STATISTICAL ANALYSIS PLAN

A PHASE 1, RANDOMIZED, DOUBLE-BLIND, DOSE ESCALATION STUDY TO EVALUATE THE SAFETY AND PHARMACOKINETICS OF A SINGLE IM DOSE OF G03-52-01 VS PLACEBO IN ADULT SUBJECTS.

SAP Version 2.0
FINAL
Date: 24 Aug 2022

for

Protocol No. G03-52-01.001

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REVISION HISTORY

Version Number	Effective Date	Changes since previous version
Final 1.0	05-Jun-2020	Original version, Not Applicable
Final 1.1	28-Jul-2020	1. Section 2. Introduction: Changed the version of the protocol from 1.0 to 2.0 2. Section 5. Changes in the conduct of the study or planned analysis: Changed the version of the protocol from 1.0 to 2.0 and removed the below explanation provided in SAP version 1.0 "1) As per protocol, each of the monoclonal antibodies of G03-52-01 will be measured by ECLA. However, they can be measured by ECLA or ELISA validated method. 2) $t_{1/2}$ (α and β) and MRT will not be analyzed for antibodies, only $t_{1/2}$ will be determined. "
Final 2.0	24-Aug-2022	1. Section 2: Reference to latest protocol version 3.0 dated 07 Sept 2021 2. Section 2.2.2: Secondary endpoints are updated 3. Section 3.1: Number of cohorts, dose of study drug, follow-up visits for cohort 4, and SRC section are updated 4. Figure 3-1: Study schematic is updated 5. Table 3-2: Schedule of Events Cohort 4 and follow up visits are updated 6. Section 3.2: Study population is updated for Cohort 4 and total of 40 subjects 7. Section 3.5: Sample size is updated for 40 8. Section 3.6: Dose of 100 mg is added for Cohort 4 9. Section 3.10: Visits are added for cohort 4 10. Section 3.12: Visits are added for cohort 4 11. Section 5: Reference to latest protocol version 3.0 dated 07 Sept 2021 12. Section 7.22.1: MedDRA Version is updated 13. Section 7.23: Interim analysis of Cohort 4 is updated 14. The cohorts A, B, C, D are referred as cohorts 1, 2, 3, 4 in line with the protocol

LIST OF ABBREVIATIONS

Abbreviation	Definition
ADA	Anti-Drug Antibody
AE	Adverse Event
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
AUC	Area Under the Curve
BLQ	Below Limit of Quantification
CK	Cytokine
CV	Coefficient of Variation
C_{max}	Maximum Plasma Titer/Concentration
CSR	Clinical study report
DMP	Data Management Plan
eCRF	Electronic Case Report Form
ECG	Electrocardiogram
ECLA	Electrochemiluminescence Assay
ELISA	Enzyme-linked Immune Sorbent Assay
GCP	Good Clinical Practice
HBsAg	Hepatitis B Surface Antigen
HCG	Human Chorionic Gonadotropic Hormone
HCV	Hepatitis C Virus
HEENT	Head, Eyes, Ears, Nose and Throat
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonization
Ig	Immunoglobulin
IM	Intramuscular
INR	International Normalized Ratio
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Corpuscular Volume
MedDRA	Medical Dictionary for Regulatory Activities
MNA	Battelle Mouse Neutralization Assay
MPV	Mean Platelet Volume
MOP	Manual of Procedures
MRT	Mean Residence Time
N/n	Number
PE	Physical Examination
PI	Principal Investigator
PK	Pharmacokinetic(s)
PT	Preferred Term
PTT	Partial Thromboplastin Time

RDW	Red Blood Cell Distribution Width
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
SRC	Safety Review Committee
TEAE	Treatment-emergent Adverse Event
T_{max}	Time to Maximum Concentration
WBC	White Blood Count

TABLE OF CONTENTS

1. INTRODUCTION

This statistical analysis plan (SAP) is consistent with the statistical methods section of the final study protocol (Version 3.0, dated 07 Sept 2021) and includes additional detail of pharmacokinetic (PK), immunogenicity, safety and tolerability summaries to be included in the clinical study report (CSR).

2. STUDY OBJECTIVES AND ENDPOINTS

2.1 Objectives

The following are the study objectives

2.1.1 Primary Objective

- To assess the safety and tolerability of escalating doses of G03-52-01 administered intramuscularly (IM) in healthy adult subjects.

2.1.2 Secondary Objective

- To assess the PK and immunogenicity of escalating doses of G03-52-01 administered IM in healthy adult subjects.

2.1.3 Exploratory Objective

Not Applicable

2.2 Endpoints

The following are the study endpoints

2.2.1 Primary Endpoints

- The occurrence of Serious Adverse Events (SAE) following administration of G03-52-01 to the final follow-up visit.
- The occurrence of Adverse Events (AE) from administration of G03-52-01 to the final follow-up visit.
- The occurrence of changes from baseline in physical examination, vital signs and clinical safety laboratory values following administration of G03-52-01 to the final follow-up visit.

