentage Reduction in Sum of Diameters of Target Lesions

For each subject in the FAS population with target lesions at baseline, target lesion sizes will be measured by sum of diameters. The best percentage change from baseline, defined as the largest decrease in target lesion size for each subject, will be summarized descriptively, and a waterfall plot of the best percentage change will be generated.

Per RECIST criteria, target lesions considered "too small to measure" will be assigned a default value of 5 mm for purposes of this analysis. Likewise, target lesions identified as "not present" at postbaseline assessments will be assigned 0 mm for this analysis. In the event a target lesion is unaccounted for in a particular postbaseline timepoint (ie, assessment missing or NE), then the overall sum of diameters for target lesions will not be evaluable for that postbaseline timepoint.

7.4.7. Percentage Change in Sum of Diameters of Target Lesions Over Time

For each subject in the FAS population with target lesions at baseline, target lesion sizes will be measured by sum of diameters. The percentage change in sum of diameter of target lesions over time will be listed and a spider plot will be generated.

7.4.8. Progression-Free Survival

Progression-free survival is defined as the length of time between the baseline visit (Day 1) and the earlier of death or PD as assessed by RECIST v1.1 and mRECIST v1.1. Date of death will be determined using the Death Report CRF.

Censoring for PFS will follow the algorithm outlined in Table 5, which is based on the FDA Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (FDA 2007).

Kaplan-Meier curves for PFS will be presented by cohort-specific tumor types. The KM estimate of median PFS will be presented with its 95% CI. The 95% CI will be calculated using the Brookmeyer and Crowley's method (Brookmeyer and Crowley 1982).

Table 5: Evaluation and Censoring of Progression-Free Survival

Situation	Outcome	Date of Progression or Censoring
No baseline tumor assessments	Censored	Date of Day 1
No valid postbaseline response assessments	Censored	Date of Day 1
Progression documented between scheduled response assessments	Progressed	Date of first overall response of PD
No progression	Censored	Date of last valid radiologic assessment (not NE and not missing)
Study discontinuation for undocumented progression	Censored	Date of last valid radiologic assessment (not NE and not missing)
Study discontinuation for toxicity or other reason	Censored	Date of last valid radiologic assessment (not NE and not missing)
New anticancer treatment started	Censored	Date of last valid radiologic assessment (not NE and not missing) on/before starting a new anticancer treatment
Death before first progressive response assessment	Progressed	Date of death
Death between adequate response assessments	Progressed	Date of death
Death or progression after more than 1 missed assessments	Censored	Date of last valid radiologic assessment (not NE and not missing) before death

NE = not evaluable.

7.4.8.1. Progression-Free Survival by RECIST v1.1

Under RECIST v1.1, PFS is defined as the length of time between the baseline visit (Day 1) and the earlier of death or first assessment of PD as assessed by RECIST v1.1.

7.4.8.2. Progression-Free Survival by mRECIST v1.1

Under mRECIST v1.1, PFS is defined as the length of time between the baseline visit (Day 1) and the earlier of death or first overall confirmed assessment of PD (as described in Section 7.4.2.2).

7.4.8.2.1. Confirmation of Progression per mRECIST v1.1

Under mRECIST v1.1, the assessment of PD will be confirmed by a second consecutive assessment at least 4 weeks but no later than 6 weeks apart with the option for continuing treatment while awaiting radiologic confirmation of progression (Table 4).

- If after the first unconfirmed PD, there is an EOT/EOS or a new treatment is started, this unconfirmed PD will be counted as a confirmed PD, and DOR will be defined as the time from the first overall response (CR or PR) to this PD, or death from any cause if occurring sooner than the PD.
- If a second PD occurs after the first unconfirmed PD, the first unconfirmed PD will be counted as a confirmed PD, and DOR will be defined as the time from the first overall response (CR or PR) to the first PD, or death from any cause if occurring sooner than the confirmed PD.
- If a CR, PR, SD, or NE occurs after the first unconfirmed PD, the unconfirmed PD will not be counted as a PD. If there is no further PD assessment, DOR will be censored.

[redacted]

7.6. Pharmacokinetic Analyses

The PK calculations will be performed, if appropriate, using commercial software such as WinNonlin® (Pharsight Corporation, Mountain View, CA). Nominal times will be used in all cases, except when the difference between the actual time and nominal time is greater than 5 minutes for samples collected up to 4 hours after administration; in these cases, actual time will be used for PK analysis.

The PK parameters of C_{max}, t_{max}, C_{min}, and AUC_{0-t} (INCAGN01949) will be summarized by part, dose, and study cycle. The log-transformed PK parameters will be compared among dose levels by using a 1-factor analysis of variance. Dose-dependent parameters (C_{max} and AUC) will be normalized to the lowest common dose before statistical comparisons. Additionally, if sufficient data are available, the dose proportionality of INCAGN01949 C_{max} and AUC will be evaluated statistically by using a power model (eg, $AUC = \alpha \cdot (dose^{\beta})$ or equivalently $\log(AUC) = \log(\alpha) + \beta \cdot \log(dose)$, where linear dose proportionality is accepted if β is not significantly different from 1).

If there is a sufficient amount of plasma concentration data from this study, then the data will be analyzed by standard population PK methods using appropriate software (eg, NONMEM). The effect of covariates on PK parameters will be evaluated. The covariates will include, but not be

limited to, demographics (age, weight, sex, race), clinical laboratory test values, and concomitant medications.

The relationship between plasma concentrations of INCAGN01949 and the baseline-subtracted change in QTc interval will be explored graphically and analyzed using a linear mixed-effect model.

[redacted]

[redacted]

8. SAFETY AND TOLERABILITY

Sample data displays are provided in Appendix A.

8.1. General Considerations

Summary tables may be replaced with listings when appropriate. For instance, an AE frequency table may be replaced with a listing if it only contains a few unique PTs reported on relatively few subjects. Data from the Part 1 portion will be summarized separately where appropriate. Additional summaries for specific subgroups may be included on an ad hoc basis.

Unless otherwise stated, table summaries will be limited to AEs occurring within 60 days of the last administration of study drug.

8.2. Adverse Events

8.2.1. Adverse Event Definitions

A TEAE is any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug. Analysis of AEs (as discussed below) will be limited to TEAEs, but data listings will include all AEs regardless of their timing in relation to study drug administration.

Adverse events will be tabulated by MedDRA PT and SOC. Severity of AEs will be graded using the NCI CTCAE. The CTCAE version 4.03 is used for this study. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

The subset of AEs considered by the investigator to be related to study drug will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AE to study drug, the AE will be considered to be treatment-related. The incidence of AEs and treatment-related AEs will be tabulated. In addition, SAEs will also be tabulated.

A grading (severity) scale is provided for each AE term. If the toxicity is not included in the CTCAE v4.03 criteria, it will be rated on a scale of 1 to 4 as follows: 1 = mild, 2 = moderate, 3 = severe, and 4 = life threatening. All toxicities will be graded based on the worst level reached, not the level they may have reached if they had not been treated. When the intensity of an AE changes over time for a reporting period (eg, between visits), each change in intensity will be collected as an AE until the event resolves. Only the worst grade will be reported in AE summaries. Also, the Grade 3 or higher AEs will be reported in a listing.

Any missing onset date, causality, or severity must be queried for resolution. Unresolved missing causality and severity will be handled according to the following rules:

- An unresolved missing causality will be considered treatment-related.
- An unresolved missing severity will be identified as an unknown severity.

For purposes of analysis, all AEs will be considered TEAEs unless the AE can unequivocally be defined as not treatment-emergent.

8.2.2. Dose-Limiting Toxicities

The number of subjects with DLTs and the type of DLT will be listed by dose level. If a dose with multiple schedules is tested, the DLTs will be summarized by dose and by schedules.

8.2.3. Maximum Tolerated Dose

- In Part 1 of the study, the MTD will be defined as 1 dose level below that at which ≥ one-third of subjects in a particular cohort have DLTs.
- In Part 2 of the study, toxicities will continue to be monitored. If the cumulative incidence of DLTs occurs in ≥ 33% of subjects after 6 subjects have been observed for at least 28 days, further enrollment may be interrupted, and the investigators and sponsor will meet and reassess the MTD. All AEs, regardless of the time of occurrence on study, may be considered in DLT determination purposes.

8.2.4. Immune-Related Adverse Events

The number of subjects with irAEs and type of irAE will be listed by dose level (and by schedules) and by tumor type. Adverse event terms will be reviewed periodically without respect to treatment group by the medical monitor and clinical scientist to determine which AE terms correspond to irAEs. This periodic review may also occur after database lock. The medical monitor and clinical scientist will also review investigator reported AEs to determine if they qualify as irAEs. For example, a rash will be counted as an irAE even if the investigator did not report it as an irAE.

8.2.5. Adverse Event Summaries

An overall summary of AEs by treatment group and by tumor type as applicable will include the following:

- Number (%) of subjects reporting any TEAEs
- Number (%) of subjects reporting any DLTs
- Number (%) of subjects reporting any SAEs
- Number (%) of subjects reporting any Grade 3 or higher TEAEs
- Number (%) of subjects reporting any TEAEs related to INCAGN01949
- Number (%) of subjects who dose interrupted INCAGN01949 because of TEAEs
- Number (%) of subjects who permanently discontinued INCAGN01949 because of TEAEs
- Number (%) of subjects with INCAGN01949 dose reductions because of TEAEs
- Number (%) of subjects who had a fatal TEAE
- Number (%) of subjects who withdrew from study because of an TEAE

The following summaries will be produced by MedDRA term (if 10 or fewer subjects appear in a table, a listing may be appropriate):

- Summary of TEAEs by SOC and PT
- Summary of TEAEs by PT in decreasing order of frequency
- Summary of TEAEs by SOC, PT, and highest CTCAE grade/maximum severity
- Summary of Grade 3 or higher TEAEs by SOC and PT
- Summary of INCAGN01949 treatment-related AEs by SOC and PT
- Summary of Grade 3 or higher INCAGN01949 treatment-related AEs by SOC and PT
- Summary of all TEAEs, treatment-related AEs, Grade 3 or 4 TEAEs, and treatment-related Grade 3 or 4 TEAEs.
- Summary of INCAGN01949 treatment-related AEs by SOC, PT, and highest CTCAE grade/maximum severity

- Summary of TEAEs leading to death by SOC and PT
- Summary of treatment-emergent SAEs by SOC and PT
- Summary of treatment-emergent SAEs by PT in descending order of frequency
- Summary of INCAGN01949 treatment-related SAEs by SOC and PT
- Summary of TEAEs leading to INCAGN01949 dose reduction by SOC and PT
- Summary of TEAEs leading to INCAGN01949 dose interruption by SOC and PT
- Summary of TEAEs leading to discontinuation of INCAGN01949 by SOC and PT
- Summary of treatment-emergent non-SAE by SOC and PT.
- Summary of irAEs by SOC and PT.
- Summary of Grade 3 or higher irAEs by SOC and PT.
- Number (%) of subjects reporting an immune-related AE (irAE)
- Number (%) of subjects reporting any Grade 3 or 4 irAE
- Number (%) of subjects reporting an immune-related treatment-related AE (irAE)
- Number (%) of subjects reporting an immune-related treatment-related Grade 3 or 4 AE (irAE)

A KM analysis of time to first TEAE of Grade 3 or higher will be conducted. A KM analysis of time to first treatment-related irAE of Grade 3 or higher will be conducted.

