Statistical Analysis Plan

Title: A Phase 1, Randomized, Double-Blind, Single-Dose and Repeat Single Dose, Dose-Escalation Study to Determine the Safety, Tolerability, and Pharmacokinetics of CD388 Intramuscular or Subcutaneous Administration in Healthy Subjects

NCT Number: NCT05285137

Document Date: 20 DEC 2023

STATISTICAL ANALYSIS PLAN

For:

Cidara Therapeutics, Inc.

PROTOCOL No. CD388.IM.SQ.1.01

A Phase 1, Randomized, Double-Blind, Single-Dose and Repeat Single Dose, Dose-Escalation Study to Determine the Safety, Tolerability, and Pharmacokinetics of CD388 Intramuscular or Subcutaneous Administration in Healthy Subjects

Altasciences Project No. CID-P1-144

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Version: Final Amendment 3.0

Date: 2023-12-20

STATISTICAL ANALYSIS PLAN AND TFL SHELLS APPROVAL

We have carefully read this statistical analysis plan and the TFL shells appendix and agree it contains the necessary information required to handle the statistical analysis of study data.

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VERSION CONTROL

Version	Date	Author	Description of Changes
1.0	2022-06-08	Riddhi Thakkar/ Blake Scadden	Not applicable
1.1	2023-04-05	Riddhi Thakkar/ Blake Scadden	SAP is being updated due to the protocol amendment 2.0 (07-Feb-2023) which added a new cohort 4B for SQ route. All impacted sections are updated.
1.2	2023-07-12	Logan Kowallis	Added relative bioavailability model.
2.0	2023-07-31	Anita Shanker	Changes described in 1.1 & 1.2
3.0	2023-12-20	Haleh Aghamolaey	SAP is being amended to align the normal reference and PCS ranges with the lab used for the study and protocol parameters. The full complement of normal reference ranges is listed in APPENDIX D. This version also addresses administrative changes.

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ABBREVIATIONS

ADA	Anti-Drug Antibodies
AE	Adverse Event
ANOVA	Analysis of Variance
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
CI	Confidence Interval
CRF	Case Report Form
CRU	Clinical Research Unit
CSF	Cerebrospinal Fluid
CSR	Clinical Study Report
CV%	Coefficient of Variability
DAR	Drug-Antibody Ratio
DMP	Data Management Plan
DSMB	Data Safety Monitoring Board
DTS	Deviation Tracking System
ECG	Electrocardiogram
FIH	First-In-Human
EOS	End of Study
ET	Early Termination
GMR	Geometric Mean Ratio
ICF	Informed Consent Form
ICH	International conference on council for harmonisation
IM	Intramuscular
IP	Investigational Product
LN	Natural Log
LSMEAN	Least Squares Mean
MEDDRA	Medical Dictionary for Regulatory Activities
NCA	Non-Compartmental Analysis
NP	Nasopharyngeal
PCS	Potentially Clinically Significant
PK	Pharmacokinetic(s)
PT	Preferred Term
SAD	Single Ascending Dose
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
SOP	Standard Operating Procedure
SQ	Subcutaneous

TEAE	Treatment-emergent Adverse Event
TFLS	Tables, Figures, and Listings
WHO-DD	World Health Organization Drug Dictionary

1 INTRODUCTION

This statistical analysis plan (SAP) provides a detailed description of the statistical methods and procedures to be implemented for the analyses of data from Protocol No. CD388.IM.SQ.1.01.

Pre-planning of analyses reduces the potential for bias and often reduces disputes between sponsor and the regulatory authority regarding the validity of the results. The same principles apply to supportive and/or sensitivity analyses. These analyses must be prospectively specified. (Good Review Practice: Clinical Review of Investigational New Drug Applications, December 2013).

The analyses described in the SAP are based upon the final protocol version Amendment 2 dated 2023-02-07.

2 STUDY OBJECTIVES

The objectives of the study and corresponding study endpoints are detailed in Table 1.

Table 1: Objectives and Related Endpoints

Objective	Endpoint	Analysis
Primary		
• To determine the safety and tolerability profile of CD388 Injection when dosed either by intramuscular (IM) or subcutaneous (SQ) administration as a single dose to healthy adult subjects.	Incidence and severity of treatment-emergent adverse events (TEAEs), including but not limited to adverse events (AEs) and serious adverse events (SAEs) (including systemic reactogenicity/ injection site reactions and hypersensitivity reactions), AEs leading to study drug discontinuation and/or study withdrawal, vital signs, 12-lead electrocardiograms (ECGs), and clinical laboratory tests (including hematology, coagulation, serum chemistry, and urinalysis), after a single dose of CD388.	Refer to Section 8
Secondary		
• To determine the plasma pharmacokinetic (PK) profile of CD388 Injection when dosed either by IM or SQ administration following a single dose and a repeated single dose to healthy adult subjects.	• Pharmacokinetic parameters following CD388 Injection administration: maximum plasma concentration (C_{max}), time to maximum plasma concentration (T_{max}), terminal elimination half-life ($t_{½}$), apparent clearance (CL/F), apparent volume of distribution (V_Z/F), area under the plasma concentration-time curve from time 0 to time of last quantifiable sample (AUC_{0-t}), area under the plasma concentration-time curve from time 0 extrapolated to infinity ($AUC_{0-\infty}$).	Refer to Section 7

Objective	Endpoint	Analysis
• To determine the safety and tolerability profile of CD388 Injection when dosed either by IM or SQ administration as a repeated single dose (after washout of 3 months or 5 effective half-lives from the first dose; whichever is longer) to healthy adult subjects.	• Incidence and severity of TEAEs, including but not limited to AEs and SAEs (including systemic reactogenicity/injection site reactions and hypersensitivity reactions), AEs leading to study drug discontinuation and/or study withdrawal, vital signs, ECGs, and clinical laboratory tests (including hematology, coagulation, serum chemistry, and urinalysis), after a repeated single dose of CD388.	Refer to Section 8
Exploratory		
• To determine the PK profile of CD388 Injection in upper respiratory tract after IM or SQ administration as a single dose to healthy adult subjects.	• Pharmacokinetic parameters following CD388 Injection administration: maximum nasopharyngeal (NP) concentration (C_{max}), time to maximum NP concentration (T_{max}), area under the NP concentration-time curve from time 0 to time of last quantifiable sample (AUC_{0-t}).	Refer to Section 7
• To identify CD388 metabolites in plasma, CD388 and its metabolites in urine, and CD388 drug-antibody ratio (DAR) distribution in plasma, and CD388 glycoforms in serum after IM or SQ administration to healthy adult subjects.	• CD388 metabolites (e.g., free zanamivir, zanamivir dimers) in plasma and urine, CD388 in urine and nasal wash, CD388 DAR distribution in plasma, and CD388 glycoforms in serum, to be reported separately.	Refer to Section 7
• To evaluate biomarkers that may be associated with AEs after CD388 Injection.	• Results of the analyses of exploratory biomarkers (including but not limited to cytokines, chemokines, acute phase reactants, etc.).	Refer to Section 9
• To evaluate CD388 immunogenicity.	• Anti-drug antibody titers in blood (plasma or serum).	Refer to Section 9
• To explore pharmacogenomics related to CD388.	• Results of the analyses of pharmacogenomic samples, to be reported separately.	Refer to Section 9

Objective	Endpoint	Analysis
• To explore the effects on cardiac safety in subjects administered CD388 Injection.	• 12-lead ECG and Holter monitoring parameters.	Refer to Section 8
• To explore the effect of CD388 injection on the occurrence of influenza-like illness (during flu season).	• Influenza-like illness reporting during the outpatient follow-up period.	Refer to Section 8

3 STUDY DESIGN

3.1 General Description

This is a first-in-human (FIH), Phase 1, single-center, prospective, randomized, double-blind study of ascending single doses of CD388 Injection administered IM or SQ to healthy adult subjects followed by another single dose of CD388 Injection administered by the same route 3 months or 5 effective half-lives, whichever is longer, after the first dose in the middle and high dose groups (dosing may be adjusted for tolerability). The goals are to assess safety, tolerability, immunogenicity (anti-drug antibodies [ADA]), and PK of CD388.

Dose levels of CD388 to be assessed will follow an ascending single dose design with the starting dose based on findings from 3-month rat and monkey toxicology studies. Within each route (IM and SQ dose, route assignment is unblinded), subjects will be randomized to receive a single dose of CD388 Injection or saline placebo (treatment assignment is blinded) according to the design. It should be noted that each cohort will be divided into 2 groups identified as "sentinel" groups (randomized 1:1) and "main" groups (randomized 7:2):

- Low dose level: Cohort 1A (IM) and Cohort 1B (SQ) – each route n = 2 sentinel and n = 9 main
- Mid dose level: Cohort 2A (IM) and Cohort 2B (SQ) – each route n = 2 sentinel and n = 9 main
- High dose level: Cohort 3A (IM) and Cohort 3B (SQ) – each route n = 2 sentinel and n = 9 main
- Highest dose level: Cohort 4B (SQ) – n = 2 sentinel and n = 9 main

For each route, the sentinel or first group of 2 subjects (1 CD388: 1 placebo) at a dose level will be administered blinded study drug and closely monitored for safety for at least 1 week. If no drug-related SAEs or drug-related Grade ≥3 AEs have occurred, the subjects in the corresponding main group may be dosed within 24 hours. The observation duration may be adjusted for the sentinel groups in Cohorts 2A, 2B, 3A, 3B, and 4B based on data from previous cohorts.

Subjects in Cohort 4B will receive a single dose of CD388 or placebo. Subjects in Cohorts 2A and 2B and Cohorts 3A and 3B will receive a second single dose of CD388 Injection or placebo after washout of 3 months or 5 effective half-lives, whichever is longer, after the first dose if it is determined that the safety and tolerability of the first dose is acceptable upon review of the cumulative safety data. Immediately prior to the second single dose, within each dose and route, any dropouts in the sentinel groups will be randomly replaced with subjects from the main groups, retaining their original treatment assignment (i.e., subjects assigned to placebo will remain placebo, and subjects assigned to CD388 will remain CD388; this may require unblinded personnel to oversee).

All subjects will be admitted to the clinical research unit (CRU) for observation and safety assessments from Day -1 (check-in) to Day 30.

Table 2: Study Cohorts

	Number of Subjects (N = 77)					
	Intramuscular (IM)			Subcutaneous (SQ)		
Dose (mg)	Cohort	CD388 (n = 24)	Placebo (n = 9)	Cohort	CD388 (n = 32)	Placebo (n = 12)
50	Cohort 1A (sentinel)	1	1	Cohort 1B (sentinel)	1	1
50	Cohort 1A (main)	7	2	Cohort 1B (main)	7	2
150	Cohort 2A (sentinel)	1	1	Cohort 2B (sentinel)	1	1

150	Cohort 2A (main)	7	2	Cohort 2B (main)	7	2
450	Cohort 3A (sentinel)	1	1	Cohort 3B (sentinel)	1	1
450	Cohort 3A (main)	7	2	Cohort 3B (main)	7	2
900	NA	NA	NA	Cohort 4B (sentinel)	1	1
900	NA	NA	NA	Cohort 4B (main)	7	2

NA= Not Applicable

Note: Immediately prior to the second single dose, within each dose and route, any dropouts in the sentinel groups will be randomly replaced with subjects from the main groups, retaining their original treatment assignment (i.e., subjects assigned to placebo will remain placebo, and subjects assigned to CD388 will remain CD388).

3.2 Investigational Product

The investigational product (IP) CD388 will be provided by the Sponsor. The placebo, normal saline, will be sourced by the site.

3.3 Study Procedures

For complete details on the study assessments to be performed for each study period, refer to APPENDIX A for Cohort 1A to 3B and APPENDIX B for Cohort 2A to 3B.

3.4 Randomization and Unblinding Procedures

After informed consent has been obtained, subjects will be screened for study eligibility before randomization.

Within each route (IM and SQ dose, route assignment is unblinded), subjects will be randomized to receive a single dose of CD388 Injection or saline placebo (study drug assignment is blinded). The study site's pharmacist (or pharmacist designee) will obtain the study drug assignment by a manual paper transaction. A subject is considered randomized when the randomization transaction is recorded in the subject's source documents.

All study personnel (including the Sponsor, Investigator, and site personnel directly involved in study conduct) and subjects will remain blinded to study drug assignment until the study is completed and the final database is locked with the exception of the pharmacy personnel, pharmacy monitor, and unblinded Sponsor personnel (such as Data Review Committee, clinical supply manager, bioanalytical, PK lead, and quality manager) who may be unblinded to study medication at any time during study conduct. The pharmacy monitor will monitor study drug preparation and accountability during the study and cases in which unblinding is required due to a safety or tolerability issue. To maintain study blinding, study drug preparation will be performed by an unblinded site pharmacist (or qualified unblinded personnel at the study site not involved with study procedures or evaluations).

4 ANALYSIS POPULATIONS

The following populations will be defined:

- **Enrolled Population:** All subjects who provide informed consent and are randomized.
- **Safety Population**: The safety population will include all randomized subjects who receive any amount of study drug.
- **Pharmacokinetic Population:** The PK population will include all randomized subjects who have received at least a portion of 1 dose of CD388 and have at least 1 evaluable postdose concentration value. Subjects administered matching placebo will not be included in the PK population.

  Pharmacokinetic Completer Population: [Dose Groups 2A, 2B, 3A, and 3B only] The PK population will include all randomized subjects who have received 2 single doses of CD388 and obtained PK samples at all visits.

5 STUDY SUBJECTS

Disposition data, analysis population information and protocol deviations will be summarized by injection route (IM or SQ), CD388 dose, and pooled placebo and listed by injection route (IM or SQ), CD388 dose and placebo as described in Table 3.

Table 3: Data Presentations for Study Subject Information

Data	Variables	Presentation
Disposition and analysis populations	Subject, completion status (i.e., completed or withdrawn from the study), reason for withdrawal from the study, analysis population determination	Listings: • Disposition, • Randomization, • Analysis populations Summary table including: • N of subjects randomized, • N and % of subjects who completed the study, • N and % of subjects discontinued from the study by primary reason for discontinuation • N and % of subjects discontinued from the treatment by primary reason for discontinuation N and % of subjects included in each of the analysis populations.
Protocol deviations	Protocol deviations	Listings: • Protocol deviations, • Pharmacokinetic (PK) sample collection time deviations Summary table: • N and % of subjects with any major deviation

5.1 Disposition

Subject disposition will be summarized for all subjects screened and randomized.

The percentages will be calculated using the number of subjects in each cohort and study drug group as the denominator.

5.2 Protocol Deviations

Deviations identified at the site will be collected in the clinic deviation tracking system (DTS) and presented in a protocol deviation listing. Protocol deviations will be listed for the safety population. The number and percentage of subjects with any major deviation will be presented.

For PK sampling time deviations, information will be derived programmatically and presented in a separate listing.

6 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Unless otherwise specified, all available data will be listed for the safety population as detailed in Table 4. Summary tables for demographics and other baseline characteristics by injection route (IM or SQ), CD388 dose, and pooled placebo will be presented for safety and PK populations.

Table 4: Data Presentations for Demographic and Other Baseline Characteristics

Data	Variables	Presentation
Demographic and other baseline characteristics	Sex, age, ethnicity, race, height (cm), weight (kg) and body mass index (BMI, kg/m2)	Listing and summary tables
Medical history	All medical history findings	Listing Note: includes coded terms (system organ class [SOC] and preferred term [PT])
Prior medications	All medications taken 30 days prior to study drug administration and concomitant medications (including vaccines, prescription medications, nonprescription medications, dietary supplements, vitamins, or herbal medications)	Listing Note: includes coded terms (anatomic therapeutic chemical [ATC] level 4 and preferred name)

Demography and baseline characteristics will be summarized using descriptive statistics.

The medical history at screening will include all queries by the medical and clinical staff related to the subject's well-being and history of relevant past medical events/experiences. Medical history will be coded to Medical Dictionary of Regulatory Activities (MedDRA) terms version 24.1 and listed by subject.

Prior medication will be coded using the World Health Organization Drug Dictionary Global B3 Sept 1, 2021, and will be listed by subject.

7 PHARMACOKINETIC ANALYSIS

The PK analysis will be carried out according to Altasciences Standard Operating Procedures (SOPs).

7.1 Missing Values

Except for predose samples (prior to the first administration), the lack of concentration values due to failure to collect the sample, a lost or compromised sample, or due to the subject's early termination from the study will be considered missing in the dataset, and no imputation will be done. Predose samples, prior to the first administration, will be imputed with zero.

