# Statistical Analysis Plan

## A PHASE 2 CLINICAL STUDY OF TJ004309 IN COMBINATION WITH ATEZOLIZUMAB (TECENTRIQ®) IN PATIENTS WITH ADVANCED OR METASTATIC OVARIAN CANCERS AND SELECTED ADVANCED SOLID TUMORS

| | |
|---|---|
| **Protocol No. (Ver.)** | TJ004309STM103 (3.0) |
| **Sponsor:** | I-Mab Biopharma US Limited |
| **CRO:** | ClinChoice Inc. |
| **Version:** | V1.0 |
| **Date:** | 22NOV2024 |

# SIGNATURE PAGE

## PREPARED BY:

**Author**

Wei Zhou, PhD

Senior biostatistician

ClinChoice Inc.

*Electronically signed by: Wei Zhou*
*Reason: I am the author*
*Date: Jan 6, 2025 09:38 EST*

Signature

Date: _____

**Reviewer**

Susan Wu

Director, Biostatistics

ClinChoice Inc.

*Electronically signed by: Susan Wu*
*Reason: I am the reviewer*
*Date: Jan 6, 2025 09:42 EST*

Signature

Date: _____

## APPROVED BY:

Claire Xu, MD, PhD

VP, Clinical Development

I-Mab Biopharma US Limited

*Electronically signed by: claire xu*
*Reason: I approve this document*
*Date: Jan 6, 2025 09:50 EST*

Signature

Date: _____

# DOCUMENT REVISON HISTORY

| VERSION | DATE | AUTHOR/ UPDATED BY | COMMENTS |
|---|---|---|---|
| V0.1 | 28-JUN-2024 | Wei Zhou | First draft |
| V0.2 | 08-OCT-2024 | Wei Zhou | Second draft |
| V1.0 | 22-NOV-2024 | Wei Zhou | Final version |

# TABLE OF CONTENTS

# LIST OF TABLES

# ABBREVIATIONS

| Abbreviation | Term |
|---|---|
| AE | Adverse event |
| ATC | Anatomical therapeutic chemical |
| BMI | Body mass index |
| BOR | Best observed response |
| CI | Confidence interval |
| CR | Complete response |
| CRF | Case report form |
| CSR | Clinical study report |
| DOR | Duration of response |
| DCR | Disease control rate |
| ECG | Electrocardiogram |
| ECOG | Eastern Cooperative Oncology Group |
| EOS | End of study |
| EOT | End of treatment |
| GC | Gastric cancer |
| HNSCC | Head and neck squamous cell carcinoma |
| iBOR | Best observed response per iRECIST |
| iCPD | Confirmed progressive disease per iRECIST |
| iCR | Complete response per iRECIST |
| iDOR | Duration of response per iRECIST |
| IMP | Investigational medicinal product |
| IO | Immuno-Oncology |
| iORR | Objective response rate per iRECIST |
| IPD | Important protocol deviations |
| iPD | Progressive disease per iRECIST |
| iPFS | Progression-free survival per iRECIST |
| iPR | Partial response per iRECIST |
| iRECIST | Immune-related RECIST |
| iSD | Stable disease per iRECIST |
| iUPD | Unconfirmed progressive disease per iRECIST |
| max | Maximum |
| MedDRA | Medical Dictionary for Regulatory Activities |
| min | Minimum |
| NCI CTCAE | National Cancer Institute Common Terminology Criteria for Adverse Events |
| NE | Not evaluable |
| NSCLC | Non-small cell lung cancer |
| OC | Ovarian carcinoma |
| ORR | Objective response rate |
| OS | Overall survival |
| PD | Pharmacodynamics |
| PD | Progressive disease |

| Abbreviation | Term |
|---|---|
| PFS | Progression-free survival |
| PR | Partial response |
| PT | Preferred term |
| RECIST | Response Elevation Criteria in Solid Tumors |
| Q3W | Once every 3 weeks |
| SAE | Serious adverse event |
| SAS® | Statistical Analysis System® |
| SD | Stable disease |
| SD | Standard deviation |
| SOC | System organ class |
| TEAE | Treatment-emergent adverse event |
| TNBC | Triple negative breast cancer |
| WHO | World Health Organization |

# 1 INTRODUCTION

The purpose of this statistical analysis plan is to describe the procedures and the statistical methods that will be used to analyze the efficacy and safety data in accordance with Protocol TJ004309STM103 Version 3.0 dated 30 September 2021. The analysis results will be presented in an abbreviated clinical study report (CSR).