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

Laboratory values and change from baseline values will be summarized descriptively by visit. Baseline will be determined according to Section 4.1.3. If there are multiple values that meet the criteria for baseline, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

Laboratory test values outside the normal range will be assessed for severity based on CTCAE grade or similar criteria where clinical intervention is required for CTCAE grading. The incidence of abnormal laboratory values and shift tables relative to baseline will be tabulated.

8.3.2. Laboratory Value Summaries

Laboratory values and change from baseline values will be summarized descriptively by visit. The baseline value will be determined using the nonmissing values collected before the first dose, prioritizing scheduled assessments for baseline identification over unscheduled visits. The last record before administration in the highest priority will be considered the baseline record. For baseline laboratory candidates with the same date and time in the same priority category, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

All test results and associated normal ranges from local laboratories will be reported in SI units. All tests with numeric values will have a unique unit per test. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units. For the limited number of cases where the associated normal ranges from a local laboratory cannot be obtained despite due diligence, if query is unsuccessful at resolving issue and analysis is mandatory then the clinical scientist and medical monitor can provide a suitable normal range to be used in determining CTC grading and flags for above and below normal.

When there are multiple laboratory nonmissing values for a subject's particular test at a scheduled visit, the laboratory value with the smallest laboratory sequence number will be used in by-visit summaries.

Numeric laboratory values will be summarized descriptively in SI units, and non-numeric test values will be tabulated when necessary. In addition, line graphs and box-and-whisker plots will be provided for hemoglobin, platelet counts, WBC, and neutrophils.

For test results that will be summarized with available normal ranges, the number and percentage of subjects with the laboratory values being low (but never high), normal, high (but never low), and both low and high will be calculated for each test. This shift summary will be produced for each test for the safety population. The denominator for the percentage calculation will use the number of subjects in the baseline category (ie, low, high, normal, missing) as the denominator for the percentage in each of the categories during the treatment period.

For all gradable laboratory parameters shift tables will be presented showing change in CTCAE grade from baseline to worst grade postbaseline for all treatment-emergent laboratory AEs. The number and percentage of subjects with the laboratory values of Grade 1, 2, 3, or 4 will be calculated for each treatment group according to the largest treatment-emergent worsening of laboratory grade. Separate summaries for abnormally high and abnormally low laboratory values will be provided when the laboratory parameter has both high and low grading criteria. The denominator for the percentage calculation will be the number of subjects in the baseline category.

In cases where differentials of hematology parameters are obtained without corresponding absolute count data, efforts will be made to investigate if the conversion to an absolute value will lead to additional abnormalities. This will be discussed with the clinical team regarding appropriate documentation and action.

8.4. Vital Signs

Values at each scheduled visit, change, and percentage change from baseline for vital signs, including systolic blood pressure, diastolic blood pressure, pulse, respiratory rate, body temperature, and weight will be summarized descriptively. Change and percentage change from baseline will be calculated using the last nonmissing value before first dose of study drug (Day 1) as the baseline value.

Criteria for clinically notable vital sign abnormalities are defined in Table 6. The abnormal values for subjects exhibiting clinically notable vital sign abnormalities will be listed along with their assigned treatment group. Alert vital signs are defined as an absolute value outside the defined range and percentage change > 25%. The abnormal values for subjects exhibiting alert vital sign abnormalities will be listed.

Table 6: Criteria for Clinically Notable Vital Sign Abnormalities

Parameter	High Threshold	Low Threshold
Systolic blood pressure	> 155 mmHg	< 85 mmHg
Diastolic blood pressure	> 100 mmHg	< 40 mmHg
Pulse	> 100 bpm	< 45 bpm
Temperature	> 38ºC	< 35.5ºC
Respiratory rate	> 24/min	< 8/min

8.5. Electrocardiograms

Timed triplicate ECGs (separated by 5 minutes) will be conducted at screening and in conjunction with the pre- and postinfusion PK timepoints on C1D1 and C6D1. The baseline ECG measurement will be the average of the 3 nonmissing triplicate ECGs performed preinfusion on C1D1.

Singleton 12-lead ECGs including heart rate, PR, QRS, QT, RR, QTcF, and JTc intervals (where applicable) will be obtained for each subject on Day 1 of every other cycle after Cycle 2 (eg, Cycle 4, Cycle 6, Cycle 8, Cycle 10, etc) during the study. Values at each scheduled visit, change, and percentage change from baseline will be summarized for each ECG parameter. Separate summaries will be provided for triplicate ECGs and singleton 12-lead ECGs.

Criteria for clinically notable ECG abnormalities are defined in Table 7. Subjects exhibiting clinically notable ECG abnormalities will be listed with study visit and assigned treatment group. Abnormal values for subjects with alert ECG values, defined as both the absolute value and the percentage change from baseline being outside normal ranges, will be identified and listed.

Table 7: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold
QTcF	> 460 msec	< 295 msec
PR	> 220 msec	< 75 msec
QRS	> 120 msec	< 50 msec
QT	> 500 msec	< 300 msec
RR	> 1330 msec	< 600 msec

QTcF = Fridericia correction.

Electrocardiogram abnormalities, both at baseline and postbaseline visits, will be tabulated by treatment group. Incidences of abnormalities will be listed separately for triplicate and singleton ECGs with study visit, assigned treatment group, and a description of the abnormality.

9. INTERIM ANALYSES

There will be no planned, formal interim analyses for the Part 1 dose escalation portion of the study. The review of accrued clinical data will be conducted by Incyte and provided to study investigators via teleconferences at the end of Part 1 of the study. Based on review of the most current safety data, the sponsor (in consultation with the study investigators and using the dose-escalation/de-escalation rules) will determine if and at what dose additional subjects should be treated in the study.

An interim analysis of efficacy will be conducted in Part 2 by applying the Simon 2-stage design. During Stage 1, 9 evaluable subjects treated at the recommended dose and schedule will be enrolled, and if no responses (CR or PR) are observed by the Week 16 assessment (at least 2 scans), then the cohort will be discontinued. The probability of early termination for Stage 1 is summarized in Table 8. If at least 1 response (CR or PR) is observed, then 8 additional subjects will be enrolled for Stage 2. Subject replacement may occur due to the biopsy requirement. In that case, the interim analysis will be conducted with the first 9 evaluable subjects for Stage 1.

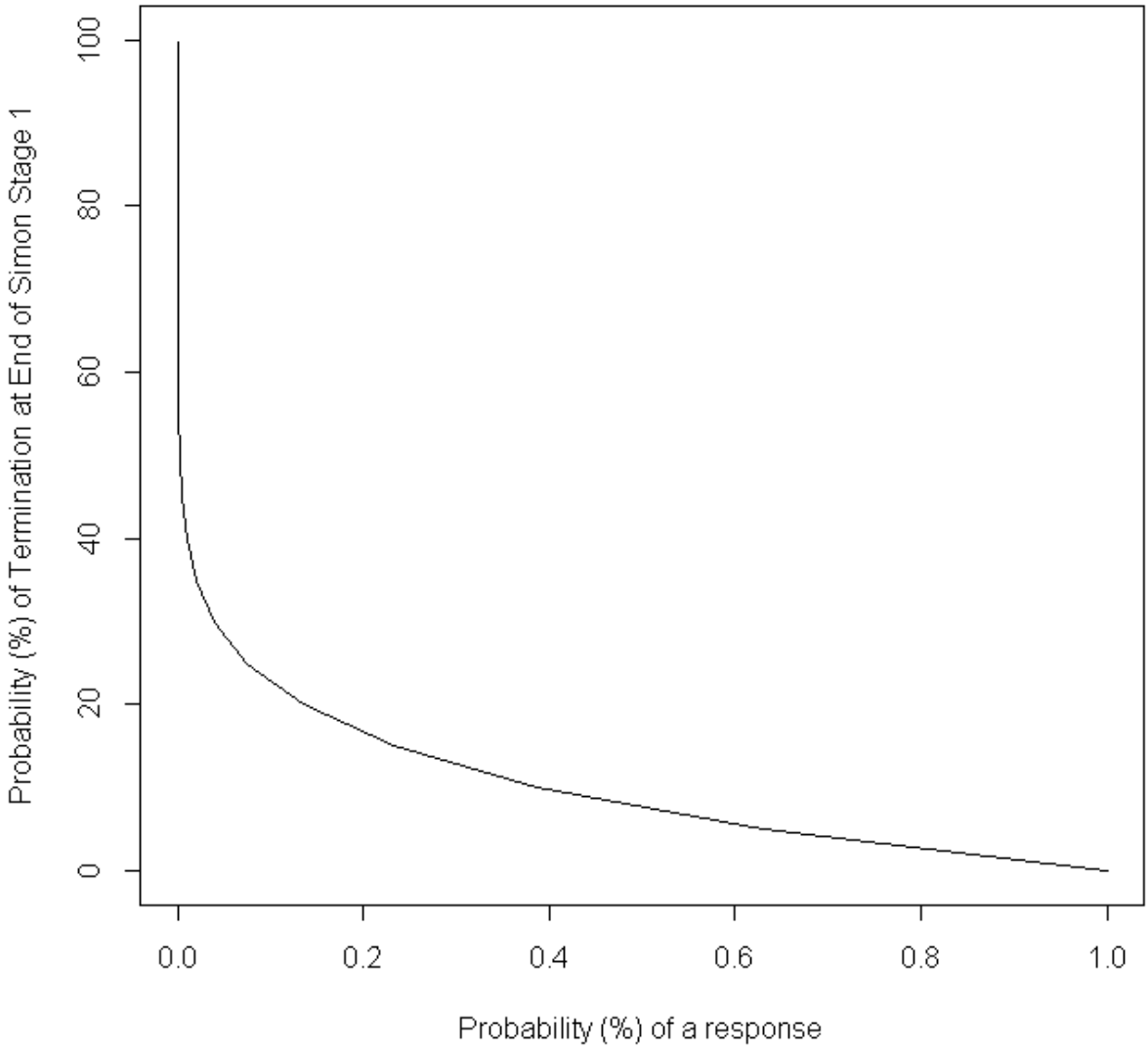
Per mRECIST v.1.1, the tumor response should be confirmed by a repeat radiographic assessment not less than 4 weeks from the date that the response was first documented. Disease progression will be confirmed by a second tumor assessment in at least 4 weeks and no later than 6 weeks after the first scan indicating PD in clinically stable subjects. The first tumor assessment is conducted at the eighth week. If a CR or PR occurs after an unconfirmed PD in at least 4 weeks but no more than 6 weeks, then the tumor assessment will be counted as a corresponding CR or PR (Table 4).

