STATISTICAL ANALYSIS PLAN

Study Title:	**A Phase 2 Study of CTX-009 in Adult Patients with Metastatic Colorectal Cancer who have received Two or Three Prior Systemic Chemotherapy Regimens**
Name of Test Drug:	CTX-009
Study Number:	CTX-009-003
Protocol Version:	3.0
Protocol Date:	05JUL2023
Analysis Type:	Final
Analysis Plan Version:	2.0
Analysis Plan Date:	5-MAY-2025
Analysis Plan Author:	David Phillips, Catalyst Clinical Research

SPONSOR STATISTICAL ANALYSIS PLAN APPROVAL

I have read this statistical analysis plan and approve this analysis of this study:

Signed by:
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Signing Time: 07-May-2025 | 7:55:14 AM EDT
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07-May-2025

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07-May-2025

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Date

CONFIDENTIAL AND PROPRIETARY INFORMATION

REVISIONS HISTORY LOG

Changes to the approved SAP should be logged in this table.

Version	Revision Date**	Author of Revision*	Section(s) Modified	Description and/or Reason(s) for Revision
1.0	Original			
2.0	5-MAY-2025	David Phillips	2	Change: The number of days from Cycle 1 Day 1 (C1D1) until the date of objective PD (~~as assessed by an Independent Central Radiology (ICR) review and~~ defined by RECIST v1.1) or the date of death (by any cause in the absence of disease progression) or the date of censoring Reason: Remove reference to ICR review.
			6	Change: Overall disease response at each visit will be evaluated according to RECIST v1.1 by the Investigator ~~and Independent Central Radiology (ICR).~~ Reason: Remove reference to ICR review.
			6.1.1.1	Change: Overall response rate (ORR), the primary efficacy endpoint, is defined as the percentage of subjects whose best overall response (BOR) is assessed as complete response (CR) or partial response (PR) as assessed by ~~an ICR review~~ Investigator review per RECIST v1.1. • Disease progression as assessed by ~~ICR review~~ Investigator review prior to reaching a CR or PR Reason: Remove reference to ICR review and clarify that investigator review will be utilized.
			6.2	Change:

				To assess the efficacy of CTX-009, the secondary tumor response endpoints will be assessed by ~~ICR~~ Investigator review. Reason: Remove reference to ICR review and clarify that investigator review will be utilized.
			6.2.1.1	Change: Disease Control Rate (DCR) is defined as the percentage of subjects with BOR of CR, PR or SD as assessed by ~~ICR~~ Investigator review according to RECIST 1.1. • Experience disease progression as assessed by ~~ICR~~ Investigator review prior to reaching a CR, PR, or SD Reason: Remove reference to ICR review and clarify that investigator review will be utilized.
			6.2.2.1	Change: Duration of Response, DOR, is defined as the time from the date of the radiological evaluation of first confirmed CR or PR to the first documented date of progressive disease (as assessed by ~~ICR~~ Investigator review) or documented death. Reason: Remove reference to ICR review and clarify that investigator review will be utilized.
			6.2.3.1	Change: Progression Free Survival (PFS) is defined as the number of days from the date of first CTX-009 dose to the date of disease progression (as assessed by ~~ICR~~ Investigator review), documented death, whichever occurs first. Subjects without PD or death will be censored at the date of last evaluable disease assessment. See section 6.2.3.3 for censoring details. Reason: Remove reference to ICR review and clarify that investigator review will be utilized.

* Provide first initial and last name.
** Update the last revision dates on the cover page and the header.

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1. LIST OF ABBREVIATIONS

Abbreviation	Full Form
ADA	anti-drug antibodies
AE	adverse event
AESI	adverse event of special interest
ANC	absolute neutrophil count
AT	All Treated Population
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
BNP	brain natriuretic peptide
BOR	best overall response
C1D1	cycle 1 day 1
CI	confidence interval
CR	complete response
CRC	colorectal cancer
CT	computed tomography
CTCAE	Common Terminology Criteria for Adverse Events
DBL	database lock
DBP	diastolic blood pressure
DCR	disease control rate
DOR	duration of response
ECG	electrocardiography
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
EDC	Electronic Data Capture
EGFR	epidermal growth factor receptor
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
EOT	end of treatment
FDA	Food and Drug Administration
GCP	good clinical practice

Abbreviation	Full Form
GI	gastrointestinal
HER2	human epidermal growth factor receptor 2
ICF	informed consent form
ICH	International Conference on Harmonization
IV	intravenous
kg	kilograms
KM	Kaplan-Meier
LEC	local ethics committee
LOQ	lower limit of quantitation
MedDRA	Medical Dictionary for Regulatory Activities
min	minute
mL	milliliter
MRI	magnetic resonance imaging
NCI	National Cancer Institute
NE	not evaluable
ORR	overall response rate
OS	overall survival
PD	progressive disease
PE	physical exam
PFS	progression free survival
PPS	per protocol set
PR	partial response
PT	preferred term
QLQ-C30	Quality of Life Questionnaire. See EORTC QLQ
QoL	quality of life
QTcF	corrected QT interval by Fredericia
RBC	red blood cell
RE	Response-Evaluable population
RECIST	response evaluation criteria in solid tumors
RR	response rate
SAE	serious adverse event

Abbreviation	Full Form
SAP	statistical analysis plan
SBP	systolic blood pressure
scFv	single chain variable fragment
SCH	human stomach cancer (cell line)
SD	stable disease
SOC	system organ class
TEAE	treatment-emergent adverse event
TLF	tables listings figures
TRAE	treatment related adverse event
ULN	upper limit of normal
WBC	white blood cell
WCBP	women of childbearing potential
WHO	World Health Organization
5-FU	5-fluorouracil

2. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of Compass Therapeutics' Protocol V3.0 05-Jul 2023 CTX-009-003 [A Phase 2 Study of CTX-009 in Adult Patients with Metastatic Colorectal Cancer who have received Two or Three Prior Systemic Chemotherapy Regimens]. The purpose of this plan is to provide specific guidelines from which the statistical analyses will proceed. This statistical analysis plan (SAP) will be completed and approved prior to database lock or any planned data analysis. Any deviations from this plan will be documented in the clinical study report.