If the actual collection time of a postdose PK sample is unknown, but a valid concentration value has been measured, the sample will be set to missing in the PK analysis and will be excluded from descriptive statistics but will be presented in listings.

Subjects who do not complete the sampling schedule may be included in the PK analysis for only the PK parameters that are judged not to be affected by the missing sample(s).

7.2 Measurements Below the Lower Limit of Quantitation

Concentration values below the LLOQ associated with predose and postdose collection times up to the first quantifiable sample will be assigned a value of zero, and with postdose collection times after first quantifiable sample will be replaced with missing for the non-compartmental analyses (NCA), mean PK profile representations as well as for descriptive statistic calculations. Descriptive statistics will not be determined for time points with more than 1/3rd of samples missing.

7.3 Actual Time

The NCA will be based on the actual sampling times, except for the pre-first dose predose samples, which will always be reported as zero, regardless of time deviations, provided that they were collected prior to dosing. Available time points before second dose and after first dose may be used as predose time points in some analyses.

The individual concentration/time profiles will be presented using actual sampling times whereas the mean concentration/time profiles and tables presenting summary statistics of concentration time series will be presented using nominal sampling times.

Actual times will be listed in the report.

7.4 Non-Compartmental Analysis

The following configuration for the NCA of CD388 in plasma or nasopharyngeal concentrations (with Phoenix® WinNonlin® version 8 or higher) will be used:

- Data: Serial sampled data
- Model/Dose options Type: Plasma (200 -202) / Extravascular
- AUC Calculation Method: Linear Up/Log Down
- Lambda Z (λ_z) calculation: Best fit method for λ_z Linear-Log regression

Reasons for excluding PK parameters will include the following:

- AUC: AUC parameters will not be estimated if less than 3 consecutive measurable concentrations are observed.

PK parameters requiring λ_z estimation (e.g., and $t_{1/2}$) will be set to Not Reported (NR) in the Tables and Listings if they meet the following:

- $R^2 < 0.8$

The PK parameters for CD388 are presented in Table 5.

Table 5: Pharmacokinetic Parameters of CD388 in Plasma

PK Parameter	Definition
Plasma Concentrations	
C_{max}	Maximum observed concentration
t_{max}	Time of maximum observed concentration; if it occurs at more than one time point, T_{max} is defined as the first time point with this value
AUC_{0-t}	Area under the concentration time curve from time 0 (dose administration) to the time of last quantifiable concentration (t_{last})
$AUC_{0-\infty}$	Area under the concentration time curve extrapolated to infinity, calculated as $AUC_{0-t} + C_{LQC}/\lambda_Z$, where C_{LQC} is the measured concentration at time t_{last} and λ_Z is the apparent elimination rate constant, estimated by linear regression of the terminal linear portion of the log concentration *versus* time curve
$t_{1/2}$	Terminal elimination half-life, calculated as $\ln(2)/\lambda_Z$
CL/F	Apparent total clearance, calculated as $Dose/AUC_{0-\infty}$
V_z/F	Apparent volume of distribution, calculated as $Dose/\lambda_Z * AUC_{0-\infty}$
Nasopharyngeal Concentrations	
C_{max}	Maximum observed concentration
t_{max}	Time of maximum observed concentration
AUC_{0-t}	Area under the concentration time curve from time 0 (dose administration) to the time of last quantifiable concentration (t_{last})
Plasma Concentrations The following plasma PK parameters will be used for PK calculation and presented in the listings only	
$AUC_{\%ext}$	Extrapolated area (i.e. percentage of $AUC_{0-\infty}$ due to extrapolation from t_{last} to infinity)
R^2	Goodness of fit statistic for the terminal elimination phase
Number of Points	Number of data points in computing λ_Z
$\lambda_{z\ Lower}$	Lower limit on time for values included in the calculation of λ_z
$\lambda_{z\ Upper}$	Upper limit on time for values included in the calculation of λ_z
λ_z	Apparent elimination rate constant, estimated by linear regression of the terminal linear portion of the log concentration *versus* time curve
t_{last}	Time of last measurable observed concentration

7.5 Statistical Methodology

All tables, figures, and listings (TFLs), when appropriate, will be summarized by cohort and by injection route.

7.5.1 Summary Statistics

Summary statistics of the individual concentration data and derived parameters will be calculated for the PK population at each nominal time point and for all PK parameters. Concentration data will be summarized by group using the following statistics: number of observations (N), arithmetic mean (mean), standard deviation (SD), minimum (min), median, maximum (max), and coefficient of variation (CV%). PK parameters will be summarized using these same statistics, as well as geometric mean and geometric mean CV%.

7.5.2 Statistical Analysis

The natural logarithmic transformation of C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$ will be used for all statistical inference. Individual ratios of untransformed parameter values will also be presented as part of the descriptive analysis.

Pharmacokinetic parameters (C_{max}, AUC_{0-t}, and $AUC_{0-\infty)}$ will be statistically analyzed using an Analysis of Variance (ANOVA) model by dose level. The fixed factors included in this model will be injection route (IM to SQ). The 90% confidence interval (CI) for the exponential of the difference in least squares means (LSmeans) between each comparison of interest (IM to SQ) will be calculated.

Pharmacokinetic parameters (C_{max}, AUC_{0-t}, and $AUC_{0-\infty)}$ will be statistically analyzed using an Analysis of Variance (ANOVA) model to assess relative bioavailability. Dose is the fixed factor. The 90% CI for the differences in LSmeans for each pairing of doses will be calculated and used to assess relative bioavailability. Injection route (IM and SQ) will be assessed in two separate models.

Pharmacokinetic parameters (C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$) for IM and SQ cohorts will also be assessed statistically for dose proportionality, using a power model:

$\ln(\text{PK parameter}) = \alpha + \beta \bullet \ln(\text{Dose}) + \varepsilon$

where α is the intercept, β is the slope and ε is the error term.

A point estimate and corresponding 90% CI will be derived for the slope (β).

T_{max} will be analyzed descriptively.

8 SAFETY ANALYSIS

Unless otherwise specified, all available data will be listed and summary tables for safety assessments will be presented by injection route (IM or SQ), CD388 dose, and pooled placebo for the safety population as detailed in Table 6.

Continuous variables will be summarized (absolute values and change from baseline) using descriptive statistics. The TEAEs occurring after the first single dose and after the second single dose will be analyzed separately.

Table 6: Data Presentations for Safety Assessment

Data	Variables	Presentation
Adverse events	Adverse event, description, date and time, severity, relationship to study drug, action taken with study drug, whether the AE caused the subject to discontinue from the study, study days, and outcome, Duration of AE, Date and time of onset, date, and time of resolution.	Listings: • Reported AEs, • Serious Adverse Event (SAE) Summary Tables, including number and percentage of subjects experiencing: • Treatment-emergent adverse events (TEAEs), • TEAEs related to study drug • TEAEs by severity, • Serious TEAEs, • Influenza-like TEAEs (reported during the outpatient follow-up period), • Adverse Events of Special Interest (AESIs), • TEAEs leading to study withdrawal • TEAEs leading to study drug withdrawal (cohorts 2a, 2b, 3a, 3b) • Overall summary will include: o At Least One TEAE o At Least One Drug-Related TEAE o Maximum Severity: ➢ Mild, ➢ Moderate ➢ Severe ➢ Life-threatening ➢ Death o At Least One SAE o At Least One Drug-Related SAE o Death o AE leading to study drug withdrawal (Pooling placebo from cohorts 2a, 2b, 3a, 3b) o AE leading to study withdrawal
Concomitant medications	All medications taken during the study (as defined in the protocol and including prior medications that are continued), dose, units, route, indication/ reason taken, and date and time.	Listing • Note: includes coded terms (anatomic therapeutic chemical [ATC] level 4 and preferred name)

<table>
<tr><th>Data</th><th>Variables</th><th>Presentation</th></tr>
<tr><td>Extent of exposure</td><td>Study drug administration dose, Route, units, date, time, Cohort</td><td>Listing</td></tr>
<tr><td>Clinical laboratory evaluations</td><td>Laboratory results (refer to section 8.2 for parameters)</td><td>Listings:
All laboratory values by category,
Subjects with a potentially clinically significant (PCS) laboratory value by category
Summary Tables:
Laboratory values and change from baseline by visit.
Number and percentage of subjects with at least one post baseline laboratory value that is deemed PCS (as defined in Table 8, Table 9,
Table 10 PCS Values for Lipids
<table>
<tr><th>• Laboratory Parameter , Unit</th><th>PCS Range</th></tr>
<tr><td>Triglycerides, mg/dl</td><td>> 500</td></tr>
<tr><td>Low Density Lipoprotein (LDL), mg/dl</td><td>> or = 190</td></tr>
<tr><td>Cholesterol, Total, mg/dl</td><td>> = or 300</td></tr>
</table>
Table 11 PCS Values for Coagulation
<table>
<tr><th>Laboratory Parameter , Unit</th><th>PCS Range</th></tr>
<tr><td>Activated partial thromboplastin time, seconds</td><td>> or = 1.66 x ULN</td></tr>
<tr><td>Prothrombin, International normalized ratio (INR), Ratio</td><td>> or = 1.5 x ULN</td></tr>
<tr><td>Prothrombin Time, seconds</td><td>> or = 1.25 x ULN</td></tr>
</table>
Table 12 PCS Values for Urinalysis</td></tr>
</table>

<table>
<tr><th>Data</th><th>Variables</th><th>Presentation</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Laboratory Parameter</th><th>PCS Range</th></tr>
<tr><td>Bilirubin</td><td>1+</td></tr>
<tr><td>Erythrocyte (/HPF)</td><td>> or = 10</td></tr>
<tr><td>Glucose</td><td>2+</td></tr>
<tr><td>Ketones</td><td>1+</td></tr>
<tr><td>Leukocyte Esterase</td><td>1+</td></tr>
<tr><td>Nitrite</td><td>1+</td></tr>
<tr><td>Occult Blood</td><td>Trace</td></tr>
<tr><td>Protein</td><td>2+</td></tr>
</table>

Table 10, Table11, Table 12) by category.
Number and percentage of subjects with a laboratory value that is deemed PCS, for each scheduled post baseline assessment time point

</td></tr>
<tr><td>Vital signs</td><td>Blood pressure, pulse, respiration rate, and body temperature</td><td>Listings:
All vital signs values,
PCS vital sign values
Summary Tables:
Vital signs values and change from baseline by visit and timepoint.
Number and percentage of subjects with at least one post baseline PCS value will be summarized for the worst post baseline value.
Number and percentage of subjects with a vital sign value that is PCS, for each scheduled postbaseline assessment time point</td></tr>
<tr><td>Physical examination</td><td>Physical examination findings</td><td>Listing:
All physical examination findings</td></tr>
<tr><td>12-Lead Digital Electrocardiograms</td><td>ECG interpretations and findings;</td><td>Listings:
All ECGs,
Clinically significant ECGs,
Summary Tables
ECGs parameters values and change from baseline by visit and timepoint.
Categorical QTCF analysis by Visit and timepoint.</td></tr>
<tr><td>Reactogenicity/Injection Site Inspection</td><td>Reactogenicity/Injection Site Inspection findings</td><td>Listing
Table</td></tr>
</table>

8.1 Adverse Events

Treatment-emergent adverse events (TEAEs) are AEs that are not present prior to the exposure to study drug or AEs that are already present that worsen in severity or frequency following exposure to study drug. All summary tables (except where noted) will present TEAEs. If a subject has more than one TEAE with the same PT (after the same dose, if applicable), it is counted once in the summary tables at the strongest relationship to study drug and at the highest severity.

All TEAEs will be coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 24.1. The listing and summaries will include coded SOC and PT. Events will be listed by study drug, subject, and AE onset date. Treatment-emergent Adverse Event duration (stop date/time - start date/time), management, concomitant laboratory, vitals, and clinical examination abnormalities will be included in the listing.

8.2 Clinical Laboratory Evaluations

Laboratory data will be presented using units as reported by the clinical laboratory. Specific hematology, clinical chemistry, urinalysis, coagulation, and serology parameters are listed in Table 7.

Table 7: Clinical Laboratory Evaluations

Laboratory Test Category	Specific Laboratory Tests	
Hematology:	Hemoglobin	Neutrophils (absolute)
	Hematocrit	Monocytes
	Erythrocyte (red blood count [RBC]) count	Eosinophils
	Quantitative platelet count	Lymphocytes
	Total leukocyte (white blood cell [WBC]) count	Basophils
	Mean corpuscular hemoglobin (MCH)	Mean corpuscular volume (MCV)
Serum Chemistry:	Aspartate aminotransferase (AST)	Calcium
	Alanine aminotransferase (ALT)	CO_2 or bicarbonate
	Alkaline phosphatase (ALP)	Blood urea nitrogen (BUN) or urea
	Albumin	Creatinine
	Total bilirubin (if total bilirubin is ≥2 × ULN with no evidence of Gilbert's syndrome, then fractionate into direct and indirect bilirubin)	Glucose
	Sodium	Chloride
	Potassium	Lipase
	Total protein	Lactate dehydrogenase (LDH)
	Phosphorus	Amylase
	Creatinine Clearance (Cockcroft-Gault)	
Lipids:	Triglycerides	Low Density Lipoproteins (LDL)
	Cholesterol, Total	
Coagulation:	Activated partial thromboplastin time (aPTT)	International normalized ratio for prothrombin time (INR/PT)
Complement Activation:	Complement C3, C4, CH50	

Laboratory Test Category	Specific Laboratory Tests	
Urinalysis:	pH	Occult blood
	Protein	Specific gravity
	Glucose	Ketones
	Appearance	Color
	Bilirubin	Leukocyte esterase
	Nitrite	Microscopic reflex if protein, nitrite, blood or leukocyte esterase are positive (WBC, RBC, epithelial cells, bacteria, casts, other findings)
Serology:	Hepatitis B surface antigen (HBsAg)	Human immunodeficiency virus (HIV) antibody
	Hepatitis C antibody	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) polymerase chain reaction (PCR)
Pregnancy	Serum beta human chorionic gonadotropin (β-hCG) pregnancy test for females of childbearing potential (screening and Day 120 only), urine or serum test at all other specified visits	Follicle-stimulating hormone (FSH), if applicable to confirm postmenopausal status, is only required once
Other	Drug (opioids, benzodiazepines, barbiturates, cocaine metabolites, cannabinoids, methamphetamines, phencyclidine, amphetamine, cotinine) and alcohol screen	

Values for continuous laboratory parameters (hematology, chemistry, urinalysis, and coagulation) will be summarized by visit and for the change from baseline using descriptive statistics. The number and percentage of subjects with at least one post baseline PCS value and value that is PCS, for each scheduled post baseline of each laboratory parameter will also be presented. Serology, alcohol/drug screen, and pregnancy test results will be presented in separate listings.

Data listings will include out-of-range flags (L, H) and whether the abnormal values are clinically significant or not and an indication of whether the value meets the PCS criterion.
PCS values for laboratory parameters (as defined in Table 8, Table 9, Table 10, Table 11, Table 12 below) will be listed by category. Normal reference ranges are presented in APPENDIX D.

