STATISTICAL ANALYSIS PLAN

Study Title:	A Phase 2 Open-Label Study of Sacituzumab Govitecan (IMMU-132) in Participants with Metastatic Solid Tumors
Name of Test Drug:	Sacituzumab Govitecan
Study Number:	IMMU-132-11
Protocol Version:	Amendment 5
Protocol Date:	17 December, 2024
Analysis Plan Version:	1.0
Analysis Plan Date:	14 April, 2025
Analysis Plan Author(s):	PPD

CONFIDENTIAL AND PROPRIETARY INFORMATION

TABLE OF CONTENTS

LIST OF IN-TEXT TABLES

LIST OF ABBREVIATIONS

AE	Adverse event
BICR	Blinded independent central review
CBR	Clinical benefit rate
CI	Confidence interval
CTFI	Chemotherapy-free interval
CRF	Case report form
CSR	Clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
DOR	Duration of response
DCR	Disease control rate
ECG	Electrocardiogram
EOI	End of infusion
EOT	End of treatment
HLT	high-level term
HNSCC	Head and neck squamous cell carcinoma
HPV	Human papillomavirus
LLT	Lower-level term
MedDRA	Medical Dictionary for Regulatory Activities
MSI-H	Microsatellite instability-high
NSCLC	Non-small cell lung cancer
ORR	Overall response rate
OS	Overall survival
PFS	Progression free survival
POC	Proof of concept
PT	Preferred term
Q1, Q3	First quartile, third quartile
SAP	Statistical analysis plan
SCC	Squamous cell carcinoma
SCLC	Small cell lung cancer
StD	Standard deviation
SOC	System Organ Class
TEAE	Treatment-emergent adverse event
TFLs	Tables, figures, and listings
TROP-2	Trophoblastic cell-surface antigen-2
WHO	World Health Organization

1. INTRODUCTION

This statistical analysis plan (SAP) describes the statistical analysis methods and defines key elements including variable definitions for analysis of data from Study IMMU-132-11 in support of the primary analysis preceding the final analysis. This SAP is based on the study protocol Amendment 5 dated 17 December 2024. Any changes made after the finalization of the SAP will be documented in the CSR.

The purpose of this primary analysis is to summarize the efficacy and safety data for all the participants from non-small cell lung cancer (NSCLC) including adenocarcinoma and squamous cell carcinoma (SCC) cohorts, endometrial carcinoma, head and neck squamous cell carcinoma (HNSCC), and small cell lung cancer (SCLC) cohorts. These cohorts are at the proof of concept (POC) stage of the study. Additional follow-up data from participants in these POC cohorts that are beyond the primary analysis data cutoff date will be summarized in the final analysis that will be prepared once all participants have completed the study.

The biomarker analysis will be described in a separate analysis plan.

Analysis methods specified in this document take precedence over those described in the protocol should there be any difference.

1.1. Study Objectives and Endpoints

The objectives of this study are to evaluate the efficacy and the safety of sacituzumab govitecan in participants with metastatic solid tumors.

Primary Objective	**Primary Endpoint**
Efficacy	
• Assess the ORR of sacituzumab govitecan in participants with metastatic solid tumors by Investigator's assessment according to the Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) criteria.	• Objective response rate (ORR) according to RECIST v1.1 by Investigator's assessment.
Secondary Objectives	**Secondary Endpoints**
Efficacy/Safety/PK/ADA delineate objectives and endpoints	
• Assess the ORR, duration of response (DOR), clinical benefit rate (CBR), and progression-free survival (PFS) of sacituzumab govitecan in participants with metastatic solid tumors by blinded independent central review (BICR) according to RECIST v1.1 criteria. • Assess the DOR, CBR, and PFS of sacituzumab govitecan in participants with metastatic solid tumors by Investigator's assessment according to RECIST v1.1 criteria.	• ORR, DOR, CBR, and PFS according to RECIST v1.1 by BICR. • DOR, CBR, and PFS, according to RECIS v1.1 by Investigator's assessment. • Overall survival (OS). • Incidence of treatment-emergent adverse events (AEs) and clinical laboratory abnormalities. • Serum concentrations of sacituzumab govitecan over time and incidence of anti-drug antibody (ADA) to sacituzumab govitecan.

• Assess the overall survival (OS) of sacituzumab govitecan in participants with metastatic solid tumors. • Assess the safety of sacituzumab govitecan in participants with metastatic solid tumors. • Assess the PK and immunogenicity of sacituzumab govitecan in participants with metastatic solid tumors.	
Exploratory Objectives	**Exploratory Endpoints**
[redacted]	

1.2. Study Design

This is a multi-cohort, open-label, Phase 2 study designed to assess the efficacy and safety of sacituzumab govitecan in adult participants with metastatic solid tumors. Upon meeting the eligibility criteria, the participants are treated with sacituzumab govitecan at 10 mg/kg via intravenous infusion on Days 1 and 8 of a 21-day cycle. The original protocol included the following cohorts: non-small cell lung cancer (NSCLC: adenocarcinoma and squamous cell carcinoma [SCC]), head and neck squamous cell carcinoma (HNSCC), and endometrial carcinoma cohorts.

With Amendment 3, this is a single stage cohort evaluation for proof of concept (POC) with recalculation of sample sizes for all the cohorts. An additional cohort for small cell lung cancer (SCLC) was added. The Sponsor will evaluate the totality of efficacy and safety data at the end of the POC stage independently for each of the cohorts, and may potentially expand the HNSCC, endometrial carcinoma, and SCLC cohorts to enroll additional participants up to a total sample size of 100 to 120 participants in each selected cohort (including participants enrolled in this initial stage). In addition, OS is included as a secondary endpoint and will be assessed for all cohorts. [redacted]

1.3. Sample Size and Power

Approximately a total of 165 participants will be enrolled for the initial POC stage, that is, 30 participants from each of NSCLC (adenocarcinoma and SCC) and HNSCC cohorts, 35 participants for the endometrial carcinoma cohort, and 40 participants for the SCLC cohort. Once the efficacy bars are reached in endometrial carcinoma, HNSCC or SCLC cohort, the Sponsor may choose to expand any of these cohorts and continue to enroll additional participants, so that approximately a total of 100 to 120 participants (including participants enrolled in the initial stage) in each selected cohort will be accrued. If one or more cohorts are expanded, the total study sample size combining participants in both the POC and the expansion stages can be approximately 225 to 420 participants.