2.1. Study Objectives and Endpoints

Primary Objective	Primary Endpoints
To assess the efficacy of CTX-009 in patients with colorectal cancer (CRC) who have received two or three systemic therapies for advanced disease as measured by confirmed overall response rate (ORR)	Percentage of patients whose best overall response (BOR) is assessed as complete response (CR), or partial response (PR) as assessed by RECIST v1.1

Secondary Objectives	Secondary Endpoints
To assess the efficacy of CTX-009 in patients with CRC as measured by disease control rate (DCR)	Percentage of patients whose BOR is assessed as CR, PR, or stable disease (SD)
To assess the efficacy of CTX-009 in patients with CRC as measured by duration of response (DOR)	The number of days between the date of the radiological evaluation that first confirmed CR or PR and the date of the radiological evaluation that first confirmed progressive disease (PD) or the date of censoring
To assess the efficacy of CTX-009 in patients with CRC as measured by progression free survival (PFS)	The number of days from Cycle 1 Day 1 (C1D1) until the date of objective PD (defined by RECIST v1.1) or the date of death (by any cause in the absence of disease progression) or the date of censoring
To assess the efficacy of CTX-009 in patients with CRC as measured by overall survival (OS).	The number of days from C1D1 until death by any cause. Patients who are still alive at the time of the analysis, or who have become lost to follow-up or withdrawn consent will be censored at their last date known to be alive.

To evaluate the safety profile of CTX-009 including immunogenicity of CTX-009 in treated patients	Incidence of Treatment Emergent Adverse Events (TEAEs) and changes in clinical abnormalities for all patients who received at least one dose of CTX-009
To characterize the pharmacokinetics of CTX-009 and explore exposure response by sparse population PK sampling	Serum concentrations of CTX-009 at specified timepoints

Pharmacokinetic Objective	Pharmacokinetic Endpoint
To characterize the pharmacokinetics of CTX-009 and explore exposure response by sparse population PK sampling	Serum concentrations of CTX-009 at specified timepoints

2.2. Study Design

This study is designed as an open-label, adaptive Simon Two Stage study to evaluate the efficacy of CTX-009 in subjects with metastatic CRC.

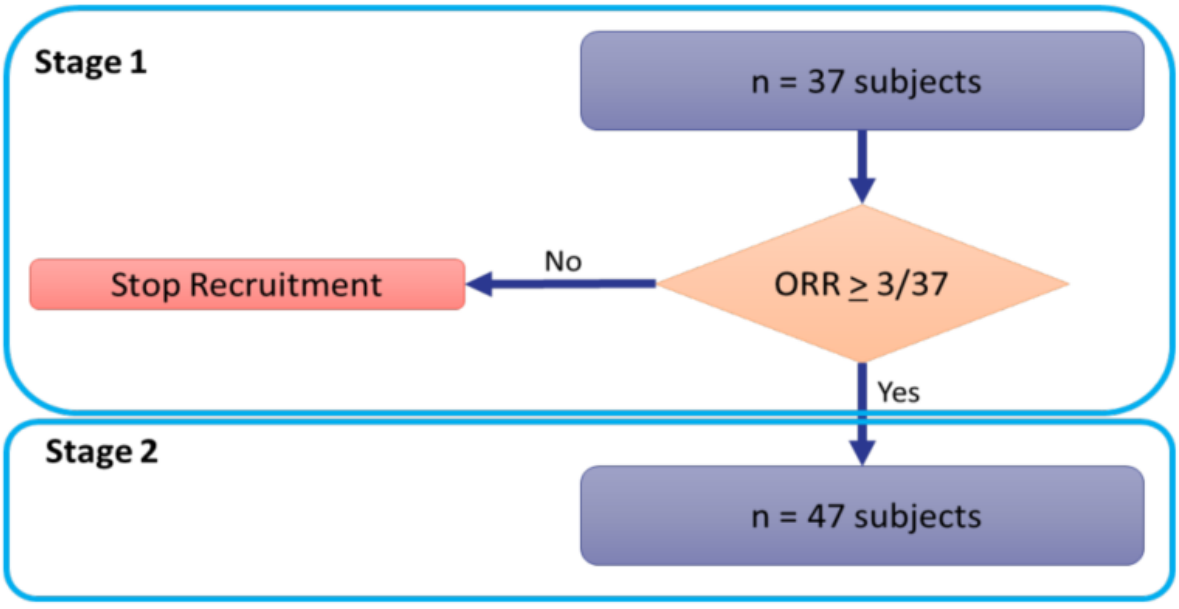
CTX-009 10 mg/kg is administered as an IV infusion once every 2 weeks in a 28-day cycle (2 infusions per cycle) until meeting treatment discontinuation criteria described in the study protocol. As described below, it is possible to reduce the dose of CTX-009 from the starting dose of 10 mg/kg by one step to 7.5 mg/kg. The dose may be reduced within the treatment cycle or at the start of the next treatment cycle. After a dose reduction, dose escalation is not permitted. A second dose reduction for recurrent toxicity is not permitted.

Table 1: CTX009 Dose Reduction

Drug	Initial Dose	Dose Reduction 1	Dose Reduction 2
CTX-009 Administer on D1 and D15 of each treatment cycle	10.0 mg/kg	7.5 mg/kg	Not Applicable

Approximately 37 response evaluable subjects will be enrolled in Stage 1. If the criteria are met to move to Stage 2, an additional 47 subjects will be enrolled.