Table 8: PCS Values for Hematology

Laboratory Parameter (Unit)	PCS Range
Absolute basophils, cells/uL	> 400
Absolute eosinophils, cells/uL	> 800
Absolute lymphocytes, cells/uL	< 600
Absolute monocytes, cells/uL	< 10, > 2100
Absolute neutrophils, cells/uL	< or = 799, > 9000
Erythrocytes, (million/uL)	Male: < 3.8, > 6.4 Female: < 3.3, > 5.5

Laboratory Parameter (Unit)	PCS Range
Hematocrit, %	<20.0, >60.0
Hemoglobin, g/dL	Male: < 10 Female: < 9.5
Leukocytes, (thousands/uL)	< 2.0. > 25.0
Platelet count, thousands/uL	<100, >700

Table 9: PCS Values for Serum Chemistry

Laboratory Parameter ,Unit	PCS Range
Alanine aminotransferase, U/L	>or=1.25 x ULN
Albumin, g/dL	<3.0, >6.0
Alkaline phosphatase, U/L	>or=2.5 x ULN
Asparate Aminotransferase, U/L	>or=1.25 x ULN
Amylase, U/L	>or=1.5 x ULN
Bilirubin total, mg/dL	>or=1.1 x ULN
Blood urea nitrogen, mg/dL	> 70
Calcium, mg/dL	<7.8, >or=12.4
Carbon dioxide, mmol/L	<16, >40
Chloride, mmol/L	<65, >130
Creatinine, mg/dL	> or = 1.1 x ULN
Creatinine Clearance, Estimated, mL/min	< 90
Glucose, nonfasting, mg/dL	<54, >160
Lipase, U/L	> or=1.5 x ULN
Phosphorus, mg/dL	<2
Potassium, mmol/L	<3 , >or=6
Protein total, g/dL	<3.0, >9.0
Sodium, mmol/L	<130, >or=150

Table 10 PCS Values for Lipids

Laboratory Parameter , Unit	PCS Range
Triglycerides, mg/dl	> 500
Low Density Lipoprotein (LDL), mg/dl	> or = 190
Cholesterol, Total, mg/dl	> = or 300

Table 11 PCS Values for Coagulation

Laboratory Parameter , Unit	PCS Range
Activated partial thromboplastin time, seconds	> or = 1.66 x ULN
Prothrombin, International normalized ratio (INR), Ratio	> or = 1.5 x ULN
Prothrombin Time, seconds	> or = 1.25 x ULN

Table 12 PCS Values for Urinalysis

Laboratory Parameter	PCS Range
Bilirubin	1+
Erythrocyte (/HPF)	> or = 10
Glucose	2+
Ketones	1+
Leukocyte Esterase	1+
Nitrite	1+
Occult Blood	Trace
Protein	2+

8.3 Vital Signs

Vital signs will include systolic and diastolic blood pressure, temperature, pulse, and respiratory rate.

Absolute and change from baseline values in vital signs measurements will be summarized descriptively by visit, and timepoint. A summary table of subjects with PCS values at any post baseline visit will be presented by visit.

Potentially clinically significant vital signs values (as defined in Table 13) will be listed by parameters.

Table 13: PCS Values for Vital Signs

Parameter (Unit)	PCS Range
Systolic Blood Pressure (mmHg)	<= 90, >= 140
Diastolic Blood Pressure (mmHg)	<= 60, >= 90
Pulse Rate (beats/min)	<= 50, >= 100
Temperature (ºC)	<= 36, > 38
Respiratory Rate (breaths/min)	<= 12, >= 20

Data listings will identify if values are “abnormal, clinically significant” or “abnormal, not clinically significant” and an indication of whether the value meets the PCS criterion.

8.4 Physical Examination Findings

The physical examination will include a general review of the following body systems: general appearance, HEENT, neck / thyroid, respiratory, cardiovascular, gastrointestinal, genitourinary, neurological, musculoskeletal / extremities, skin and other. Physical examination results, with abnormal and clinically significant abnormal findings flagged will be listed.

8.5 12-Lead ECG Analysis

12- Lead safety ECG results will be summarized descriptively by visit and timepoint and change from baseline will be presented. Data listings will identify if values are “abnormal, clinically significant” or “abnormal, not clinically significant”.

Outliers with respect to QTcF will also be tabulated for the following categories:

Absolute value > 450 msec and ≤ 480 msec

Absolute value > 480 msec and ≤ 500 msec

Absolute value > 500 msec

Increase from baseline >= 30 msec and < 60 msec

Increase from baseline >= 60 msec

8.6 Reactogenicity/Injection Site Inspection

Reactogenicity/Injection Site Inspection will be summarized descriptively, by injection route (IM or SQ), CD388 dose, pooled placebo, time since last dose (days:hrs;min), resolution date and time and maximum intensity based on Table 8 of the protocol for severity assessments. Additionally, data listings will be provided.

9 PHARMACOGENOMICS, BIOMARKER AND ANTI-DRUG ANTIBODIES EVALUATIONS

Additional blood samples will be collected for pharmacogenomics and exploratory biomarker evaluation, and additional blood and urine samples will be collected for exploratory metabolite identification, to be reported separately. Analyses of lost DNA and biomarkers may be conducted at the Sponsor's discretion and reported separately from the study report. After discharge from the CRU, additional sample collection for PK and ADA will be performed at specified time points after dosing.

Analysis of the ADA results is to be determined and may include determination of the subject's positive/negative ADA status at baseline, treatment-emergent ADA in subjects with a negative baseline, as well as a post-baseline increase in titer for subjects with positive ADA at baseline.

10 DATA HANDLING AND PRESENTATION

All safety and statistical outputs will be generated using SAS software, version 9.4. All programs used to generate statistical analyses will be validated according to Altasciences's SOPs). Draft tables, figures and listings will be provided in RTF format.

10.1 Safety Analysis Presentation

Generally, summaries will be presented by injection route (IM or SQ), CD388 dose, pooled placebo and where applicable, by visit and timepoint. Study days will be calculated relative to the study drug administration after the first single dose or second single dose wherever it is applicable.

Study days will be included in adverse events and concomitant medication listings in addition to dates. Study days will be calculated relative to the first day of study drug administration (Day 1) derived as (event date - first day of study drug administration) +1 for events after the first day of dosing and (event date - first day of study drug administration) for events before the first day of dosing.

The following general comments also apply to all statistical analyses and data presentations:

- Duration variables will be calculated using the general formula: (end date - start date) +1.
- If the reported value of a clinical laboratory parameter cannot be used in a statistical summary table (e.g., a character string is reported for a parameter of the numerical type), a coded value must be appropriately determined and used in the statistical analyses. In general, a value or lower and upper limit of normal range such as '<10' or '≤5' will be treated as '10' or '5' respectively, and a value such as '>100' will be treated as '100'. However, the actual values as reported in the database will be presented in data listings.

In general, summary statistics for raw variables (i.e., variables measured at the study site or central laboratory) will be displayed as follows:

- Minima and maxima will be displayed to the same number of decimal places as the raw data.
- Means, medians, and quartiles will be displayed to 1 additional decimal place.
- Standard deviations will be displayed to 2 additional decimal places.
- Percentages will be displayed to 1 decimal place. Percentages between 0 and 0.1 (exclusive) will be displayed as '<0.1'.

The numbers of decimal places for summary statistics of derived variables (i.e., variables that are not measured by the study site but are calculated for analysis based on other measured variables) will be determined on a case-by-case basis. In general:

- Minima and maxima will be displayed to the commonly used unit of precision for the parameter.
- Means, medians, quartiles, and confidence limits will be displayed to 1 additional decimal place.
- Standard deviations will be displayed to 2 additional decimal places.

10.2 Pharmacokinetic Analysis Presentation

In general, all PK summary tables will be presented for the PK population.

Individual raw PK concentrations will be displayed with the same precision as received from the bioanalytical laboratory.

Precision for individual PK parameters will be displayed as follows:

- Concentration-related PK parameters (e.g., C_{max}, AUCs) will be displayed with the same precision as the raw PK concentration data,
- Apparent clearance (CL/F) and volume of distribution (V_z/F) will be reported to 3 significant figures,
- Parameters associated with time (e.g., t_{max}, $t_{1/2}$) will be displayed with 2 decimal places,
- Percentages and ratios will be displayed with 2 decimal places,
- Coefficient of determination (R^2) and elimination rate constant (λ_z) will be displayed with 4 decimal places.

Summary statistics for concentration and PK parameters will be displayed with the same precision as the individual values, with the exception of number of observations (N) and CV% which will be presented with 0 and 1 decimal place, respectively.

10.3 Analysis Timepoints

Unless otherwise specified, the baseline value will be defined as the last non-missing evaluation prior to the first dose of study medication and for the second dose of cohorts 2 and 3 on dosing date with timepoint marked as “predose” will be considered as baseline for the second dose analysis tests.

11 INTERIM ANALYSES AND DATA SAFETY MONITORING

Three blinded interim analyses of selected safety and PK data, one for the first dose level, another for the second dose level, and a third at the time when the 900 mg cohort completes Day 30. These interim analyses are for internal decision making or health authority interaction. Study team members involved in day-to-day trial related activities will not have access to interim analysis data which might unblind them at the subject level.

12 GENERAL INFORMATION RELATED TO DATA PRESENTATIONS

The formats and layouts of TFLs are provided in a separate document and are common displays. Their numbering and general content follow the International Conference on Harmonisation (ICH) E3 guidelines. Actual formats and layouts may be altered slightly from those presented as necessary to accommodate actual data or statistics.

Minor format changes will not require updates to the SAP; rather they may be documented in a Note to SAP.

APPENDIX A SCHEDULE OF EVENTS, First Single Dose, Cohorts 1A, 1B, 2A, 2B, 3A, and 3B

	Screening	Clinical Research Unit (CRU) Inpatient Stay										Outpatient CRU Visits [a]			
Day (Window)	**-28 to -2**	**-1**	**1**	**2**	**3–6**	**7**	**9**	**11**	**14**	**21**	**30**	**OV1 (±3)**	**OV2 (±5)**	**OV3 (±7)**	**OV4 [b] (±14)**
Informed consent	X														
Inclusion/Exclusion criteria [c]	X	X													
Medical history/demographics	X														
Complete physical with vital signs (BP, RR, HR, oral temperature, height, weight, BMI)	X														
Targeted physical with vital signs (BP, RR, HR, oral temperature)		X	X [d]	X	X	X			X	X	X	X	X	X	X
Safety ECG [e]	X	X	X			X					X				X
Holter Monitor ECG [f]			X	X	X										
Laboratory evaluations (CBC with/platelets, serum chemistry, urinalysis)	X	X		X	X [g]	X			X	X	X	X	X	X	X
Lipids, coagulation, complement activation [h]	X														
Virology screening (HBV, HCV, HIV)	X														
Virology screening (SARS-CoV-2)		X													
Serum/urine pregnancy test, FSH [i]	X	X									X	X	X	X	X
Drug/alcohol screen [j]	X	X													
Randomization		X													
Dosing of study drug			X												
Reactogenicity/injection site inspection [k]			X	X	X										
PK sample collection [l]			X	X	X	X	X	X	X	X	X	X	X	X	X
Samples for metabolite identification and CD388 DAR distribution [m]			X	X					X		X			X	
Samples for CD388 glycoforms [n]			predose	X		X			X	X	X	X		X	

Day (Window)	Screening	Clinical Research Unit (CRU) Inpatient Stay										Outpatient CRU Visits [a]			
	-28 to -2	-1	1	2	3–6	7	9	11	14	21	30	OV1 (±3)	OV2 (±5)	OV3 (±7)	OV4 [b] (±14)
Pharmacogenomics blood sample [o]			predose												
Exploratory biomarker samples			predose		X [g]										
Anti-drug antibodies			predose						X		X	X	X	X	X
Nasopharyngeal swab collection [p]			predose	X	X	X	X	X	X	X	X				
Assess and record AEs [q]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medications/procedures review [r]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Abbreviations: AEs = adverse events; BMI = body mass index; BP = blood pressure, CBC = complete blood count; COVID-19 = coronavirus disease 2019; CRU = clinical research unit; DAR = drug-antibody ratio; ECG = electrocardiogram; FSH = follicle-stimulating hormone; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HR = heart rate; hr = hour; ICF = informed consent form; OV = outpatient visit; PK = pharmacokinetic; RR = respiration rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Schedule of Events: First Single Dose, Cohorts 1A, 1B, 2A, 2B, 3A, and 3B

a. For subjects in Cohorts 1A and 1B: outpatient visits will occur at Day 45 (OV1), Day 60 (OV2), Day 90 (OV3), and Day 120 (OV4).
For subjects in Cohorts 2A, 2B, 3A, and 3B, timing of outpatient visits will occur at Day 45 (OV1), ~2× $t_{½}$ (OV2), ~3× $t_{½}$ (OV3), and ~4× $t_{½}$ (OV4), pending PK data from Cohorts 1A and 1B. If 2 half-lives have passed by OV2, the visit may be omitted.

b. For subjects who discontinue study early, the OV4 procedures should be performed.

c. For subjects in Cohorts 2A, 2B, 3A, and 3B, reconfirmation of inclusion and exclusion criteria (retesting of FSH not required) is to be completed at second single dose period's CRU check-in and prior to the second single dose of CD388 Injection or placebo.

d. On Day 1, the targeted physical examination should be performed predose. Vital signs collection will occur predose, 6 hours postdose, and as clinically indicated.

e. 12-lead ECG is to be performed at screening, at CRU check-in on Day -1, predose (immediately prior to study drug administration) and 6 hours postdose (±10 minutes) on Day 1, and as indicated in the Schedule. Subjects are to be resting and semi-recumbent when ECG is being conducted.

f. For Cohorts 1A, 1B, 2A, 2B, 3B: Continuous 12-lead digital ECG recording will be performed using a 12-lead Holter ECG monitor. Pharmacodynamic ECG tracings, including all 12-leads and of 10 seconds duration, will be extracted in triplicate for 5-minute observation periods at 60, 45, and 30 minutes predose; and at 2, 4, 6, 8, 10, 12, 24, 30, 36, and 48 hours postdose (expected time to maximum concentration is 1 to 2 days after administration). The Holter monitor will be removed on Day 3. The Holter monitor may be removed once on Day 2 for up to 15 minutes for shower/bathing, at least 2 hours away from the next ECG timepoint (i.e., 30, 36, or 48 hours postdose).

   For Cohort 3A: Continuous 12-lead digital ECG recording will be performed using a 12-lead Holter ECG monitor. Pharmacodynamic ECG tracings, including all 12 leads and of 10 seconds duration, will be extracted in triplicate at prespecified time points for a 5-minute observation period starting from 1 hour before dosing, then at 72, 76, 80, 84, 96, 102, 106, 110, 118, and 120 hours after administration of study drug, and stored in a digital format. The Holter monitor may be removed once on Day 5 for up to 15 minutes for shower/bathing, at least 1 hour away from the next ECG timepoint. The Holter monitor will be removed on Day 6.

Schedule of Events: First Single Dose, Cohorts 1A, 1B, 2A, 2B, 3A, and 3B (continued)

g. Laboratory evaluations need to be performed once during the Day 3–6 interval.

h. Performed at screening, and as clinically indicated (e.g., if the Investigator has concerns regarding an SAE, anti-drug antibody reaction in a subject with hypersensitivity reaction, fever, serious rash, joint/bone pain, cough, proteinuria, or clinically meaningful changes in the white cell differential or liver function tests).

i. A sensitive serum pregnancy test (β-human chorionic gonadotropin) is required at screening and OV4 for females of childbearing potential. FSH (if applicable to confirm postmenopausal status) is only required once. Urine pregnancy test may be performed at all other time points.

j. Drug and alcohol screen is to be performed during the outpatient visits if vital signs are abnormal (see in protocol Appendix 2).

k. At indicated visits, inspection of administration site and surrounding area will be performed twice daily (once between approximately 2–4 hours postdose, and once approximately 8–12 hours postdose), with any abnormal findings reported as AE s. Reactions will be rated according to the scale provided in protocol Table 7.

l. For Cohorts 1A, 1B, 2A, 2B, 3B: Blood samples for PK analysis will be collected predose (-24 hour window); post-dose at 2, 4, and 12 hours (each ±10 minute window); 24 hours (±30 minute window); 48 hours (±1 hour window); 72, 96, 120 hours (each ±2 hour window); and Days 7, 9, 11, 14, 21, 30 (each ±2 hour window). Postdose samples collected at outpatient CRU visits at OV1, OV2, OV3, and OV4 have the same windows (i.e., in ±days) as the visits.

   For Cohort 3A: Blood samples for PK analysis will be collected predose (-24 hour window); post-dose at 12 and 24 hours (±30 minute window); 48 hours (±1 hour window); 72, 84, 96, 108, 120 hours (each ±2 hour window); and Days 7, 9, 11, 14, 21, 30 (each ±2 hour window). Postdose samples collected at outpatient CRU visits at OV1, OV2, OV3, and OV4 have the same windows as the visits.

m. Blood samples for metabolite identification (e.g., free zanamivir, zanamivir dimers) and CD388 DAR distribution will be collected on Day 1 at 2 hours postdose, on Day 2 at 24 hours postdose, on Days 14 and 30, and at OV3. Urine samples for metabolite identification will be collected on Day 1 from 0–12 hours and from 12–24 hours postdose, on Day 2 from 24–48 hours postdose, on Day 14 over a 24-hour period, and over a 24-hour period that starts on Day 29 and ends prior to CRU check-out on Day 30.

n. Serum samples for CD388 glycoforms will be collected predose on Day 1 and once in the morning on Days 2, 7, 14, 21, and 30, and at the OV1 and OV3 visits.

o. A mandatory pharmacogenomic (DNA) blood sample will be collected once, preferably on Day 1 (collection at another time point is allowed if necessary) to allow for pharmacogenomic research related to CD388.

p. Nasopharyngeal swab samples will be collected predose on Day 1, and on Days 2, 5, 7, 9, 11, 14, 21, and 30.

q. Adverse events (including influenza-like illness which will be tested for both COVID-19 and flu) will be collected for all subjects from the time of signing the ICF through 4 months after the last dose of study drug, whichever is longer.

r. Concomitant procedures used to treat an AE will be recorded from the time of CD388 Injection/placebo administration until the final study visit.