2.2.2 Secondary Endpoints

- The pharmacokinetic assessment of C_{max}, T_{max} and $AUC_{(0-t)}$ as measured by the validated Battelle Mouse Neutralization Assay (MNA) for serotypes A and B

    - Pharmacokinetic samples will be tested by MNA at pre-dose and on Days 4, 30, 60, 90, and 120 for Cohorts 1-3.
    - Pharmacokinetic samples will be tested by MNA at pre-dose, 2-hour post-dose (for future use), and on Days 4, 30, 45, 60, 90, and 120 for Cohort 4.

- The assessment of C_{max}, T_{max}, half-life (α and β), MRT and $AUC_{(0-t)}$ for each of the monoclonal antibodies of G03-52-01 as measured by a validated electrochemiluminescence assay (ECLA) or enzyme-linked immunosorbent assay (ELISA) method.

  - PK samples will be tested by ECLA or ELISA at pre-dose, and at 2, 4, 8, 24, 48, and 72 hours post injection, and on Days 4, 8, 15, 30, 45, 60, 90, and 120 for Cohorts 1-3.
  - Pharmacokinetic samples will be tested by ECLA or ELISA at pre-dose, 6 hours post dose, and on Days 1, 2, 4, 8, 15, 30, 45, 60, 90, 120, and 180 for Cohort 4.

- Samples will be tested to evaluate presence of anti-drug antibodies (ADA) collected for all cohorts.

  - Samples will be tested for ADA at pre-dose and on Days 15, 30, 45, 60, 90, and 120 for Cohorts 1-3.
  - Samples will be tested for ADA at pre-dose and on Days 45, 60, 90, 120, and 180 for Cohort 4.