In Amendment 3, the sample size for the POC stage was not based on formal power calculation but to ensure the accuracy for the estimation of ORR. For each cohort of NSCLC, assuming the true ORR is 25%, a sample size of 30 participants will ensure the half-width of the 95% CI is ≤ 0.155; for the HNSCC cohort, assuming the true ORR is 22%, a sample size of 30 participants in the POC stage will ensure the half-width of the 95% CI is ≤ 0.148; for the endometrial carcinoma cohort, assuming the true ORR is 23%, a sample size of 35 participants will ensure the half-width of the 95% CI is ≤ 0.139; for the SCLC cohort, assuming the true ORR is 25%, a sample size of 40 participants will ensure the half-width of the 95% CI is ≤ 0.134.

2. TYPE OF PLANNED ANALYSES

2.1. Interim Analysis

No formal interim analysis is planned in the current protocol amendment 5.

2.2. Primary Analysis

The primary analysis includes the efficacy and safety analyses from data in the POC stage for all cohorts. It could potentially be used for different regulatory, publication, and conferences purposes.

2.3. Final Analysis

A final analysis primarily for safety updates will be performed after all participants have completed the study.

3. GENERAL CONSIDERATIONS FOR DATA ANALYSES

Analyses pertaining to the study's primary and secondary objectives and the corresponding end points will be conducted as described in respective sections of this SAP. Any notable analyses, adjustments to analyses, or analyses not conducted due to lack of data (such as insignificant numbers of participants in subgroups) or due to other technical constraints will be noted, if included in the CSR.

Unless otherwise specified, separate analyses will be conducted by cohort. Data from participants enrolled in the 2 NSCLC cohorts before and after the removal of TROP-2 expression criterion from the protocol will be summarized separately. Additional information is provided in section 3.2. All efficacy analysis will be analyzed using the Full Analysis Set and all safety analyses will be analyzed using the Safety Analysis Set unless otherwise specified.

Analysis results will be presented using descriptive statistics. For categorical variables, the number and percent of participants in each category will be presented; for continuous variables, the number of participants (n), mean, standard deviation (StD), median, first quartile (Q1), third quartile (Q3), minimum, and maximum will be presented.

By-participant listings will be presented for all participants in the Enrolled Analysis Set/Full Analysis Set/Safety Analysis Set and sorted by participant, visit date, and time (if applicable). Data collected on log forms, such as AEs, will be presented in chronological order within the participant. The cohorts to which participants were initially assigned will be used in the listings. Age, sex at birth, race, and ethnicity will be included in the listings, as space permits.

Throughout this SAP, both study drug and study treatment refer to sacituzumab govitecan and the two terms are used interchangeably.

3.1. Analysis Sets

For each analysis set, the number and percent of participants eligible for inclusion will be summarized by cohort.

3.1.1. Enrolled Analysis Set

The Enrolled Analysis Set includes all participants who have been assigned enrollment dates. This analysis set will be used to summarize the tables of key study dates, enrollment, disposition, and eligibility criteria deviations.

3.1.2. Full Analysis Set

The Full Analysis Set includes all participants who took at least 1 dose of sacituzumab govitecan. This is the primary analysis set for efficacy analyses.

3.1.3. Efficacy Evaluable Analysis Set

The Efficacy Evaluable Analysis Set includes all participants in the Full Analysis Set who had measurable disease at baseline and at least one post-baseline tumor assessment. This analysis set will be used for the sensitivity analysis of the primary efficacy endpoint.

3.1.4. Safety Analysis Set

The Safety Analysis Set includes all participants who took at least 1 dose of sacituzumab govitecan. This is the primary analysis set for safety analyses. The Safety Analysis Set and the Full Analysis Set are the same for this primary analysis.

3.1.5. Pharmacokinetic Analysis Set

The PK analysis will be conducted on the Pharmacokinetic Analysis Set, defined as all randomized participants who received at least 1 dose of SG per the protocol and have at least 1 evaluable post-treatment serum concentration of SG, total SN-38, free SN-38, or total antibody (hRS7 IgG).

3.1.6. Immunogenicity Analysis Set

The immunogenicity analysis will be conducted on the Immunogenicity Analysis Set, defined as all randomized participants who received at least 1 dose of SG and have at least 1 evaluable posttreatment anti-SG antibody test result.

3.2. Participant Grouping

For all the safety and efficacy analyses, the data for the cohorts (i.e., NSCLC, endometrial carcinoma, HNSCC and SCLC) will be presented separately for each cohort.

The data for the NSCLC cohorts will be presented on each of the following groups:

1) all NSCLC participants (adenocarcinoma and squamous cell cancer cohorts combined) enrolled in original protocol and protocol amendment 1, where TROP-2 expression criteria is mandated

2) adenocarcinoma cohort enrolled under amendments 2 and 3

3) squamous cell cohort enrolled under amendments 2 and 3

Please note: TROP-2 expression requirement was removed in amendments 2 and 3. Therefore, NSCLC participants enrolled before the removal of TROP-2 expression criteria were grouped separately.

3.3. Strata and Covariates

Not applicable.

3.4. Examination of Participant Subgroups

Selected efficacy endpoints (e.g., ORR, DOR, PFS, and OS) in the cohorts below will be summarized by different subgroups as specified below:

- Endometrial carcinoma: Prior chemotherapy and immunotherapy vs Without prior immunotherapy
- HNSCC: HPV positive vs HPV negative/missing; Oropharynx carcinoma vs Non-Oropharynx carcinoma
- SCLC: Chemotherapy-free Interval (CTFI) < 90 Days vs Chemotherapy-free Interval (CTFI) >= 90 Days; Gender; Age group : < 65 years old vs ≥ 65 years old; Responders (best response with CR or PR) vs non-responders (best response with SD and PD) vs Non-responders (best response with SD, PD and not reported/not available) in last anti-cancer therapy.

  For the SCLC cohort, the chemotherapy-free interval (CTFI) is defined as the time from the last dose of chemotherapy (includes Carboplatin and Cisplatin) to the occurrence of disease progression in the prior anti-cancer therapy.

Additionally, for all cohort，the TEAE summary table will be examined by age group (< 65 years vs ≥ 65 years).

3.5. Multiple Comparisons

Not applicable.

3.6. Data Handling Conventions and Transformations

Baseline value is defined as the last measurement that was observed on or prior to the date of first dose, unless otherwise specified.

See Appendix 2 for details.

3.7. Assessment of COVID-19 Impact

This study was ongoing during the novel coronavirus (COVID-19) pandemic, which has an impact on the study conduct. Some participants were unable to attend onsite visits due to the "shelter-in-place" guidelines, site closures, and/or other reasons. Since this study's database does not specifically collect any COVID-19 related information, no analysis will be conducted to assess COVID-19 impact.

4. PROTOCOL DEVIATIONS

Participants who did not meet at least one eligibility criterion for study entry but enrolled in the study will be summarized by cohort based on the All Enrolled Analysis Set. The summary will also present the number and percent of participants who did not meet specific criteria.