APPENDIX B SCHEDULE OF EVENTS, Second Single Dose, Cohorts 2A, 2B, 3A, & 3B

	Clinical Research Unit (CRU) Inpatient Stay										Outpatient CRU Visits [a]			
Day (Window)	**-1 (±10)**	**1**	**2**	**3-6**	**7**	**9**	**11**	**14**	**21**	**30**	**OV1 (±3)**	**OV2 (±5)**	**OV3 (±7)**	**OV4 [b] (±14)**
Inclusion/Exclusion criteria [c]	X	X												
Complete physical with vital signs (BP, RR, HR, oral temperature, height, weight, BMI)	X													
Targeted physical with vital signs (BP, RR, HR, oral temperature)		X [d]	X	X	X			X	X	X	X	X	X	X
Safety ECG [e]	X	X			X					X				X
Laboratory evaluations (CBC with/platelets, serum chemistry, urinalysis)	X		X	X [f]	X			X	X	X	X	X	X	X
Virology screening (HBV, HCV, HIV)	X													
Virology screening (SARS-CoV-2)	X													
Urine Pregnancy [g]	X													
Drug/alcohol screen [h]	X													
Dosing of Study Drug (Cohorts 2 and 3 only)		X												
Reactogenicity/injection site inspection [i]		X	X	X										
PK sample collection [j]		X	X	X	X	X	X	X	X	X	X	X	X	X
Samples for metabolite identification [k]		X	X					X		X			X	
Exploratory biomarker samples		predose		X [f]										
Anti-drug antibodies		predose						X		X	X	X	X	X
Nasopharyngeal swab/nasal wash collection [l]		predose	X	X	X	X	X	X	X	X				
Assess and record AEs [m]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medications/procedures review [n]	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Abbreviations: AEs = adverse events; BMI = body mass index; BP = blood pressure, CBC = complete blood count; COVID-19 = coronavirus disease 2019; CRU = clinical research unit; ECG = electrocardiogram; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HR = heart rate; hr = hour; ICF = informed consent form; PK = pharmacokinetic; RR = respiration rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Schedule of Events: Second Single Dose, Cohorts 2A, 2B, 3A, and 3B

a. For subjects in Cohorts 2A, 2B, 3A, and 3B: outpatient visits will occur at Day 45 (OV1), Day 84 (OV2), Day 126 (OV3), and Day 168 (OV4).
b. For subjects who discontinue study early, the Day 168 procedures should be performed.
c. Reconfirmation of inclusion and exclusion criteria (retesting of FSH not required) is to be completed at CRU check-in on Day -1 and prior to the second single dose of CD388 Injection or placebo on Day 1.
d. On Day 1, the targeted physical examination should be performed predose. Vital signs collection will occur predose, 6 hours postdose, and as clinically indicated.
e. 12-lead ECG is to be performed at CRU check-in on Day -1, predose (immediately prior to study drug administration on Day 1) and 6 hours postdose (±10 minutes), and as indicated in the Schedule. Subjects are to be resting and semi-recumbent when ECG is being conducted.
f. Laboratory evaluations need to be performed once during the Day 3–6 interval.
g. Urine pregnancy test is required for females of childbearing potential at CRU check-in on Day -1.
h. Drug and alcohol screen is to be performed during the outpatient visits if vital signs are abnormal (see in protocol Appendix 2).
i. At indicated visits, inspection of administration site and surrounding area will be performed twice daily (once between approximately 2–4 hours postdose, and once approximately 8–12 hours postdose), with any abnormal findings reported as AEs. Reactions will be rated according to the scale provided in protocol Table 7.
j. Blood samples for PK analysis will be collected predose (-24 hour window); post-dose at 24 hours (±30 minute window); 48 hours (±1 hour window); 72, 96, 120, 144, 168 hours (each ±2 hour window); and Days 9, 10, 11, 12, 14, 21, 30 (each ±2 hour window). Postdose samples collected at outpatient CRU visits on Days 45, 60, 90, and 120 have the same windows (i.e., in ±days) as the visits.
k. Blood samples for metabolite identification (e.g., free zanamivir, zanamivir dimers) will be collected on Day 1 at 2 hours postdose, on Day 2 at 24 hours postdose, on Day 30, and on Day 90. Urine samples for metabolite identification will be collected on Day 1 from 0–48 hours, from 48–96 hours, and from 96–144 hours postdose, on Day 14 over a 24-hour period, and over a 24-hour period that starts on Day 29 and ends prior to CRU check-out on Day 30.
l. Nasopharyngeal swab samples will be collected predose on Day 1, and on Days 2, 5, 7, 9, 11, 14, 21, and 30. Nasal wash collection will occur at the time of C_{max} as determined from the first single dose (approximately 144 hours after dosing).
m. Adverse events (including influenza-like illness which will be tested for both COVID-19 and flu) will be collected for all subjects as indicated below:

Cohort	AE/SAE monitoring period from signing of Informed Consent Form:
1A, 1B	Through 4 months after the dose of study drug
2A, 2B, 3A, 3B	Through 205 days after the last dose of study drug (Day 206 ±10 days)

Note: the final AE assessment will be conducted via a follow-up phone call to the subject.

n. Concomitant procedures used to treat an AE will be recorded from the time of CD388 Injection/placebo administration until the final study visit.

APPENDIX C SCHEDULEOF EVENTS, Single Dose, Cohort 4B

	Screening	Clinical Research Unit (CRU) Inpatient Stay										Outpatient CRU Visits				
Day (Window)	**-28 to -2**	**-1**	**1**	**2**	**3–6**	**7**	**9**	**11**	**14**	**21**	**30**	**45 (±3)**	**84 (±5)**	**126 (±7)**	**168 (±14)**	**206 [a] (±10)**
Informed consent	X															
Inclusion/Exclusion criteria	X	X														
Medical history/demographics	X															
Complete physical with vital signs (BP, RR, HR, oral temperature, height, weight, BMI)	X															
Targeted physical with vital signs (BP, RR, HR, oral temperature)		X	X [b]	X	X	X			X	X	X	X	X	X	X	X
Safety ECG [c]	X	X	X			X					X					X
Holter Monitor ECG [d]			X	X	X											
Laboratory evaluations (CBC with/platelets, serum chemistry, urinalysis)	X	X		X	X [e]	X			X	X	X	X	X	X	X	X
Lipids, coagulation, complement activation [f]	X															
Virology screening (HBV, HCV, HIV)	X															
Virology screening (SARS-CoV-2)		X														
Serum/urine pregnancy test, FSH [g]	X	X									X	X	X	X	X	X
Drug/alcohol screen [h]	X	X														
Randomization		X														
Dosing of study drug			X													
Reactogenicity/injection site inspection [i]			X	X	X											
PK sample collection [j]			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Samples for metabolite identification and CD388 DAR distribution [k]			X	X					X		X		X	X		
Samples for CD388 glycoforms [l]			predose	X		X			X	X	X	X		X		

	Screening	Clinical Research Unit (CRU) Inpatient Stay										Outpatient CRU Visits				
Day (Window)	**-28 to -2**	**-1**	**1**	**2**	**3–6**	**7**	**9**	**11**	**14**	**21**	**30**	**45 (±3)**	**84 (±5)**	**126 (±7)**	**168 (±14)**	**206 [a] (±10)**
Pharmacogenomics blood sample [m]			predose													
Exploratory biomarker samples			predose		X [e]											
Anti-drug antibodies			predose						X		X	X	X	X	X	X
Nasopharyngeal swab/nasal wash collection [n]			predose	X	X	X	X	X	X	X	X					
Assess and record AEs [o]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medications/ procedures review [p]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Abbreviations: AEs = adverse events; BMI = body mass index; BP = blood pressure, CBC = complete blood count; COVID-19 = coronavirus disease 2019; CRU = clinical research unit; DAR = drug-antibody ratio; ECG = electrocardiogram; FSH = follicle-stimulating hormone; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HR = heart rate; hr = hour; ICF = informed consent form; OV = outpatient visit; PK = pharmacokinetic; RR = respiration rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Schedule of Events: Single Dose, Cohort 4B

a. For subjects who discontinue study early, the Day 206 procedures should be performed.

b. On Day 1, the targeted physical examination should be performed predose. Vital signs collection will occur predose, 6 hours postdose, and as clinically indicated.

c. 12-lead ECG is to be performed at screening, at CRU check-in on Day -1, predose (immediately prior to study drug administration) and 6 hours postdose (±10 minutes) on Day 1, and as indicated in the Schedule. Subjects are to be resting and semi-recumbent when ECG is being conducted.

d. Continuous 12-lead digital ECG recording will be performed using a 12-lead Holter ECG monitor. Pharmacodynamic ECG tracings, including all 12-leads and of 10 seconds duration, will be extracted in triplicate for 5-minute observation period starting from 1 hour before dosing, then at 72, 76, 80, 84, 96, 102, 106, 110, 118, and 120 hours after administration of study drug, and stored in a digital format. The Holter monitor will be removed on Day 6. The Holter monitor may be removed once on Day 5 for up to 15 minutes for shower/bathing, at least 1 hour away from the next ECG timepoint.

e. Laboratory evaluations need to be performed once during the Day 3–6 interval.

f. Performed at screening, and as clinically indicated (e.g., if the Investigator has concerns regarding an SAE, anti-drug antibody reaction in a subject with hypersensitivity reaction, fever, serious rash, joint/bone pain, cough, proteinuria, or clinically meaningful changes in the white cell differential or liver function tests).

g. A sensitive serum pregnancy test (β-human chorionic gonadotropin) is required at screening and OV4 for females of childbearing potential. FSH (if applicable to confirm postmenopausal status) is only required once. Urine pregnancy test may be performed at all other time points.

h. Drug and alcohol screen is to be performed during the outpatient visits if vital signs are abnormal (see in protocol Appendix 2).

Schedule of Events: Single Dose, Cohort 4B (continued)

i. At indicated visits, inspection of administration site and surrounding area will be performed twice daily (once between approximately 2–4 hours postdose, and once approximately 8–12 hours postdose), with any abnormal findings reported as AEs. Reactions will be rated according to the scale provided in protocol Table 7.

j. Blood samples for PK analysis will be collected predose (-24 hour window); post-dose at 12 and 24 hours (±30 minute window); 48 hours (±1 hour window); 72, 84, 96, 108, 120 hours (each ±2 hour window); and Days 7, 9, 11, 14, 21, 30 (each ±2 hour window). Postdose samples collected at outpatient CRU visits at Days 45, 84, 126, 168, and 206 have the same windows (i.e., in ±days) as the visits.

k. Blood samples for metabolite identification (e.g., free zanamivir, zanamivir dimers) will be collected on Day 1 at 2 hours postdose, on Day 2 at 24 hours postdose, on Day 30, Day 84, and on Day 126. Urine samples for metabolite identification will be collected from 0–48 hours, from 48–96 hours, and from 96–144 hours postdose, and over a 24 hour period on Days 10, 14, and 21, and over a 24-hour period that starts on Day 29 and ends prior to CRU check-out on Day 30.

l. Serum samples for CD388 glycoforms will be collected predose on Day 1 and once in the morning on Days 2, 7, 14, 21, and 30, and at the Day 45 and Day 126 visits.

m. A mandatory pharmacogenomic (DNA) blood sample will be collected once, preferably on Day 1 (collection at another time point is allowed if necessary) to allow for pharmacogenomic research related to CD388.

n. Nasopharyngeal swab samples will be collected predose on Day 1, and on Days 2, 5, 7, 9, 11, 14, 21, and 30. Nasal wash collection will occur on Day 7.

o. Adverse events (including influenza-like illness which will be tested for both COVID-19 and flu) will be collected for all subjects from the time of signing the ICF through 205 days after the dose of study drug (Day 206 ±10 days) (this final AE assessment will be conducted via a follow-up phone call to the subject).

p. Concomitant procedures used to treat an AE will be recorded from the time of CD388 Injection/placebo administration until the final study visit.

APPENDIX D LABORATORY NORMAL REFERENCE RANGES

HEMATOLOGY

Laboratory Parameter (Unit)	Normal Reference Range
Absolute basophils, cells/uL	Male gender, Age to 133Y: 0-200 Female gender, Age to 133Y: 0-200
Absolute eosinophils, cells/uL	Male gender, Age to 133Y: 15-500 Female gender, Age to 133Y: 15-500
Absolute lymphocytes, cells/uL	Male gender, Age to 18Y: 1200-5200 Male gender, Age to 133Y: 850-3900 Female gender, Age to 18Y: 1200-5200 Female gender, Age to 133Y: 850-3900
Absolute monocytes, cells/uL	Male gender, Age to 18Y: 200-900 Male gender, Age to 133Y: 200-950 Female gender, Age to 18Y: 200-900 Female gender, Age to 133Y: 200-950
Absolute neutrophils, cells/uL	Male gender, Age to 18Y: 1800-8000 Male gender, Age to 133Y: 1500-7800 Female gender, Age to 18Y: 1800-8000 Female gender, Age to 133Y: 1500-7800
Erythrocytes, (million/uL)	Male gender, Age to 18Y: 4.10-5.70 Male gender, Age to 133Y: 4.20-5.80 Female gender, Age to 18Y: 3.80-5.10 Female gender, Age to 133Y: 3.80-5.10
Hematocrit, %	Male gender, Age to 18Y: 36.0-49.0 Male gender, Age to 133Y: 38.5-50.0 Female gender, Age to 18Y: 34.0-46.0 Female gender, Age to 133Y: 35.0-45.0

Laboratory Parameter (Unit)	Normal Reference Range
Hemoglobin, g/dL	Male gender, Age to 18Y: 12.0-16.9 Male gender, Age to 133Y: 13.2-17.1 Female gender, Age to 18Y: 11.5-15.3 Female gender, Age to 133Y: 11.7-15.5
Mean Corpuscular Hemoglobin (pg)	Male gender, Age to 18Y: 25.0-35.0 Male gender, Age to 133Y: 27.0-33.0 Female gender, Age to 18Y: 25.0-35.0 Female gender, Age to 133Y: 27.0-33.0
Mean Corpuscular Volume (fL)	Male gender, Age to 18Y: 78.0-98.0 Male gender, Age to 133Y: 80.0-100.0 Female gender, Age to 18Y: 78.0-98.0 Female gender, Age to 133Y: 80.0-100.0
Leukocytes, (thousands/uL)	Male gender, Age to 18Y: 4.10-5.70 Male gender, Age to 133Y: 4.20-5.80 Female gender, Age to 18Y: 3.80-5.10 Female gender, Age to 133Y: 3.80-5.10
Platelet count, thousands/uL	Male gender, Age to 133Y: 140-400 Female gender, Age to 133Y: 140-400

SERUM CHEMISTRY

Laboratory Parameter ,Unit	Normal Reference Range
Alanine aminotransferase, U/L	Male gender, Age to 133Y: 9-46 Female gender, Age to 133Y: 6-29
Albumin, g/dL	Male gender, Age to 133Y: 3.6-5.1 Female gender, Age to 133Y: 3.6-5.1
Alkaline phosphatase, U/L	Male gender, Age to 19Y: 46-169 Male gender, Age to 49Y: 36-130 Male gender, Age to 133Y: 35-144