2.2.3 Exploratory Endpoint

Not Applicable

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3. STUDY DESIGN

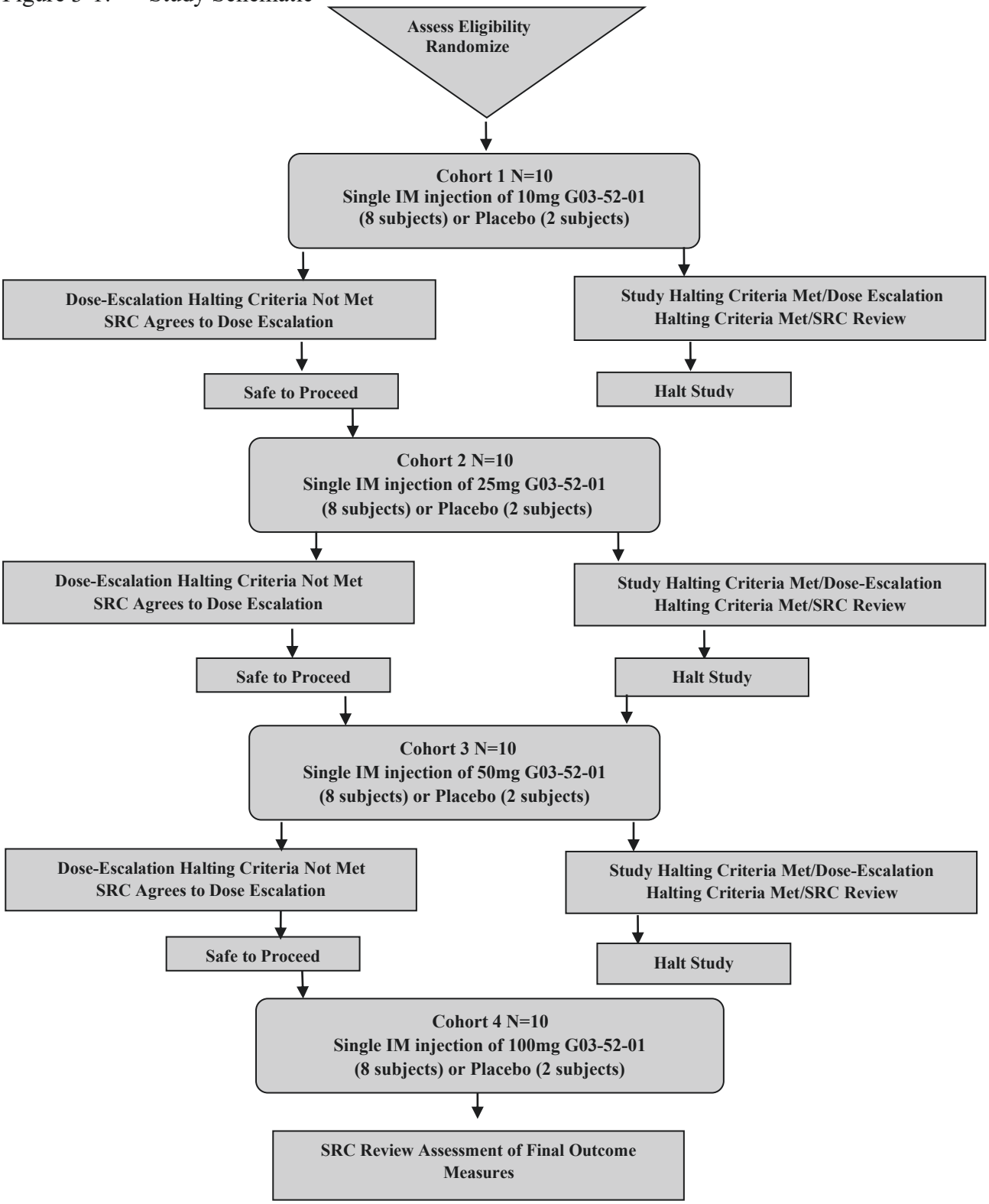
3.1 General

A Phase 1, randomized, double-blind, placebo-controlled dose escalation trial of four dose cohorts of 10 subjects (1: 10 mg, 2: 25 mg, 3: 50 mg and 4: 100 mg). Dosing for each cohort is as follows: Two sentinel subjects will be administered a single IM dose (one G03-52-01, one placebo). The dosing of the remaining eight subjects within that cohort will not be initiated until at least 24 hours have passed and no AEs have occurred that meet halting criteria, and no safety signals have occurred that in the opinion of the investigator warrant further investigation. The remaining eight subjects in the cohort will be admitted as scheduled without delay. Dose escalation will not occur until safety data through Day 8 is reviewed by the Safety Review Committee (SRC) composed of the Principal Investigator (PI), Ology Bioservices Medical Lead, and the ICON Medical Monitor. Objective dose-escalation criteria and safety evaluations will be utilized. The study will consist of a twenty-eight-day screening period and 12-hour clinic stay. Follow-up visits will occur at 24 hours, 48 hours, and 72 hours post dose and on Days 4, 8, 15, 30, 45, 60, 90, and 120 for Cohort 1-3. Follow-up visits for subjects in Cohort 4 will occur at on Days 1, 2, 4, 8, 15, 30, 45, 60, 90, 120, and 180. An SRC meeting will be held if halting criteria are met or safety concerns arise.

Table 3-1: Cohorts

Cohort	Dose of G03-52-01	Number of Subjects
1	10 mg	10 subjects (8 active, 2 placebo)
2	25 mg	10 subjects (8 active, 2 placebo)
3	50 mg	10 subjects (8 active, 2 placebo)
4	100 mg	10 subjects (8 active, 2 placebo)

Figure 3-1: Study Schematic



Note: Sentinel dosing will occur within each cohort.

Table 3-2: Schedule of Events

Study Visit	Screening[1] 01	Baseline 02	03	04	05 Cohort 1-3 Only	06	07	08	09	10	11	12	13 / Early Term	14 Cohort 4 Only
Study Day (Window)	-28 to -3	**0**	**24 hr**	**48 hr**	**72 hr**	**4**	**8±1**	**15±1**	**30±1**	**45±3**	**60±3**	**90±3**	**120±3**	**180±3**
Review Inc/ ExcI Criteria	X	X												
Review Medical History	X	X												
Review Contraception/menses	X													
Perform Abbreviated PE[3]	X	X												
Perform Symptom-Directed PE[13]		X	X	X	X	X	X	X	X	X	X	X	X	X
Obtain Vital Signs[4]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Obtain Screening Labs[5]	X													
Obtain Clinical Safety Labs[6]		X					X	X	X				X[18]	X
Serum β-HCG	X[7]													
Urine pregnancy test		X				X				X			X[18]	X
Urine Dipstick[8]	X	X											X[18]	X
Urine Toxicology	X	X												
Breathalyzer test	X	X												
Immunogenicity (ADA)[14]		X						X	X	X	X	X	X	X

Study Visit	**Screening[1] 01**	**Baseline 02**	**03**	**04**	**05 Cohort 1-3 Only**	**06**	**07**	**08**	**09**	**10**	**11**	**12**	**13 / Early Term**	**14 Cohort 4 Only**
Study Day (Window)	-28 to -3	**0**	**24 hr**	**48 hr**	**72 hr**	**4**	**8±1**	**15±1**	**30±1**	**45±3**	**60±3**	**90±3**	**120±3**	**180±3**
Hypersensitivity Panel[15]		X												
12-lead ECG[9]	X													
Viral Serology[10]	X													
PK samples[11]		X	X	X	X	X	X	X	X	X	X	X	X	X
MNA		X[16]				X			X	X[17]	X	X	X	
Concomitant Medications[2]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Randomization		X												
Study Drug Administration		X												
Future Use Sample[12]		X					X		X					
Counsel on the avoidance of pregnancy	X		X	X	X	X	X	X	X	X	X	X	X	X
Counsel on avoidance of botulinum toxin and vaccines	X		X	X	X	X	X	X	X	X	X	X	X	X
AE Review		X	X	X	X	X	X	X	X	X	X	X	X	X
SAE Review		X	X	X	X	X	X	X	X	X	X	X	X	X

1. Screening will be completed within 28 days prior to administration of study drug and may require more than one visit.
2. Concomitant medications including all of the following: prescription drugs, over-the –counter drugs, herbs, vitamins, nutritional supplements, illicit and recreational substance use, birth control information.

3. PE includes height and weight at screening.

4. Vital Signs to include sitting diastolic and systolic blood pressure, heart rate, and oral temperature. Vital signs will be checked just before injection and every visit.