Protocol deviations occurring after participants entered the study are documented during routine monitoring. The number and percent of participants with important protocol deviations and the total number of important protocol deviations by deviation reason (e.g., nonadherence to study drug, violation of select inclusion/exclusion criteria) will be summarized by cohort for the Full Analysis Set.

5. PARTICIPANT INFORMATION

5.1. Participant Enrollment and Disposition

Key study dates (i.e., first participant enrolled, last participant enrolled, last participant last visit for the primary endpoint) will be provided.

A summary of participant enrollment will be provided by cohort for each country.

A summary of participant disposition will be provided by cohort based on the Enrolled Analysis Set. This summary will present the number of participants enrolled, and the number of participants in each of the categories listed below:

- The treated participants (received at least 1 dose of study drug)
- Continuing treatment
- Discontinued from treatment with reasons for discontinuation of treatment
- Continuing on study
- Discontinued from study with reasons for discontinuation of study

A by-participant listing for disposition will be provided for the Enrolled Analysis Set, including their informed consent dates, first/last dose dates, discontinued from treatment date/reason and discontinued from study date/reason.

5.2. Extent of Study Drug Exposure

Treatment exposure will be summarized for the Safety Analysis Set using the following measures:

- Number of doses administered
- Descriptive statistics of duration of treatment (months), along with number of participants with treatment duration longer than or equal to 3 months, 6 months, 12 months, and 24 months; Duration of treatment (in days) will be calculated as (date of the last non-zero dose − date of the first non-zero dose + 1) and converted to months by dividing by 30.4375
- Number and percent of participants with dose reduction according to percent of dose reduction (25% or 50% dose reduction per CRF form as the dose level of sacituzumab govitecan is only allowed to reduce from 10 mg/kg to 7.5 or 5 mg/kg) and reasons for dose reduction
- Descriptive statistics of time to first dose reduction.

- Relative dose intensity (RDI) will be calculated as described below in section 5.2.2 and summarized. Cumulative dosage and relative dose intensity will be summarized by descriptive statistics, and relative dose intensity will be additionally summarized by the categories (e.g., < 70%, 70% to < 90%, 90% to < 110%, ≥ 110%).

5.2.1. Administered Dosage

Administered dose (mg) for each infusion is calculated per CRF form from ("Dose calculated" × "Actual volume administered"/"Total volume prepared").

Administered dosage (mg/kg) of each infusion in a cycle is calculated by dividing the administered dose (mg) by most recent weight (kg) prior to current dosing.

5.2.2. Relative Dose Intensity

Total amount of study drug administered (mg/kg) for each participant is defined as the sum of all administered dosages (mg/kg) of all infusions the participant received in the study.

Relative dose intensity (RDI) (%) for each participant is calculated: dividing the participant's total amount of study drug administered dosage (mg/kg) by the total amount of study drug expected to be administered (mg/kg).

$$\text{RDI (\%)} = \frac{Total\ amount\ of\ study\ drug\ administered\ (mg/kg)}{10\ (\text{mg/kg}) * \text{number of planned SG doses}} \text{ x } 100$$

$$\text{Number of Planned Doses} = \left(\frac{Last\ Nonzero\ Dose\ Date - Forst\ Nonzero\ Dose\ Date + X}{21}\right) * 2$$

- If the remainder $\left(\frac{\text{Last Nonzero Dose Date} - \text{First Nonzero Dose Date} + 1}{21}\right) \leq 7$, the number of expected doses in the last cycle is 1, and $X = \frac{21}{2} * 1 - 0 = 10.5$.

- If the remainder $8 \leq \left(\frac{\text{Last Nonzero Dose Date} - \text{First Nonzero Dose Date} + 1}{21}\right) < 21$, the number of expected doses in the last cycle is 2, and $X = \frac{21}{2} * 2 - 7 = 14$.

The RDI calculation will be performed using the general formula above and details are described in programming specifications.

5.3. Demographics and Baseline Characteristics

Participant demographics and baseline characteristics will be summarized with descriptive statistics by cohort for the Full Analysis Set.

Baseline demographic data summaries will include age, age by categories [< 65 years, ≥ 65 years], sex, race, ethnicity.

Baseline characteristics will include but are not limited to: Eastern Cooperative Oncology Group (ECOG) performance status score, and tobacco, alcohol use status.

In particular, for HNSCC cohort, the number of percent of participants with the following baseline disease characteristics will be summarized: HPV status (negative, positive), site of disease (oral cavity, oropharynx, larynx, etc.) and HPV positive with site of disease at oropharynx. For SCLC, the status of prophylactic brain irradiation will be summarized.

A by-participant listing for demographics and baseline characteristics will be provided for the Full Analysis Set.

5.4. Prior Anti-cancer Therapy

The number and percent of participants with different regimens, therapy type (e.g., chemotherapy, hormonal therapy, immunotherapy, targeted agents and other), setting status in last therapy (neoadjuvant, adjuvant, advanced/metastatic, unknown, and other), best response in the last therapy, time from disease progression in last therapy to study entry and last therapy to study entry will be summarized. Study entry refers to the date of first dose of study drug and the last therapy refers to the prior anti-cancer therapy with the last end date before study entry.

For individual cohorts, the number and the percent of participants with the following information below will also be summarized:

HNSCC and Endometrial carcinoma cohorts:

- Chemotherapy + Immunotherapy
- Chemotherapy + Immunotherapy + ≤ 3 Lines of Therapies
- Chemotherapy + Immunotherapy + MSI-H Status (Yes) (for Endometrial cohort Only)

SCLC cohort:

- CTFI < 90 days vs CTFI ≥ 90 days
- Immunotherapy-free interval < 90 days vs ≥ 90 days (similar to CTFI)
- Chemotherapy
    - Carboplatin + Etoposide
    - Cisplatin + Etoposide
- Immunotherapy
    - Atezolizumab
    - Durvalumab
    - Nivolumab

A by-participant listing for prior anti-cancer therapy will be provided for the Full Analysis Set.

5.5. Disease History

Time from initial diagnosis to study entry, stage at initial diagnosis, stage at study enrollment, time from initial diagnosis to confirmed metastatic disease, time from confirmed metastatic disease to study entry, and area of disease involvement at study enrollment will be summarized in the table of disease history. Study entry refers to the date of first dose of study drug.

A by-participant listing for disease history will be provided for the Full Analysis Set.

5.6. Medical History

General medical history will be collected at screening for general conditions (i.e., conditions not specific to the disease being studied). Medical history will be coded using the current Medical Dictionary for Regulatory Activities (MedDRA) dictionary.