Laboratory Parameter ,Unit	Normal Reference Range
	Female gender, Age to 19Y: 36-128 Female gender, Age to 49Y: 31-125 Female gender, Age to 133Y: 37-153
Asparate Aminotransferase, U/L	Male gender, Age to 133Y: 7-25 Female gender, Age to 133Y: 7-25
Amylase, U/L	Male gender, Age to 133Y: 21-101 Female gender, Age to 133Y: 21-101
Bilirubin total, mg/dL	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Blood urea nitrogen, mg/dL	Male gender, Age to 19Y: 7-20 Male gender, Age to 133Y: 7-25 Female gender, Age to 19Y: 7-20 Female gender, Age to 133Y: 7-25
Calcium, mg/dL	Male gender, Age to 19Y: 8.9-10.4 Male gender, Age to 133Y: 8.6-10.3 Female gender, Age to 19Y: 8.9-10.4 Female gender, Age to 49Y: 8.6-10.2 Female gender, Age to 133Y: 8.6-10.4
Carbon dioxide , mmol/L	Male gender, Age to 133Y: 20-32 Female gender, Age to 133Y: 20-32
Chloride, mmol/L	Male gender, Age to 133Y: 98-110 Female gender, Age to 133Y: 98-110

Laboratory Parameter ,Unit	Normal Reference Range
Creatinine, mg/dL	Male gender, Age to 19Y: 0.60-1.26 Male gender, Age to 49Y: 0.60-1.35 Male gender, Age to 59Y: 0.70-1.33 Male gender, Age to 69Y: 0.70-1.25 Male gender, Age to 79Y: 0.70-1.18 Male gender, Age to 133Y: 0.70-1.11 Female gender, Age to 19Y: 0.50-1.00 Female gender, Age to 49Y: 0.50-1.10 Female gender, Age to 59Y: 0.50-1.05 Female gender, Age to 69Y: 0.50-0.99 Female gender, Age to 79Y: 0.60-0.93 Female gender, Age to 133Y: 0.60-0.88
Creatinine Clearance, Estimated, mL/min	Male gender, Age to 133Y: >/=90 mL/Min Female gender, Age to 133Y: >/=90 mL/Min
Glucose, nonfasting, mg/dL	Male gender, Age to 133Y: 65-139 Female gender, Age to 133Y: 65-139
Lactate dehydrogenase, U/L	Male gender, Age to 49Y: 100-220 Male gender, Age to 133Y: 120-250 Female gender, Age to 49Y: 100-200 Female gender, Age to 133Y: 120-250
Lipase, U/L	Male gender, to 133Y: 7-60 Female gender, to 133Y: 7-60
Phosphorus, mg/dL	Male gender, Age 18Y: 3.0-5.1 Male gender, Age 20Y: 2.7-5.0 Male gender, Age to 64Y: 2.5-4.5 Male gender, Age to 133Y: 2.1-4.3 Female gender, Age: 18Y: 3.0-5.1 Female gender, Age: 20Y: 2.7-5.0 Female gender, Age to 64Y: 2.5-4.5 Female gender, Age to 133Y: 2.1-4.3

Laboratory Parameter ,Unit	Normal Reference Range
Potassium, mmol/L	Male gender, Age to 19Y: 3.8-5.1 Male gender, Age to 133Y: 3.5-5.3 Female gender, Age to 19Y: 3.8-5.1 Female gender, Age to 133Y: 3.5-5.3
Protein total, g/dL	Male gender, Age to 19Y: 6.3-8.2 Male gender, Age to 133Y: 6.1-8.1 Female gender, Age to 19Y: 6.3-8.2 Female gender, Age to 133Y: 6.1-8.1
Sodium, mmol/L	Male gender, Age to 133Y: 135-146 Female gender, Age to 133Y: 135-146
Serum beta human chorionic gonadotropin (β-hCG), TOTAL, QL	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: Non-Pregnant: Negative; Pregnant: Positive
Follicle-stimulating hormone (FSH)	Female gender, Age to 133Y: Follicular Phase: 2.5-10.2 Mid-cycle Phase: 3.1-17.7 Luteal Phase: 1.5-9.1 Postmenopausal: 23.0-116.3

LIPIDS

Laboratory Parameter , Unit	Normal Reference Range
Triglycerides, mg/dl	Male gender, Age to 19Y: <90 Male gender, Age to 133Y: <150 Female gender, Age to 19Y: <90 Female gender, Age to 133Y: <150
Low Density Lipoprotein (LDL), mg/dl	Male gender, Age to 19Y: <110 Male gender, Age to 133Y: <100 Female gender, Age to 19Y: <110 Female gender, Age to 133Y: <100

Cholesterol, Total, mg/dl	Male gender, Age to 19Y: >45 Male gender, Age to 133Y: > OR = 40 Female gender, Age to 19Y: >45 Female gender, Age to 133Y: > OR = 50

COAGULATION

Laboratory Parameter , Unit	Normal Reference Range
Activated partial thromboplastin time, seconds	Male gender, Age to 133Y: 23-32 Female gender, Age to 133Y: 23-32
Prothrombin, International normalized ratio (INR), Ratio	Male gender, Age to 133Y: 0.9-1.1 Female gender, Age to 133Y: 0.9-1.1
Prothrombin Time, seconds	Male gender, Age to 133Y: 9.0-11.5 Female gender, Age to 133Y: 9.0-11.5

COMPLEMENT ACTIVATION

Laboratory Parameter , Unit	Normal Reference Range
Complement Component C3C (C3, C4, CH50), mg/dl	Male gender, Age to 80Y: 82-193 Male gender, Age > or = 81Y: Not Established Female gender, Age to 80Y: 82-193 Female gender, Age > or = 81Y: Not Established

URINALYSIS

Laboratory Parameter	Normal Reference Range
Appearance	Male gender, Age to 133Y: CLEAR Female gender, Age to 133Y: CLEAR
Bilirubin	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
Color	Male gender, Age to 133Y: YELLOW Female gender, Age to 133Y: YELLOW
Erythrocyte (/HPF)	Male gender, Age to 133Y: < or = 2 Female gender, Age to 133Y: < or = 2
Glucose	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
Ketones	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
Leukocyte Esterase	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
Nitrite	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
Occult Blood	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
pH	Male gender, Age to 133Y: 5.0-8.0 Female gender, Age to 133Y: 5.0-8.0
Protein	Male gender, Age to 133Y: Negative Female gender, Age to 133Y: Negative
Specific Gravity	Male gender, Age to 133Y: 1.001-1.035 Female gender, Age to 133Y: 1.001-1.035

SEROLOGY

Laboratory Parameter , Unit	Normal Reference Range
Hepatitis B surface antigen (HBsAg)	Male gender, Age to 133Y: NON-REACTIVE Female gender, Age to 133Y: NON-REACTIVE
Hepatitis C antibody	Male gender, Age to 133Y: NON-REACTIVE Female gender, Age to 133Y: NON-REACTIVE
Human immunodeficiency virus (HIV) antibody	Male gender, Age to 133Y: NON-REACTIVE Female gender, Age to 133Y: NON-REACTIVE

OTHER

Laboratory Parameter , Unit	Normal Reference Range
Opioids	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Benzodiazepines	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Barbiturates	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Cocaine metabolites	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Cannabinoids	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Methamphetamines	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Phencyclidine	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE

Amphetamine	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Cotinine, MCG/m:	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE
Alcohol	Male gender, Age to 133Y: NEGATIVE Female gender, Age to 133Y: NEGATIVE

ALTASCIENCES

TABLE, FIGURE, AND LISTING SHELLS

Cidara Therapeutics, Inc.

PROTOCOL No.: CD388.IM.SQ.1.01

A Phase 1, Randomized, Double-Blind, Single-Dose and Repeat Single Dose, Dose-Escalation Study to Determine the Safety, Tolerability, and Pharmacokinetics of CD388 Intramuscular or Subcutaneous Administration in Healthy Subjects

Protocol Version (Date): Amendment 2.0 (07-Feb-2023)

Altasciences Project No. CID-P1-144

Prepared by:

Altasciences Inc.
575 Armand-Frappier Boulevard
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Version: Final Amendment 3.0
Date: 2023-12-20

ALTASCIENCES

Version Control

Version	Date	Author	Description of Changes
1.0	2022-06-08	Riddhi Thakkar/ Blake Scadden	Not applicable
1.1	2023-04-05	Riddhi Thakkar/ Blake Scadden	A SAP is being updated due to the protocol amendment 2.0 (07-Feb-2023) which added a new cohort 4B for SQ route. All impacted sections are updated.
1.2	2023-07-12	Logan Kowallis	Added relative bioavailability model table – Table 14.6.2.1.
2.0	2023-07-31	Anita Shanker	Changes described in 1.1 & 1.2
3.0	2023-12-20	Haleh Aghamolaey	Shells are being amended to align the changes that were made to SAP Amendment 3.0. This version also addresses layout changes to match with protocol. Shells layouts for reactogenicity are updated to have a clear presentation of the content.

ALTASCIENCES

TABLE 14.2.1MOCK SHELLS

TABLE MOCK SHELLS

The templates indicate the content that will be presented in the summary tables. The appearance, e.g., the layout of the table, fonts, footnotes, or other typographic detail, may be different in the final versions of the tables.

ALTASCIENCES

Table 14.2.3 Template T1.1: Subject Disposition (All Subjects)

Table 14.1.1.1
Subject Disposition
(All Subjects)

		IM Route				SQ Route				
		CD388 50 mg	CD388 150 mg	CD388 450 mg	Pooled Placebo	CD388 50 mg	CD388 150 mg	CD388 450 mg	CD388 900 mg	Pooled Placebo
Subjects Randomized [N]		xx	xx	xx	xx	xx	xx	xx	xx	xx
Subjects Completed the Study [n(%)]	Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
If No, Primary Reason for Study Withdrawal [n(%)]	Reason 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Reason 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Reason 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
If No, Primary Reason for Treatment Withdrawal [n(%)]	Reason 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Reason 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Reason 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects Included in Each Analysis Population [n(%)]	Enrolled Population	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Safety Population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

PK Population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Date: VERSION - YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

IM = Intramuscular; SQ = Subcutaneous

Note: The percentages will be calculated using the number of subjects in each cohort and study drug group as the denominator.
<Programming Note> It can be presented separately (i.e. IM one page and SQ another).

Table 14.2.4 Template T1.2: Demographics and Baseline Characteristics (Safety Population)

Table 14.1.2.1
Demographics and Baseline Characteristics
(Safety Population)

		IM Route				SQ Route				
		CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	Pooled Placebo (N = XX)
Age (years)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Sex [n(%)]	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race [n(%)]	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Race1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Race2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity [n(%)]	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Hispanic/Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not Hispanic/Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Weight (kg)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Height (cm)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Body Mass Index (kg/m^2)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Date: VERSION - YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

IM = Intramuscular; SQ = Subcutaneous

Note: Percentages are based on the number of subjects in the Safety population as the denominator.

Programming Note: Table 14.1.2.2: "Demographics and Baseline Characteristics – PK Population" will follow the same layout.

ALTASCIENCES

Table 14.2.5 Template T1.3: Protocol Deviation (Safety Population)

Table 14.1.1.3
Protocol Deviation
(Safety Population)

		IM Route				SQ Route				
		CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	Pooled Placebo (N = XX)
Deviation Category	Major	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	…									

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IM = Intramuscular; SQ = Subcutaneous

Note: Percentages are based on the number of subjects in the safety population as the denominator.

ALTASCIENCES

Table 14.2.6 Template T2.1: Pharmacokinetic Data of CD388– Plasma (Pharmacokinetic Population),

Table 14.2.1.1.1.x
Descriptive Statistics of Plasma CD388 Concentration Data Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)
(PK Population)

				Time (h)								
				0	2	4	12	24	48	72	….	696
Cohort	Route of Administration	CD388 Dose (mg)		Concentration (Units)								
			N Mean SD Min Median Max CV%									
Lower Limit of Quantitation is xx.x (Units) NC: Not Calculated, NS: No Sample												

x = 1 through 8 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B and PK Completer Population (Cohorts 2A, 2B, 3A and 3B only)
<DOSE> = 50 mg, 150 mg, 450 mg, and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Programming Note:

Table 14.2.1.1.2.x: "Descriptive Statistics of Plasma CD388 Concentration Data Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>) >" will follow the same layout.

Table 14.2.2.1.1.x: "Descriptive Statistics of Nasopharyngeal CD388 Concentration Data Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Table 14.2.2.1.2.x: "Descriptive Statistics of Nasopharyngeal CD388 Concentration Data Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

ALTASCIENCES

Table 14.2.7 Template T2.2: Pharmacokinetic Parameters Summaries of CD388– Plasma (Pharmacokinetic Population)

Table 14.2.1.2.1.x
Descriptive Statistics of Plasma CD388 Pharmacokinetic Parameter Estimates Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)
(PK Population)

Cohort	Route of Administration	CD388 Dose (mg)		C_{max} (Unit)	T_{max} (Unit)	AUC_{0-t} (Unit)	…	Vz/F (Unit)
			N Mean SD Min Median Max CV% GeoMean GeoMean CV%					
NC: Not Calculated								

x = 1 through 8 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B and PK Completer Population (Cohorts 2A, 2B, 3A and 3B only)
<DOSE> = 50 mg, 150 mg, 450 mg and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Programming Note:

Table 14.2.1.2.2.x: "Descriptive Statistics of Plasma CD388 Pharmacokinetic Parameter Estimates Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Table 14.2.2.2.1.x: "Descriptive Statistics of Nasopharyngeal CD388 Pharmacokinetic Parameter Estimates Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Table 14.2.2.2.2.x: "Descriptive Statistics of Nasopharyngeal CD388 Pharmacokinetic Parameter Estimates Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

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Table 14.2.8 Template T2.3: PK Parameters Assessment of CD388 for <Cohort> SQ relative to IM – (Pharmacokinetic Population)

Table 14.2.3.1
Statistical Analysis of Plasma CD388 Pharmacokinetic Parameters Between IM and SQ Administration
(PK Population)

Dose	Parameter (unit)	n	Geometric LSmeans [1]		SQ/IM Ratio (%)	90% Confidence Interval (%)	
			IM Route	SQ route		Lower Bound	Upper Bound
xx mg							
	C_{max} (unit)	xxx	xxxxxx	xxxxxx	xxx	xxx	xxx
	AUC_{0-t} (unit)	xxx	xxxxxx	xxxxxx	xxx	xxx	xxx
	$AUC_{0-\infty}$ (Unit)	xxx	xxxxxx	xxxxxx	xxx	xxx	xxx
…							

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IM = Intramuscular(Reference); SQ = Subcutaneous(Test)

[1] Geometric Least Square (LS)means are based on the exponential of LSmeans of ln-transformed values
Note(s):
An analysis of variance (ANOVA) was performed on the ln-transformed parameters with the following fixed factors: Injection route.
The ratio and 90% confidence interval (CI) were obtained by exponentiating the resulting difference between each comparison of interest (IM to SQ) least-squares means and its corresponding 90% CI.

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Table 14.2.10 Template T2.4: Dose Proportionality Analysis – (Pharmacokinetic Population)

Table 14.2.4.1
Dose Proportionality Analysis of Plasma CD388 Pharmacokinetic Parameters
(PK Population)

Route	Parameter (Unit)	n	Estimate of Intercept (α)	Estimate of Slope (β)	90% Confidence Interval of Slope	
					Lower Bound	Upper Bound
IM						
	C_{max} (Unit)	xxx	xxx	xxx	xxxxx	xxxxx
	AUC_{0-t} (Unit)	xxx	xxx	xxx	xxxxx	xxxxx
	$AUC_{0-\infty}$ (Unit)	xxx	xxx	xxx	xxxxx	xxxxx
SQ						
	C_{max} (Unit)	xxx	xxx	xxx	xxxxx	xxxxx
	AUC_{0-t} (Unit)	xxx	xxx	xxx	xxxxx	xxxxx
	$AUC_{0-\infty}$ (Unit)	xxx	xxx	xxx	xxxxx	xxxxx

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IM = Intramuscular; SQ = Subcutaneous
Note: Proportionality analysis was performed using a power model: ln(PK parameter) = α + β × ln(dose) + error, with β as slope.

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Table 14.2.5.1
Summary of Positive Anti-drug Antibodies Titer
(Safety Population)

	IM Route				SQ Route				
	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	Pooled Placebo (N = XX)
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Positive ADA	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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IM = Intramuscular; SQ = Subcutaneous.
Notes: Percentages are based on the number of subjects in the Safety population (N).