5. Subjects should be fasting for Screening Laboratory Tests that will include hemoglobin, WBC with differential, absolute neutrophil count and platelet count. MCV, MCH, MCHC, RDW, MPV, which are included in a complete blood count with differential, will not be graded, serum creatinine, BUN, calcium, total bilirubin, direct bilirubin, indirect bilirubin, alkaline phosphatase, PT, PTT, INR, ALT, AST, sodium, potassium, and total CK. Subjects in cohort 4 only will have NX02 levels drawn at screening

6. Subjects should be fasting for Clinical Safety Laboratory Tests that will include hemoglobin, WBC with differential, absolute neutrophil count and platelet count. MCV, MCH, MCHC, RDW, MPV, which are included in a complete blood count with differential, will not be graded, serum creatinine, BUN, calcium, total bilirubin, direct bilirubin, indirect bilirubin, alkaline phosphatase, PT, PTT, INR, ALT, AST, sodium, potassium, and total CK.

7. A serum pregnancy test will be obtained for all women of reproductive capacity. Results must be confirmed as negative before study product is dosed.

8. A urine dipstick will be done to evaluate for presence of protein, glucose or blood in urine. If dipstick is abnormal, a complete urinalysis with microscopic will be performed.

9. A 12-lead ECG will be done during screening.

10. Viral Serology includes HIV, HBsAg and antibody to HCV.

11. Subjects in Cohorts 1-3 will have PK samples taken at the following times: pre-dose, 2, 4, 8, 24, 48, and 72 hours post injection and on days 4, 8, 15, 30, 45, 60, 90, and 120. Subjects in Cohort 4 will have PK samples taken at pre-dose, 6 hours post-dose, and on days 1, 2, 4, 8, 15, 30, 45, 60, 90, 120, and 180.

12. Serum from subjects who give consent will be stored for future use. On Days 0, 8, and 30.

13. The subject will be under direct observation during at least the initial 30 minutes of the injection. A physical examination will be performed at approximately 30 minutes after starting the injection and again in response to subject symptoms which will include the following: General appearance including alertness and any difficulty breathing, HEENT, Chest, Heart, Skin and Joints.

14. Draw prior to dosing at baseline for all Cohorts. Subjects in Cohorts 4 will not have ADA blood draws on Day 15 or Day 30. Cohort 4 will have ADA drawn on follow- up Days 45, 60, 90, 120 and 180.

15. The Hypersensitivity Panel includes cytokine and complement panels, IgE, and tryptase. Draw 14ml prior to dosing. If a subject develops anaphylaxis or anaphylactoid reaction, an additional 14 mL sample will be drawn during the event and another will be drawn after the event.

16. MNA: To be drawn pre-dose for All Cohorts. Cohort 4 subjects will also have a 2-hour post dose optional (+/- 10 minutes) draw.

17. MNA at Day 45 for Cohort 4 only.

18. Cohorts 1-3 only.

3.2 Study Population

Forty healthy male and female subjects, ages 18 to 45 years old and BMI of ≥18.5 and ≤35 kg/m^2, will be enrolled in four cohorts. Up to four alternates per cohort will be recruited.

3.3 Evaluations at Screening and Check-in

The screening period will be a maximum of 28 days and there will be a 12-hour inpatient stay. Subjects meeting inclusion/exclusion criteria will be admitted to the clinical unit the day of the injection and the procedures as per Table 3-2 will be performed prior to study drug administration.

3.4 Randomization and Treatment Assignments

Eligible subjects will be randomly assigned to study drug G03-52-01 within four dosing cohorts to either active or placebo in an overall 4:1 ratio. For each dosing cohort, the first two subjects will be randomized in a 1:1 fashion to active and placebo to ensure that one of the first two subjects receives active treatment and the other control. An alternate subject will be admitted to the unit for each two-subject group. If one of the first two subjects is not randomized for any reason, then the alternate subject will receive the next consecutive randomization number. The product assignment of the remaining eight subjects in each cohort will be a simple random sample to ensure the 4:1 ratio for the dosing cohort.

Randomized treatment assignments will be generated by a statistician at ICON PLC. Randomization will occur following admittance to the unit and confirmation of eligibility is confirmed. The randomization list will be generated by the unblinded study biostatistician and transferred to the unblinded study pharmacist prior to start of the study.

If 2 or more subjects withdraw, are lost to follow up or terminate prior to Day 8, those subjects need to be replaced to ensure that data for at least 7 subjects is available for review.

If 2 or more subjects withdraw, are lost to follow up or terminate prior to Day 60 or are not compliant with all PK draws through Day 15, they may be replaced.

If more than 2 subjects withdraw, are lost to follow up or terminate following the Day 8 SRC review of safety data, the site will attempt to replace those subjects in that dose group at the time of the next planned cohort.

The detailed randomization scheme and distribution list will be described in the randomization plan.

3.5 Determination of Sample Size

This is a Phase 1 study first in humans with four dosing cohorts and no formal sample size calculations based on testing a statistical hypothesis were constructed. Four dosing groups of ten, each with eight participants assigned the active group and two assigned to the control group, are

practical and provide sufficient information for a total sample size of 40 for a Phase 1 trial primarily designed to assess safety.

If ten subjects are studied, then the probability of at least one subject experiencing an event of toxicity can range from 0.728 to 0.996 assuming true event rates between 0.15 and 0.5 Additionally, if no events are observed in a cohort of six dosed subjects receiving G03-52-01 the upper bound of an exact 95% confidence interval for the true proportion is 0.46.