Table 8: Probability of Early Termination at Stage 1 for Simon 2-Stage Design

True Response Rate	Probability of Early Termination at Stage 1
15%	23.2%
20%	13.4%
25%	7.5%
30%	4.0%
35%	2.1%

Figure 3 provides the probabilities of early termination with regard to the efficacy analysis of the primary endpoint.

Figure 3: Probabilities of Early Termination for Futility at the End of Simon Stage 1 Based on Various Assumed Rates of Response to a Given Dose Level



10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 9.

Table 9: Statistical Analysis Plan Versions

SAP Version	Date
Original	05 JAN 2017

11. REFERENCES

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Mosteller RD. Simplified calculation of body surface area. N Engl J Med 1987;317:1098.

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APPENDIX A. PLANNED TABLES AND FIGURES

This appendix provides a list of the planned tables and figures for the CSR. Standard tables will follow the conventions in the Standard Safety Tables initial version. Shells are provided for nonstandard tables. In-text tables are identical in structure and content as appendix tables, but follow a Rich Text Format.

The list of tables, figures, and the shells are to be used as guideline. Modifications of the list or shells that do not otherwise affect the nature of the analysis will not warrant an amendment to the SAP.

Tables

Table No.	Title	Population	Standard	In-Text
Baseline and Demographic Characteristics				
1.1 Disposition				
1.1.1.1	Analysis Populations	Part 1 FAS Population	X	X
1.1.1.2	Analysis Populations	Part 2 FAS Population	X	X
1.1.2.1	Summary of Subject Disposition	Part 1 FAS Population	X	X
1.1.2.2	Summary of Subject Disposition	Part 2 FAS Population	X	X
1.1.3.1	Summary of Number of Subjects Enrolled By Site	Part 1 FAS Population	X	X
1.1.3.2	Summary of Number of Subjects Enrolled By Site	Part 2 FAS Population	X	X
1.2 Demography				
1.2.1	Summary of Demographics	Part 1 FAS Population	X	X
1.2.2	Summary of Demographics	Part 2 FAS Population	X	X
1.3 Baseline Characteristics				
1.3.1.1	Summary of Baseline Disease Characteristics and Disease History	Part 1 FAS Population	X	X
1.3.1.2.1	Summary of Baseline Disease Characteristics and Disease History	Endometrium Part 2 FAS Population	X	X
1.3.1.2.2	Summary of Baseline Disease Characteristics and Disease History	Melanoma Part 2 FAS Population	X	X
1.3.1.2.3	Summary of Baseline Disease Characteristics and Disease History	NSCLC Part 2 FAS Population	X	X
1.3.1.2.4	Summary of Baseline Disease Characteristics and Disease History	Ovarian Part 2 FAS Population	X	X

Table No.	Title	Population	Standard	In-Text
1.3.1.2.5	Summary of Baseline Disease Characteristics and Disease History	RCC Part 2 FAS Population	X	X
1.4 Prior Medication and Concomitant Medication				
1.4.1.1	Summary of Prior Cancer Therapy	Part 1 FAS Population	X	
1.4.1.2	Summary of Prior Cancer Therapy	Part 2 FAS Population	X	
1.4.2.1	Summary of Prior Medications	Part 1 FAS Population	X	
1.4.2.2	Summary of Prior Medications	Part 2 FAS Population	X	
1.4.3.1	Summary of Concomitant Medications	Part 1 FAS Population	X	
1.4.3.2	Summary of Concomitant Medications	Part 2 FAS Population	X	
1.5+ Others				
1.5.1	Summary of General Medical History	Part 1 FAS Population	X	
1.5.2	Summary of General Medical History	Part 2 FAS Population	X	
Efficacy				
2.1.1	Summary of Best Response, Duration of Response, and Duration of Disease Control under RECIST v1.1	Part 1 FAS Population		X
2.1.2	Summary of Best Response, Duration of Response, and Duration of Disease Control under RECIST v1.1	Part 2 FAS Population		X
2.2.1	Summary of Best Response, Duration of Response, and Duration of Disease Control under mRECIST v1.1	Part 1 FAS Population		X
2.2.2	Summary of Best Response, Duration of Response, and Duration of Disease Control under mRECIST v1.1	Part 2 FAS Population		X
2.3.1	Summary of Progression-Free Survival under RECIST v1.1	Part 1 FAS Population		X
2.3.2	Summary of Progression-Free Survival under RECIST v1.1	Part 2 FAS Population		X
2.4.1	Summary of Progression-Free Survival under mRECIST v1.1	Part 1 FAS Population		X
2.4.2	Summary of Progression-Free Survival under mRECIST v1.1	Part 2 FAS Population		X
2.5	Summary of PK Parameters	PK Evaluable Population		
[redacted]	[redacted]	[redacted]		
Safety				
3.1 Dose Exposure				
3.1.1.1	Summary of Study Drug Exposure	Part 1 FAS Population	X	X
3.1.1.2	Summary of Study Drug Exposure	Part 2 FAS Population	X	X

Table No.	Title	Population	Standard	In-Text
3.1.2.1	Summary of Study Drug Exposure by Visit	Part 1 FAS Population	X	X
3.1.2.2	Summary of Study Drug Exposure by Visit	Part 2 FAS Population	X	X
3.2 Adverse Events				
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events	Part 1 FAS Population	X	X
3.2.1.2	Overall Summary of Treatment-Emergent Adverse Events	Part 2 FAS Population	X	X
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	
3.2.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1 FAS Population	X	X
3.2.3.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 2 FAS Population	X	X
3.2.4.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1 FAS Population	X	X
3.2.4.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 2 FAS Population	X	X
3.2.5.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part 1 FAS Population	X	
3.2.5.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part 2 FAS Population	X	
3.2.6.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	X
3.2.6.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	X
3.2.7.1	Summary of INCAGN01949 Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	X
3.2.7.2	Summary of INCAGN01949 Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	X
3.2.8.1	Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	
3.2.8.2	Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	

Table No.	Title	Population	Standard	In-Text
3.2.9.1	Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1 FAS Population	X	X
3.2.9.2	Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 2 FAS Population	X	X
3.2.10.1	Summary of INCAGN01949 Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part 1 FAS Population	X	
3.2.10.2	Summary of INCAGN01949 Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part 2 FAS Population	X	
3.2.11.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	X
3.2.11.2	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	X
3.2.12.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	X
3.2.12.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	X
3.2.13.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1 FAS Population	X	X
3.2.13.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 2 FAS Population	X	X
3.2.14.1	Summary of Non-Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	
3.2.14.2	Summary of Non-Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	
3.2.15.1	Summary of INCAGN01949 Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	X
3.2.15.2	Summary of INCAGN01949 Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	X
3.2.16.1	Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Reduction by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	
3.2.16.2	Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Reduction by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	

Table No.	Title	Population	Standard	In-Text
3.2.17.1	Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Interruption by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	
3.2.17.2	Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Interruption by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	
3.2.18.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCAGN01949 by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population	X	X
3.2.18.2	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCAGN01949 by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population	X	X
3.2.19.1	Summary of Treatment-Emergent Immune-Related Adverse Events (Investigator Identified) by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population		
3.2.19.2	Summary of Treatment-Emergent Immune-Related Adverse Events (Investigator Identified) by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population		
3.2.20.1	Summary of Treatment-Emergent Immune-Related Adverse Events (Sponsor Identified) by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population		
3.2.20.2	Summary of Treatment-Emergent Immune-Related Adverse Events (Sponsor Identified) by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population		
3.2.21.1	Summary of Treatment-Emergent Immune-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part 1 FAS Population		
3.2.21.2	Summary of Treatment-Emergent Immune-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part 2 FAS Population		
3.2.22.1	Summary of Grade 3 or Higher Treatment-Emergent Immune-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1 FAS Population		
3.2.22.2	Summary of Grade 3 or Higher Treatment-Emergent Immune-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part 2 FAS Population		
3.2.23	Life Table Estimate of Time to First Grade 3 or Higher Treatment-Emergent Adverse Event	Part 2 FAS Population		
3.3 Laboratory				
3.3.1	Summary of Laboratory Values - Hematology	Part 2 FAS Population	X	
3.3.2.1	Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value	Part 1 FAS Population	X	X
3.3.2.2	Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value	Part 2 FAS Population	X	X
3.3.3	Summary of Laboratory Values - Chemistry	Part 2 FAS Population	X	
3.3.4.1	Shift Summary of Chemistry Laboratory Values in CTC Grade - To the Worst Abnormal Value	Part 1 FAS Population	X	X

Table No.	Title	Population	Standard	In-Text
3.3.4.2	Shift Summary of Chemistry Laboratory Values in CTC Grade - To the Worst Abnormal Value	Part 2 FAS Population	X	X
3.4 Vital Signs				
3.4.1.1	Summary of Systolic Blood Pressure (mmHg)	Part 1 FAS Population	X	
3.4.1.2	Summary of Systolic Blood Pressure (mmHg)	Part 2 FAS Population	X	
3.4.2.1	Summary of Diastolic Blood Pressure (mmHg)	Part 1 FAS Population	X	
3.4.2.2	Summary of Diastolic Blood Pressure (mmHg)	Part 2 FAS Population	X	
3.4.3.1	Summary of Heart Rate (bpm)	Part 1 FAS Population	X	
3.4.3.2	Summary of Heart Rate (bpm)	Part 2 FAS Population	X	
3.4.4.1	Summary of Respiration Rate (bpm)	Part 1 FAS Population	X	
3.4.4.2	Summary of Respiration Rate (bpm)	Part 2 FAS Population	X	
3.4.5.1	Summary of Body Temperature (ºC)	Part 1 FAS Population	X	
3.4.5.2	Summary of Body Temperature (ºC)	Part 2 FAS Population	X	
3.4.6.1	Summary of Body Weight (kg)	Part 1 FAS Population	X	
3.4.6.2	Summary of Body Weight (kg)	Part 2 FAS Population	X	
3.5 ECG				
3.5.1.1	Summary of PR Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.1.2	Summary of PR Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	
3.5.2.1	Summary of RR Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.2.2	Summary of RR Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	
3.5.3.1	Summary of QT Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.3.2	Summary of QT Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	
3.5.4.1	Summary of QRS Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.4.2	Summary of QRS Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	
3.5.5.1	Summary of QTcF Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.5.2	Summary of QTcF Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	