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Table 14.2.6.1
Relative Bioavailability Analysis of Plasma CD388 Pharmacokinetic Parameters
(PK Population)

Route	Parameter (Unit)	n	LSMeans Dose 1	LSMeans Dose 2	Dose 1/Dose 2 Difference	90% Confidence Interval of Difference	
						Lower Bound	Upper Bound
IM							
	C_{max} (Unit)	xxx	xxx	xxx	xxx	xxxxx	xxxxx
	AUC_{0-t}(Unit)	xxx	xxx	xxx	xxx	xxxxx	xxxxx
	$AUC_{0-\infty}$ (Unit)	xxx	xxx	xxx	xxx	xxxxx	xxxxx
SQ							
	C_{max} (Unit)	xxx	xxx	xxx	xxx	xxxxx	xxxxx
	AUC_{0-t}(Unit)	xxx	xxx	xxx	xxx	xxxxx	xxxxx
	$AUC_{0-\infty}$ (Unit)	xxx	xxx	xxx	xxx	xxxxx	xxxxx

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IM = Intramuscular; SQ = Subcutaneous
Note: ANOVA model includes dose as fixed factor.

Table 14.2.13 Template T3.1: Treatment-Emergent Adverse Events (TEAEs) - Overall Summary (Safety Population)

Table 14.3.1.1
Treatment-Emergent Adverse Events (TEAEs) - First Dose - Overall Summary
(Safety Population)

	IM Route				SQ Route				
	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	Pooled Placebo (N = XX)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Subjects With at Least One TEAE [1][2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects With At Least One Drug-Related TEAE [2] [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Maximum Severity [2]									
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Life-threatening	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects With at Least One TEAE SAE [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject with at Least One TEAE Drug-Related SAE [2] [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to study withdrawal [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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IM = Intramuscular; SQ = Subcutaneous; TEAE = Treatment-Emergent Adverse Event.
Notes:
[1] A Treatment-Emergent Adverse Event (TEAE) is an adverse event which starts or worsens after treatment with study drug.
[2] Percentages are based on the number of subjects in the Safety population (N).
[3] Drug-related TEAEs are those TEAEs reported by the Investigator as having a “Reasonable Possibility” of being related to study treatment.

<Programming Note>

Table 14.3.1.2: "Treatment-Emergent Adverse Events (TEAEs) - Second Dose - Overall Summary" i.e., Cohorts 2A, 2B, 3A, 3B, and pooled placebo of respective route will follow the same layout.

ALTASCIENCES

Table 14.2.14 Template T3.2: Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.3
Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term- First Dose
(Safety Population)

	IM Route				SQ Route				
MedDRA System Organ Class Preferred Term	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	Pooled Placebo (N = XX) n (%)	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	CD388 900 mg (N = XX n (%)	Pooled Placebo (N = XX) n (%)
Subjects with at least one TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Date: VERSION - YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

IM = Intramuscular; SQ = Subcutaneous.
Notes:
For each row category, a subject with two or more adverse events in that category is counted only once.
Percentages are based on the number of subjects in the safety population (N).
Adverse events are coded into system organ class and preferred term using MedDRA Version 24.1.

<Programming Note>

Table 14.3.1.4: "Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term- Second Dose" i.e., Cohorts 2A, 2B, 3A, 3B and pooled placebo of respective route will follow the same layout.

ALTASCIENCES

Table 14.2.15 Template T3.3: Drug-Related Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.5
Drug-Related Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term- First Dose
(Safety Population)

	IM Route				SQ Route				
MedDRA System Organ Class Preferred Term	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	Pooled Placebo (N = XX) n (%)	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	CD388 900 mg (N = XX) n (%)	Pooled Placebo (N = XX) n (%)
Subjects with at least one TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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IM = Intramuscular; SQ = Subcutaneous.
Notes:
For each row category, a subject with two or more adverse events in that category is counted only once.
Percentages are based on the number of subjects in the safety population (N).
Drug-related TEAEs are those TEAEs reported by the Investigator as having a “Reasonable Possibility” of being related to study treatment.
Adverse events are coded into system organ class and preferred term using MedDRA Version 24.1.
<Programming Note>

Table 14.3.1.6: "Drug-Related Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term - Second Dose" i.e., Cohorts 2A, 2B, 3A, 3B, and pooled placebo of respective route will follow the same layout.
Table 14.3.1.11: "Drug-Related Serious Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – First Dose" will follow the same layout.
Table 14.3.1.12: "Drug-Related Serious Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – Second Dose" i.e., Cohorts 2A, 2B, 3A, 3B, and pooled placebo of respective route will follow the same layout.

Table 14.2.16 Template T3.4: Treatment-Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Maximum Severity (Safety Population)

Table 14.3.1.7
Treatment-Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Maximum Severity – First Dose
(Safety Population)

		IM Route				SQ Route				
System Organ Class/ Preferred Term	Maximum Severity	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	Pooled Placebo (N = XX)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Subjects With at Least One TEAE	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1										
	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

…	Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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IM = Intramuscular; SQ = Subcutaneous.
Notes:
For each PT, a subject with two or more adverse events in that category is counted only once at the maximum level.
Percentages are based on the number of subjects in the safety population (N).
Adverse events are coded into system organ class and preferred term using MedDRA Version 24.1.
<Programming Note>

Table 14.3.1.8: "Treatment-Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Maximum Severity - Second Dose" i.e., Cohorts 2A, 2B, 3A, 3B, and pooled placebo of respective route will follow the same layout.

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Table 14.2.17 Template T3.5: Serious Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.9
Serious Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – First Dose
(Safety Population)

	IM Route				SQ Route				
MedDRA System Organ Class Preferred Term	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	Pooled Placebo (N = XX) n (%)	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	CD388 900 mg (N = XX n (%)	Pooled Placebo (N = XX) n (%)
Subjects with at least one TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

IM = Intramuscular; SQ = Subcutaneous.
Notes:
For each row category, a subject with two or more adverse events in that category is counted only once.
Percentages are based on the number of subjects in the safety population (N).
Adverse events are coded into system organ class and preferred term using MedDRA Version 24.1.

<Programming Note>

Table 14.3.1.10: "Serious Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term - Second Dose" i.e., Cohorts 2A, 2B, 3A, 3B, and pooled placebo of respective route will follow the same layout.

ALTASCIENCES

Table 14.2.18 Template T3.6: Influenza-like Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.13
Influenza-like Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – First Dose
(Safety Population)

	IM Route				SQ Route				
MedDRA System Organ Class Preferred Term	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	Pooled Placebo (N = XX) n (%)	CD388 50 mg (N = XX) n (%)	CD388 150 mg (N = XX) n (%)	CD388 450 mg (N = XX) n (%)	CD388 900 mg (N = XX) n (%)	Pooled Placebo (N = XX) n (%)
Subjects with at least one TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Date: VERSION - YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

IM = Intramuscular; SQ = Subcutaneous.
Notes:
For each row category, a subject with two or more adverse events in that category is counted only once.
Percentages are based on the number of subjects in the safety population (N).
Influenza-like TEAE are those events which were collected during Follow-up Period.
Adverse events are coded into system organ class and preferred term using MedDRA Version 24.1.

<Programming Note>

Table 14.3.1.14: “Influenza-like Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term - Second Dose” i.e., Cohorts 2A, 2B, 3A, 3B and pooled placebo of respective route will follow the same layout.
<Programming Note>

Table 14.3.1.14: “Influenza-like Treatment-Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term - Second Dose” i.e., Cohorts 2A, 2B, 3A, 3B and pooled placebo of respective route won’t be populated if no data is available.

Table 14.2.19 Template T4.1: Summary of <Laboratory Panel> (Safety Population)

Table 14.3.2.x
Summary of <Laboratory Panel>
(Safety Population)
<Parameter (Unit)>

		IM Route								SQ Route									
		CD388 50 mg (N = XX)		CD388 150 mg (N = XX)		CD388 450 mg (N = XX)		Pooled Placebo (N = XX)		CD388 50 mg (N = XX)		CD388 150 mg (N = XX)		CD388 450 mg (N = XX)		CD388 900 mg (N = XX)		ETC. (N = XX)	
Visit		Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Baseline [1]	n	xx		xx		xx		xx		xx		xx		xx		xx		xx	
	Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
	Median	xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x	
	Minimum, Maximum	xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx	
Day xx	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

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	IM Route				SQ Route				
	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	ETC. (N = XX)
Visit	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline	Observed / Change from Baseline

Date: VERSION – YYYY-MM-DD | Data Source: xxx | Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous; SD = Standard Deviation.
[1] Note: Baseline is the measurement of the last predose measurement was used.
<Laboratory Panel> = Hematology; Chemistry; Urinalysis; Coagulation; Lipid;
<Programming Note>
It can be presented separately (i.e., IM one page and SQ another).
ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo

Table 14.2.20 Template T4.2: Summary of Potentially Clinically Significant (PCS) Values <Laboratory Panel> (Safety Population)

Table 14.3.2.6
Number (Percentage) of Subjects with Potentially Clinically Significant (PCS) Values in Hematology at Any Post-baseline Visit
Safety Population

			IM Route				SQ Route				
			CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	ETC. (N = XX)
Visit	Parameter	PCS Criteria	n/m (%)	n/m (%)	n/m (%)	n/m (%)	n/m (%)	n/m (%)	n/m (%)	n/m (%)	n/m(%)
	Albumin		x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
			x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	Alanine aminotransferase (F)		x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	Alanine aminotransferase (M)		x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	...										
Pre-Dose	Albumin										
			x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
			x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	Alanine aminotransferase (F)		x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	Alanine aminotransferase (M)		x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)		x/xx (xx.x)

IM = Intramuscular; SQ = Subcutaneous
Note: n is the number of subjects who met the PCS criteria. Denominator (m) is the number of subjects with non-PCS baseline and at least one post-baseline assessment when calculating the percentage.

<Laboratory Panel> = Hematology; Chemistry; Urinalysis; Coagulation; Lipid;
<Programming Note>
ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo
It can be presented separately (i.e., IM one page and SQ another).

ALTASCIENCES

Table 14.2.21 Teplate T5.1: Summary of Vital Signs (Safety Population)

Table 14.3.3.1
Summary of Vital Signs
(Safety Population)
<Parameter (Unit)>

			IM Route								SQ Route									
			CD388 50 mg (N = XX)		CD388 150 mg (N = XX)		CD388 450 mg (N = XX)		Pooled Placebo (N = XX)		CD388 50 mg (N = XX)		CD388 150 mg (N = XX)		CD388 450 mg (N = XX)		CD388 900 mg (N = XX)		ETC. (N = XX)	
Visit	Timepoint		Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Baseline	Pre-Dose	n	xx		xx		xx		xx		xx		xx		xx		xx		xx	
		Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
		Median	xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x	
		Minimum, Maximum	xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx	
Day xx	hrs	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.x)
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	….																			

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous; SD = Standard Deviation.

Note: Baseline is the measurement of the last predose measurement was used.

<Parameter (unit)> = Systolic Blood Pressure (mmHg), Diastolic Blood Pressure (mmHg), Pulse Rate (beats/min), Temperature (C), Respiratory Rate (breaths/min)

<Programming Note>

ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo

It can be presented separately (i.e., IM one page and SQ another).

Table 14.2.22 Template T5.2: Summary of Potentially Clinically Significant (PCS) Values Vital Signs (Safety Population)

Table 14.3.3.2
Number (Percentage) of Subjects with Potentially Clinically Significant (PCS) Values in Vital Signs at Post-baseline Visit
Safety Population

		IM Route				SQ Route				
Timepoint	Parameter / PCS Criteria	CD388 50 mg (N = XX) n/m (%)	CD388 150 mg (N = XX) n/m (%)	CD388 450 mg (N = XX) n/m (%)	Pooled Placebo (N = XX) n/m (%)	CD388 50 mg (N = XX) n/m (%)	CD388 150 mg (N = XX) n/m (%)	CD388 450 mg (N = XX) n/m (%)	CD388 900 mg (N = XX) n/m (%)	ETC. (N = XX) n/m (%)
Subjects with at least one PCS Value	Systolic Blood Pressure									
	<=90 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	>=140 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	xxx.x)	x (xx.x)	x (xx.x)	xxx.x)
	Diastolic Blood Pressure									
	<=60 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	>=90 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Pulse Rate									
	<=50 beats/min	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	>=100 beats/min	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	...									
Pre-Dose	Systolic Blood Pressure									
	<=90 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	>=140 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Diastolic Blood									

Pressure													
<=60 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
>=90 mmHg	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Pulse Rate													
<=50 beats/min	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
>=100 beats/min	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

...

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous.
Note: n is the number of subjects who met the PCS criteria. Denominator (m) is the number of subjects with non-PCS baseline and at least one post-baseline assessment when calculating the percentage.

<Programming Note>
ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo
It can be presented separately (i.e., IM one page and SQ another).

ALTASCIENCES

Table 14.2.24 Template T5.3: ECG: Observed Values and Changes from Baseline (Safety Population)

Table 14.3.4.1
ECG: Observed Values and Changes from Baseline
(Safety Population)
<Parameter (Unit)>

			IM Route								SQ Route							
			CD388 50 mg (N = XX)		CD388 150 mg (N = XX)		CD388 450 mg (N = XX)		Pooled Placebo (N = XX)		CD388 50 mg (N = XX)		CD388 150 mg (N = XX)		CD388 450 mg (N = XX)		ETC. (N = XX)	
Visit	Timepoint		Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Baseline		n	xx		xx		xx		xx		xx		xx		xx		xx	
		Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
		Median	xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x		xx.x	
		Minimum, Maximum	xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx		xx, xx	
Day xx	Pre-Dose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Minimum, Maximum	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	….																	

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous; SD = Standard Deviation.

Note: Baseline is the measurement of the last predose measurement was used.

<Parameter (unit)> = ECG Mean Ventricular Rate (msec), PR Interval (msec), QRS Duration (msec), QT Interval (msec), QTcF Interval (msec)

<Programming Note>
ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo . CD388 900 mg be added
It can be presented separately (i.e., IM one page and SQ another).

Table 14.2.25 Template T5.4: ECG: Maximum QTcF Categorical Analysis (Safety Population)

Table 14.3.4.2
ECG: Maximum QTcF Categorical Analysis
(Safety Population)

			IM Route				SQ Route				
Nominal Day		Category	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	ETC. (N = XX)
Day xx	Absolute Values	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		> 450 msec and ≤ 480 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		> 450 msec and ≤ 500 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		> 500 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Increases from Baseline	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		> 30 msec and ≤ 60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		> 60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day xx	Absolute Values	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		> 450 msec and ≤ 480 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		> 450 msec and ≤ 500 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		> 500 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Increases from Baseline	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		> 30 msec and ≤ 60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…		> 60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

…

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous; SD = Standard Deviation.

Note: Baseline is the measurement of the last predose measurement was used.

<Programming Note>
ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo
It can be presented separately (i.e., IM one page and SQ another).

ALTASCIENCES

Table 14.2.26 Template T5.4: Reactogenicity/Injection Site Inspection (Safety Population)

Table 14.3.5.1
Summary of Reactogenicity/Injection Site Inspection
(Safety Population)

	IM Route				SQ Route				
	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	Pooled Placebo (N = XX)	CD388 50 mg (N = XX)	CD388 150 mg (N = XX)	CD388 450 mg (N = XX)	CD388 900 mg (N = XX)	ETC. (N = XX)
Subject With at Least One Injection Site Reaction [n(%)]	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)
Injection Site XX Grade 1	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)	Xx (xx.x)

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

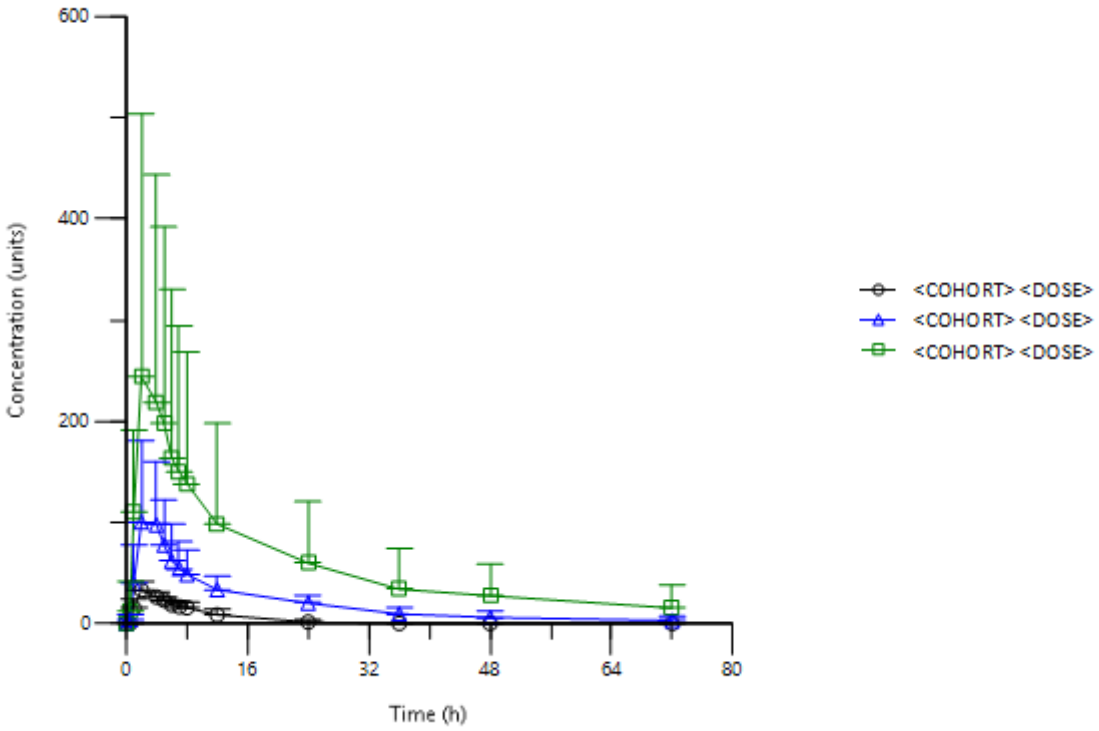
IM = Intramuscular; SQ = Subcutaneous.
Note: Baseline is the measurement of the last predose measurement was used.
<Programming Note>
ETC.= for SQ: Cohort 4B CD388 – Pooled Placebo
It can be presented separately (i.e., IM one page and SQ another).