3.6 Study Drug Administration

G03-52-01 will be administered IM as a single dose at concentrations of 10 mg, 25 mg, 50 mg, and 100 mg by varying the administration volume. Placebo will be 0.9% Sodium Chloride Injection, USP is a sterile, non-pyrogenic, isotonic solution of sodium chloride and water for injection.

G03-52-01 and placebo should be administered as a single IM injection to the central, thickest portion of the deltoid and the injection must be completed within 30 minutes after preparation.

3.7 Concomitant Medications

Concomitant medication information will be recorded at Screening for the prior 28 days. At each subsequent study visit each new concomitant medication and changes to existing medications will be recorded. Subjects will be required not to utilize non-study medication or herbal supplements during the study except those deemed necessary by the site PI or sub investigator. Any drug (e.g., over-the-counter herbal supplement, vitamins or prescription) use by the subject during the course of the trial will be recorded in the subject's source documents and on the appropriate eCRF.

Subjects will be instructed to refrain from the receipt of any of the medication/ product as per Section 5.8 of the protocol during study participation unless medically indicated and deemed immediately necessary by their private physician.

3.8 Drug Administration and Compliance

G03-52-01 and placebo should be administered as a single IM injection to the central, thickest portion of the deltoid. Water for injection will be used to reconstitute the G03-52-01 for IM injection. The placebo will be normal saline without the addition of G03-52-01. The product should be used within 30 minutes upon reconstitution.

Complete records and documentation of study product receipt, accountability, dispensation, temperature monitoring, and storage conditions, and final disposition of the study product will be maintained. All study products, whether administered or not, must be documented on the appropriate study product accountability record or dispensing log.

3.9 Evaluation of Efficacy

Not Applicable

3.10 Evaluation Pharmacokinetic and Sampling Schedule

Six-mL samples of blood for PK samples will be drawn at the following times: pre-dose, and at 2, 4, 8, 24, 48, and 72 hours post dose and on Days 4, 8, 15, 30, 45, 60, 90, and 120 for cohorts 1-3 & pre-dose, at 6 hours post-dose, and on days 1, 2, 4, 8, 15, 30, 45, 60, 90, 120 and 180 for cohort 4. Serum will be analyzed for levels of each of the monoclonal antibodies using a validated ECLA or ELISA. All PK samples will be tested by ECLA or ELISA.

Three 10-mL samples of blood will be drawn to be analyzed for neutralizing antibody concentrated using the validated Battelle MNA. PK samples will be tested by the Battelle MNA for serotypes A and B at pre-dose and on Days 4, 30, 60, 90, and 120 for cohorts 1-3 & at pre-dose, and on days 4, 30, 45, 60, 90 and 120 for cohort 4.

PK samples will be collected as described in Table 3-2.

3.11 Evaluation of Pharmacodynamics and Sampling Schedule

Not Applicable

3.12 Evaluation of Immunogenicity and Sampling Schedule

Six-mL samples of blood will be drawn at pre-dose, on Days 15, 30, 45, 60, 90, and 120 for determining the presence of ADA using a validated ECLA that measures of total anti-drug antibody in serum for Cohorts 1-3.

Six-mL samples of blood will be drawn pre-dose and on Days 45, 60, 90, 120, and 180 for determining the presence of ADA using a validated ECLA that measures total anti-drug antibody in serum for Cohort 4. This will be done to assess immunogenicity.

Immunogenicity samples will be collected as described in Table 3-2.

3.13 Evaluation of Other Parameters and Sampling Schedule

Not Applicable

3.14 Evaluation of Treatment Safety

Study products safety will be assessed as per sections 3.15 to 3.21.

3.15 Adverse Events

An AE is defined as any untoward medical occurrence in a subject administered a pharmaceutical product during the course of a clinical investigation. An AE can therefore be any

unfavorable and unintended sign, symptom, or disease temporally associated with the use of a study drug, whether or not thought to be related to the study drug.

A treatment-emergent AE (TEAE) is defined as any event not present before exposure to study drug or any event already present that worsens in either intensity or frequency after exposure to study drug.

An SAE is any untoward medical occurrence that at any dose:

- Results in death,
- Is life-threatening*,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Congenital anomaly/birth defect;
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions

**Life-threatening adverse event. An adverse event is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event, had it occurred in a more severe form, might have caused death.*

Subjects will be monitored throughout the study for AEs, from the time informed consent is obtained through End of Study (EOS). Any medical condition that is present at the time the subject is screened should be considered as baseline and not reported as an AE. However, if the condition increases in severity or frequency at any time during the study, it should be recorded as an AE.

All AEs must be graded for severity and relationship to study product based on the Investigator's assessment. AEs will be followed until resolution or stability even if this extends beyond the study-reporting period. Resolution of an AE is defined as the return to pretreatment status or stabilization of the condition with the expectation that it will remain chronic. Follow-up procedures, evaluations, and outcomes will be recorded on the subject's case report forms.

The following details will be collected: description of the AE, onset date, action taken with study drug (dose not changed, dose reduced, drug interruption, drug withdrawn, dose increased and not applicable), date of resolution, outcome (recovered/resolved, not recovered/not resolved, recovered/resolved with sequelae, recovering/resolving, fatal and unknown), severity (mild, moderate, severe), seriousness (yes, no), causality/relationship to study drug (not related, possibly related and definitely related), additional treatment required.