Table No.	Title	Population	Standard	In-Text
3.5.6.1	Summary of JTc Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.6.2	Summary of JTc Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	
3.5.7.1	Summary of HR Interval (msec) from Central Lab 12-Lead ECG	Part 1 FAS Population	X	
3.5.7.2	Summary of HR Interval (msec) from Central Lab 12-Lead ECG	Part 2 FAS Population	X	
3.5.8.1	Summary of Outliers of QT, RR, and QTcF Interval Values from Central 12-Lead ECG	Part 1 FAS Population	X	
3.5.8.2	Summary of Outliers of QT, RR, and QTcF Interval Values from Central 12-Lead ECG	Part 2 FAS Population	X	
[redacted]				

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Figure No.	Title
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4.1.2	Kaplan-Meier Estimates of Duration of Response
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[redacted]	[redacted]
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Table 1.1.1.1

Analysis Populations
(Population: Part 1 FAS Population)

Variable	Treatment Group			
	Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Number(%) of Subjects in the Part 1 FAS Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the PK Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the [redacted] Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the PP Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the [redacted] Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the [redacted] Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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Abbreviations: PK = Pharmacokinetics; [redacted]; PP = Per Protocol; [redacted]

Reference: Listing 2.##

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Table 1.1.1.2

Analysis Populations
(Population: Part 2 FAS Population)

Variable	Recommended Dose					
	Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Number(%) of Subjects in the Part 2 FAS Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the PK Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the [redacted] Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the PP Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the [redacted] Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number(%) of Subjects in the [redacted] Evaluable Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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TABLE 1.1.2.1

Summary of Subject Disposition
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Number(%) of Subjects in the Part 1 FAS Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Primary Reason for Discontinuation of Treatment:				
Adverse Event	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)
Lost to Follow-up	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Physician Decision	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pregnancy	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Protocol Violation	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Study Terminated by the Sponsor	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Withdrawal by Subject	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)
Primary Reason for Discontinuation of Study:				
Death	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)
Physician Decision	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Protocol Violation	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Study Terminated by Sponsor	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Withdrawal by Subject	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)

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TABLE 1.1.2.2

Summary of Subject Disposition
(Population: Part 2 FAS Population)

Variable	Recommended Dose					
	Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Number(%) of Subjects in the Part 2 FAS Population	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Primary Reason for Discontinuation of Treatment:						
Adverse Event	xx(xx.x)	xx(xx.x)	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)	xx(xx.x)	xx(xx.x)
Lost to Follow-up	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Physician Decision	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pregnancy	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Protocol Violation	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Study Terminated by the Sponsor	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Withdrawal by Subject	xx(xx.x)	xx(xx.x)	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)	xx(xx.x)	xx(xx.x)
Primary Reason for Discontinuation of Study:						
Death	xx(xx.x)	xx(xx.x)	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)	xx(xx.x)	xx(xx.x)
Physician Decision	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Protocol Violation	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Study Terminated by Sponsor	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Withdrawal by Subject	xx(xx.x)	xx(xx.x)	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)	xx(xx.x)	xx(xx.x)

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TLF VERSION: Draft

TABLE 1.1.3.1

Summary of Number of Subjects Enrolled by Site
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Site 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Site 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Site 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX. LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.##

PROTOCOL: INCAGN 1949-101
DRUG/INDICATION: OX40/Advanced or Metastatic Solid Tumors
TLF VERSION: Draft

TABLE 1.1.3.2

Summary of Number of Subjects Enrolled by Site
(Population: Part 2 FAS Population)

	Recommended Dose					
Variable	Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Site 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Site 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Site 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Reference: Listing 2.##

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TLF VERSION: Draft

TABLE 1.2.1
Summary of Demographics
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Age (yrs)				
n	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Mean	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
STD	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Min	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Median	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Max	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Sex – n (%)				
Male	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Female	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Race – n (%)				
White/Caucasian	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Black/African-American	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Asian	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
American-Indian/Alaska Native	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Native Hawaiian/Pacific Islander	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)
Ethnicity – n (%)				
Hispanic or Latino	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not Hispanic or Latino	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not Reported	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)
Other	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.##

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TABLE 1.2.2
Summary of Demographics
(Population: Part 2 FAS Population)

Variable	Recommended Dose: Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Age (yrs)						
n	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Mean	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
STD	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Min	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Median	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Max	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Sex – n (%)						
Male	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Female	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Race – n (%)						
White/Caucasian	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Black/African-American	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Asian	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
American-Indian/Alaska Native	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Native Hawaiian/Pacific Islander	xx(xx.x)	xx(xx.x)	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)	xx(xx.x)	xx(xx.x)
Ethnicity – n (%)						
Hispanic or Latino	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not Hispanic or Latino	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not Reported	xx(xx.x)	xx(xx.x)	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)	xx(xx.x)	xx(xx.x)
Other	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.##

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TABLE 1.3.1.1

Summary of Baseline Disease Characteristics and Disease History
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Solid Tumor Cancer Type				
Cancer 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Cancer 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Cancer 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Current Stage				
Advanced	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Metastatic	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Inoperable	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
PD-L1 Status Determined				
Positive	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Negative	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)
Number of Prior Regimens	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of Advanced/Metastatic Regimens	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of Subjects with Prior Immuno Therapy	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of Subjects with Prior PD1/L1 Therapy	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.2

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TABLE 1.3.1.2.1

Summary of Baseline Disease Characteristics and Disease History
(Population: Endometrium Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Adenocarcinoma Grade	
Grade 1	xx(xx.x)
Grade 2	xx(xx.x)
Grade 3	xx(xx.x)
Other	xx(xx.x)
Current Sites of Disease	
Site 1	xx(xx.x)
Site 2	xx(xx.x)
Site 3	xx(xx.x)
MSI Test Status Determined	
MSI-High	xx(xx.x)
MSI-Low	xx(xx.x)
MSS-Stable	xx(xx.x)
Unknown	xx(xx.x)
PD-L1 Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
Number of Prior Regimens	xx(xx.x)
Number of Advanced/Metastatic Regimens	xx(xx.x)
Number of Subjects with Prior Immuno Therapy	xx(xx.x)
Number of Subjects with Prior PD1/L1 Therapy	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: MSI = Microsatellite Instability
Reference: Listing 2.4.1

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TABLE 1.3.1.2.2

Summary of Baseline Disease Characteristics and Disease History
(Population: Melanoma Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Current Classification M:	
M0	xx(xx.x)
M1a	xx(xx.x)
M1b	xx(xx.x)
M1c	xx(xx.x)
Current Sites of Disease	
Site 1	xx(xx.x)
Site 2	xx(xx.x)
Site 3	xx(xx.x)
BRAF Status Determined	
Positive/Mutant	xx(xx.x)
Negative/Wild-type/No Mutations Detected	xx(xx.x)
Unknown	xx(xx.x)
PD-L1 Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
Number of Prior Regimens	xx(xx.x)
Number of Advanced/Metastatic Regimens	xx(xx.x)
Number of Subjects with Prior Immuno Therapy	xx(xx.x)
Number of Subjects with Prior PD1/L1 Therapy	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.1

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TABLE 1.3.1.2.3
Summary of Baseline Disease Characteristics and Disease History
(Population: NSCLC Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Stage at Initial Diagnosis	
Stage I	xx(xx.x)
Stage II	xx(xx.x)
Stage IIIA	xx(xx.x)
Stage IIIB	xx(xx.x)
Stage IV	xx(xx.x)
Unknown	xx(xx.x)
Histopathology	
Adenocarcinoma	xx(xx.x)
Large Cell Carcinoma	xx(xx.x)
Bronchoalveolar	xx(xx.x)
Squamous	xx(xx.x)
Adenosquamous(mixed)	xx(xx.x)
Other	xx(xx.x)
Smoking History	
Yes	xx(xx.x)
No	xx(xx.x)
Smoking Ongoing	
Yes	xx(xx.x)
No	xx(xx.x)
Current Stage	
Stage I	xx(xx.x)
Stage II	xx(xx.x)
Stage IIIA	xx(xx.x)
Stage IIIB	xx(xx.x)
Stage IV	xx(xx.x)
Unknown	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
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TABLE 1.3.1.2.3
Summary of Baseline Disease Characteristics and Disease History
(Population: NSCLC Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Current Sites of Disease	
Site 1	xx(xx.x)
Site 2	xx(xx.x)
Site 3	xx(xx.x)
EGFR Status Determined	
Positive/Mutant	xx(xx.x)
Negative/Wild-type/No Mutations Detected	xx(xx.x)
Unknown	xx(xx.x)
KRAS Mutation Determined	
Mutated	xx(xx.x)
Wild-type/No Mutations Detecte	xx(xx.x)
Unknown	xx(xx.x)
ALK Re-arrangement Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
PD-L1 Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
ROS1 Re-arrangement Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
Number of Prior Regimens	xx(xx.x)
Number of Advanced/Metastatic Regimens	xx(xx.x)
Number of Subjects with Prior Immuno Therapy	xx(xx.x)
Number of Subjects with Prior PD1/L1 Therapy	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.1

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TABLE 1.3.1.2.4

Summary of Baseline Disease Characteristics and Disease History
(Population: Ovarian Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Histology	
Serious	xx(xx.x)
Endometrioid	xx(xx.x)
Mucinous	xx(xx.x)
Clear Cell	xx(xx.x)
Brenner	xx(xx.x)
Mixed Epithelial	xx(xx.x)
Grade	
Grade I	xx(xx.x)
Grade II	xx(xx.x)
Grade III	xx(xx.x)
Unknown	xx(xx.x)
Current Sites of Disease	
Site 1	xx(xx.x)
Site 2	xx(xx.x)
Site 3	xx(xx.x)
BRCA Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
Not Done	xx(xx.x)
PD-L1 Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.1

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TABLE 1.3.1.2.4

Summary of Baseline Disease Characteristics and Disease History
(Population: Ovarian Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Number of Prior Regimens	xx(xx.x)
Number of Advanced/Metastatic Regimens	xx(xx.x)
Number of Subjects with Prior Immuno Therapy	xx(xx.x)
Number of Subjects with Prior PD1/L1 Therapy	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.1

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TABLE 1.3.1.2.5

Summary of Baseline Disease Characteristics and Disease History
(Population: RCC Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
Stage at Initial Diagnosis	
Stage 1	xx(xx.x)
Stage 2	xx(xx.x)
Stage 3	xx(xx.x)
Stage 4	xx(xx.x)
Unknown	xx(xx.x)
Histology	
Clear cell renal cell carcinoma	xx(xx.x)
Other	xx(xx.x)
Current Stage of Disease	
Stage 1	xx(xx.x)
Stage 2	xx(xx.x)
Stage 3	xx(xx.x)
Stage 4	xx(xx.x)
Unknown	xx(xx.x)
Current Sites of Disease	
Site 1	xx(xx.x)
Site 2	xx(xx.x)
Site 3	xx(xx.x)
MSKCC Criteria	
Favorable	xx(xx.x)
Intermediate	xx(xx.x)
Poor	xx(xx.x)
Unknown	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: MSKCC = Memorial Sloan-Kettering Cancer Center
Reference: Listing 2.4.1