General medical history will be summarized by system organ class (SOC) and preferred term (PT) and sorted by frequency in SOC and by decreasing frequency in PT for the Full Analysis Set.

A by-participant listing of general medical history will be provided by participant ID number in ascending order.

5.7. Prior and Concomitant Medications

Medications collected at screening and during the study will be coded using the current version of the World Health Organization (WHO) Drug dictionary.

5.7.1. Prior Medications/Radiation Therapies/Surgeries and Procedures

5.7.1.1. Prior Medications

Prior medications are defined as any medications taken before a participant took the first study drug.

Prior medications will be summarized by Anatomical Therapeutic Chemical (ATC) drug class Level 2 and preferred name using the number and percent of participants for each cohort. A participant reporting the same medication more than once will be counted only once within each ATC drug class when calculating the number and percent of participants who received that medication. The summary will be ordered alphabetically by ATC medical class and then by preferred term in order of descending overall frequency within each ATC medical class. For drugs with the same frequency, sorting will be done alphabetically.

For the purposes of analysis, any medication with a start date prior to the first dosing date of study drug will be included in the prior medication summary regardless of when the stop date is. If a partial start date is entered the medication will be considered prior unless the month and year (if day is missing) or year (if day and month are missing) of the start date are after the first

dosing date. Medications with a completely missing start date will be included in the prior medication summary, unless otherwise specified.

Summaries will be based on the Safety Analysis Set. No formal statistical testing is planned.

5.7.1.2. Prior Radiation Therapies

Prior radiation therapy will be reported in a by-participant listing.

5.7.1.3. Prior Cancer Surgeries and Procedures

Prior cancer surgeries and procedures will be reported in a by-participant listing only.

5.7.2. Concomitant Medications

Concomitant medications are defined as medications taken while a participant took the study drug. Use of concomitant medications will be summarized by Anatomical Therapeutic Chemical (ATC) drug class Level 2 and preferred name using the number and percent of participants for each cohort. A participant reporting the same medication more than once within each ATC drug class will be counted only once when calculating the number and percent of participants who received that medication. The summary will be ordered alphabetically by ATC medical class and then by preferred term in descending overall frequency within each ATC medical class. For drugs with the same frequency, sorting will be done alphabetically.

For the purposes of analysis, any medications with a start date prior to or on the first dosing date of study drug and continued to be taken after the first dosing date or started on or after the first dosing date of study drug and continued until 30 days after the treatment discontinuation will be considered concomitant medications. Medications started and stopped on the same day as the first dosing date or 30 days after the treatment discontinuation will also be considered concomitant. Medications with a stop date prior to the date of first dosing date of study drug or a start date beyond 30 days after the treatment discontinuation will be excluded from the concomitant medication summary. If a partial stop date is entered, any medication with the month and year (if day is missing) or year (if day and month are missing) prior to the date of first study drug administration will be excluded from the concomitant medication summary. If a partial start date is entered, any medication with the month and year (if day is missing) or year (if day and month are missing) after the study drug stop date will be excluded from the concomitant medication summary. Medications with completely missing start and stop dates will be included in the concomitant medication summary, unless otherwise specified. Summaries will be based on the Safety Analysis Set. No formal statistical testing is planned.

All prior and concomitant medications (other than per-protocol study drugs) will be provided in a by-participant listing sorted by participant ID number and administration date in chronological order.

5.8. Non-protocol Specific Procedures/Surgeries

Non-protocol specific procedures/surgeries will be reported in a by-participant listing only.

6. EFFICACY ANALYSES

Efficacy analyses will be performed primarily based on the Full Analysis Set and may be also performed for selected endpoints based on the Efficacy Evaluable Analysis Set.

For the purposes of analysis for tumor response-based endpoints including ORR, DCR (disease control rate), CBR, BOR, DOR and PFS, documented progression refers to progression based on radiologic assessment as determined by the investigator or central review (BICR), not clinical progression.

Tumor response-based endpoints, including ORR, DCR, CBR, DOR, and PFS will be analyzed based on both investigator reviewed and BICR results.

6.1. Primary Efficacy Endpoint

6.1.1. Definition of the Primary Efficacy Endpoint

The primary efficacy endpoint of this study is objective response rate (ORR) defined as the proportion of all participants with measurable disease at baseline who achieve complete response (CR) or partial response (PR) that is confirmed at least 4 weeks after initial documentation of response per RECIST v1.1, as determined by investigator. Tumor response assessments after the date of participants receiving subsequent anticancer therapy will be excluded from the analysis. The response definition of each response category is based on RECIST v1.1.

6.1.2. Statistical Hypothesis for the Primary Efficacy Endpoint

There is no statistical hypothesis for the POC stage.

6.1.3. Analysis of the Primary Efficacy Endpoint

ORR will be summarized for the Full Analysis Set along with the number and percent of participants in each response category.

The 2-sided 95% exact confidence interval (CI) of ORR based on Clopper-Pearson method {Clopper 1934} will be provided for each cohort.

Additionally, a plot of target-lesion tumor burden over visit (spider plot) will be provided for the Full Analysis Set, where the tumor burden is defined as the percent change from baseline in total sum of target lesion diameters. A plot of maximum tumor burden reduction (waterfall plot) and a table of maximum tumor burden reduction will be provided for the Full Analysis Set, where maximum tumor burden reduction is defined as the best percent change from baseline in total sum of target lesion diameters. A plot of participants' overall response assessment over visit (swimmer plot) will be provided for the Full Analysis Set.

6.1.4. Sensitivity Analysis of the Primary Efficacy Endpoint

A sensitivity analysis of the primary endpoint may be performed based on the Efficacy Evaluable Analysis Set.

6.2. Secondary Efficacy Endpoints

6.2.1. Definition of Secondary Efficacy Endpoints

Clinical Benefit Rate (CBR)

CBR is defined as confirmed CR + PR + SD for at least 6 months, according to RECIST v1.1 by the investigator or BICR. For participants who have best response of SD, the duration of SD is defined as the time from the date of first dose of study drug to the first documentation of PD or death due to any cause.

Disease Control Rate (DCR)

Disease control rate (DCR) is defined as the proportion of participants who achieve a confirmed CR, PR, or stable disease (SD) as assessed by the investigator or BICR per RECIST v1.1.

Time to Response (TTR)

Time to onset of objective response (CR or PR) will be calculated for objective responders as the time from the date of first dose of study drug to the first documentation of response according to RECIST v1.1.

Time-to-response (TTR) by RECIST v1.1 will be summarized based only on participants who achieved a best overall response of confirmed CR or PR. TTR will be summarized by descriptive statistics, and by the number and percent of responders whose TTR is within 3 months, 6 months, and 12 months.