# 2 OBJECIVES AND ENDPOINTS

## 2.1 OBJECTIVES

### 2.1.1 Primary Objectives

- Part 1: To assess the efficacy of TJ004309 combined with atezolizumab in a cohort of patients with platinum-resistant IO naïve ovarian carcinoma and a separate biomarker enriched cohort of subjects with selected tumor types
- Part 2: To further evaluate and confirm the efficacy in targeted patient population based on the efficacy observed in Part 1

### 2.1.2 Secondary Objectives

- To evaluate the safety and tolerability of TJ004309 when combined with the standard dose of atezolizumab
- Part 1: To characterize the pharmacokinetic profile of TJ004309 when administered in combination with atezolizumab
- Part 1: To determine the immunogenicity of TJ004309 when administered in combination with atezolizumab

### 2.1.3 Exploratory Objectives

- To investigate the expression of PD-L1, CD73, and other immune subset markers (CD8, CD68, CD19 and CD163) in tumor biopsies at baseline and on treatment, and their associations with clinical responses
- To examine the CD73 enzymatic activity of tumor biopsies
- To study the whole genome gene expression profiles in tumor biopsies

## 2.2 ENDPOINTS

### 2.2.1 Primary Endpoints

- Efficacy within each tumor type: ORR by RECIST v1.1

### 2.2.2 Secondary Endpoints

- The safety and tolerability of TJ004309 when combined with the standard dose of atezolizumab

- ORR by iRECIST
- Duration of response (DOR) by RECIST v1.1 and iRECIST
- Disease control rate (DCR) by RECIST v1.1 and iRECIST
- Progression-free-survival (PFS) by RECIST v1.1 and iRECIST
- Overall survival (OS)
- Immunogenicity and pharmacokinetic profiles of the combination treatment

### 2.2.3 Exploratory Endpoints

- CD73 enzymatic activity of tumor biopsies at baseline and on-treatment tumor biopsies
- Expression of PD-L1, CD73 and other immune subset markers (CD8, CD68, CD19 and CD163)
- Whole genome gene expression profiles in tumor biopsies at baseline and on-treatment tumor biopsies

# 3 STUDY DESIGN

## 3.1 OVERALL STUDY DESIGN

This is a multicenter, open label, Phase 2 study of TJ004309 in combination with atezolizumab in patients with advanced or metastatic solid tumors. This clinical study will be conducted in two parts. Part 1 of the study will include two cohorts: Cohort 1 will include Immuno-Oncology (IO) treatment naïve ovarian cancer patients who have progressed on or after platinum therapy; and Cohort 2 will include patients with head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC), gastric cancer (GC), triple negative breast cancer (TNBC), or ovarian carcinoma with PD-L1 expression ≥ 1% (Table 1). All subjects will be evaluated for antitumor activity on a regular basis as specified in the protocol and their clinical status classified according to RECIST 1.1 and iRECIST. Treatments may continue until clinically significant disease progression, unacceptable toxicity, or subject/Investigator decision to withdraw. Based on the efficacy observation in Part 1, Part 2 of the study will further evaluate the efficacy in selected targeted patient populations and will be initiated after reaching agreement with the regulatory agency.

TJ004309 will be given in combination with atezolizumab 1200 mg every 3 weeks (Q3W) beginning with Cycle 1 Day 1 (C1D1). Premedication will be given prior to the initial infusion of TJ004309 to mitigate infusion related reactions. Each cycle will be 21 days in duration.

**Table 1: Study Drug Dosing Schedule - Part 1**

| Cohort | TJ004309 Q3W | Atezolizumab Q3W | Subjects |
|---|---|---|---|
| Cohort 1: Platinum resistant or refractory IO naïve ovarian carcinoma (OC) | 20 mg/kg | 1200 mg flat dose | N=30 |
| Cohort 2: HNSCC, NSCLC, GC, TNBC, OC | 20 mg/kg | 1200 mg flat dose | N=30 |

Up to 30 subjects will be enrolled in each cohort. If two or less responses are observed from the first 15 subjects in Cohort 1, the enrolment might be stopped based on rules from a Simon's 2-stage design. If 3 or more responses are observed from the first 15 subjects in Cohort 1 from Part 1, then Part 2 of the study may be initiated earlier. If any response is observed from Cohort 2, an additional cohort with up to 30 subjects may be opened with a specific tumor type after reviewing all other available data at that time.