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TABLE 1.3.1.2.5

Summary of Baseline Disease Characteristics and Disease History
(Population: RCC Part 2 FAS Population)

Variable	Recommended Dose (N=xx)
PD-L1 Status Determined	
Positive	xx(xx.x)
Negative	xx(xx.x)
Unknown	xx(xx.x)
Number of Prior Regimens	xx(xx.x)
Number of Advanced/Metastatic Regimens	xx(xx.x)
Number of Subjects with Prior Immuno Therapy	xx(xx.x)
Number of Subjects with Prior PD1/L1 Therapy	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: MSKCC = Memorial Sloan-Kettering Cancer Center
Reference: Listing 2.4.1

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TABLE 1.4.1.1

Summary of Prior Cancer Therapy
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Number(%) of Subjects with any Prior Cancer Therapy				
Medication Class				
Generic Name 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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Reference: Listing 2.##

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TABLE 1.4.1.2

Summary of Prior Cancer Therapy
(Population: Part 2 FAS Population)

Variable	Recommended Dose: Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Number(%) of Subjects with any Prior Cancer Therapy						
Medication Class						
Generic Name 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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TABLE 1.4.2.1

Summary of Prior Medications
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Number(%) of Subjects with any Prior Medications				
Medication Class				
Generic Name 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.9

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TABLE 1.4.2.2

Summary of Prior Medications
(Population: Part 2 FAS Population)

	Recommended Dose					
Variable	Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Number(%) of Subjects with any Prior Medication						
Medication Class						
Generic Name 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.9

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TABLE 1.4.3.1

Summary of Concomitant Medications
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Number(%) of Subjects with any Concomitant Medications				
Medication Class				
Generic Name 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.9

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TABLE 1.4.3.2

Summary of Concomitant Medications
(Population: Part 2 FAS Population)

	Recommended Dose					
Variable	Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Number(%) of Subjects with any Concomitant Medication						
Medication Class						
Generic Name 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Generic Name 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.4.9

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TABLE 1.5.1

Summary of General Medical History
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Total (N=xx)
Number(%) of Subjects with any General Medical History				
System Organ Class 1				
Preferred Term 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Preferred Term 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Preferred Term 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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Reference: Listing 2.4.8

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TABLE 1.5.2

Summary of General Medical History
(Population: Part 2 FAS Population)

Variable	Recommended Dose: Endometrium (N=xx)	Ovarian (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Total (N=xx)
Number(%) of Subjects with any General Medical History						
System Organ Class 1						
Preferred Term 1	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Preferred Term 2	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Preferred Term 3	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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Reference: Listing 2.4.8

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TABLE 2.1.1

Summary of Best Response, Duration of Response, and Duration of Disease Control under RECIST v1.1
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose Level 1 (N=##)	Dose Level 2 (N=##)	Dose Level 3 (N=##)
Overall Response[1]	### (###.#)	### (###.#)	### (###.#)
Complete Response	### (###.#)	### (###.#)	### (###.#)
Partial Response	### (###.#)	### (###.#)	### (###.#)
Stable Disease	### (###.#)	### (###.#)	### (###.#)
Progressive Disease	### (###.#)	### (###.#)	### (###.#)
Unable to Evaluate	### (###.#)	### (###.#)	### (###.#)
RECIST v1.1 Criteria			
Number of Responders (%)[2]	###.# (###.#)	###.#(###.#)	###.#(###.#)
Median Duration of Response (Days) [3]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)
Median Duration of Disease Control (Range) [4]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.5.1
[1] Under RECIST v1.1, the best response is determined on subject level using the highest overall response achieved postbaseline prior to and including the first PD, in the order of CR, PR, SD, PD, and NE.
[2] Under RECIST v1.1, for objective responders, duration of response is the time from the first overall response contributing to an objective response (CR or PR) to the earlier of the subject's death from any cause or first assessment of PD.
[3] Median time and the 95% CI were estimated using Brookmeyer and Crowley.
[4] Under RECIST v1.1, duration of disease control is defined as the time from the first report of SD or better until disease progression determined under RECIST v1.1 or death from any cause if occurring sooner than progression. Confidence intervals are calculated based on the exact method for binomial distributions.

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TABLE 2.1.2

Summary of Best Response, Duration of Response, and Duration of Disease Control under RECIST v1.1
(Population: Part 2 FAS Population)

	Recommended Dose				
Variable	Endometrium (N=##)	Melanoma (N=##)	NSCLC (N=##)	RCC (N=##)	Ovaian (N=##)
Overall Response[1]	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Complete Response	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Partial Response	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Stable Disease	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Progressive Disease	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Unable to Evaluate	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
RECIST v1.1 Criteria					
Number of Responders (%)[2]	###.# (###.#)	###.#(###.#)	###.#(###.#)	###.#(###.#)	
Median Duration of Response (Days) [3]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	
Median Duration of Disease Control (Range) [4]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Reference: Listing 2.5.1
[1] Under RECIST v1.1, the best response is determined on subject level using the highest overall response achieved postbaseline prior to and including the first PD, in the order of CR, PR, SD, PD, and NE.
[2] Under RECIST v1.1, for objective responders, duration of response is the time from the first overall response contributing to an objective response (CR or PR) to the earlier of the subject's death from any cause or first assessment of PD.
[3] Median time and the 95% CI were estimated using Brookmeyer and Crowley.
[4] Under RECIST v1.1, duration of disease control is defined as the time from the first report of SD or better until disease progression determined under RECIST v1.1 or death from any cause if occurring sooner than progression. Confidence intervals are calculated based on the exact method for binomial distributions.

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TABLE 2.2.1

Summary of Best Response, Duration of Response, and Duration of Disease Control under mRECIST v1.1
(Population: Part 1 FAS Population)

	Treatment Group		
Variable	Dose Level 1 (N=##)	Dose Level 2 (N=##)	Dose Level 3 (N=##)
Overall Response[1]	### (###.#)	### (###.#)	### (###.#)
Complete Response	### (###.#)	### (###.#)	### (###.#)
Partial Response	### (###.#)	### (###.#)	### (###.#)
Stable Disease	### (###.#)	### (###.#)	### (###.#)
Progressive Disease	### (###.#)	### (###.#)	### (###.#)
Unable to Evaluate	### (###.#)	### (###.#)	### (###.#)
RECIST v1.1 Criteria			
Number of Responders (%)[2]	###.# (###.#)	###.# (###.#)	###.# (###.#)
Median Duration of Response (Days) [3]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)
Median Duration of Disease Control (Range)[4]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)

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Reference: Listing 2.5.1
Note: mRECIST v1.1 requires confirmation of progressive disease 4 to 6 weeks after the initial progression whenever possible.
[1] Under mRECIST v1.1, for objective responders, duration of response is the time from the first overall response contributing to an objective response (CR or PR) to the earlier of the subject's death from any cause or first assessment of PD as assessed by mRECIST v1.1. If after an unconfirmed PD, a subject had EOS/EOT or started a new anti-cancer therapy, the unconfirmed PD will be counted as a PD. If after an unconfirmed PD a subject had an SD, PR, CR, or NE, the PD will not be counted as a PD and will be counted as the corresponding CR, PR, SD, or NE for the time point at which the SD, PR, CR, or NE occurred.
[2] Under mRECIST v1.1, the best response is determined on subject level using the highest overall response achieved postbaseline prior to and including the first confirmed PD, in the order of CR, PR, SD, PD, and NE.
[3] Median time and the 95% CI were estimated using Brookmeyer and Crowley.
[4] Under mRECIST v1.1, duration of disease control is defined as the time from the first report of SD or better until disease progression determined under mRECIST v1.1 or death from any cause if occurring sooner than progression. Confidence intervals are calculated based on the exact method for binomial distributions.

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TABLE 2.2.2

Summary of Best Response, Duration of Response, and Duration of Disease Control under mRECIST v1.1
(Population: Part 2 FAS Population)

	Recommended Dose				
Variable	Endometrium (N=##)	Melanoma (N=##)	NSCLC (N=##)	RCC (N=##)	Ovarian (N=##)
Overall Response[1]	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Complete Response	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Partial Response	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Stable Disease	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Progressive Disease	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
Unable to Evaluate	### (###.#)	### (###.#)	### (###.#)	### (###.#)	
RECIST v1.1 Criteria					
Number of Responders (%)[2]	###.# (###.#)	###.# (###.#)	###.# (###.#)	###.# (###.#)	
Median Duration of Response (Days) [3]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	
Median Duration of Disease Control (Range)[4]	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	###.# (###.#, ###.#)	

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Reference: Listing 2.5.1
Note: mRECIST v1.1 requires confirmation of progressive disease 4 to 6 weeks after the initial progression whenever possible.
[1] Under mRECIST v1.1, for objective responders, duration of response is the time from the first overall response contributing to an objective response (CR or PR) to the earlier of the subject's death from any cause or first assessment of PD as assessed by mRECIST v1.1. If after an unconfirmed PD, a subject had EOS/EOT or started a new anti-cancer therapy, the unconfirmed PD will be counted as a PD. If after an unconfirmed PD a subject had an SD, PR, CR, or NE, the PD will not be counted as a PD and will be counted as the corresponding CR, PR, SD, or NE for the time point at which the SD, PR, CR, or NE occurred.
[2] Under mRECIST v1.1, the best response is determined on subject level using the highest overall response achieved postbaseline prior to and including the first confirmed PD, in the order of CR, PR, SD, PD, and NE.
[3] Median time and the 95% CI were estimated using Brookmeyer and Crowley.
[4] Under mRECIST v1.1, duration of disease control is defined as the time from the first report of SD or better until disease progression determined under mRECIST v1.1 or death from any cause if occurring sooner than progression. Confidence intervals are calculated based on the exact method for binomial distributions.