The study will consist of a Screening Period (up to 14 days), a Treatment Period (continuous treatment until disease progression, unacceptable toxicity, death, or withdrawal of consent), and a Follow-up Period (estimated 18 months from the first dose of CTX-009). Subjects may continue on CTX-009 beyond disease progression if they are deriving clinical benefit. The study design is presented below.



It is estimated that the total study duration is approximately 18 months.

2.3. Sample Size and Power

A planned sample size of a minimum of 84 total subjects (37 evaluable subjects in Stage 1 and, if criteria are met, 47 additional in Stage 2) will have approximately 90% power on a two-sided alpha of 0.05 based on a Simon 2 Stage optimal design with a lower response rate bound of 5% and an upper bound of 15%.

3. TYPE OF PLANNED ANALYSIS

This analysis plan outlines planned analysis procedures for the final analysis which is planned to occur after database lock (DBL). All tables, figures, and listings (TFLs) described in this SAP are planned to be included in the final analysis.

Per protocol, Stage 1 results will be evaluated after approximately 37 response evaluable subjects are enrolled, and a decision made to halt recruitment or to continue enrolling up to another 47 subjects for a total of approximately 84 subjects minimum. All analyses described in this plan will occur at study completion.

4. GENERAL CONSIDERATIONS FOR DATA ANALYSES

4.1. Analysis Sets

4.1.1. All Treated (AT)

AT includes all subjects who received at least 1 dose of CTX-009. All efficacy data and safety data will be analyzed based on All Treatment unless otherwise specified.

4.1.2. Response-Evaluable (RE)

RE includes all subjects who received CTX-009 and had baseline and at least 1 post-baseline response assessment or discontinued treatment due to disease progression (including death caused by disease progression) within 8 weeks (± 5 days window) of the first dose of CTX-009. This analysis set, if differs from All Treated, will be used for the sensitivity analysis of selected efficacy endpoints, unless otherwise specified.

4.2. Missing Data

4.2.1. Efficacy Endpoints

Imputation missing data of other efficacy endpoints may be used and is described in relevant sections of this SAP.

4.2.2. Adverse Events and Concomitant Medications

Imputation of missing or partial dates for AEs and concomitant medications will be used to determine TEAEs and the prior/concomitant status of medication. More specifically, date imputation will only be used to ensure that AEs will be considered treatment-emergent, and medications will be considered concomitant in instances where it cannot be determined definitively that they are not. Imputed dates will never be used in listings unless otherwise indicated (dates will appear as collected) and will never be used to alter other fields collected in the EDC such as AE resolution status (this information will remain as collected). To handle missing or partial dates for AEs or concomitant medications, the following rules will be applied:

Start Dates:

1. If the day portion of the start date is missing, then the start date will be set equal to the date of first dose of study drug, provided the start month and year are the same as the first dose of study drug date and the stop date is either after the first dose of study drug or cannot be determined definitively to be prior to the first dose of study drug (e.g., end date is completely missing). Otherwise, the missing day portion will be assigned “01”.

2. If both the day and month of the start date are missing, then the start date will be set equal to the date of first dose of study drug provided the start year is the same as the first dose of study drug and the stop date is either after the first dose of study drug or cannot be determined definitively to be prior to the first dose of study drug (e.g., end date is

completely missing). Otherwise, the event will be assumed to start on the first day of the given year (e.g., ??-???-2023 will be imputed as 01-JAN-2023).

3. If the start date is completely missing and the stop date is either after the dose of study drug or cannot be determined definitively to be prior to the first dose of study drug (e.g., end date is completely missing), the start date will be estimated to be the day of study drug dosing. Otherwise, the start date will be estimated to be the first day of the same year as the stop date.

4.3. Data Handling Conventions and Transformations

The following conversion factors will be used to convert days into weeks, months, or years:

1 week = 7 days, 1 month = 30.4375 days, 1 year = 365.25 days.

Duration in days is calculated as End Date - Start Date +1.

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).

4.3.1. Conventions for Summaries and Subjects Listings

Unless otherwise stated, the following conventions will be followed in summaries and subject listings:

Categorical data will generally be summarized with counts and percentages of subjects in each category by overall. The denominator used for the percentage calculation will be clearly defined in the footnote if it is different from the number of subjects noted in the column header. Continuous data will generally be summarized with descriptive statistics including n (number of non-missing values), mean, standard deviation (SD), median, minimum (min), and maximum (max).

For reporting conventions, mean and median should generally be displayed to one more decimal place than the raw data and standard deviation should be displayed to two more decimal places than the raw data. Percentages will be reported to one decimal place.

Missing statistics, when they cannot be calculated due to the nature of the data, will be presented as 'NA', i.e., 'Not Applicable.' For example, for n=1, standard deviation (SD) cannot be computed and will be presented in the summary as 'NA.'

4.3.2. Definition of Baseline and Study Day 1

Unless otherwise noted, baseline is defined as the last non-missing value recorded prior to the first dose of CTX-009.

Study day will be defined relative to the date of first dose:

- Study Day 1 is defined as the day of first dose of CTX-009.
- If Date of Assessment/Visit >= Date of First Dose:

  Study Day = (Date of Assessment/Visit - Date of First Dose) + 1.
- If Date of Assessment/Visit < Date of First Dose:

  Study Day = (Date of Assessment/Visit - Date of First Dose).

The day of treatment start date will be Day 1, and the day immediately before Day 1 will be Day -1. There will be no Day 0, in alignment with international data standards for clinical trials. Unless specified otherwise, study day will be calculated only for complete dates. In subject listings, study day will generally be displayed only for complete dates even if date imputation is implemented.