FIGURE MOCK SHELLS

The templates indicate the content that will be presented in the figures. The appearance, e.g., the actual time points or values, the layout of the figure, fonts, or other typographic detail, may be different in the final versions of the figures.

Table 14.2.27 Template F1: Mean (+SD) Concentration-Time Profile – Plasma (PK Population)

Figure 14.2.1.1.1.x.y
Mean (+SD) Plasma CD388 Concentration-Time Profiles Following a Single <ADMIN> of CD388 to Healthy Subjects <SCALE>



x = 1 for Intramuscular Injection, 2 for Subcutaneous Injection

x= <ADMIN>; y=<SCALE>
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<SCALE> = Linear or Semi-logarithmic

Note: Semi-logarithmic figure will also be presented. 3 (IM) or 4 (SQ) cohorts will be included in these figures. Time scale will be adjusted to match data.

Programming Note:

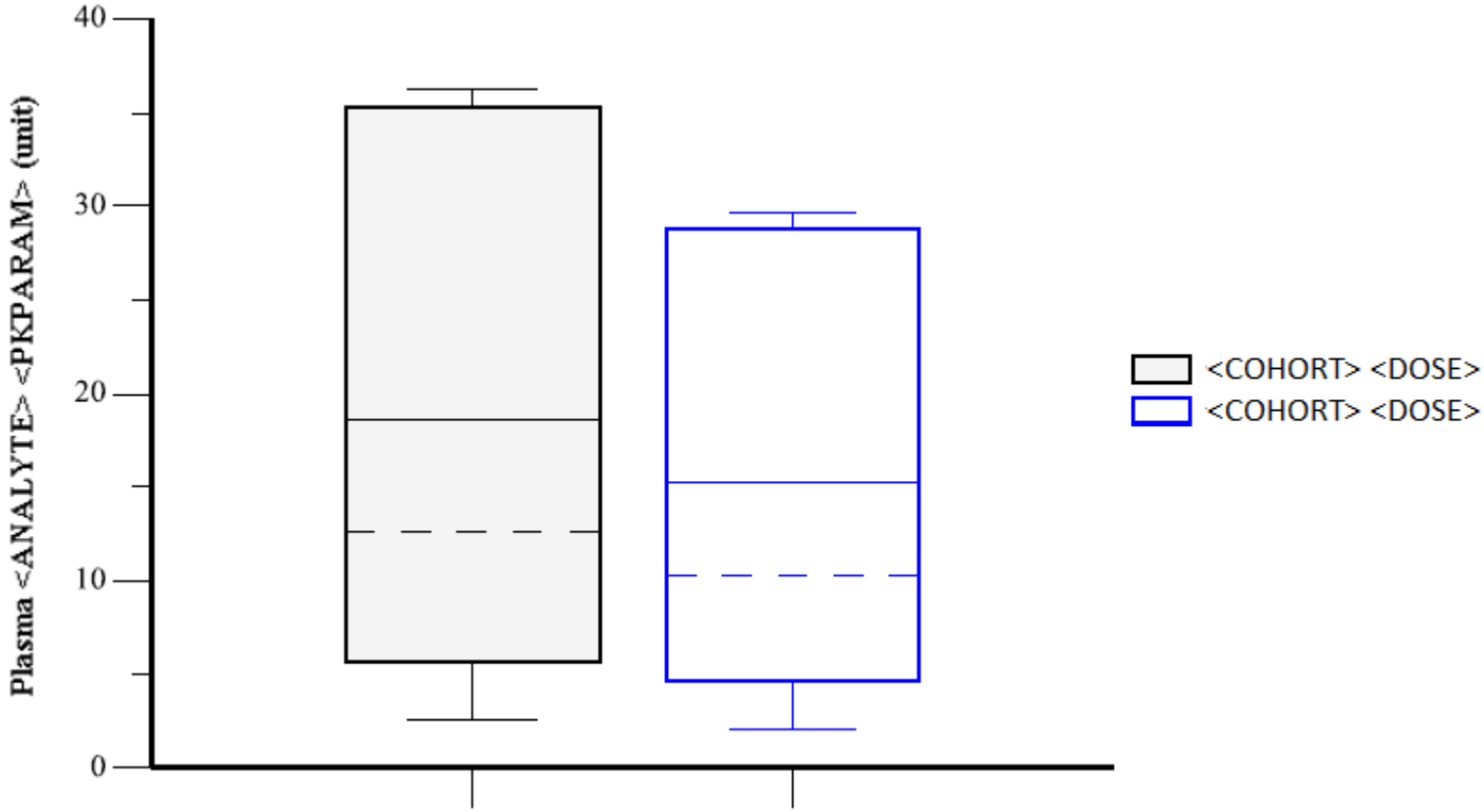
Figure 14.2.1.1.2.x.y: "Mean (+SD) Plasma CD388 Concentration-Time Profiles Following a Repeated Single <ADMIN> of CD388 to Healthy Subjects <SCALE>" will follow the same layout.

Figure 14.2.2.1.1.x.y: "Mean (+SD) Nasopharyngeal CD388 Concentration-Time Profiles Following a Single <ADMIN> of CD388 to Healthy Subjects <SCALE>" will follow the same layout.

Figure 14.2.2.1.2.x.y: "Mean (+SD) Nasopharyngeal CD388 Concentration-Time Profiles Following a Repeated Single <ADMIN> of CD388 to Healthy Subjects <SCALE>" will follow the same layout.

Table 14.2.28 Template F2: Box-and-Whiskers Plot of Plasma CD388 <PKPARAM> – Plasma (PK Population)

Figure 14.2.1.2.1.x.y
Box-and-Whiskers Plot of Plasma CD388 <PKPARAM> Following a Single <ADMIN> of CD388 to Healthy Subjects



x = 1 for Intramuscular Injection, 2 for Subcutaneous Injection
y = 1 for Cmax,2 for AUC0-t, and 3 for AUC0-∞ for plasma or 1 for Cmax, and 2 for AUC0-t for nasopharyngeal
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<PKPARAM> = Cmax, AUC0-t, and AUC0-∞ for plasma or Cmax, and AUC0-t for nasopharyngeal

Note: 3 (IM) or 4 (SQ) cohorts will be included in these figures.

Programming Note:

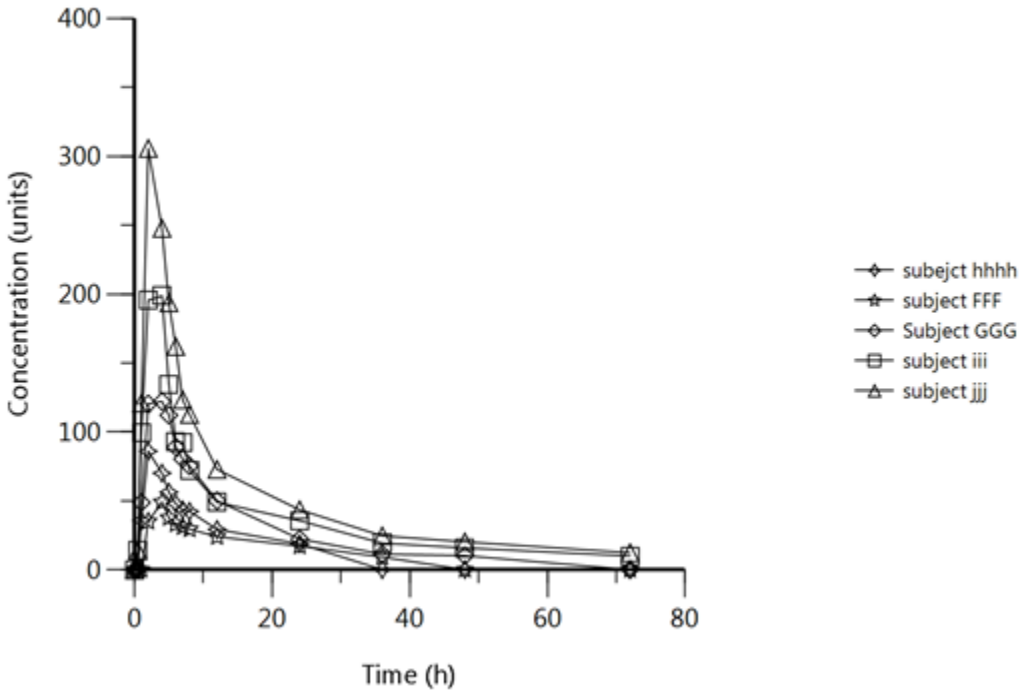
Figure *14.2.1.2.2.x.y*: "Box-and-Whiskers Plot of Plasma CD388 <PKPARAM> Following a Single <ADMIN> of CD388 to Healthy Subjects" will follow the same layout.

Figure 14.2.2.2.1.x.y: "Box-and-Whiskers Plot of Nasopharyngeal CD388 <PKPARAM> Following a Single <ADMIN> of CD388 to Healthy Subjects" will follow the same layout.

Figure 14.2.2.2.2.x.y: "Box-and-Whiskers Plot of Nasopharyngeal CD388 <PKPARAM> Following a Repeated Single <ADMIN> of CD388 to Healthy Subjects" will follow the same layout.

Table 14.2.29 Template F3: Individual Plasma CD388 Concentration-Time Profiles – (PK Population)

Figure 16.2.6.1.7.x
Individual Plasma CD388 Concentration-Time Profiles Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Linear Scale)



x = x = 1 through 7 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B
<DOSE> = 50 mg, 150 mg, 450 mg and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Note: All subjects per cohort will be included in one figure. Time scale will be adjusted to match data.

Programming Note:

Figure 16.2.6.1.8.x: "Individual Plasma CD388 Concentration-Time Profiles Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Semi-Logarithmic Scale)" will follow the same layout.

Figure: 16.2.6.1.9.x: "Individual Plasma CD388 Concentration-Time Profiles Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Linear Scale)" will follow the same layout.

Figure 16.2.6.1.10.x: "Individual Plasma CD388 Concentration-Time Profiles Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Semi-Logarithmic Scale)" will follow the same layout.

Figure 16.2.6.2.7.x.y: "Individual Nasopharyngeal CD388 Concentration-Time Profiles Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Linear Scale)" will follow the same out.

Figure 16.2.6.2.8.x.y: "Individual Nasopharyngeal CD388 Concentration-Time Profiles Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Semi-Logarithmic Scale)" will follow the same out.

Figure 16.2.6.2.9.x.y: "Individual Nasopharyngeal CD388 Concentration-Time Profiles Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Linear Scale)" will follow the same layout.

Figure 16.2.6.2.10.x.y: "Individual Nasopharyngeal CD388 Concentration-Time Profiles Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>, Semi-Logarithmic Scale)" will follow the same layout.

LISTING MOCK SHELLS

The templates indicate the content that will be presented in the listings. The appearance, e.g., the layout of the table, fonts, or other typographic detail, may be different in the final versions of the outputs.

Note: Additional visits could be added to present the data in the DB, where necessary (e.g. Early Termination / Unscheduled Visit). See the CRF and the protocol for more details.

ALTASCIENCES

Table 14.2.30 Template L1: Randomization

Listing 16.1.7
Randomization

Subject ID	Route/Cohort	Randomization Date	Randomization Number	Treatment
xxxx		DDMONYYYY	xxxx	xxx
…				

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas
IM = Intramuscular; SQ = Subcutaneous

ALTASCIENCES

Table 14.2.31 Template L2: Subject Disposition (Safety Population)

Listing 16.2.1
Subject Disposition
(Safety Population)

Subject ID	Route/Cohort/Treatment	Completed	Date of Completion or Withdrawal	Withdrawal	
				Primary Reason	Last Day
xxxx	xxx	Yes	DDMONYYYY		
xxxx	xxxx	No	DDMONYYYY	Xxxxxxx	Day xx
…					

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

Programming Note: If Primary Reason for Discontinuation is Adverse Event, include AE # and verbatim term.

ALTASCIENCES

Table 14.2.32 Template L3.1: Protocol Deviations (Safety Population)

Listing 16.2.2.1
Protocol Deviations
(Safety Population)

Subject ID	Deviation Reference ID	Date	Route/Cohort/Treatment	Description of Protocol Deviation	Classification	Category	Assessment Type
xxxx	xxxxx	DDMONYYYY	xxx	Xxxxxxx	Major	Missed Procedures/Assessments	Medical History
	xxxxx		xxx	xxxxxx	Minor	Order of Procedures/Assessments	Demographics
…							

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

ALTASCIENCES

Table 14.2.33 Template L3.2: Pharmacokinetic Blood Sample Deviations (Safety Population)

Listing 16.2.2.2
Pharmacokinetic Blood Sample Deviations
(Safety Population)

Route/Cohort/Treatment	Visit	Elapsed Time (h)	Subject ID	Deviation (min)

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

ALTASCIENCES

Table 14.2.34 Template L4.1: Inclusion/Exclusion Criteria Violations (Safety Population)

Listing 16.2.3.1
Inclusion/Exclusion Criteria Violations
(Safety Population)

Subject ID	Visit	Route/Cohort/Treatment	Type	Criterion Number	Criterion	Comment(s)
xxxx	xx	Xx/xx	Inclusion	xx	Xxxxxxx	
			Exclusion	xx	Xxxxxxxxxx	
…						

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

Programming Note: The column "Comment(s)" may be removed if it is not populated.

ALTASCIENCES

Table 14.2.35 Template L4.2: Analysis Population

Listing 16.2.3.2
Analysis Population

Subject ID	Route/Cohort/Treatment	Enrolled Population	Safety Population	PK Population	Reason for Exclusion from the PK Population
xxxx	xxx		Yes	Yes	
…					

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

Programming Note: If any of the Reason for Exclusion columns is not populated, they will be removed.

ALTASCIENCES

Table 14.2.36 Template L5.1: Demographics and Informed Consent (Safety Population)

Listing 16.2.4.1
Demographics and Informed Consent
(Safety Population)

Subject ID	Route/Cohort/ Treatment	Informed Consent Date	Sex	Age (years)	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m2)
xxxx	xx	DDMONYYYY	Xxxx	xx	White	Xxxxx			
xxxx	xx	DDMONYYYY	Xxxx	xx	Other: Specify	Xxxxx			
…									

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

BMI = Body Mass Index; IM = Intramuscular; SQ = Subcutaneous

Age at Informed Consent

ALTASCIENCES

Table 14.2.37 Template L5.2: Medical History (Safety Population)

Listing 16.2.4.2
Medical History
(Safety Population)

Subject ID	Route/Cohort/Treatment	MH #	System Organ Class/ Preferred Term	Medical/Surgical History Description	Start Date	End Date/ Ongoing
xxxx	xx	x	Xxxxxx/ Xxxxx	Xxxxxxxxxxx	DDMONYYYY	DDMONYYYY
…						

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas
MH = Medical History; IM = Intramuscular; SQ = Subcutaneous

ALTASCIENCES

Table 14.2.38 Template L5.3: Prior and Concomitant Medications (Safety Population)

Listing 16.2.4.3
Prior and Concomitant Medications
(Safety Population)

Subject ID	Route/Cohort/Treatment	Treatment Date and Time	CM #	P/C/PC	Drug Class/ Preferred Term/ Verbatim Text	Dosing Information*	Start Date (Day)** and Time/ Stop Date (Day)** and Time/ Ongoing	Indication/ Administered for AE?/ AE Number / Preferred Term
xxxx	xx	DDMONYYYY HH:MM	x	C	Analgesics/ Paracetamol/ Tylenol	xxx/ mg/ Once/ Oral	DDMONYYYY (xx) HH:MM/ DDMONYYYY (xx) HH:MM	Headache/ Yes/ AE # 4/ Headache
…								

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

C = Concomitant; P = Prior; PC = Prior and Concomitant; CM = Concomitant Medication; IM = Intramuscular; SQ = Subcutaneous

*Dose/ Unit/ Frequency/ Route
**Start and stop day are relative to Day 1.
Notes: Prior and concomitant medications are coded into drug class and preferred term using WHODrug September 1, 2021.
Prior medications are identified as medications started within 30 days before screening and prior to the administration of investigational product. Concomitant medications are identified as medications taken following administration of IP.