Duration of Response (DOR)

Duration of response (DOR) is defined as the time interval from the date of first response (CR or PR) to the earlier of the first documentation of definitive disease progression or death from any cause as assessed by the investigator per RECIST v1.1, which occurs first. The analyses of DOR will be based on the participants in the Full Analysis Set who achieve a confirmed CR or PR. The censoring rules for DOR are specified in Table 1.

DOR in months will be derived as (date of event/censoring – date of first response [CR or PR] + 1) / 30.4375.

Table 1. Censoring Rules for DOR

Case	Outcome	Date of Event/Censoring
Continued scheduled response assessments until objective PD or death		
PD or death documented after ≤ 1 missed disease assessments, and before other anti-cancer therapy, if any	Event	PD or Death date, whichever occurs first
PD or death immediately after ≥ 2 consecutive missed disease assessments, or after other anti-cancer therapy, if any	Censored	Date of last adequate tumor assessment prior to the earlier date of >= 2 consecutive missed disease assessment and other anti-cancer therapy, if any
Continued scheduled response assessments without objective PD or death		
Other anti-cancer treatment is initiated	Censored	Date of last adequate tumor assessment before starting other anti-cancer treatment
Other anti-cancer treatment is not initiated	Censored	Date of last adequate tumor assessment

Progression Free Survival (PFS)

PFS will be defined as the time from the date of first dose of study drug to the date of first documentation of disease progression by investigator assessment or BICR based on RECIST v1.1 or death due to any cause, whichever comes first. The censoring rules for PFS are specified in Table 2.

Table 2. Censoring Rules for PFS

Case	Outcome	Date of Event/Censoring
No adequate response assessment after the first dose		
No baseline tumor assessment or alive	Censored	First dose date
Died prior to second scheduled disease assessment without initiation of other anti-cancer therapy	Event	Death date
Died immediately after ≥ 2 consecutive missed assessments or new anti-cancer therapy, if any	Censored	First dose Date
Continued scheduled response assessments until objective PD or death		
PD or death documented after ≤ 1 missed disease assessments, and before other anti-cancer therapy, if any	Event	PD or Death date, whichever occurs first
PD or death immediately after ≥ 2 consecutive missed disease assessments, or after other anti-cancer therapy, if any	Censored	Date of last adequate tumor assessment prior to the earlier date of >= 2 consecutive missed disease assessment and other anti-cancer therapy, if any
Continued scheduled response assessments without objective PD or death		
Other anticancer treatment is initiated	Censored	Date of last adequate tumor assessment before starting other anti-cancer treatment
Other anticancer treatment is not initiated	Censored	Date of last adequate response assessment

Overall Survival (OS)

OS will be measured from the date of first dose of study drug to death from any cause. Participants not known to have died are censored on the date they were last known to be alive.

6.2.2. Analysis Methods for Secondary Efficacy Endpoints

Clinical Benefit Rate (CBR) and Disease Control Rate (DCR)

CBR and DCR will be summarized for the Full Analysis Set along with the number and percent of participants in each response category. 95% confidence intervals of CBR and DCR will be calculated using the Clopper Pearson method {Clopper 1934}. An additional sensitivity analysis of CBR and DCR may be performed based on the Efficacy Evaluable Analysis Set.

Duration of Response (DOR)

The analysis of duration of response (DOR) will be performed using the Kaplan-Meier method for the responding participants in the Full Analysis Set. Median, Q1, and Q3 of the DOR will be provided along with the corresponding 95% CI for each cohort. Kaplan-Meier curves will be provided by cohort.

The follow-up time for DOR, defined as the time from the first documentation of response according to RECIST v1.1. to the date of death or the last known alive date if participants are not dead, will be summarized descriptively.

Progression Free Survival (PFS)

A Kaplan-Meier analysis will be performed for the PFS data using the Full Analysis Set. Median PFS will be derived and 95% confidence will be calculated based on Brookmeyer and Crowley method {Brookmeyer 1982}. The milestone PFS rate at 3 months, 6 months, 12 months, 18 months will be derived from the KM curve.

Overall Survival (OS)

A Kaplan-Meier analysis will be performed for the OS data using the Full Analysis Set. Median OS will be derived, and 95% confidence will be calculated based on Brookmeyer and Crowley method {Brookmeyer 1982}. The milestone OS rate at 6 months, 12 months, and 24 months will be derived from the KM curve.

The follow-up time for OS, defined as the time from the date of first dose of study drug to the date of death or the last known alive date if participants are not dead, will be summarized descriptively.

7. SAFETY ANALYSES

7.1. Adverse Events and Deaths

7.1.1. Adverse Events Dictionary

Clinical and laboratory adverse events (AEs) will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). System organ class (SOC), high level group term (HLGT), high level term (HLT), preferred term (PT), and lower level term (LLT) will be provided in the AE dataset.

7.1.2. Adverse Events Severity

Adverse events are graded by the investigator as Grade 1, 2, 3, 4, or 5 according to NCI CTCAE Version 5.0. The severity grade of events for which the investigator did not record severity will be categorized as "missing" for tabular summaries and data listings. The missing category will be listed last in summary presentation.

7.1.3. Relationship of Adverse Events to Study Drug

Related AEs are those for which the investigator selected "Related" or "Possibly Related" on the AE CRF to the question of "Related to Study Treatment." Relatedness will always default to the investigator's choice, not that of the medical monitor. Events for which the investigator did not record relationship to study drug will be considered related to study drug for summary purposes. However, by-participant data listings will show the relationship as missing.

7.1.4. Serious Adverse Events

Serious adverse events (SAEs) will be identified and captured as SAEs if the AEs met the definitions of SAEs that were specified in the study protocol. SAEs captured and stored in the clinical database will be reconciled with the SAE database from the Gilead Patient Safety Department before data finalization.

7.1.5. Treatment-Emergent Adverse Events

7.1.5.1. Definition of Treatment-Emergent Adverse Events

Treatment-emergent adverse events (TEAEs) are defined as any AEs with an onset date on or after the study drug start date and no later than 30 days after last dose of study drug or the day before initiation of subsequent anticancer therapy, whichever comes first.

7.1.6. Summaries of Adverse Events and Deaths

Treatment-emergent AEs will be summarized based on the Safety Analysis Set.

7.1.6.1. Summaries of AE Incidence

Treatment-emergent AEs, SAEs, grade 3 or worse TEAEs, treatment-related TEAEs, TEAEs leading to study drug discontinuation, TEAEs leading to study drug interruption, TEAEs leading to dose reduction, TEAEs leading to death, protocol - defined AEs of special interest and other safety observations will be summarized based on the Safety Analysis Set. SAEs occurring beyond reporting period may be listed.