5. PATIENT DISPOSITION

5.1. Disposition of Patients

A summary of patient disposition will be provided for all screened patients. This summary will present the number of patients screened and the number and percent of patients for the following disposition categories:

- Patients in each analysis set (AT, RE)
- Patients who discontinued CTX-009 with summary of reasons for CTX-009 discontinuation
- Patients who discontinued the study with summary of reasons for study discontinuation

The All-Treated set will be used as the basis for percentages, as appropriate. No inferential statistics will be generated.

Patient listings of the following will be generated:

- Patient disposition
- Informed consent and eligibility
- Subject visits
- Study population/response evaluability

5.2. Extent of Exposure

CTX-009 is administered via intravenous infusion. CTX-009 is administered 10 mg/kg biweekly, on Day 1 and Day 15 of every 28-day cycle. Dose reductions to 7.5 mg/kg biweekly can be administered due to specific AEs.

Exposure details including dates and times of infusions, total dose administered (mg), dose modification status, and reasons for dose modifications (if applicable), will be listed. All summaries will be displayed for the AT population. No inferential statistics will be provided.

Duration of exposure to CTX-009 will be defined as [(earliest date of (date of start date of last cycle +13 days), death date, end of study date) – date of first dose of CTX-009]/7, regardless of temporary interruptions in CTX-009 administration (recorded to one decimal place, e.g., 4.5 weeks). If a unit other than weeks is chosen for display, the formula will be adjusted accordingly.

Dose modification status will be summarized with counts and percentages of subjects in the following categories as well as overall, as reported on the study drug CRF:

- Dose decrease and reasons: adverse event versus other
- $\geq$ 1 dose delay and reasons: adverse event versus other

- ≥ 1 infusion interrupted and reasons: adverse event versus other
- ≥ 1 dose skipped and reasons: adverse event versus other
- ≥ 1 dose modification and reasons: adverse event
- Number of subjects with dose discontinued due to adverse event

The total number of infusions, cumulative dose, dose intensity, and relative dose intensity, will also be summarized using the definitions below.

- Cumulative dose (mg/kg) = Sum of all (total dose administered [mg] ÷ last available weight [kg], where the last available measurement of weight before each dose cycle is used) for all doing visits
- Weekly dose intensity (mg/kg/week) = (Cumulative dose) ÷ (Duration of treatment)
- Planned weekly dose intensity (mg/kg/week) = 2*10mg/kg/4 weeks = 5mg/kg/week
- Relative dose intensity (%) = (Weekly dose intensity) ÷ (Planned weekly dose intensity) * 100

Relative dose intensity will be summarized categorically for <70%, 70% to <90%, 90% to <110%, and >=110%.

Subject listings will be generated for CTX-009 administration as well as study drug exposure.

5.3. Protocol Deviations

Protocol deviations will be documented by Clinical Research personnel. A protocol deviation is defined as any change, divergence, or departure from the study design, or procedures defined in the protocol.

Protocol deviations are classified as major or minor. Major protocol deviations may significantly impact the completeness, accuracy, and/or reliability of key study data or significantly affect a subject's rights, safety, efficacy, or well-being.

Major protocol deviations may include but are not limited to the following:

- Patients who were enrolled into the study even though they did not meet eligibility criteria
- Patients who developed withdrawal criteria during the study but were not withdrawn
- Patients who received an incorrect dose of investigational product (NOTE: This is not always a major deviation and should be assessed by Compass and the Medical Monitor)
- Patients who received an excluded concomitant treatment during the study
- Patients who were not properly consented prior to undergoing a study specified procedure

- Failing to collect data necessary for interpretation of the study's primary endpoints

The Protocol Deviation Assessment Plan will contain more detailed or current information.

Counts and percentages of subjects with major protocol deviations by deviation category will be summarized for the AT analysis set. A listing of all protocol deviations will also be provided.

5.4. Demographics and Baseline Characteristics

The following demographic and baseline characteristics will be summarized with descriptive statistics or counts and percentages of subjects as appropriate for the AT population:

- Age derived at informed consent
- Age categories (<65 versus ≥65 years old)
- Sex (male, female)
    - For females, the percentage of those of child-bearing potential will also be presented
- Race (summarized as Asian, Black or African American, White, Unknown or Other)
- Ethnicity (summarized as Hispanic or Latino, Not Hispanic or Latino, or Unknown)
- Baseline Weight (kg)
- ECOG Performance status (0 vs. 1)
- Anatomic Subsite of Primary Tumor (summarized as Left- sided (Sigmoid Descending), Right sided (Cecum, Ascending) or Transverse or Rectum)
- KRAS status (summarized as Mutant or Wild type or unknown)
- MSI status (summarized as MSI-H or non- MSI-H (MSI-L or MSS))

Subject demographic and baseline characteristics will also be presented in by-subject listings for the AT population.

5.5. Medical and Disease History

Medical history terms will be coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.1 or higher.

Medical history will be summarized by system organ class (SOC) and preferred term (PT) for the AT population. Subjects will only be counted once at each level of summation.

Summaries will be sorted by decreasing total incidence by SOC and PT within each SOC; for ties in frequency, sorting will be performed alphabetically.

Disease history will be summarized for the AT population for the following categories:

- NRAS Mutation (wild type, mutant, unknown)
- BRAF Mutation (wild type, mutant, unknown)

Medical history, and disease history will also be presented in by-subject listings for the AT population.

5.6. Prior Cancer Therapy

An overall summary of the following prior cancer therapy categories will be summarized for all subjects for the AT analysis set. In the summary, the number and percentage of subjects that had the following will be presented:

- Any Prior Cancer Surgery (Yes/No)
- Any Prior Cancer Drug Therapy
- Prior Cancer Drug Therapy
    - First Line
    - Second Line
    - Third Line
    - Neoadjuvant
    - Adjuvant
    - Maintenance
    - Other
- Reason for Discontinuation of First Line Prior Cancer Drug Therapy
    - Disease Progression
    - Intolerability
    - Subject Decision
    - Unknown
    - Other

A subject listing of prior cancer surgery and prior radiation therapy will be generated for the AT population.