### 3.2 END OF STUDY DEFINITION

A patient is considered to have completed the study treatment period if they complete the End-of-Study (EOS) visit and, as required, any further follow-up of ongoing serious adverse events (SAEs) regardless of relationship to study drug and/or non-serious adverse events (AEs) considered to be possibly, probably or definitely related to study drug until either resolution or determined by the Investigator to be chronic or stable.

### 3.3 SAFETY FOLLOW-UP PERIOD

After the treatment periods, all subjects will enter a safety follow-up period and will be evaluated for safety, tolerability, and tumor response (if applicable) for at least 90 days after the last dose of study drug, or 30 days following cessation of study treatment if the subject initiates new anticancer therapy, whichever is earlier. Subjects will be required to return to the study sites for three (3) safety follow-up visits (approximately 30, 60 and 90 days after the last dose of study drug), except those subjects who withdraw consent for study participation. After treatment discontinuation, in the event of continuing serious adverse events (SAEs), subjects will be followed until resolution or stabilization of the SAEs (regardless of the relationship to the IMP). Any subject who has an ongoing non-serious AE that is possibly related or related to the IMP or study procedures at the 90-day post-treatment Follow-up visit will be followed up, where possible, until resolution or until the unresolved non-serious AE is judged by the Investigator (or designee) to have stabilized. Any subject who has an ongoing non-serious AE that is not related or unlikely related to the IMP or study procedures at the Follow-up visit, can be closed out as ongoing at the Investigator's discretion. If a subject initiates a new anticancer therapy within 30 days after the last dose of study treatment, one (1) Post-Treatment Safety Follow-Up visit should occur approximately 30 days after the last dose of study drug and therefore subsequent follow-up visits will not be required.

### 3.4 RESPONSE/SURVIVAL FOLLOW-UP PERIOD

Subjects who do not experience progressive disease prior to treatment discontinuation will continue to have radiologic and clinical tumor assessments every 9 weeks for the first year and every 12 weeks during the second year until progression is confirmed, consent withdrawal, start of a new anti-cancer treatment, loss to follow-up, or death, whichever comes first. These subjects will also be followed by telephone every 12 weeks during the second year. The duration for response/survival follow-up is approximately 2 years from the first dose of study drug.

## 4 STATISTICAL CONSIDERATIONS

### 4.1 GENERAL CONSIDERATIONS

The below conventions will be used:

- Continuous variables will be summarized using descriptive statistics namely the sample size (n), mean, standard deviation (SD), median, minimum (min) and maximum (max). Mean and median will be rounded to one more decimal place than the original data (up to 3 decimals). Standard deviation will be rounded to two more decimal places than the original data. Minimum and maximum will have the same decimal place as the original data.

- Categorical variables will be summarized using counts and percentages with 2-sided 95% confidence intervals (CIs) where appropriate. Percentages will be rounded to 1 decimal place.

- As Part 2 of the study was not initiated due to an insufficient number of clinical responses observed in Part 1, summary tables and data listings will only be presented for Part 1. Summary tables will be presented by cohort and overall, and data listings will be presented by cohort and subject.

### 4.2 SAMPLE SIZE DETERMINATION

For Part 1 of the study, the sample size is not based on formal statistical considerations. Rather, it is based on a desire to obtain sufficient safety, tolerability, pharmacokinetic, pharmacodynamic, and preliminary efficacy information while exposing as few patients as possible to the investigational treatment. With up to 30 patients per cohort, Part 1 of the study provides an opportunity to further investigate the safety profile and explore tumor activities in a more selective patient population and helps to make decision for the Part 2 design.

### 4.3 BASELINE AND STUDY DAY DEFINITIONS

#### 4.3.1 Baseline Definition

Baseline is defined as the last non-missing measurement prior to the first dose of study drug. If multiple values are present for the same time point (same date if time is absent,

or same datetime), the average of the non-missing values will be used as the baseline. If there is no non-missing measurement prior to the first dose, the baseline value will not be imputed and will remain missing.

### 4.3.2 Study Day

Study day will be calculated to show the day of an event relative to the reference start date.

The reference start date (Day 1) is defined as the first dose day of the study treatment.

- Study day = (event date – reference start date +1) if the event date is on or after the reference start date
- Study day = (event date – reference start date) if the event date is prior to the reference start date

There is no study day 0. The study day will be missing when the event date is missing or incomplete.