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TABLE 2.3.1

Summary of Progression-Free Survival under RECIST v1.1 [1]
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose Level 1 (N=##)	Dose Level 2 (N=##)	Dose Level 3 (N=##)
Number (%) of Subjects with Disease Progression or Death			
Observed	### (###.#)	### (###.#)	### (###.#)
Deaths	### (###.#)	### (###.#)	### (###.#)
Disease Progression	### (###.#)	### (###.#)	### (###.#)
Censored	### (###.#)	### (###.#)	### (###.#)
Median Time to Event (95% CI) [2]	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 3 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 6 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 9 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 12 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)

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Reference: Listing 2.#
[1] Under RECIST v1.1, progression free survival was defined as the length of time between the baseline visit (Day 1) and the earlier of death or first assessment of disease progression as assessed by RECIST v1.1.
[2] The median time and the 95% CI were estimated using Brookmeyer and Crowley.
Abbreviation: CI = Confidencce Interval

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TABLE 2.3.2

Summary of Progression-Free Survival under RECIST v1.1 [1]
(Population: Part 2 FAS Population)

	Recommended Dose				
Variable	Endometrium (N=##)	Melanoma (N=##)	NSCLC (N=##)	RCC (N=##)	Ovarian (N=##)
Number (%) of Subjects with Disease Progression or Death					
Observed	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Deaths	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Disease Progression	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Censored	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Median Time to Event (95% CI) [2]	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 3 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 6 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 9 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 12 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)

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Reference: Listing 2.#
[1] Under RECIST v1.1, progression free survival was defined as the length of time between the baseline visit (Day 1) and the earlier of death or first assessment of disease progression as assessed by RECIST v1.1.
[2] The median time and the 95% CI were estimated using Brookmeyer and Crowley.
Abbreviation: CI = Confidencce Interval

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TABLE 2.4.1

Summary of Progression-Free Survival under mRECIST v1.1 [1]
(Population: Part 1 FAS Population)

Variable	Treatment Group: Dose Level 1 (N=##)	Dose Level 2 (N=##)	Dose Level 3 (N=##)
Number (%) of Subjects with Disease Progression or Death			
Observed	### (###.#)	### (###.#)	### (###.#)
Deaths	### (###.#)	### (###.#)	### (###.#)
Disease Progression	### (###.#)	### (###.#)	### (###.#)
Censored	### (###.#)	### (###.#)	### (###.#)
Median Time to Event (95% CI) [2]	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 3 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 6 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 9 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 12 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)

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Reference: Listing 2.#
[1] Under mRECIST v1.1, progression free survival was defined as the length of time between the baseline visit (Day 1) and the earlier of subject's death or first overall confirmed response of PD.
[2] The median time and the 95% CI were estimated using Brookmeyer and Crowley.
Abbreviation: CI = Confidencce Interval

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TABLE 2.4.2

Summary of Progression-Free Survival under mRECIST v1.1 [1]
(Population: Part 2 FAS Population)

Variable	Recommended Dose				
	Endometrium (N=##)	Melanoma (N=##)	NSCLC (N=##)	RCC (N=##)	Ovarian (N=##)
Number (%) of Subjects with Disease Progression or Death					
Observed	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Deaths	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Disease Progression	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Censored	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Median Time to Event (95% CI) [2]	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 3 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 6 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 9 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)
Month 12 Survival Rate (95% CI)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)	##.# (##.#,##.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: CI = Confidencce Interval
Reference: Listing 2.#
[1] Under mRECIST v1.1, progression free survival was defined as the length of time between the baseline visit (Day 1) and the earlier of subject's death or first overall confirmed response of PD.
[2] The median time and the 95% CI were estimated using Brookmeyer and Crowley.

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Table 3.1.1.1

Summary of Study Drug Exposure
(Population: Part 1 FAS Population)

Dose Level and Frequency (mg/kg)	Variable	Descriptive Summary					
		N	Mean	STD	Min	Median	Max
Dose 1	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
Dose 2	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
Dose 3	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

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[a] Duration of treatment (days) = Date of last dose – Date of first dose + 1.
[b] Average dose (mg/kg) = [total actual dose taken (mg/kg) by the subject]/[number of cycles with a nonzero dose]
[c] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]

Abbreviations: Min = minimum; Max = maximum; STD = standard deviation;
Reference: Listings 2.6.1

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Table 3.1.1.2
Summary of Study Drug Exposure
(Population: Part 2 FAS Population)

Cancer Type (mg/kg)	Variable	Descriptive Summary					
		N	Mean	STD	Min	Median	Max
Endometrial	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
Melanoma	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
NSCLC	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
Ovarian	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
RCC	Number of Treatment Cycles	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Duration of Treatment (Days)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Average Dose (mg/kg)	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[a] Duration of treatment (days) = Date of last dose – Date of first dose + 1.
[b] Average dose (mg/kg) = [total actual dose taken (mg/kg) by the subject]/[number of cycles with a nonzero dose]
[c] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviations: Min = minimum; Max = maximum; STD = standard deviation;
Reference: Listings 2.6.1

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Table 3.1.2.1

Summary of Study Drug Exposure by Visit
(Population: Part 1 FAS Population)

		Descriptive Summary				
Dose Level(mg)	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
Dose 1	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.1

Summary of Study Drug Exposure by Visit
(Population: Part 1 FAS Population)

		Descriptive Summary				
Dose Level(mg)	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
Dose 2	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.1

Summary of Study Drug Exposure by Visit
(Population: Part 1 FAS Population)

		Descriptive Summary				
Dose Level(mg)	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
Dose 3	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.2

Summary of Study Drug Exposure by Visit
(Population: Part 2 FAS Population)

Descriptive Summary

Tumor Type	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
Endometrium	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.2

Summary of Study Drug Exposure by Visit
(Population: Part 2 FAS Population)

		Descriptive Summary				
Tumor Type	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
Melanome	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.2

Summary of Study Drug Exposure by Visit
(Population: Part 2 FAS Population)

Descriptive Summary

Tumor Type	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
NSCLC	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.2

Summary of Study Drug Exposure by Visit
(Population: Part 2 FAS Population)

		Descriptive Summary				
Tumor Type	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
Ovarian	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.1.2.2

Summary of Study Drug Exposure by Visit
(Population: Part 2 FAS Population)

		Descriptive Summary				
Tumor Type	Visit	Average Dose(mg)[a]	STD	Min	Median	Max
RCC	Cycle 1	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 2	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 3	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 4	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 5	xxx.xx	xxx.xx	xxx	xxx.x	xxx
	Cycle 6	xxx.xx	xxx.xx	xxx	xxx.x	xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
[a] Average dose (mg) = [total actual dose taken by each subject (mg) in a cycle]/[number of subjects with a nonzero dose in that cycle]
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listing 2.6.1

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Table 3.2.1.1

Overall Summary of Treatment-Emergent Adverse Events
(Population: Part 1 FAS Population)

	Dose Level (mg/kg)				
	Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Dose 4 (N=xx)	Total (N=xx)
Subjects who had a TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had a treatment-related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had a SAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had an AE of grade 3 or higher	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had a fatal AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had AE leading to - discontinuation of study medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had a DLT	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had an irAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Subjects who had a Grade 3 or higher irAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Immune-Related Adverse Event: any AE consistent with an immune phenomenon associated with drug exposure after all other etiologies have been eliminated.
Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.
Treatment-Related AEs: treatment-emergent AEs judged as related by the investigator or with a missing causality.

Reference: Listings 2.6.#

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Table 3.2.1.2

Overall Summary of Treatment-Emergent Adverse Events
(Population: Part 2 FAS Population)

	Cancer Type					
Variable	Endometrium (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Ovarian (N=xx)	Total (N=xx)
Subjects who had a TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had a treatment-related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had a SAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had an AE of grade 3 or higher	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had a fatal AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had AE leading to - discontinuation of study medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had a DLT	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had an irAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Subjects who had a Grade 3 or higher irAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Immune-Related Adverse Event: any AE consistent with an immune phenomenon associated with drug exposure after all other etiologies have been eliminated.
Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.
Treatment-Related AEs: treatment-emergent AEs judged as related by the investigator or with a missing causality.

Reference: Listings 2.6 xx

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Table 3.2.2.1

Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Dose Level (mg/kg)				
	Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Dose 4 (N=xx)	Total (N=xx)
Number (%) of subjects with any treatment-emergent adverse events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 3	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)
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 3	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)
System Organ Class 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred term 1	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)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.
Note #: xxxxxxxxx
Reference: Listings 2.6 xx

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Table 3.2.2.2

Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Cancer Type					
	Endometrium (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Ovarian (N=xx)	Total (N=xx)
Number (%) of subjects with any treatment-emergent adverse events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 3	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)	
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 3	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)	
System Organ Class 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Preferred term 1	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)	

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.
Note #: xxxxxxxxx
Reference: Listings 2.6 xx

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Table 3.2.3.1

Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 1 FAS Population)

	Dose Level (mg/kg)				
MedDRA Preferred Term	Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)	Dose 4 (N=xx)	Total (N=xx)
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs:any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted only once under each MedDRA preferred term.
Note 2: Footnote explaining how the descending frequency is driven (table specific).
Note x: Other customized footnotes (study dependent).
Reference: Listings 2.6 xx

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Table 3.2.3.2

Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 2 FAS Population)

	Cancer Type					
MedDRA Preferred Term	Endometrium (N=xx)	Melanoma (N=xx)	NSCLC (N=xx)	RCC (N=xx)	Ovarian (N=xx)	Total (N=xx)
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Xxxxxxxxxxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs:any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted only once under each MedDRA preferred term.
Note 2: Footnote explaining how the descending frequency is driven (table specific).
Note x: Other customized footnotes (study dependent).
Reference: Listings 2.6 xx

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Table 3.2.4.1

Summary of Grade 3 or Higher Treatment- Emergent Adverse Events
by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.4.2

Summary of Grade 3 or Higher Treatment- Emergent Adverse Events
by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.5.1

Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity
(Population: Part 1 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Dose 1 (N=xxx)					Dose 2 (N=xxx)					Dose 3 (N=xxx)				
	G1	G2	G3	G4	Any	G1	G2	G3	G4	Any	G1	G2	G3	G4	Any
Number (%) of subjects with any adverse event	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
System Organ Class 1	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 1	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 2	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 3	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
...	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
System Organ Class 2	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 1	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 2	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 3	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
...	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under the highest grade; AEs with unknown severity were included only in the 'Any' column.

Severity vs CTCAE Grade: Mild=G1, Moderate=G2, Severe=G3, Life-Threatening=G4.
Reference: Listings 2.6 xx

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Table 3.2.5.2

Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Endometrium (N=xxx)					Melanoma (N=xxx)					NSCLC (N=xxx)				
	G1	G2	G3	G4	Any	G1	G2	G3	G4	Any	G1	G2	G3	G4	Any
Number (%) of subjects with any adverse event	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
System Organ Class 1	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 1	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 2	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 3	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
...	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
System Organ Class 2	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 1	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 2	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
Preferred term 3	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)
...	xx	xx	xx	xx	xxx (xx.x)	xx	xx	xx	xx	xxx(xx.x)	xx	xx	xx	xx	xxx (xx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under the highest grade; AEs with unknown severity were included only in the 'Any' column.