5.6.1. Prior Cancer Drug Therapy

Prior cancer drug therapy is coded to anatomical therapeutic chemical (ATC) classes, ATC1 to ATC4, and preferred name using the World Health Organization (WHO) Drug Dictionary Global

B3 September 2022. The WHO preferred name and ATC classes will be attached to the clinical database.

The number and percentage of subjects with prior exposure to the following cancer drug therapies will be summarized:

- Bevacizumab
- Fluoropyrimidine
- Oxaliplatin
- Irinotecan
- Cytotoxic Agents
- Pembrolizumab
- Anti-EGFR
- Anti-HER2
- Other

Prior cancer drug therapy will be summarized by ATC2 class and preferred name for the AT analysis set. At each level of summary (ATC2, preferred name), multiple drug use will be counted only once per subject.

Prior cancer therapy will be presented in subject listings for the AT population.

6. EFFICACY ANALYSIS

Tumor assessment data will be summarized for the AT population. The RE population will be used for sensitivity analyses for analysis of the primary endpoint of ORR.

Tumor assessments are performed during screening, every 8 weeks from cycle 1 day 1 until disease progression or the start of subsequent new anticancer therapy, including in subjects who discontinue treatment for reasons other than disease progression and any unscheduled visits at the Investigator's discretion.

Overall disease response at each visit will be evaluated according to RECIST v1.1 by the Investigator.

Overall disease response over time will be presented in a swimmer plot. The percentage change in target lesion sum of diameter and the maximum percent change in target lesion sum of diameter will be presented in a spider plot and waterfall plot, respectively.

All efficacy data will be listed in by-subject listings

6.1. Primary Efficacy Analysis

6.1.1. Overall Response Rate

6.1.1.1. Definition of Overall Response Rate

Overall response rate (ORR), the primary efficacy endpoint, is defined as the percentage of subjects whose best overall response (BOR) is assessed as complete response (CR) or partial response (PR) as assessed by Investigator review per RECIST v1.1.

For each subject, the BOR is the best response across all tumor assessments after the date of first dose of CTX-009 until documented disease progression or subsequent new anticancer therapy. For subjects who achieve a CR or PR, a follow-up response assessment occurring at least 4 weeks after the first CR/PR is required to confirm the response. The minimum duration for a BOR of SD is defined as at least 6 weeks after the first dose of CTX-009.

Tumor response assessments on or after the date of subjects receive post study treatment anti-cancer therapy will be excluded from the analysis.

Subjects will be considered non-responders for the primary endpoint of ORR according to one of the following:

- Have received post study treatment anti-cancer therapy prior to achieving CR or PR
- Death prior to reaching a CR or PR
- Disease progression as assessed by Investigator review prior to reaching a CR or PR

- Drop out for any reason prior to reaching a CR or PR

6.1.1.2. Analysis of Overall Response Rate

Confirmed and unconfirmed BOR will be summarized and tabulated based on response category [CR, PR, SD, PD, or not evaluable (NE)] by using counts and percentages for the AT population. The ORR and two-sided exact 95% CI will be provided.

6.1.1.3. Sensitivity Analysis of Overall Response Rate

An additional sensitivity analysis will be conducted to examine the robustness of the analysis of ORR in the AT population using the RE population with the same methodology as described for the primary analysis of ORR with the AT population.

6.2. Secondary Efficacy Analyses

To assess the efficacy of CTX-009, the secondary tumor response endpoints will be assessed by Investigator review.

6.2.1. Disease Control Rate

6.2.1.1. Definition of Disease Control Rate

Disease Control Rate (DCR) is defined as the percentage of subjects with BOR of CR, PR or SD as assessed by Investigator review according to RECIST 1.1. The minimum duration for a BOR of SD is defined as at least 6 weeks after the first dose of CTX-009.

Subjects will be considered non-responders for the secondary endpoint of DCR according to one of the following:

- Do not have sufficient baseline or on-study tumor status information is not adequate for response status assessment
- Have received post study treatment anti-cancer therapy prior to achieving CR, PR, or SD
- Do not have post baseline tumor assessment
- Experience death prior to reaching a CR, PR, or SD
- Experience disease progression as assessed by Investigator review prior to reaching a CR, PR, or SD
- Drop out for any reason prior to reaching a CR, PR, or SD

6.2.1.2. Analysis of Disease Control Rate

Confirmed and unconfirmed BOR will be summarized and tabulated based on response category [CR, PR, SD, PD, or not evaluable (NE)] using counts and percentages for the AT population. The DCR and two-sided exact 95% CI will be provided.

6.2.2. Duration of Response

6.2.2.1. Definition of Duration of Response

Duration of Response, DOR, is defined as the time from the date of the radiological evaluation of first confirmed CR or PR to the first documented date of progressive disease (as assessed by Investigator review) or documented death. Subjects without PD or death will be censored. DOR (in weeks) will be calculated as (First Date of PD or Death − First Date of CR or PR)/7. DOR will be calculated only for the subgroup of subjects with confirmed CR or PR. Censoring rules as stated in section 6.2.3.3 for PFS will apply for analysis of DOR.

6.2.2.2. Analysis of Duration of Response

The number and percentage of subjects experiencing an event and censored will be reported. The Kaplan-Meier method will be used to estimate the survival curve. The median, Q1, and Q3 survival times will be reported along with the corresponding two-sided 95% CI using Kaplan-Meier estimation. The two-sided 95% CIs will be generated using the Brookmeyer-Crowley method.

Estimates of the DOR curves obtained from the KM estimation will be presented and displayed graphically.