## 4.4 ANALYSIS VISIT WINDOWS

Analysis visit windows will not be used for this study.

## 4.5 HANDLING OF MISSING AND INCOMPLETE DATA

Missing/incomplete data will not be imputed unless otherwise specified.

### 4.5.1 Dates Imputation Rules

Missing/incomplete start date of subsequent anti-tumor therapies (the earliest start date of subsequent systemic therapies, radiotherapies or surgeries/procedures) will be imputed as follows:

- If day is missing, use the date of the last dose of study drug + 1 day if it is in the same year and month as the available partial date; otherwise use day 1 of the month.
- If month and day are both missing, use the date of the last dose of study drug + 1 day if it is in the same year as the available partial date; otherwise use January 1$^{st}$.
- If the date is completely missing, use the date of the last dose of study drug + 1 day.

Missing/incomplete adverse event start dates will be imputed as follows:

- If day is missing, use the first dose date of the study treatment if it is in the same year and month as the available partial date; otherwise use day 1 of the month.

- If month and day are both missing, use the first dose date of the study treatment if it is in the same year as the available partial date; otherwise use January 1st of the year.
- If the date is completely missing, no imputation will be applied.

A missing/incomplete death date will be imputed as the complete last date known to be alive +1 day, day 1 of the month if only missing day or January 1st if missing day and month, whichever occurs last.

A missing/incomplete last alive date will be imputed to be the death date if a complete death date is available; otherwise the last alive date will be derived from the last available visit/assessment date.

### 4.6 ANALYSIS SOFTWARE

SAS® Enterprise Guide 8.2 will be used for data analysis and reporting.

# 5 PROTOCOL DEVIATIONS

Protocol deviations will be listed by subject for the safety analysis set.

# 6 STUDY SUBJECTS

The safety analysis set will be used for the summary tables and data listings in this section unless specified otherwise.

### 6.1 SUBJECT DISPOSITION

The number and percentage of enrolled subjects in each of the following categories will be summarized:

- Subjects enrolled
- Subjects who received any dose of treatment
- Subjects who did not receive any dose of treatment
- Subjects who discontinued treatment and reasons
- Subjects who completed the study
- Subjects who withdrew early from the study and reasons

Subject disposition information will be listed by subject for the safety analysis set.

### 6.2 ANALYSIS SETS

The following analysis sets are defined:

| Analysis set | Definition |
|---|---|
| Safety analysis set | All subjects who receive at least 1 dose of study drug |
| Efficacy evaluable analysis set | All subjects who receive at least 1 dose of study drug and undergo at least 1 post-baseline tumor assessment. Subjects who die before the first scheduled post-baseline tumor assessment will be included in this evaluable set. |

The number and percentage of enrolled subjects in each analysis set will be summarized.

### 6.3 DEMOGRAPHICS AND BASELINE CHARACTERISTICS

The following summaries will be presented:

- Demographics
    - Age (years) at enrollment
    - Sex
    - Childbearing potential for female: fertile/non-fertile. Reason if non-fertile.
    - Ethnicity
    - Race
- Baseline Characteristics
    - Height, weight and BMI
    - ECOG status

Demographics and baseline characteristics will be listed by subject.

### 6.4 PRIMARY TUMOR DIAGNOSIS

Primary tumor diagnosis will be listed by subject.

### 6.5 GENERAL MEDICAL HISTORY

Medical history events will be coded to system organ class (SOC) and preferred term (PT) using the Medical Dictionary for Regulatory Activities (MedDRA) version 25.1. The number and percentage of subjects who experienced at least one medical history event will be summarized by SOC and PT. A subject who had multiple medical history events in a SOC/PT category will only be counted once for that category.

### 6.6 PRIOR SYSTEMIC THERAPY

Prior systemic therapies will be listed by subject.

### 6.7 PRIOR RADIOTHERAPY

Prior radiotherapies will be listed by subject.

### 6.8 PRIOR SURGICAL/PROCEDURE THERAPY

Prior surgical/procedure therapies will be listed by subject.

### 6.9 PRIOR AND CONCOMITANT MEDICATIONS

All medications collected on the CRF page 'Prior and Concomitant Medications' will be coded to the anatomical therapeutic chemical (ATC) level 3 and preferred name using the WHO Drug Dictionary Global B3 format of September 2022 release. The number and percentage of subjects who had at least one prior or concomitant medication will be summarized by ATC level 3 and preferred name. A subject who had multiple prior or concomitant medications in an ATC level 3/preferred name category will only be counted once for that category.