Severity vs CTCAE Grade: Mild=G1, Moderate=G2, Severe=G3, Life-Threatening=G4.
Reference: Listings 2.6 xx

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Table 3.2.6.1

Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.
Note #: xxxxxxxxx
Reference: Listings 2.6 xx */

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Table 3.2.6.2

Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.
Note #: xxxxxxxxx
Reference: Listings 2.6 xx */

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Table 3.2.7.1

Summary of INCAGN01949 Treatment-Related Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.7.2

Summary of INCAGN01949 Treatment-Related Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.8.1

Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.8.2

Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.9.1

Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events
by MedDRA Preferred Term in Order of Decreasing Order of Frequency
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.9.2

Summary of Grade 3 or Higher INCAGN01949 Treatment-Related Adverse Events
by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under the highest grade; AEs with unknown severity were included only in the 'Any' column.
Note x: Other customized footnotes (study dependent).
Severity vs CTCAE Grade: Mild=G1, Moderate=G2, Severe=G3, Life-Threatening=G4.
Reference: Listings 2.6 xx

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Table 3.2.10.1

Summary of INCAGN01949 Treatment-Related Adverse Events
by MedDRA System Organ Class, Preferred Term, and Maximum Severity
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under the highest grade; AEs with unknown severity were included only in the 'Any' column.
Note x: Other customized footnotes (study dependent).
Severity vs CTCAE Grade: Mild=G1, Moderate=G2, Severe=G3, Life-Threatening=G4.
Reference: Listings 2.6 xx

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Table 3.2.10.2

Summary of INCAGN01949 Treatment-Related Adverse Events
by MedDRA System Organ Class, Preferred Term, and Maximum Severity
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under the highest grade; AEs with unknown severity were included only in the 'Any' column.
Note x: Other customized footnotes (study dependent).
Severity vs CTCAE Grade: Mild=G1, Moderate=G2, Severe=G3, Life-Threatening=G4.
Reference: Listings 2.6 xx

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Table 3.2.11.1

Summary of Treatment-Emergent Adverse Events with a Fatal Outcome
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.11.2

Summary of Treatment-Emergent Adverse Events with a Fatal Outcome
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.12.1

Summary of Serious Treatment-Emergent Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.12.2

Summary of Serious Treatment-Emergent Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.13.1

Summary of Serious Treatment-Emergent Adverse Events
by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs:any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted only once under each MedDRA preferred term.
Note 2: Footnote explaining how the descending frequency is driven (table specific).
Note x: Other customized footnotes (study dependent).
Reference: Listings 2.6 xx

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Table 3.2.13.2

Summary of Serious Treatment-Emergent Adverse Events
by MedDRA Preferred Term in Decreasing Order of Frequency
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted only once under each MedDRA preferred term.
Note 2: Footnote explaining how the descending frequency is driven (table specific).
Note x: Other customized footnotes (study dependent).
Reference: Listings 2.6 xx

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Table 3.2.14.1

Summary of Non-Serious Treatment-Emergent Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.14.2

Summary of Non-Serious Treatment-Emergent Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.15.1

Summary of INCAGN01949 Treatment-Related Serious Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.15.2

Summary of INCAGN01949 Treatment-Related Serious Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.16.1

Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Reduction
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.16.2

Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Reduction
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.17.1

Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Interruption
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.17.2

Summary of Treatment-Emergent Adverse Events Leading to INCAGN01949 Dose Interruption
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.18.1

Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCAGN01949
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.18.2

Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCAGN01949
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.19.1

Summary of Treatment-Emergent Immune-Related Adverse Events (Investigator Identified)
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.19.2

Summary of Treatment-Emergent Immune-Related Adverse Events (Investigator Indentified)
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.20.1

Summary of Treatment-Emergent Immune-Related Adverse Events (Sponsor Identified)
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.20.2

Summary of Treatment-Emergent Immune-Related Adverse Events (Sponsor Identified)
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.21.1

Summary of Treatment-Emergent Immune-Related Adverse Events
by MedDRA System Organ Class, Preferred Term, and Maximum Severity
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.21.2

Summary of Treatment-Emergent Immune-Related Adverse Events
by MedDRA System Organ Class, Preferred Term, and Maximum Severity
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.22.1

Summary of Grade 3 or Higher Treatment-Emergent Immune-Related Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 1 FAS Population)

This table follows same shell as that for 3.2.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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Table 3.2.22.2

Summary of Grade 3 or Higher Treatment-Emergent Immune-Related Adverse Events
by MedDRA System Organ Class and Preferred Term
(Population: Part 2 FAS Population)

This table follows same shell as that for 3.2.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Treatment-Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication.

Note 1: Subjects were counted once under each MedDRA system organ class and preferred term.

Reference: Listings 2.6 xx

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TABLE 3.2.23
Life Table Estimate of Time to First Grade 3 or Higher Treatment-Emergent Adverse Event
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Adenocarcinoma of the Endometrium			
	0-3 W	>=3-6 W	>=6-9 W	>=9-18 W
Number (%) of Subjects with any Adverse Events	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)

Note: Percentage of subjects for each event was based on the effective sample size of the time interval (number of subjects at risk at the beginning of the interval minus half of the censored subjects during the time interval)

Reference: Listing 2.##

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TABLE 3.2.23
Life Table Estimate of Time to First Grade 3 or Higher Treatment-Emergent Adverse Event
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Melanoma			
	0-3 W	>=3-6 W	>=6-9 W	>=9-18 W
Number (%) of Subjects with any Adverse Events	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)

Note: Percentage of subjects for each event was based on the effective sample size of the time interval (number of subjects at risk at the beginning of the interval minus half of the censored subjects during the time interval)

Reference: Listing 2.##

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TABLE 3.2.23
Life Table Estimate of Time to First Grade 3 or Higher Treatment-Emergent Adverse Event
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	NSCLC			
	0-3 W	>=3-6 W	>=6-9 W	>=9-18 W
Number (%) of Subjects with any Adverse Events	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)

Note: Percentage of subjects for each event was based on the effective sample size of the time interval (number of subjects at risk at the beginning of the interval minus half of the censored subjects during the time interval)

Reference: Listing 2.##

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TABLE 3.2.23
Life Table Estimate of Time to First Grade 3 or Higher Treatment-Emergent Adverse Event
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	Ovarian			
	0-3 W	>=3-6 W	>=6-9 W	>=9-18 W
Number (%) of Subjects with any Adverse Events	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)

Note: Percentage of subjects for each event was based on the effective sample size of the time interval (number of subjects at risk at the beginning of the interval minus half of the censored subjects during the time interval)

Reference: Listing 2.##

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TABLE 3.2.23
Life Table Estimate of Time to First Grade 3 or Higher Treatment-Emergent Adverse Event
(Population: Part 2 FAS Population)

MedDRA System Organ Class/ MedDRA Preferred Term	RCC			
	0-3 W	>=3-6 W	>=6-9 W	>=9-18 W
Number (%) of Subjects with any Adverse Events	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
System Organ Class 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 1	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 2	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)
Preferred Term 3	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)	###/###.# (###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)

Note: Percentage of subjects for each event was based on the effective sample size of the time interval (number of subjects at risk at the beginning of the interval minus half of the censored subjects during the time interval)

Reference: Listing 2.##

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Table 3.3.1

Summary of Laboratory Values - Hematology
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxxx (xxxx)

			Descriptive Summary						N (%) of Subjects		
Cancer Type	Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High
Endometrium	Baseline	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
	xxxxx	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
	EOS	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
Melanoma	Baseline	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
	xxxxx	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
	EOS	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum

Reference: Listings 2.7.xx

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Table 3.3.1

Summary of Laboratory Values - Hematology
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxxx (xxxx)

			Descriptive Summary						N (%) of Subjects		
Cancer Type	Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High
NSCLC	Baseline	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
	xxxxx	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
	EOS	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
RCC	Baseline	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
	xxxxx	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
	EOS	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum

Reference: Listings 2.7.xx

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Table 3.3.1

Summary of Laboratory Values - Hematology
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxxx (xxxx)

			Descriptive Summary						N (%) of Subjects		
Cancer Type	Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High
Ovarian	Baseline	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
	xxxxx	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			
	EOS	Measured	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx	xxx (xxx.x)	xxx (xxx.x)	xxx (xxx.x)
		Change	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx			
		% Change	xx	xx.xx	xxx.xxx	xxx.x	xx.xx	xxx.x			

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum

Reference: Listings 2.7.xx

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Table 3.3.2.1

Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 1 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

	Baseline[1]		Worst Post-Baseline Value [2]					
Dose Level (mg/kg)	Grade	n (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Dose 1	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
Dose 2	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.2.1

Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 1 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

	Baseline[1]		Worst Post-Baseline Value [2]					
Dose Level (mg/kg)	Grade	n (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Dose 3	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
Dose 4	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.2.1

Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 1 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

	Baseline[1]		Worst Post-Baseline Value [2]					
Dose Level (mg/kg)	Grade	n (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Total	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.2.2

Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

	Baseline[1]		Worst Post-Baseline Value [2]					
Cancer Type	Grade	n (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Endometrium	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
Melanoma	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.2.2

Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

	Baseline[1]		Worst Post-Baseline Value [2]					
Cancer Type	Grade	n (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
NSCLC	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
RCC	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.2.2

Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

	Baseline[1]		Worst Post-Baseline Value [2]					
Cancer Type	Grade	n (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Ovarian	Grade 0	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 1	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 2	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 3	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Grade 4	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Missing	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%
	Total	xxx xx.x%	xxx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%	xx xx.x%

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.3

Summary of Laboratory Values - Chemistry
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

This table follows same shell as that for 3.3.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note: xxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.4.1

Shift Summary of Chemisty Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 1 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

This table follows same shell as that for 3.3.2.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.3.4.2

Shift Summary of Chemisty Laboratory Values in CTC Grade - To the Worst Abnormal Value
(Population: Part 2 FAS Population)

Laboratory Test (unit): xxxxxxxx (xxxxx)

This table follows same shell as that for 3.3.2.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

[1] The percentages for the baseline column were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of subjects with a given grade at baseline as the denominator.
Worst post-baseline laboratory value was the worst grade observed post-baseline for a given subject.

Note x: xxxxxxxx
Reference: Listings 2.7.xx

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Table 3.4.1.1

Summary of Systolic Blood Pressure (mmHg)
(Population: Part 1 FAS Population)

Dose Level (mg/kg) :Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for SBP is 85 - 155 mm/Hg. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.1

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Table 3.4.1.2

Summary of Systolic Blood Pressure (mmHg)
(Population: Part 2 FAS Population)

Cancer Type :Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for SBP is 85 - 155 mm/Hg. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.1

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Table 3.4.2.1

Summary of Diastolic Blood Pressure (mmHg)
(Population: Part 1 FAS Population)

Dose Level (mg/kg) :Dose 1

This table follows same shell as that for 3.4.1.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for DBP is 40 - 100 mmHg. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.2.2

Summary of Diastolic Blood Pressure (mmHg)
(Population: Part 2 FAS Population)

Cancer Type :Endometrium

This table follows same shell as that for 3.4.1.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for DBP is 40 - 100 mmHg. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.3.1

Summary of Heart Rate (bpm)
(Population: Part 1 FAS Population)

Dose Level (mg/kg) :Dose 1

This table follows same shell as that for 3.4.1.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for Pulse is 45 - 100 bpm. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.3.2

Summary of Heart Rate (bpm)
(Population: Part 2 FAS Population)

Cancer Type :Endometrium

This table follows same shell as that for 3.4.1.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for Pulse is 45 - 100 bpm. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.4.1

Summary of Respiration Rate (bpm)
(Population: Part 1 FAS Population)

Dose Level (mg/kg) :Dose 1

This table follows same shell as that for 3.4.1.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: normal range for Respiratory Rate is 8 - 24 breaths/min. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.4.2

Summary of Respiration Rate (bpm)
(Population: Part 2 FAS Population)

Cancer Type :Endometrium

This table follows same shell as that for 3.4.1.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: normal range for Respiratory Rate is 8 - 24 breaths/min. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.5.1

Summary of Body Temperature (°C)
(Population: Part 1 FAS Population)

Dose Level (mg/kg) :Dose 1

This table follows same shell as that for 3.4.1.1

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for Body Temperature is 35.5 - 38 C. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.5.2

Summary of Body Temperature (°C)
(Population: Part 2 FAS Population)

Cancer Type :Endometrium

This table follows same shell as that for 3.4.1.2

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the last value collected before the first dose of study drug.
Note 2: The normal range for Body Temperature is 35.5 - 38 C. Alert values are defined as the measured value being outside the normal range and the percent change from baseline being > 25%.