6.2.3. Progression Free Survival

6.2.3.1. Definition of Progression Free Survival

Progression Free Survival (PFS) is defined as the number of days from the date of first CTX-009 dose to the date of disease progression (as assessed by Investigator review), documented death, whichever occurs first. Subjects without PD or death will be censored at the date of last evaluable disease assessment. See section 6.2.3.3 for censoring details.

Time to PFS = [(Date of PD or Death) – Date of First CTX-009 Dose]

6.2.3.2. Analysis of Progression Free Survival

The number and percentage of subjects experiencing an event and censored will be reported. The Kaplan-Meier method will be used to estimate the survival curve. The median, Q1, and Q3 survival times will be reported along with the corresponding two-sided 95% CI using Kaplan-Meier estimation. The 95% CIs will be generated using the Brookmeyer and Crowley method.

Estimates of the PFS curve obtained from the KM estimation will be presented and displayed graphically.

6.2.3.3. Censoring Rules for Progression Free Survival

Scenario	**Outcome – Date of Event or Censoring**
Lack of adequate baseline tumor assessment and no death	Censored – date of last OS follow-up
Lack of post-baseline on-study tumor assessments and no death	Censored – date of last OS follow-up
Death but lack of post-baseline on-study tumor assessments or lack of adequate baseline tumor assessment	Event – date of death
End of study without documented PD, death, or start of subsequent new anti-cancer therapy	Censored – date of last OS follow-up
Started subsequent new anti-cancer therapy prior to PD or Death	Censored – date of start of subsequent anti-cancer therapy

6.2.4. Overall Survival

6.2.4.1. Definition of Overall Survival

Overall survival (OS) is defined as the number of days from the date of first CTX-009 dose to the date of documented death. Subjects without death will be censored at the last known date that the subject was alive.

Time to OS = (Date Death – Date of First CTX-009 Dose)

6.2.4.2. Analysis of Overall Survival

The number and percentage of subjects experiencing an event and censored will be reported. The Kaplan-Meier method will be used to estimate the survival curve. The median, Q1, and Q3 survival times will be reported along with the corresponding two-sided 95% CI using Kaplan-Meier estimation. The 95% CIs will be generated using the Brookmeyer and Crowley method.

Estimates of the OS curve obtained from the KM estimation will be presented and displayed graphically.

7. QUALITY OF LIFE ANALYSIS

Evaluation of QoL will be reported by subjects using the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (EORTC-QLQ-C30).

The EORTC QLQ-30 is a questionnaire developed to assess the general aspects of health-related quality of life of cancer subjects. It incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), a global health status/QoL scale, and a few single items assessing additional symptoms commonly reported by cancer subjects (dyspnea, loss of appetite, insomnia, constipation, and diarrhea), and financial impact of the disease.

QLQ-C30 will be transformed into a 1 – 100 scale using EORTC guidelines. A high score for a functional scale represents a high/healthy level of functioning whereas a high score for a symptom scale or item represents a high level of symptomatology or problems.

The scoring procedure for each of the scales is the same and consists of computing the raw score and then computing the actual scale score by making a linear transformation to standardize the score to values from 0 to 100 as shown below.

$$\text{Raw Score} = (I_1+I_2+\ldots+I_n) / n$$

For **Functional scales**:

$$\text{Score} = 100 \times [1 - (\text{Raw Score} - 1) / \text{Range}]$$

For **Symptom scales / items** and **Global health status / QoL**:

$$\text{Score} = 100 \times [(\text{Raw Score} - 1) / \text{Range})]$$

Where I_1, I_2, … I_n are the individual items and range is the difference between the maximum possible value of raw score and the minimum possible value.

The range of raw score equals the range of the item values. Most items are scored 1 to 4, giving range = 3. The exceptions are the items contributing to the Global Health Status / QoL, which are 7-point questions with range = 6. See Table 2 for scales, ranges, and associated item numbers.

Table 2 QLQ-C30 Score System

Scale/Single Item	Range	Item Numbers
Global Health Status / QoL		
Global Health Status / QoL	6	29,30
Functional Scales		
Physical Functioning	3	1,2,3,4,5
Role Functioning	3	6,7

Emotional Functioning	3	21,22,23,24
Cognitive Functioning	3	20,25
Social Functioning	3	26,27
Symptom Scales / Items		
Fatigue	3	10, 12, 18
Nausea and vomiting	3	14, 15
Pain	3	9, 19
Dyspnea	3	8
Insomnia	3	11
Appetite loss	3	13
Constipation	3	16
Diarrhea	3	17
Financial difficulties	3	28

Each scale score of the EORTC-QLQ-30 will be summarized using continuous statistics at each visit for the AT population. Change from baseline of each scale will be summarized at each visit similarly to actual scores. Mean scores over time will be plotted.

Any scales that have more than 50% of the items missing will have the scale score designated as missing for that subject. Missing items will not be imputed for raw scores.

EORTC-QLQ-30 will be presented in by-subject listings for the AT population.

8. SAFETY ANALYSIS

Safety data will be analyzed based on the AT population. No inferential statistics will be generated for safety summaries.

8.1. Adverse Events and Deaths

All AEs and serious adverse events (SAEs) occurring in subjects will be reported from the date of informed consent through 30 days after the last dose of CTX-009 or until the subject is determined to be a screen failure. AEs considered at least possibly related to CTX-009 should be followed until resolution, return to baseline, or deemed chronic or stable.

8.1.1. Adverse Event Coding and Dictionary

Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 25.1 or higher. System Organ Class (SOC), High Level Group Term, High Level Term, and Preferred Term (PT) will be attached to the clinical database.

8.1.2. Adverse Event Severity

Adverse events will be assessed for severity according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 or higher. Missing severity grade of events for which the investigator did not record severity will be categorized as "missing" for tabular summaries and data listings. Missing CTCAE grades will not be imputed and will be summarized and listed as-is.