### 6.10 PRIOR AND CONCOMITANT PROCEDURES

All procedures collected on the CRF page 'Prior and Concomitant Procedures' will be coded to SOC and PT using MedDRA version 25.1. The number and percentage of subjects who had at least one prior or concomitant procedures will be summarized by SOC and PT. A subject who had multiple prior or concomitant procedures in a SOC/PT category will only be counted once for that category.

### 6.11 SUBSEQUENT SYSTEMIC THERAPY

Subsequent systemic therapies will be listed by subject.

### 6.12 SUBSEQUENT RADIOTHERAPY

Subsequent radiotherapies will be listed by subject.

### 6.13 SUBSEQUENT SURGERY/PROCEDURE

Subsequent surgeries/procedures will be listed by subject.

## 7 STUDY DRUG EXPOSURE AND ADMINISTRATION

The safety analysis set will be used for the summary tables and data listings in this section.

A summary of study drug exposure will be presented for TJ004309 and atezolizumab, respectively, and will include:

- Treatment duration (months).

- Total cumulative dose (mg) infused, calculated as the sum of the actual doses infused.
- Number of treatment cycles initiated.

A treatment cycle is defined as a cycle in which the subject received any amount of study drug. Each cycle will be 21 days in duration. If a cycle is prolonged due to toxicity, it should still be counted as one cycle.

The treatment duration (months) for a subject on a study drug is calculated as [min(last dose date + 20, date of study completion (or discontinuation), date of death) - first dose date + 1]/30.4375.

A summary of infusion modifications for TJ004309 will be presented where the number and percentage of subjects are calculated for the following categories:

- Number of interrupted infusions (1, 2, >=3)
- Number of infusions where infusion rate was decreased (1, 2, >=3)
- Number of partial infusions (1, 2, >=3)

The study drug exposure and infusion modifications for each study drug will be listed by subject. The infusion administration information for each study drug per study visit will also be listed by subject.

# 8 EFFICACY ANALYSIS

The efficacy evaluable analysis set will be used for the efficacy summary.

The anti-tumor efficacy of the combination of TJ004309 and atezolizumab will be summarized by best of response (BOR) and objective response rate (ORR) assessed by the Response Evaluation Criteria in Solid Tumors (RECIST 1.1) and immune RECIST (iRECIST) guidelines. All tumor response data (including unscheduled tumor assessments) will be used in the efficacy analysis.

Efficacy endpoints such as duration of response (DOR), progression-free survival (PFS) and overall survival (OS) will not be reported due to the abbreviated nature of the CSR to be produced.

## 8.1 BEST OVERALL RESPONSE (BOR) AND OBJECTIVE RESPONSE RATE (ORR) PER RECIST V1.1

Responses to the study treatment are categorized per RECIST 1.1 as the following (from the best to the worst): complete response (CR), partial response (PR), stable disease (SD), progressive disease (PD) and not evaluable (NE).

Per RECIST 1.1, the best overall response (BOR) for a subject is the best response of CR, PR, SD, PD and NE observed from the first dose of study drug until PD or the end of

treatment, whichever occurs earlier. The objective response rate (ORR) is the proportion of subjects whose BOR is either CR or PR.

## 8.2 iBOR AND iORR PER iRECIST

iRECIST is based on RECIST 1.1 but adapted to account for the unique tumor response seen with immunotherapeutic drugs. iRECIST introduces new criteria of unconfirmed progressive disease (iUPD) and confirmed progressive disease (iCPD) to prevent the discontinuation of study treatment in cases of pseudoprogression. Immune responses assigned by the iRECIST criteria are (from the best to the worst): complete response (iCR), partial response (iPR), stable disease (iSD), unconfirmed progressive disease (iUPD), confirmed progressive disease (iCPD) and not evaluable (NE).

There is no distinct iRECIST assessment until radiographic disease progression based on RECIST 1.1. For participants who show evidence of radiological PD by RECIST 1.1 as determined by the Investigator, the Investigator will decide whether to continue a participant on study treatment until repeat tumor imaging is obtained for confirmation of PD by iRECIST.

Per iRECIST, the best overall response (iBOR) for a subject is the best response of iCR, iPR, iSD, iUPD, iCPD and NE observed from the first dose of study drug until iCPD or the end of treatment, whichever occurs earlier. The objective response rate (iORR) is the proportion of subjects whose iBOR is either iCR or iPR.