A brief, high-level summary of the number and percent of participants who experienced at least 1 TEAE in the categories described below will be provided by cohort. All deaths observed in the study will also be included in this summary.

The number and percent of participants who experienced at least 1 TEAE will be provided and summarized by SOC, PT and cohort:

- TEAEs
- TEAEs with Grade 3 or higher
- TE treatment-related AEs
- TE treatment-related AEs with Grade 3 or higher
- TE SAEs
- TE treatment-related SAEs
- TEAEs leading to discontinuation of study drug
- TEAEs leading to death
- TE Treatment-related AEs leading to death
- TEAEs leading to interruption of study drug
- TEAEs leading to dose reduction

For AE categories described below, summaries will be provided by SOC, PT, maximum severity and cohort:

- TEAEs
- TE Treatment-related AEs

- TE Treatment-related AEs with Grade 3 or higher

For AE categories described below, summaries will be provided by PT and cohort:

- TEAEs reported by >=10% participants
- TE treatment-related AEs reported by >=5% participants
- TEAEs with CTCAE Grade 3 or higher reported by >=2% participants
- TE SAE reported by >=2% participants
- TEAEs leading to dose reduction
- TEAEs leading to interruption of study drug
- TEAEs leading to discontinuation of study drug

Multiple events will be counted only once per participant in each summary. Adverse events will be summarized and listed first in alphabetic order of SOC, and then by PT in descending order of total frequency within each SOC. For summaries by severity grade, the worst severity will be used for those AEs that occurred more than once in an individual participant during the study.

In addition to the above summary tables, all TEAEs, TE SAEs, TE treatment-related AEs, and TE treatment-related SAEs will be summarized by PT only, in descending order of total frequency.

In addition, data listings will be provided for the following:

- AEs, indicating whether the event is treatment emergent
- SAEs
- Deaths
- AEs with CTCAE Grade 3 or higher
- AEs leading to discontinuation of any study drug
- AEs leading to dose interruption of study drug
- AEs leading to death

7.1.6.2. Summary of Death

A summary (number and percent of participants) of deaths will be provided by cohort. Summary will include the following categories:

- All deaths
- Deaths within 30 days of the last dosing of study drug
- Deaths beyond 30 days of the last dosing of study drug

The attribution of death, if available, will also be summarized.

7.1.7. Additional Analysis of Adverse Events

7.1.7.1. Subgroup Analysis of TEAE

The subgroup analysis for the TEAE by age (< 65, ≥ 65 years) will be performed by SOC, PT, and age group for the Safety Analysis Set.

7.1.7.2. Treatment-emergent Adverse Events of Special Interest (TEAESI)

Definitions of treatment-emergent adverse events of special interest (TEAESI) for SG are provided in Table 3.

Table 3. Definitions of Adverse Events of Special Interest

AESI	Definition
Serious infections secondary to neutropenia	Preferred terms under SOC: Infections and Infestations [a] (serious infections occurring after AE of neutropenia of any grade)
Severe diarrhea	Preferred term: diarrhea (Grade 3 or higher)
Hypersensitivity[b]	Preferred terms under: Hypersensitivity SMQ (narrow) and Anaphylactic Reaction SMQ (broad and narrow)[c]
Neutropenia[d]	Preferred terms: neutropenia, neutrophil count decreased, febrile neutropenia

AE = adverse event; AESI = adverse event of special interest; MedDRA = Medical Dictionary for Regulatory Activities; SMQ = Standardized MedDRA Query; SOC = system organ class
All definitions are based on MedDRA Version 26.1 or higher.

a Serious AEs from the Infections and Infestations SOC that occurred within 11 days of neutropenia, febrile neutropenia, or neutrophil count decreased.

b For the category of hypersensitivity, only events with onset dates on the day of or 1 day after study drug administration are included.

c Anaphylactic Reaction SMQ (broad and narrow) is an algorithmic SMQ.

d Grouped AE terms.

A high-level summary of the number and percent of participants who experienced at least 1 TEAESI in the categories described below will be provided by cohort. The following summaries will be provided for TEAESIs by Category, PT and cohort:

- TEAESI
- TEAESIs with Grade 3 or higher
- Treatment-related TEAESIs
- TE Serious AESI
- TEAESIs leading to interruption of study drug
- TEAESIs leading to discontinuation of study drug
- TEAESIs leading to dose reduction of study drug
- TEAESIs leading to death

A corresponding data listing of TEAESIs will be provided.

7.2. Laboratory Evaluations

Selected laboratory test data will be summarized. Local laboratory results will be standardized using the International System SI unit.

Graded laboratory abnormalities will be defined using the grading scheme. The worst toxicity grade during the study will be tabulated.

The number and percent of participants with treatment-emergent laboratory abnormalities will be summarized by cohort. A treatment-emergent laboratory abnormality will be defined as any value that increases at least 1 toxicity grade from baseline during the treatment emergent period.

A by-participant listing for laboratory test results will be provided by participant ID number and visit in chronological order for hematology, serum chemistry, and urinalysis separately. Values falling outside of the relevant reference range and/or having a severity grade of 1 or higher on the CTCAE severity grade will be flagged in the data listings, as appropriate.

Laboratory abnormalities that occur before the first dose of study drug or after the participant has been discontinued from treatment for ≥ 30 days will be included in a data listing.

7.2.1. Summaries of Numeric Laboratory Results

Descriptive statistics will be provided by cohort for each laboratory test specified in the study protocol as follows:

- Baseline values
- Values at each postbaseline time point
- Change and percent change from baseline at each postbaseline time point

A baseline laboratory value will be defined as the last measurement obtained on or prior to the date/time of first dose of study drug. Change from baseline to a postbaseline visit will be defined as the visit value minus the baseline value. The mean, median, Q1, Q3, minimum, and maximum values will be displayed to the reported number of digits; StD values will be displayed to the reported number of digits plus 1.

7.2.2. Graded Laboratory Values

The CTCAE Version 5.0 will be used to assign toxicity grades (0 to 4) to laboratory results for analysis. Grade 0 includes all values that do not meet the criteria for an abnormality of at least Grade 1. For laboratory tests with criteria for both increased and decreased levels, analyses for each direction (i.e., increased, decreased) will be presented separately. Local labs will be graded based on the central lab normal ranges with in-house macro.

7.2.2.1. Treatment-Emergent Laboratory Abnormalities

Treatment-emergent laboratory abnormalities are defined as values that increase at least 1 toxicity grade from baseline at any postbaseline time point, up to and including the date of last dose of study drug plus 30 days or the day before initiation of subsequent anticancer therapy, whichever occurs first. If the relevant baseline laboratory value is missing, any abnormality of at least Grade 1 observed within the time frame specified above will be considered treatment emergent.