Reactogenicity (Other conditions, local and systemic reactions) will also be collected.

3.16 Clinical Laboratory Assessments

The following laboratory tests will be done at screening and end of study. Subjects should be fasting, which means no food or drink (other than water) for at least eight hours prior to

sampling. Safety labs with a Grade 1 value will not exclude a subject from participation but will serve as their baseline value.

Table 3-3: Laboratory Evaluations

Category	Evaluation items
Hematology	Hemoglobin, WBC with differential, absolute neutrophil count and platelet count. MCV, MCH, MCHC, RDW, MPV.
Chemistry	Serum creatinine, BUN, calcium, total bilirubin, direct bilirubin, indirect bilirubin, alkaline phosphatase, PT, PTT, INR, ALT, AST, sodium, potassium, and total CK.
Urinalysis	Dipstick: Urine protein, blood and glucose. Menstruating females failing with a positive blood on urine dipstick may be retested following cessation of menses.
Other tests	Viral Serology Tests (HIV, HBsAg and antibody to HCV), Urine toxicology (cocaine (and metabolite), barbiturates, benzodiazepines, opiates, THC, methamphetamine/amphetamine, methadone and PCP), Urine pregnancy test, Serum β-hCG test

Immunogenicity samples will be collected as described in Table 3-2.

3.17 Vital Signs

Vital sign assessments including systolic and diastolic blood pressure (BP) [measured after sitting for at least 10 minutes], heart rate (HR), and oral temperature will be performed at each in-clinic study visit. Vital signs that are thought to be aberrant due to an error in measurement may be repeated. During screening and follow-up, a measurement that is a Grade 1 may be repeated once if the PI believes a transient condition led to the aberrant value.

Vital signs obtained at screening will serve as baseline values for the subject. Grade 1 values are allowable unless deemed clinically significant by the study investigator.

3.18 Electrocardiograms

A 12-lead ECG will be performed at screening and reviewed by the study PI or a co-Investigator to assess the cardiac status of a subject for eligibility for enrollment. ECGs will be performed after the subject rests quietly in a supine position for at least 10 minutes. To be eligible for participation, the QTc interval should be ≤450ms, and there must be no clinically significant ECG abnormalities according to the study investigators and may be repeated once. ECG will be recorded at Screening visit.

3.19 Physical Examinations

An abbreviated physical examination (PE) will be conducted at the screening visit and Day 0. Height and weight will be obtained at screening. An abbreviated PE is distinguished from a complete PE as all body system assessments are not required (e.g., pelvic, rectal, etc.).

On Day 0, the PE will focus assessment for the presence of the following in order to detect signs of a hypersensitivity reaction:

- General appearance including alertness and any difficulty breathing.
- HEENT (confirm no swelling of lips/tongue/uvula)
- Chest (confirm no stridor or wheezing)
- Heart (assess regularity of rhythm)
- Skin (confirm no hives, examine for any eruptions)
- Joints (confirm no swelling, warmth, or tenderness)

A symptom- directed PE will be performed at all other in-clinic study visits. Any new findings on examination post dosing or worsening of existing conditions are to be reported as AEs.

3.20 Other Safety Assessments

3.20.1 Hypersensitivity Panel

A hypersensitivity panel includes cytokine and complement panels, IgE and tryptase. This 14 mL sample will be drawn on Day 0 prior to dosing. The sample will be processed only if the subject has a hypersensitivity reaction. If a subject develops anaphylaxis or anaphylactoid reaction, an additional 14 mL sample will be drawn during the event and another will be drawn after the event.

3.21 Protocol Deviation Reporting

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or protocol-specific MOP requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly. All protocol deviations must be addressed in study subject source documents.

3.22 Medical and Surgical History

Medical history will be obtained by direct interview. Subjects will be queried regarding a history of significant medical disorders of the head, eyes, ears, nose, throat (HEENT), mouth, cardiovascular system, lungs, gastrointestinal tract, liver, pancreas, kidney, urologic, nervous system, blood, lymph glands, endocrine system, musculoskeletal system, skin, and genital/reproductive tract. A history of any allergies, cancer, immunodeficiency, psychiatric

illness, substance abuse, and autoimmune disease will be solicited. The medical history will include current and past medical diagnoses, hospitalizations and major surgical procedures. The medical history will be obtained at screening and updated upon admittance to the unit on Day 0.

4. CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSIS

All analyses specified in this SAP are consistent with the final study protocol (Version 3.0, dated 7 Sept 2021).

Any changes in the analysis provided or any additional analysis performed will be documented in CSR.

5. QUALITY CONTROL AND QUALITY ASSURANCE METHODS FOR DATA ANALYSIS

Case report forms will be monitored and collected by ICON. All monitored CRFs will be sent to the Data Management group at ICON and processed according to the ICON Study Specific Procedure Data Management Plan (DMP). The DMP describes CRF data processing, edit checks, data query management, medical dictionary coding, SAE reconciliation, data transfers, and data quality review through database lock or any necessary reopening of the database. After database lock, the data will be retrieved from the database using SAS®.