ALTASCIENCES

Table 14.2.39 Template L6.1: Investigational Product Administration (Safety Population)

Listing 16.2.5.1
Investigational Product Administration – First Dose
(Safety Population)

Subject ID	Administration Day	Route/Cohort/Treatment	Date	Time (HH:MM)	Was the treatment administered?	Dose (Unit)	Route	Injection Site Number	Anatomical Location	Other, Specify	Side (From Subject's Perspective)	Directionality
xxxx	xx	Xx/xx	DDMONYYYY	HH:MM	Yes	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
	xx	Xx/xx	DDMONYYYY	HH:MM	xx	xx	xx	xx	xx	xx	xx	xx
…												

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

Programming Note: The column "Dosing Comment(s)" may be removed if it is not populated.

Listing 16.2.5.2: "Investigational Product Administration – Second Dose" will follow the same layout.

ALTASCIENCES

Table 14.2.40 Template L7.1: Individual Plasma CD388 Pharmacokinetic Data (PK Population)

Listing 16.2.6.1.1.x
Individual Plasma CD388 Concentration Data Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)

				Time (h)								
				0	2	4	12	24	48	72	…	696
Cohort	Route of Administration	CD388 Dose (mg)	Subject	Concentration (Units)								
Lower Limit of Quantitation is xx.x (Units) NC: Not Calculated, NS: No Sample												

x = 1 through 7 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B
<DOSE> = 50 mg, 150 mg, 450 mg and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Programming Note:

Listing 16.2.6.1.2.x: "Individual Plasma CD388 Concentration Data Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.1.x: "Individual Nasopharyngeal CD388 Concentration Data Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.2.x: "Individual Nasopharyngeal CD388 Concentration Data Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

ALTASCIENCES

Table 14.2.41 Template L7.2: Individual Urine Concentration Data (PK Population)

Listing 16.2.6.1.3.x
Individual Urine <ANALYTE> Concentration Data Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)

				Interval (Units)					
				0 - 12	12 - 24	24 - 48	312 - 336	…	672 - 696
Cohort	Route of Administration	CD388 Dose (mg)	Subject	Concentration (Units)					
Lower Limit of Quantitation is xx.x (Units) NC: Not Calculated, NS: No Sample									

x = 1 through 7 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B

<ANALYTE> = free zanamivir, zanamivir dimers
<DOSE> = 50 mg, 150 mg, 450 mg and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Programming Note:

Listing 16.2.6.1.3.1: "Individual Urine Free Zanamivir Concentration Data Following <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.3.2: "Individual Urine Zanamivir Dimers Concentration Data Following <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

ALTASCIENCES

Table 14.2.42 Template L7.3: Individual Plasma CD388 Pharmacokinetic Parameters (PK Population)

Listing 16.2.6.1.4.x
Individual Plasma CD388 Pharmacokinetic Parameter Estimates Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)

Cohort	Route of Administration	CD388 Dose (mg)	Subject	C_{max} (Unit)	T_{max} (Unit)	AUC_{0-t} (Unit)	…	Vz/F (Unit)
NC: Not Calculated								

x = 1 through 7 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B
<DOSE> = 50 mg, 150 mg, 450 mg, and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Programming Note:

Listing 16.2.6.1.5.x: "Individual Plasma CD388 Pharmacokinetic Parameter Estimates Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.4.x: "Individual Nasopharyngeal CD388 Pharmacokinetic Parameter Estimates Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.5.x: "Individual Nasopharyngeal CD388 Pharmacokinetic Parameter Estimates Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

ALTASCIENCES

Table 14.2.43 Template L7.4: Actual Pharmacokinetic Plasma Sampling Times (PK Population)

Listing 16.2.6.1.6.x
Actual Pharmacokinetic Plasma Sampling Times Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)

				Time (h)								
				0	2	4	12	24	48	72	….	696
Cohort	Route of Administration	CD388 Dose (mg)	Subject	Actual Time (h)								
NS: No Sample												

x = 1 through 7 for Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B
<DOSE> = 50 mg, 150 mg, 450 mg, and 900 mg for Cohorts 1A/1B, 2A/2B, 3A/3B, and 4B, respectively.
<ADMIN> = Intramuscular Injection for Cohorts 1A, 2A, and 3A or Subcutaneous Injection for Cohorts 1B, 2B, 3B, and 4B.
<COHORT> = Cohorts 1A, 1B, 2A, 2B, 3A, 3B, and 4B.

Programming Note:

Listing 16.2.6.1.7.x: "Actual Pharmacokinetic Plasma Sampling Times Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.6.x: "Actual Pharmacokinetic Nasopharyngeal Sampling Times Following a Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

Listing 16.2.6.2.7.x: "Actual Pharmacokinetic Nasopharyngeal Sampling Times Following a Repeated Single <ADMIN> of <DOSE> CD388 to Healthy Subjects (<COHORT>)" will follow the same layout.

ALTASCIENCES

Table 14.2.44 Template L7.5: Anti-Drug Antibodies (Safety Population)

Listing 16.2.6.2
Anti-Drug Antibodies
(Safety Population)

Subject ID	Route/Cohort /Treatment	Timepoint	Results	Actual Date/ Time	Not Done
xxxx	xx	xx.x	xxx		
…					

ALTASCIENCES

Table 14.2.45 Template L8: Adverse Events (Safety Population)

Listing 16.2.7.1
Adverse Events
(Safety Population)

Subject ID	Onset Day*	Route/Cohort /Treatment	AE #/TEAE	System Organ Class/ Preferred Term/ Verbatim Term	Start Date and Time/ End Date and Time	Time from Dosing**/ Duration (DD:HH:MM)	Severity/ Serious AE/ Relationship to Study Drug/ Outcome	Study Drug Action Taken/ Other Action Taken/CM Administered?/CM Number/CM Preferred Term
xxxx	xx	xx	xx	Xxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxxxxxxxxx / xxxxxxxxx	DDMONYYYY HH:MM/ DDMONYYYY HH:MM	DD:HH:MM/ DD:HH:MM	Mild/ Expected/No/ Probable/ xxxxx	xxxxxxxxxxxxxxxxx/ Subject withdrawn
			xx	Xxxxxxxxxxxxxxxxxxx/ Xxxx xxxxxxxxxx/ Xxxxxxxxxxxxx	DDMONYYYY HH:MM/ DDMONYYYY	DD:HH:MM/ DD days	xxxx/ xxxx/ Yes - Reason(s)/ Xxxx/ xxxxxxxxx	xxxxxxxxxxxxxxx/No/Yes/CM # 2/ Paracetamol
…								

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

AE = Adverse Event, CM = Concomitant Medication; IM = Intramuscular; SQ = Subcutaneous;
*Onset day is relative to Day 1.
**Time from dosing is relative to treatment date.
Notes: A Treatment-Emergent Adverse Event (TEAE) is an adverse event which starts or worsens after treatment with study drug. If the start date or time is missing then the AE is considered to be a TEAE, unless the information available implies otherwise. Depending where a TEAE occurred, relationship was clinically assessed in terms of treatment.
Adverse events are coded into system organ class and preferred term using MedDRA Version 24.1.

ALTASCIENCES

Table 14.2.46 Template L9.1: <Laboratory Panel> (Safety Population)

Listing 16.2.8.1.x
<Laboratory Panel>
(Safety Population)

Subject ID	Parameter (Unit)	Route/Cohort/Treatment	Visit	Result	High/Low Flag	Clinical Significance	PCS Flag	Reason Not Done
xxxx	Xxxxxxx (unit)	xx	Screening	x.x		Clinically Significant		
			Day xx	x.x	High	Not Clinically Significant		
			Day xx	x.x				
			Day x	x.x				
…								

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous ; PCS = Potentially Clinically Significant

<Laboratory Panel> = Hematology; Chemistry; Urinalysis, Coagulation, Lipids

Programming Note: The column "Reason Not Done/Comments" may be removed if it is not populated.

ALTASCIENCES

Table 14.2.47 Template L9.2: Serology (Safety Population)

Listing 16.2.8.1.6
Serology
(Safety Population)

Subject ID	Route/Cohort/Treatment	Visit	SARS-CoV-2 (PCR)	HIV Antibody	Hepatitis B Surface Antigen (HBsAg)	Hepatitis C Antibody
xxxx	xxx	xxx			Negative	Negative
…						

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous; HIV = Human Immunodeficiency Virus; SARS-CoV-2 = Severe Acute Respiratory Syndrome Coronavirus 2; PCR = Polymerase Chain Reaction

ALTASCIENCES

Table 14.2.48 Template L9.3: Urine Drugs of Abuse Screen (Safety Population)

Listing 16.2.8.1.5.1
Urine Drugs of Abuse Screen
(Safety Population)

Subject ID	Route/Cohort/Treatment	Visit	Alcohol	Amphetamine	Barbiturates	Benzodiazepines	Cannabinoids	Cocaine	Cotinine	Methamphetamine	Oxycodone Opiate	Phencyclidine
xxxx	xx	Screening	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
		Day xx	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
…													

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

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Listing 16.2.8.1.5.2
Urine Samples
(Safety Population)

Subject ID	Route/Cohort/Treatment	Visit	Start Time	End Time	Sample Volume
xxxx	xx	Screening			
		Day xx			
…					

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

Abbreviation(s) : IM = Intramuscular; SQ = Subcutaneous

ALTASCIENCES

Table 14.2.49 Template L9.4: Pregnancy Test (Safety Population)

Listing 16.2.8.1.6
Serum Pregnancy Test
(Safety Population)

Subject ID	Route/Cohort/Treatment	Visit	Date and Time of Assessment	Lab Test	Specimen Type	Result
xxxx	xx	Screening	DDMONYYYY HH:MM			
		Day xx	DDMONYYYY HH:MM			
…						

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous;

Table 14.2.50 Template L9.5: FSH Test (Safety Population)

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Listing 16.2.8.1.7
Follicle Stimulating Hormone Testing
(Safety Population)

Subject ID	Parameter (Units)	Route/Cohort/Treatment	Visit	Result	High/Low Flag	Clinical Significance
xxxx	Follicle Stimulating Hormone (mIU/mL)	xx	Screening			
			Day xx			
…						

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

IM = Intramuscular; SQ = Subcutaneous

ALTASCIENCES

Table 14.2.51 Template L10.1: Vital Signs (Safety Population)

Listing 16.2.8.2.1
Vital Signs
(Safety Population)

Subject ID	<Parameter (Unit)>	Route/Cohort /Treatment	Visit	Time Point	Date and Time of Assessment	Result	Investigator's Evaluation	PCS Flag/ Time Occurrence after Dosing (DD:HH:MM)	Reason Not Done/ Comments
xxxx	Xxxxxxx (unit)		Screening		DDMONYYYY HH:MM	x.x	Normal	xx	xx
			Day xx		DDMONYYYY HH:MM	x.x	Abnormal - Clinically Significant	xx	xx
			Day x		DDMONYYYY HH:MM	x.x	Normal	xx	xx
			Day xx		DDMONYYYY HH:MM	x.x	Normal	xx	xx
			Day xx	Predose	DDMONYYYY HH:MM	x.x	Normal	xx	xx
				xx					
			…						
…									

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

CS = Clinically Significant; DBP = Diastolic Blood Pressure; NCS = Not Clinically Significant; SBP = Systolic Blood Pressure; IM = Intramuscular; SQ = Subcutaneous; PCS = Potentially Clinically Significant.

<Parameter (unit)> = Systolic Blood Pressure, (mmHg) Diastolic Blood Pressure (mmHg), Pulse Rate (beats/min), Temperature (C), Respiratory Rate (breaths/min)

Programming Notes: The column "Reason Not Done" will be removed if it is not populated.

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Table 14.2.52 Template L10.2: 12-Lead Electrocardiogram (ECG) (Safety Population)

Listing 16.2.8.2.2
12-Lead Electrocardiogram (ECG)
(Safety Population)

Subject ID	Route/Cohort/Treatment	Visit	Date and Time of Assessment	Overall Interpretation	Abnormal Findings	HR (bpm)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Reason Not Done
xxxx	xxxx	Screening	DDMONYYYY HH:MM	Normal		xx	xxx	xx	xxx	xxx	
			DDMONYYYY HH:MM	Normal		xx	xxx	xx	xxx	xxx	
			DDMONYYYY HH:MM	Normal		xx	xxx	xx	xxx	xxx	
			DDMONYYYY HH:MM	Normal		xx	xxx	xx	xxx	xxx	
		Day xx	DDMONYYYY HH:MM	NCS	Xxxxxx	xx	xxx	xx	xxx	xxx	
…											

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

CS = Clinically Significant; NCS = Not Clinically Significant; HR = Heart Rate; IM = Intramuscular; SQ = Subcutaneous

Programming Note: The column "Reason Not Done" will be removed if it is not populated.

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Table 14.2.53 Template L10.4: Physical Examination (Safety Population)

Listing 16.2.8.2.3
Physical Examination
(Safety Population)

Subject ID	Route/Cohort/Treatment	Visit	Date of Assessment	Body System	Result	Abnormality	Description
xxxx	xxxxx	Screening	DDMONYYYY	Head and Neck	NCS	Xxxxxxxx	
				Cardiovascular	Normal		
				Respiratory	Normal		
				Gastrointestinal	Normal		
				General Appearance	Normal		
				…			
		Day xx	DDMONYYYY	Xxxxxx	CS	Xxxxxxxx	
		…					
		Day xx	DDMONYYYY	Xxxxxx	CS	Xxxxxxxx	
…							

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas

CS = Clinically Significant; NCS = Not Clinically Significant; IM = Intramuscular; SQ = Subcutaneous

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Table 14.2.54 Template L10.5: Reactogenicity/Injection Site Inspection (Safety Population)

Listing 16.2.8.2.4
Reactogenicity/Injection Site Inspection
(Safety Population)

Subject ID	Route/Cohort/Treatment	Description	Onset Date/Time (Time Since Last Dose)	Resolution Date/Time (Duration)	Maximum Intensity/ Relatedness
xxxx	xxxxx		DDMONYYYY		Grade 1/Related
					Grade 2/ Related
					Grade 3/ Related
					Grade 4/ Related
				…	
		Day xx	DDMONYYYY	Xxxxxx	Xxxxxx
		…			
		Day xx	DDMONYYYY	Xxxxxx	Xxxxxx
…					

Date: VERSION - YYYY-MM-DD Data Source: xxx Program Source: xxx.sas
IM = Intramuscular; SQ = Subcutaneous

Note(s): Time Since Last Dose is DAYS:HRS:MIN. Pain: Mild = Does not interfere with activity; Moderate = Repeated use of non-narcotic pain reliever >24 hours or interferes with activity; Severe = Any use of narcotic pain reliever or prevents daily activity; Life-threatening = Emergency room (ER) visit or hospitalization. Tenderness: Mild = Mild discomfort to touch; Moderate = Discomfort with movement; Severe = Significant discomfort at rest; Life-threatening = ER visit or hospitalization. Erythema/Redness: Mild = 2.5–5 cm; Moderate = 5.1–10 cm; Severe = >10 cm; Life-threatening = Necrosis or exfoliative dermatitis. Induration/Swelling: Mild = 2.5–5 cm and does not interfere with activity; Moderate = 5.1–10 cm or interferes with activity; Severe = >10 cm or prevents daily activity; Life-threatening = Necrosis.

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