## 8.3 PRESENTATION

The efficacy summary will include the following:

- Number and percentage of subjects who died before the first response assessment
- Number and percentage of subjects who had at least one response assessment per RECIST 1.1
- Number and percentage of each response (i.e. CR, PR, SD, PD, NE) as the best overall response per RECIST 1.1
- Observed objective response rate (per RECIST 1.1) and the 95% Clopper-Pearson confidence interval
- Number and percentage of subjects who had at least one response assessment per iRECIST
- Number and percentage of each response (i.e. iCR, iPR, iSD, iUPD, iCPD, NE) as the best overall response per iRECIST
- Observed objective response rate (per iRECIST) and the 95% Clopper-Pearson confidence interval

# 9 SAFETY ANALYSIS

The safety analysis set will be used for data summaries and listings in this section.

## 9.1 ADVERSE EVENTS

Adverse events (AEs) will be coded to the system organ class (SOC) and preferred term (PT) using MedDRA version 25.1. Toxicity grading is based on the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.

All AE summaries will be limited to the treatment-emergent adverse events (TEAEs). A TEAE is defined as an AE that has an onset or a worsening in severity during or after the first dose of study drug and up to 30 days after the last dose of study drug, or one day prior to the subsequent anti-tumor therapy, whichever occurs earlier. An AE that has a change in severity will be recorded as two separate AEs on the CRF under the same SOC/PT of different severity levels. If an AE has a missing onset date, it will be considered as a TEAE in the below situations:

- An AE whose onset date and end date are both missing.
- An AE where the onset date is missing and the end date is after the first dose date of study drug
- An AE where the onset date is missing, the end date is on the first dose date of study drug, and the end time (hh:mm) is absent or after the initiation of the first dose of study drug.

An overall summary of TEAEs will be presented to include the number and percentage of subjects with at least 1 TEAE in the following categories:

- Any TEAE
- Serious TEAE
- TEAE of CTCAE grade >=3
- TEAE of maximum CTCAE Grade 3
- TEAE of maximum CTCAE Grade 4
- TEAE of maximum CTCAE Grade 5
- Infusion-related reaction
- TEAE related to any study drug
- TEAE related to TJ004309
- TEAE related to atezolizumab
- Serious TEAE related to any study drug
- Serious TEAE related to TJ004309

- Serious TEAE related to atezolizumab
- TEAE of CTCAE grade >=3 related to any study drug
- TEAE of CTCAE grade >=3 related to TJ004309
- TEAE of CTCAE grade >=3 related to atezolizumab
- TEAE leading to any study drug discontinuation
- TEAE leading to TJ004309 discontinuation
- TEAE leading to atezolizumab discontinuation
- TEAE leading to death

In addition, the number and percentage of subjects with at least one TEAE in the following categories will be summarized by SOC and PT (unless noted otherwise below) for each cohort and overall:

- Any TEAE (summarized by SOC, PT and maximum CTCAE grade)
- Serious TEAE
- TEAE of CTCAE grade >=3 (summarized by SOC, PT and maximum CTCAE grade)
- TEAE of CTCAE grade >=3 related to any study drug (summarized by SOC, PT and maximum CTCAE grade)
- TEAE of CTCAE grade >=3 related to TJ004309 (summarized by SOC, PT and maximum CTCAE grade)
- Infusion-related reactions
- TEAE related to any study drug
- TEAE related to TJ004309
- TEAE related to atezolizumab
- Serious TEAE related to any study drug
- Serious TEAE related to TJ004309
- Serious TEAE related to atezolizumab
- TEAE leading to any study drug discontinuation
- TEAE leading to TJ004309 discontinuation
- TEAE leading to atezolizumab discontinuation
- TEAE leading to death

SOC/PT categories in the TEAE summaries will be sorted in a frequency decreasing order for overall. A subject who had multiple TEAEs in a SOC/PT category will only be counted

once for that category. The causal relationship between the treatment and an AE will be assessed by the Investigator. For summary purposes, if relationship to the treatment is missing for a TEAE, it will be assumed to be related to the treatment; if the CTCAE grade is missing for a TEAE, it will be assumed to be grade 3; if a subject experienced multiple TEAEs in the same SOC/PT category, the maximum CTCAE grade and the strongest causal relationship to treatment among these TEAEs will be used.

All AEs collected on the CRF page 'Adverse Events' will be listed by subject.