7.2.2.2. Summaries of Laboratory Abnormalities

The following summaries (number and percent of participants) for treatment-emergent laboratory abnormalities will be provided by lab test and cohort; participants will be categorized according to the most severe postbaseline abnormality grade for a given lab test:

- TE laboratory abnormalities
- Grade 3 or 4 laboratory abnormalities

For all summaries of laboratory abnormalities, the denominator is the number of participants in the Safety Analysis Set with non-missing postbaseline values.

A by-participant listing of treatment-emergent Grade 3 or 4 laboratory abnormalities will be provided by participant ID number and time point in chronological order. This listing will include all test results that were collected throughout the study for the lab test of interest, with all applicable severity grades displayed.

7.2.3. Liver-related Laboratory Evaluations

Liver function abnormalities after initial study drug administration will be examined and summarized for selected chemistry and hematology parameters.

7.2.4. Shifts Relative to the Normal Range

Shift tables will be presented by showing change in severity grade from baseline to the worst grade postbaseline for selected chemistry parameters (Creatinine/Glucose) and hematology parameters (Hemoglobin/Platelet Count/WBC count/Absolute neutrophil count).

7.3. Body Weight, Height, and Vital Signs

During treatment, participant's body weight will be measured at Screening, on Day 1 of each treatment cycle (or more frequently if the participant's body weight changed by > 10% since the previous administration), at the end of treatment (EOT) Visit, and at the 30-Day Safety Follow-up Visit. Participant's height will only be measured at Screening.

Vital sign measurements (systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature) will be taken at the Screening/Baseline visit (within 28 days of C1D1), C1D1 prior to infusion and other timepoints during the study if clinically indicated.

All the collected information will be presented for each participant in a by-participant data listing.

7.4. Electrocardiogram Results

The standard 12-lead electrocardiogram (ECG) will be obtained at the Screening/Baseline visit (within 28 days of C1D1), C1D1 prior to infusion, and repeated during the study if clinically indicated.

As ECG comments were collected as free text field, a listing will be produced for ECG parameters along with any investigator comments that may be provided.

7.5. Other Safety Measures

No additional safety measures are specified in the protocol.

7.6. Changes From Protocol-Specified Safety Analyses

There are no deviations from the protocol-specified safety analyses.

8. PHARMACOKINETIC (PK) AND IMMUNOGENICITY ANALYSES

8.1. Pharmacokinetics Analyses

Descriptive summary of PK concentration (SG, free SN-38 and total antibody - hRS7 IgG) and PK parameters will be summarized by visits. A listing of PK concentrations will also be provided. Participants in the PK population will be included for analyses.

Pharmacokinetics analyses including population pharmacokinetics (PopPK), exposure-efficacy and exposure-safety analyses will be described in separate analyses plans.

Data from this study may be combined with data from other studies for PopPK and exposure response analyses. If applicable, results from such analyses may be summarize d in a separate report, rather than in a CSR.

8.2. Immunogenicity (Anti-Drug Antibodies) Analysis

Summary of ADA prevalence, incidence (treatment-emergent and treatment-boosted), transience, and persistence will be calculated. Titer summaries at each time point per participant may also be produced for ADA-positive participants. If the ADA is further characterized as neutralizing or otherwise, the overall rate of neutralizing antibody occurrence will also be reported. CCI [redacted].

9. BIOMARKER ANALYSIS

CCI [redacted]

10. REFERENCES

Brookmeyer R, Crowley J. A confidence interval for the median survival time. Biometrics 1982;38:29-41.

Clopper CJ, Pearson ES. The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomial. Biometrika 1934;26 (4):404-13.

11. SOFTWARE

SAS® Software Version 9.4. or above SAS Institute Inc., Cary, NC, USA.

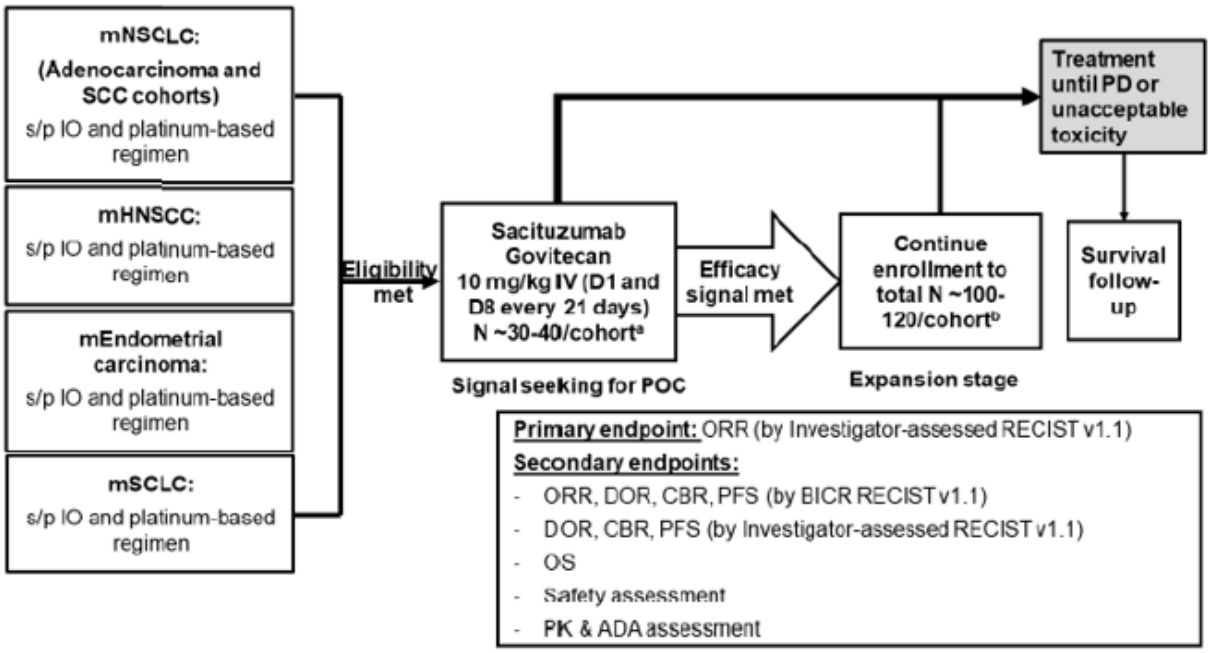
12. SAP REVISION

Revision Date (DD MMM YYYY)	Section	Summary of Revision	Reason for Revision
10 March 2020		Initial version 1.0	
28 June 2023		Update the SAP based on Gilead standard SAP template and only include the NSCLC cohorts	To support sacituzumab govitecan filing
10 April 2025		Include all the cohorts for the primary analysis, including efficacy and safety analyses	For regulatory, conference, and publication purposes
	3.2	Update "Participant Grouping"	Added more cohorts
	3.4	Add "Examination of Participant Subgroups"	Added some subgroups in TFLs
	5.2.1	Updated the calculation of RDI	To align with the global change for the RDI of SG at Gilead
	5.4	Update the layout of this section	Follow the Gilead template to provide more details
	5.7	Update the definition of prior and concomitant medication	To align with oncology SAP template
	6.3	CCI [redacted]	To match the additional analysis in TFLs
	7.1.7	Update AESI	To align with the global change for AESI at Gilead