Reference: Listings 2.8.XX

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Table 3.4.6.1
Summary of Body Weight (kg)
(Population: Part 1 FAS Population)

Dose Level (mg/kg)	Visit	Descriptive Summary				
		N	Mean	STD	Min	Median	Max
Dose 1	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
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Reference: Listings 2.10.1 */

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Table 3.4.6.1
Summary of Body Weight (kg)
(Population: Part 1 FAS Population)

Dose Level (mg/kg)	Visit	Descriptive Summary				
		N	Mean	STD	Min	Median	Max
Dose 2	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
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Table 3.4.6.1
Summary of Body Weight (kg)
(Population: Part 1 FAS Population)

Dose Level (mg/kg)	Visit	Descriptive Summary				
		N	Mean	STD	Min	Median	Max
Dose 3	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.10.1 */

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Table 3.4.6.2
Summary of Body Weight (kg)
(Population: Part 2 FAS Population)

Cancer Type	Visit	Descriptive Summary				
		N	Mean	STD	Min	Median	Max
Endometrium	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.10.1 */

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Table 3.4.6.2
Summary of Body Weight (kg)
(Population: Part 2 FAS Population)

Cancer Type	Visit	Descriptive Summary				
		N	Mean	STD	Min	Median	Max
Melanoma	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
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Table 3.4.6.2
Summary of Body Weight (kg)
(Population: Part 2 FAS Population)

Cancer Type	Visit	Descriptive Summary					
		N	Mean	STD	Min	Median	Max
NSCLC	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
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Table 3.4.6.2
Summary of Body Weight (kg)
(Population: Part 2 FAS Population)

Cancer Type	Visit	Descriptive Summary					
		N	Mean	STD	Min	Median	Max
Ovarian	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
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Table 3.4.6.2
Summary of Body Weight (kg)
(Population: Part 2 FAS Population)

Cancer Type	Visit	Descriptive Summary				
		N	Mean	STD	Min	Median	Max
RCC	Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 2	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 3	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 4	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 5	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Cycle 6	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	EOS	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx
	% Change from Baseline	xxx	x.xxxx	x.xxxxx	x.xxx	x.xxxx	x.xxx

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.10.1 */

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Table 3.5.1.1

Summary of PR Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline definition is from SAP.
Note 2: The normal range for PR is 75 - 220 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.1.2

Summary of PR Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline definition is from SAP.
Note 2: The normal range for PR is 75 - 220 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.2.1

Summary of RR Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for RR is 600 - 1330 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.2.2

Summary of RR Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for RR is 600 - 1330 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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TLF VERSION: Draft

Table 3.5.3.1

Summary of QT Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for QT is 300 - 500 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.3.2

Summary of QT Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for QT is 300 - 500 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.4.1

Summary of QRS Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg): Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for QRS is 50 - 120 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.4.2

Summary of QRS Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for QRS is 50 - 120 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.5.1

Summary of QTcF Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for QTcF is 295 - 460 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.5.2

Summary of QTcF Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for QTcF is 295 - 460 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.6.1

Summary of JTc Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.6.2

Summary of JTc Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.7.1

Summary of HR Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for HR is 40 - 100 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.7.2

Summary of HR Interval (msec) from Central Lab 12-Lead ECG
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

		Descriptive Summary						Low		Normal		High		Alert	
Study Visit	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
Week xx	Measured	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x
	% Change	xxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x	xxx	xx.x

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.
Note 2: The normal range for HR is 40 - 100 mm/Hg.
Alert values are defined as the measured value being outside the normal range and the percent change from Baseline being > 25%.
Abbreviation: STD = Standard Deviation; Min = Minimum; Max = Maximum.
Reference: Listings 2.9.4

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Table 3.5.8.1

Summary of Outliers of QT, RR and QTcF Interval Values from Central Lab 12-Lead ECG by Visit
(Population: Part 1 FAS Population)

Dose Level (mg/kg) : Dose 1

Dose Level (mg/kg)	Study Visit	Variable	Number (%) of Subjects QT (ms)	QTcB (ms)	QTcF (ms)
Dose 1	Baseline	Number of Subjects	xxx	xxx	xxx
		Measured Value>=450 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=480 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=500 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
	Week xx	Number of Subjects	xxx	xxx	xxx
		Measured Value>=450 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=480 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=500 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=30 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=60 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
	At any time during the study	Number of Subjects	xxx	xxx	xxx
		Measured Value>=450 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=480 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=500 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=30 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=60 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.

Reference: Listings 2.9.4

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Table 3.5.8.2

Summary of Outliers of QT, RR and QTcF Interval Values from Central Lab 12-Lead ECG by Visit
(Population: Part 2 FAS Population)

Cancer Type : Endometrium

			Number (%) of Subjects		
Cancer Type	Study Visit	Variable	QT (ms)	QTcB (ms)	QTcF (ms)
Endometrium	Baseline	Number of Subjects	xxx	xxx	xxx
		Measured Value>=450 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=480 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=500 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
	Week xx	Number of Subjects	xxx	xxx	xxx
		Measured Value>=450 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=480 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=500 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=30 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=60 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
	At any time during the study	Number of Subjects	xxx	xxx	xxx
		Measured Value>=450 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=480 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Measured Value>=500 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=30 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)
		Change From Baseline>=60 ms	xx(xxx.x)	xx(xxx.x)	xx(xxx.x)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST DATE(TIME): MMDDYYYY(hh:mm)

Note 1: Baseline is the average of all measurements collected before the first dose of study drug.

Reference: Listings 2.9.4

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TABLE 3.6.1

[redacted]
(Population: [redacted] Evaluable Population)

Test (Unit): PD Marker (Unit)

		Descriptive Summary						N (%) of Subjects [1]		
Visit		N	Mean	STD	Min	Median	Max	Below LLOQ	Within LOQ	Above ULOQ
Baseline	Measured	###	##.##	##.##	##.#	##.##	##.#	### (###.#)	### (###.#)	### (###.#)
Cycle 2	Measured	###	##.##	##.##	##.#	##.##	##.#	### (###.#)	### (###.#)	### (###.#)
	Change	###	##.##	##.##	##.#	##.##	##.#			
	% Change	###	##.##	##.##	##.#	##.##	##.#			
Cycle 3	Measured	###	##.##	##.##	##.#	##.##	##.#	### (###.#)	### (###.#)	### (###.#)
	Change	###	##.##	##.##	##.#	##.##	##.#			
	% Change	###	##.##	##.##	##.#	##.##	##.#			
Cycle 4	Measured	###	##.##	##.##	##.#	##.##	##.#	### (###.#)	### (###.#)	### (###.#)
	Change	###	##.##	##.##	##.#	##.##	##.#			
	% Change	###	##.##	##.##	##.#	##.##	##.#			
Cycle 5	Measured	###	##.##	##.##	##.#	##.##	##.#	### (###.#)	### (###.#)	### (###.#)
	Change	###	##.##	##.##	##.#	##.##	##.#			
	% Change	###	##.##	##.##	##.#	##.##	##.#			
Cycle 6	Measured	###	##.##	##.##	##.#	##.##	##.#	### (###.#)	### (###.#)	### (###.#)
	Change	###	##.##	##.##	##.#	##.##	##.#			
	% Change	###	##.##	##.##	##.#	##.##	##.#			

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)
Note:For descriptive summaries, subject study visits with analysis values outside of the limits of quantification used ½ of the LLOQ if below the LLOQ or the ULOQ if above the LLOQ for calculations.
[1] LLOQ = Lower Limit of Quantification. LOQ = Limit of Quantification. ULOQ = Upper Limit of Quantification.

Abbreviations: Min = Minimum; Max = Maximum; STD = standard deviation.

Reference: Listing x.x.x

PROTOCOL: INCAGN 1949-101 (Page n of N)
DRUG/INDICATION: OX40/Advanced or Metastatic Solid Tumors DATABASE VERSION: XXXXX2016
TLF VERSION: Draft

TABLE 3.6.2

[redacted]

(Population: [redacted] Evaluable Population)

Test (Unit): [redacted] (Unit)

Test (Unit)	Visit	Percent Change From Baseline	Dose 1 (N=xx)	Dose 2 (N=xx)	Dose 3 (N=xx)
[redacted] (Unit)	Cycle 2	Subjects with Both Results	### (###.#)	### (###.#)	### (###.#)
		Subjects with >50% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >25% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >10% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >0% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >0% increase	### (###.#)	### (###.#)	### (###.#)
		Subjects with >10% increase	### (###.#)	### (###.#)	### (###.#)
		Subjects with >25% increase	### (###.#)	### (###.#)	### (###.#)
		Subjects with >50% increase	### (###.#)	### (###.#)	### (###.#)
	Cycle 3	Subjects with Both Results	### (###.#)	### (###.#)	### (###.#)
		Subjects with >50% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >25% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >10% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >0% reduction	### (###.#)	### (###.#)	### (###.#)
		Subjects with >0% increase	### (###.#)	### (###.#)	### (###.#)
		Subjects with >10% increase	### (###.#)	### (###.#)	### (###.#)
		Subjects with >25% increase	### (###.#)	### (###.#)	### (###.#)
		Subjects with >50% increase	### (###.#)	### (###.#)	### (###.#)

FOLDER\PROGRAM\OUTPUT: XXXXXX\XXXXXX.SAS\XXXXXX.LST
DATE(TIME): MMDDYYYY(hh:mm)
Reference: Listing 2.##

Signature Manifest

Document Number: IC-STS-SAP-0080 **Revision:** 0
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INCAGN 1949-101 SAP Review

Approval

Name/Signature	Title	Date	Meaning/Reason
[redacted]	[redacted]	05 Jan 2017, 04:11:26 PM	Approved
[redacted]	[redacted]	06 Jan 2017, 09:04:50 AM	Approved
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