### 9.2 DEATHS

Deaths during study and their primary causes will be listed.

### 9.3 CLINICAL LABORATORY PARAMETERS

Hematology, chemistry, coagulation, thyroid function testing, CA125 test, dipstick urinalysis and microscopic laboratory results will be listed by visit per subject.

### 9.4 VITAL SIGNS

Vital sign measurements (systolic/diastolic blood pressure, pulse rate, respiratory rate and body temperature) will be listed by visit per subject.

### 9.5 12-LEAD ELECTROCARDIOGRAM (ECG)

Investigator's overall interpretation of the 12-lead ECG result as normal or abnormal in each assessment will be listed per subject, along with whether the abnormality was clinically significant or not, and the abnormality details if clinically significant.

### 9.6 ECOG PERFORMANCE STATUS

ECOG performance status will be listed by visit per subject.

### 9.7 PHYSICAL EXAMINATION

Abnormal physical examination results will be listed per subject.

## 10 PHARMACOKINETIC/PHARMACODYNAMIC ANALYSES

Pharmacokinetic and pharmacodynamic analyses will not be performed.

## 11 IMMUNOGENICITY ANALYSIS

Immunogenicity analysis will not be performed.

## 12 EXPLORATORY BIOMARKER ANALYSIS

Exploratory biomarker analysis will not be performed.

# 13 REFERENCES

None.

# TJ004309STM103-SAP-V1.0

Final Audit Report 2025-01-06

| | |
|---|---|
| Created: | 2025-01-06 |
| By: | Wei Zhou (wei.zhou@clinchoice.com) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAE128UXdBlUo9eMi7hHaYm5srKE6Jrnc3 |

## "TJ004309STM103-SAP-V1.0" History

Document created by Wei Zhou (wei.zhou@clinchoice.com)
2025-01-06 - 2:33:38 PM GMT- IP address: 104.9.92.132

Document emailed to Wei Zhou (wei.zhou@clinchoice.com) for signature
2025-01-06 - 2:36:01 PM GMT

Wei Zhou (wei.zhou@clinchoice.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-01-06 - 2:37:01 PM GMT

Wei Zhou (wei.zhou@clinchoice.com) authenticated with Adobe Acrobat Sign.
Challenge: The user clicked on the signature field: 'Signature Field 1'.
2025-01-06 - 2:37:49 PM GMT

Document e-signed by Wei Zhou (wei.zhou@clinchoice.com)
Signing reason: I am the author
Signature Date: 2025-01-06 - 2:38:42 PM GMT - Time Source: server- IP address: 104.9.92.132

Document emailed to Susan Wu (susan.wu@clinchoice.com) for signature
2025-01-06 - 2:38:43 PM GMT

Email viewed by Susan Wu (susan.wu@clinchoice.com)
2025-01-06 - 2:40:07 PM GMT- IP address: 104.47.57.254

Susan Wu (susan.wu@clinchoice.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-01-06 - 2:40:59 PM GMT

Susan Wu (susan.wu@clinchoice.com) authenticated with Adobe Acrobat Sign.
Challenge: The user clicked on the signature field: 'Signature Field 2'.
2025-01-06 - 2:42:06 PM GMT

Document e-signed by Susan Wu (susan.wu@clinchoice.com)

Signing reason: I am the reviewer

Signature Date: 2025-01-06 - 2:42:25 PM GMT - Time Source: server- IP address: 136.49.210.14

Document emailed to claire.xu@imabbio.com for signature

2025-01-06 - 2:42:26 PM GMT

Email viewed by claire.xu@imabbio.com

2025-01-06 - 2:43:30 PM GMT- IP address: 52.102.7.37

claire.xu@imabbio.com authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2025-01-06 - 2:49:38 PM GMT

claire.xu@imabbio.com authenticated with Adobe Acrobat Sign.

Challenge: The user clicked on the signature field: 'Signature Field 3'.

2025-01-06 - 2:50:13 PM GMT

Signer claire.xu@imabbio.com entered name at signing as claire xu

2025-01-06 - 2:50:34 PM GMT- IP address: 71.163.180.19

Document e-signed by claire xu (claire.xu@imabbio.com)

Signing reason: I approve this document

Signature Date: 2025-01-06 - 2:50:36 PM GMT - Time Source: server- IP address: 71.163.180.19

Agreement completed.

2025-01-06 - 2:50:36 PM GMT