8.1.3. Relationship of Adverse Events to Study Drug

Study treatment related (TR) AEs are defined as AEs whose relationship to CTX-009 is marked as definitely related, probably related, or possibly related. Missing relationship to any CTX-009 will be considered related to CTX-009 for summary purposes but data listings will show these relationships as "missing".

8.1.4. Serious Adverse Events

Serious adverse events are those identified in the clinical database as serious.

8.1.5. Treatment Emergent Adverse Events

A treatment emergent adverse event (TEAE) is defined as an AE that started or worsened in severity on or after the date CTX-009 was first administered to 30 days after the last dose of CTX-009. Since time of adverse event was not captured in the EDC, adverse events reported on the date of first CTX-009 administration will be considered TEAE unless indicated as pre-dose in the adverse events eCRF.

8.1.6. Summaries of Adverse Events and Deaths

An overview of AEs will be provided including counts and percentages of subjects for the following:

- Any TEAEs
- Any TRAE
- Any serious TEAE
- Any serious TRAE
- Any grade ≥ 3 TEAE
- Any grade ≥ 3 TRAE
- Any TEAE leading to treatment discontinuation
- Any TEAE leading to treatment modification/interruption
- Any TEAE leading to death
- Any Treatment-emergent Adverse Events of Special Interest (AESI)

Counts and percentages of subjects will also be presented by SOC and PT for the following summaries of TEAEs: TEAEs, TRAEs, serious TEAE, serious TRAEs, and Grade 3 or higher TEAEs. Summaries of TEAEs leading to treatment discontinuation, leading to modification or interruption, and leading to death will be generated by SOC and PT.

Summaries of TEAEs by SOC, PT, and maximum severity will be provided for the following categories: TEAEs, TRAEs, serious TEAEs, and serious TRAEs.

Summaries of AESIs will be presented by AESI category and PT for the following: treatment emergent AESIs and treatment related AESIs. AESIs are defined as the following:

- Gastrointestinal or tumor perforation
- Pulmonary hypertension
- Hemoptysis and bleeding
- Surgery and wound healing complication.

AESIs will be identified according to search criteria specified in Appendix 3 and confirmed as an AESI by Sponsor prior to database lock/freeze and release of treatment assignment.

The following summaries of TEAEs will be presented by PT using counts and percentages of subjects: TEAEs, grade 3 or higher TEAEs, TRAEs, and grade 3 or higher TRAEs.

Multiple occurrences of an event will be counted once only per subject in each summary. For summaries by severity grade, the most severe event will be selected. For data presentation, in summaries of AEs by SOC and PTs, AEs will be sorted by decreasing total frequency of SOC then PT within the SOC. Ties between SOCs and PTs within SOCs will be sorted alphabetically.

Subject listings of all TEAEs, serious TEAEs, TRAEs, TEAEs leading to discontinuation of CTX-009, TEAEs leading to modification/interruption of CTX-009, TEAEs leading to death, and AESIs will be provided.

8.1.7. Mapping of Adverse Event Coding

To facilitate ease of review of adverse events of similar coded terms, the following adverse event SOCs and PTs will be remapped according to Table 4 and 5 below.

Table 4: SOC and PT for Hematology Abnormalities Recorded as TEAEs

MEDDRA Coded Term	Converted MEDDRA Term
SOC	
Investigations	Blood and Lymphatic Systems Disorders
PT	
Hemoglobin decreased	Anemia (or Anaemia)
White blood cell count increased	Leukocytosis
White blood cell count decreased	Leukopenia
Lymphocyte count decreased	Lymphopenia
Neutrophil count decreased	Neutropenia
Platelet count decreased	Thrombocytopenia

Table 5: SOC and PT for Chemistry Abnormalities Recorded as TEAEs

MEDDRA Coded Term	Converted MEDDRA Term
SOC	
Investigations	Metabolism and Nutrition Disorders
PT	
Blood albumin decreased	Hypoalbuminaemia
Blood calcium increased	Hypercalcaemia
Blood calcium decreased	Hypocalcaemia
Blood glucose increased	Hyperglycaemia
Blood glucose decreased	Hypoglycaemia
Blood potassium increased	Hyperkalaemia
Blood potassium decreased	Hypokalaemia
Blood sodium increased	Hypernatraemia
Blood sodium decreased	Hyponatraemia
Blood phosphorus increased	Hyperphosphataemia
Blood phosphorus decreased	Hypophosphataemia
Blood uric acid increased	Hyperuricaemia

8.2. Clinical Laboratory Assessments

Summaries of laboratory data (hematology, chemistry, and urinalysis [only proteinuria]) will be provided for the AT population. All statistical analyses of laboratory values will be performed using International System units.

Subject listings of lab results for the AT population will be provided for each of the following laboratory categories: hematology, chemistry, coagulation, urinalysis, and serology.

8.2.1. Summaries of Numeric Laboratory Results

All continuous laboratory parameters will be summarized descriptively for value at baseline, value at each post-baseline analysis visit, and change from baseline at each post-baseline analysis visit.

Troponin sub-types will be excluded from continuous summaries due to diversity of assays used to assess concentration.

8.2.2. Graded Laboratory Values

Laboratory assessments will be classified according to the NCI-CTCAE criteria version 5.0 or higher. Laboratory values considered to be normal by CTCAE criteria, meaning they do not qualify as Grade 1 – 4, will be assigned a severity grade of 0. Some laboratory tests have criteria for both increase and decreased levels; analyses for each direction will be presented separately.

Shifts in grade from baseline to the worst post-baseline (including unscheduled visits) NCI-CTCAE grade will be summarized by number and percentage of subjects within each category. Summaries of shifts in NCI-CTCAE grade from baseline to worst post-baseline will be produced for hematology, chemistry, coagulation, and proteinuria from urinalysis.