13. APPENDICES

Appendix 1. Study Schema

Appendix Figure 1. Study IMMU-132-11 Schema



ADA = anti drug antibody; BICR = blinded independent central review; CBR = clinical benefit rate; D = day; DOR = duration of response; IO = immune-oncology; IV = intravenous; m = metastatic; mHNSCC = metastatic head and neck squamous cell carcinoma; mNSCLC = metastatic non-small cell lung cancer; mSCLC = metastatic small cell lung cancer; ORR = objective response rate; OS = overall survival; POC = proof of concept; PD = progressive disease; PFS = progression free survival; PK = pharmacokinetic; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors Version 1.1; SCC = squamous cell carcinoma; s/p = status post

a Exact sample size calculations for each of the cohorts for POC stage are outlined in the protocol.

b Expansion stage planned only for HNSCC, endometrial, and SCLC cohorts (if efficacy signal met in the POC stage).

Appendix 2. Data Handling Conventions and Transformations

Data Handling for Derivation of Treatment-emergent Adverse Events

If the onset date of the AE is incomplete and the AE stop date is not prior to the first dosing date of study drug, then the month and year (or year alone if month is not recorded) of onset determine whether an AE is treatment emergent. The event is considered treatment emergent if both of the following 2 criteria are met:

- The AE onset is the same as or after the month and year (or year) of the first dosing date of study drug, and
- The AE onset date is the same as or before the month and year (or year) of the date corresponding to 30 days after the date of the. last dose of study drug.

An AE with completely missing onset and stop dates, or with the onset date missing and a stop date later than the first dosing date of study drug, will be considered to be treatment emergent. In addition, an AE with the onset date missing and incomplete stop date with the same or later month and year (or year alone if month is not recorded) as the first dosing date of study drug will be considered treatment emergent.

For missing/incomplete AE start/end dates, please see Appendix 3.

PK Data Handling and Convertion

Non-PK data that are continuous in nature but are less than the lower limit of quantitation (LOQ) or above the upper LOQ will be imputed as follows:

- A value that is 1 unit less than the LOQ will be used to calculate descriptive statistics if the datum is reported in the form of "< x" (where x is considered the LOQ). For example, if the values are reported as < 50 and < 5.0, values of 49 and 4.9, respectively, will be used to calculate summary statistics. An exception to this rule is any value reported as < 1 or < 0.1, etc. For values reported as < 1 or < 0.1, a value of 0.9 or 0.09, respectively, will be used to calculate summary statistics.

- A value that is 1 unit above the LOQ will be used to calculate descriptive statistics if the datum is reported in the form of "> x" (where x is considered the LOQ). Values with decimal points will follow the same logic as above.

- The LOQ will be used to calculate descriptive statistics if the datum is reported in the form of "≤ x" or "≥ x" (where x is considered the LOQ).

If methods based on the assumption that the data are normally distributed are not adequate, analyses may be performed on log-transformed data or nonparametric analysis methods may be used, as appropriate.

Sparse PK concentration values that are below the limit of quantitation (BLQ) will be presented as "BLQ" in the data listing.

Appendix 3. Missing Data/Partial Dates Imputation Rules

Missing Data Imputation for Missing Date of Birth

The following conventions will be used for the imputation of date of birth when it is partially missing or not collected:

In general, age collected at Day 1 (the randomization date) (in years) will be used for analyses and presented in listings. If age at Day 1 is not available for a participant, then age derived based on date of birth and the Day 1 visit date will be used instead. If an enrolled participant was not dosed with any study drug, the randomization date will be used instead of the Day 1 visit date.

For screen failures, the date the first informed consent was signed will be used for the age derivation.

Missing normal ranges for laboratory parameters

When either the lower limit of normal, the upper limit of normal or both are missing or are not machine readable, a standardized reference range will be used.

Missing Data Imputation for Missing Adverse Event/Concomitant Medication Start Date

1) Missing day only

- If the month and year of the AE/the concomitant medication are the same as the month and year of the first dose date, the first dose date day will be used.
- • If the month and year are before the month and year of the first dose date, the first day of the month will be assigned to the missing day.
- • If the month and year are after the month and year of the first dose date, the first day of the month will be assigned to the missing day.

2) Missing day and month

- If the year is the same as the year of the first dose date, the first dose date day and month will be used.
- If the year is prior to the year of the first dose date, December 31 will be assigned to the missing fields.
- If the year is after the year of the first dose date, January 1 will be assigned to the missing fields.

3) Missing day, month, and year

- Uncertain: unable to impute.

The imputed start date should be prior or equal to the end date of the AE or medication. If only month is missing, then it will be imputed in a similar way as scenario 2) above. If both year and month missing and day not missing, then it will be imputed in a similar way as scenario 3) above.

Missing Data Imputation for Missing Adverse Event/Concomitant Medication Stop Date

4) Missing day only

- The month and year are the same as the month and year of the first dose date: use the last date of the month.
- The month and year are before the month and year of the first dose date: use the last date of the month.
- The month and year are after the month and year of the first dose date: use the last date of the month.

5) Missing day and month

- The year is the same as the year of the first dose date: use December 31.

6) Missing year

- Uncertain: unable to impute.

7) Missing month

- The year is the same as the year of the first dose date: use December.
- The year is before the year of the first dose date: use December.
- The year is after the year of the first dose date: use December.

If the death date is available and the imputed end date is after the death date, the death date will be used.

If the imputed end date is before the start date of the AE or medication, then make end date equals to start date.

Missing Data Imputation for Disease Diagnosis Date

8) Missing day only

- The first day of the month will be assigned to the missing day

9) Missing day and month

- January 1 will be assigned to the missing fields

10) Missing year

- Uncertain: unable to impute

IMMU-132-11_SAP_Primary Analysis v1.0

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date (dd-MMM-yyyy hh:mm:ss)
PPD	Biostatistics eSigned	14-Apr-2025 22:37:24