6. PHARMACOKINETIC AND IMMUNOGENICITY ASSESSMENTS

6.1 Pharmacokinetic Assessment

Pharmacokinetic parameters for serum concentrations for each monoclonal antibody (NX01, NX02, NX11, XB10, XB18, and XB23) and serotypes (A and B) will be estimated separately using non-compartmental analysis (Phoenix™ WinNonlin®, version 8.0 or later; Certara L.P., Princeton, New Jersey, USA) and actual sample collection timepoints.

PK parameters will include, samples analysed using MNA method for Serotypes A and B:

Parameter	Definition
$AUC_{(0-t)}$	Area under the concentration time-curve to the last concentration above the lower limit of quantitation
C_{max}	Maximum observed concentration
T_{max}	Time of maximum observed concentration

PK parameters will include, samples analysed using ECLA or ELISA method for each of the monoclonal antibodies of G03-52-01:

Parameter	Definition
$AUC_{(0-\infty)}$	Area under the concentration time-curve extrapolated to infinity
$AUC_{(0-t)}$	Area under the concentration time-curve to the last concentration above the lower limit of quantitation
CL/F	Apparent oral clearance of drug following extravascular administration (total clearance)
C_{max}	Maximum observed concentration
Kel	Elimination rate constant
$t_{1/2}$	Terminal elimination half-life
T_{max}	Time of maximum observed concentration
V_z/F	Volume of distribution during terminal phase following extravascular administration

AUC will be computed using the log-linear trapezoidal rule. The value of AUC%extrap should be less than or equal to 20% for the $AUC_{(0-\infty)}$ to be considered well estimated. If this proportion is >20%, then the values of $AUC_{(0-\infty)}$ will be treated with caution. When $AUC_{(0-\infty)}$ is calculated and tabulated, the AUC%extrap will also be tabulated. Where AUC%extrap >20%, $AUC_{(0-\infty)}$ and all related parameters (i.e. CL/F and V_z/F) will be presented but excluded from the calculation of summary statistics. All values excluded from the summaries should be flagged in the individual listings with an explanation for the exclusion.

The apparent terminal phase rate-constant (Kel) will be estimated by log-linear regression of the concentration-time data associated with this phase. The decision as to which data points describe

the terminal phase will be reached by inspecting the semi-logarithmic plot of the data, only considering concentrations at time points beyond T_{max}. A minimum of three data points will be used for the estimation of Kel preferably covering a time span of at least 2 times $t_{1/2}$. Ideally, the adjusted r^2 value associated with the estimated Kel will be ≥0.80. Poorly estimated Kel (i.e. if estimated over a time time span less than 2 times $t_{1/2}$ or adjusted R^2 <0.80), the corresponding $t_{1/2}$ and other parameters derived using Kel (i.e. $AUC_{(0-\infty)}$, CL/F, V_z/F, and $t_{1/2}$) will be flagged in the report and excluded from deriving PK parameters dependent on Kel.

In addition, population PK models will be developed for each of the monoclonal antibodies of G03-52-01 using nonlinear mixed-effect modelling. A separate Modelling & Simulation Analysis Plan will describe this analysis and the results will be reported separately to the CSR.

6.1.1 Treatment of Outliers

Individual concentration-time points, if considered anomalous, may be excluded from the analysis at the discretion of the pharmacokinetics following a review of the available documentation. Any such exclusion will be discussed with the sponsor and clearly outlined in the study report.

Entire individual study drug profiles for a subject may be excluded following review of the available documentation and discussion with the sponsor. However, results of analysis with and without the excluded profiles may be presented in the study report. Any such exclusion will be clearly listed in the study report along with justification for exclusion.

Any anomalous concentration values observed at predose will be identified and discussed in the CSR. Pharmacokinetic parameters will be computed if the predose concentration value is not greater than 5% of C_{max} for a given patient. If the predose concentration value is greater than 5% of the subsequent C_{max}, concentration and the PK parameter data for the given subject will be listed but excluded from the PK summaries and statistical analysis. The analysis may be repeated with and without these subjects as deemed appropriate.

6.1.2 Non-Quantifiable Concentrations

All concentration values reported as no results (not collected or not determined) values will be treated as missing. For the calculation of concentration summaries, all concentrations below the quantifiable limit (BLQ) will be treated as zero. For the purpose of calculating summary statistics and plotting mean and individual concentration time profiles, BLQ values will be treated as zero prior to the first measurable concentration. After the first measurable concentration, subsequent BLQ values will be treated as missing. Descriptive statistics at any point will only be calculated if at least 2/3 of the individual data were measured and were quantifiable.

6.2 Immunogenicity

Immunogenicity will be assessed by the development of antibody titers. The presence of ADA will be evaluated over the course of the post-injection period.

7. STATISTICAL METHODS

7.1 General

The statistical analysis will be conducted following the principles specified in the International Council for Harmonization (ICH) Topic E9 Statistical Principles for Clinical Trials (CPMP/ICH/363/96).

All statistical analyses will be performed using the statistical software SAS GRID Linux/SAS Studio and any exceptions will be detailed in the CSR.

All results collected in the database will be presented in listings. Both observed values and change-from-baseline values for each subject will be given where applicable. All continuous data will be listed with the same precision as presented in the database. Cohort, Subject ID, treatment and visit will be used to sort data listings.