8.2.3. Troponin Sub-types and Brain Natriuretic Peptide Shift from Baseline

A summary of the shift from baseline of Troponin sub-types (analyzed in aggregate) and Brain Natriuretic Peptide (BNP) levels by scheduled visit will be generated. Categories will be summarized according to respective assay ranges as low, normal, and high. The number and percentage of subjects within each category will be presented. The worst post-baseline shift using scheduled and unscheduled visits will be presented as well. Subjects reporting more than one Troponin sub-type concentration at a single visit will have the worst category used in the summary.

Spaghetti plots will be generated of troponin sub-types (analyzed in aggregate) and BNP as ratios of upper limit of normal (ULN) by study day. The ratio of upper limit of normal will be calculated as the reported assay concentration divided by the ULN reported by the respective assay. Subjects reporting more than one troponin sub-type concentration at a single visit will have the highest ratio of ULN used in the plots.

8.3. Body Weight and Vital Signs

Summaries of vital signs (systolic blood pressure, diastolic blood pressure, temperature, and heart rate) will be provided for the AT population.

Vital sign data will be summarized descriptively for value at baseline, value at each post-baseline analysis visit, and change from baseline at each post-baseline analysis visit.

A summary will be produced for potentially significant vital sign parameters. The number and percentage of subjects with at least one post-baseline potentially significant vital sign abnormality (in both directions, i.e., both elevated and below normal values) will be presented. Both the scheduled and unscheduled assessments will be used to identify potentially significant abnormalities.

The criteria for potentially significant abnormalities are defined as follows:

Potentially significant elevated values

- Systolic BP:
  - ≥ 150mmHg
- Diastolic BP:
  - ≥ 100 mmHg
- Body temperature:
  - ≥ 38°C
- Pulse rate:
  - >=100

Potentially significant below normal values

- Systolic BP:
  - ≤ 90 mmHg

Vital sign data will also be presented in by-subject listings.

8.4. 12-Lead Electrocardiogram (ECG)

Summarizes of ECG data will be provided for the AT population.

ECG data [heart rate, PR interval, QT interval, and corrected QT interval by Fredericia (QTcF)] will be summarized descriptively for value at baseline, value at each post-baseline analysis visit, and change from baseline at each post-baseline analysis visit.

A summary of potentially significant post-baseline findings will be produced using the number and percentages of subjects with at least one post-baseline potentially significant finding of each category. Both the scheduled and unscheduled assessments will be used to identify potentially significant findings. The thresholds are as described below:

- QTcF :> 450 msec, ≤ 450 msec
- PR interval
  - ≥ 200 msec
- QRS duration
  - ≥ 120 msec
  - ≤60 msec
- Heart Rate
  - ≥ 100 beats per minute (bpm)

8.5. Immunogenicity

A listing will be provided of all available immunogenicity data.

8.6. Eastern Cooperative Oncology Group Performance Status

ECOG performance status will be listed for completeness in a by-subject listing.

8.7. Physical Examination

Findings of physical examination will be listed in a by-subject listing.

8.8. Echocardiogram

Findings of echocardiogram will be listed in a by-subject listing.

8.9. Concomitant Medications and Procedures

8.9.1. Concomitant Medications

Medications will be coded to ATC classes, ATC1 to ACT4, and preferred name using the WHO Drug Dictionary Global B3 Sep2022. The WHO preferred name and ATC classes will be attached to the clinical database.

Concomitant medications are medications, other than study drugs, which started prior to first dose date of CTX-009 and continued after first dose as well as those started after first dose date. Prior medications are medications, other than study drugs, which started before first administration of CTX-009.

Concomitant medications will be summarized by ATC2 and preferred name for the AT population. A subject will be counted only once within a given drug class and within a given drug name, even if he/she received the same medication at different times. If any concomitant medication is classified into multiple ATC classes, the medication will be summarized separately under each of these ATC classes.

All prior and concomitant medications will be listed in a by-subject listing.

8.9.2. Concomitant Procedures

A subject listing of concomitant and post procedures will be generated.

9. PHARMACODYNAMIC/EXPLORATORY BIOMARKER ANALYSES

Pharmacodynamic analyses involving changes in peripheral blood monocyte subpopulations, serum cytokines, and tumor tissue cellular subpopulations and biomarker expression will be descriptive in nature. Summary tabulations may be produced if data from a sufficient number of subjects are collected. Additional details on the pharmacodynamic analyses will be provided in a separate analysis plan**.**

10. SOFTWARE

SAS Software Version 9.4. SAS Institute Inc., Cary, NC, USA.

11. APPENDICES

Appendix 1. Table of Contents for Statistical Tables, Figures, and Listings

A separate file will be maintained that identifies all tables, figures, and listings to be provided. This document will be updated as appropriate during the development of tables, figures, and listings.

Appendix 2. Adverse Events of Special Interest

Adverse Event of Special Interest	SMQ/PT	Term(s)
Gastrointestinal or tumor perforation	SMQ	Gastrointestinal perforation (narrow search)
	PT	Tumour perforation Tumour rupture
Pulmonary hypertension	SMQ	Pulmonary hypertension (narrow search)
Hemoptysis and bleeding	SMQ	Haemorrhage terms (excl laboratory terms)
Surgery and wound healing complication	PT	Impaired healing Incision site impaired healing Excessive granulation tissue

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Electronic Record and Signature Disclosure: Accepted: 4/2/2024 4:28:08 PM ID: 5ca3dafb-89d6-43dd-a4d1-17ab5ba451cd		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	5/6/2025 5:07:46 PM
Certified Delivered	Security Checked	5/7/2025 11:51:11 AM
Signing Complete	Security Checked	5/7/2025 11:51:41 AM
Completed	Security Checked	5/7/2025 11:51:41 AM

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