Unless otherwise noted, continuous variables will be summarized using number of non-missing observations (n), arithmetic mean (mean), standard deviation (SD), median, minimum, maximum, lower quartile and upper quartile; categorical variables will be summarized using the frequency count and the percentage of subjects in each category.

In the data listings, study day relative to the study product dosing date for each cohort may be presented. Study day relative to dose will be calculated as: event date – study product dose date (+ 1 if event date ≥ dose date).

All subjects who received placebo in each of the cohorts will be combined and presented along with the other dose levels until specified otherwise.

Baseline will be the latest available measurement prior to the study product dose date in each cohort.

7.2 Handling of Dropouts or Missing Data

All attempts will be made to collect all data per protocol. No imputation will be performed for missing values.

If the character result is reported for quantitative laboratory parameter then for summary and analysis it will be changed as follows into numerical value –

a) If less than '<' sign is used then the value will be reduced by 1 point from the last precision digit

b) If greater than '>' sign is used then 1 point will be added to the last precision digit.

Eg: if the lab parameter is reported to 2 decimal precision, <40.01 then for summary and analysis it will be treated as 40.00, if lab parameter is reported as whole number >40 then it will be considered as 41 and if the parameter is reported with 1 decimal precision <40.1 then it will be considered as 40.0.

7.2.1 Handling of missing/ incomplete dates for AE

Imputation rules for missing or partial AE start date are defined below:

If only Day of AE start date is missing:

If the start date has month and year but day is missing, the first day of the month will be imputed

- If this date is earlier than the first dose date, then the first dose date will be used instead.
- If this date is later than the stop date (possibly imputed), then the stop date will be used instead.

If Day and Month of AE start date are missing:

If the start date has year, but day and month are missing, the 1st of January will be imputed

- If this date is earlier than the first dose date, then the first dose date will be used instead.
- If this date is later than the stop date (possibly imputed), then the stop date will be used instead.

If Year of AE start date is missing:

If the year of AE start is missing or AE start date is completely missing, then imputation will not be done.

If the AE end date (full or partial) is before the first dose date, then the AE should be considered as a pre-treatment AE. Otherwise, the AE will be considered as TEAE.

Missing dates for Concomitant medication will be imputed similarly as described above for AE.

7.3 Multiple Comparisons and Multiplicity

Not Applicable

7.4 Adjustments for covariates

Not Applicable

7.5 Multicenter Studies

This is a single-center study.

7.6 Examination of Subgroups

There is no planned subgroup analysis.

7.7 Coding Dictionaries

Medical history and AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 23.0 or later. Medical procedures, prior and concomitant medications will not be coded.

7.8 Analysis Populations

7.8.1 Safety Population

All subjects who received study product will be included in the safety population and analyzed as treated.

7.8.2 Pharmacokinetic Analysis Population

The PK analysis population will consist of all subjects who received G03-52-01 injection and have sufficient evaluable PK samples for the reliable estimation of PK parameters for at least one of the monoclonal antibodies or serotypes A and B.

7.9 Subject Accountability

Summaries of analysis populations and subject disposition will be presented by each G03-52-01 cohort, Placebo (pooled across all cohorts) and overall will contain the following information:

- Number of subjects who are enrolled
- Number and percent of subjects who are randomized
- Number and percent of subjects who are dosed
- Number and percent of subjects who completed the study
- Number and percent of subjects who discontinued early and reason for early discontinuation
- Number and percent of subjects in the Safety and PK Analysis Population

This summary will be based on Enrolled Subjects.

Subject disposition and analysis populations, eligibility criteria satisfaction and consent information will be presented in listings.

7.10 Protocol Deviations

All protocol deviations captured will be listed by subject. These will be summarized by dose cohort and control group.

7.11 Subject Demographics and Baseline Characteristics

Subject demographics and baseline characteristics such as age, sex, race, ethnicity, height, weight, and Body Mass Index (BMI) will be summarized by dose cohort and control group. Individual subject demographics and baseline characteristics will be presented in listings. Demographics will be summarized for the Safety Population.

7.12 Medical and Surgical History

Medical history will be coded using the MedDRA, Version 23.0 or later and listed.

7.13 Other Baseline Characteristics

Not Applicable

7.14 Prior and Concomitant Medications

All concomitant procedures, prior and concomitant medications will be listed by subject.

7.15 Measurements of Treatment Compliance

As this is a single dose injection study, treatment compliance will not be separately summarized. It will be presented as part of drug administration listing.

7.16 Physical Examinations

All physical examination results will be presented in a subject listing.

7.17 Pharmacokinetic Analysis

PK parameters will be summarized by dose levels using descriptive statistics for each monoclonal antibodies (NX01, NX02, NX11, XB10, XB18, and XB23) and serotypes (A and B), separately. PK Analysis Population will be used for all listings, concentration summary, PK parameter summary and graphical presentation.

The individual sampling and subject concentration-time will be listed and displayed graphically on linear and semi-log scales. The concentrations will be summarized descriptively by nominal time point in tabular and graphical formats (linear and semi-log scales) for each monoclonal antibodies (NX01, NX02, NX11, XB10, XB18, and XB23) and serotypes (A and B), separately. Summary statistics (n, mean, SD, coefficient of variation [CV%], median, minimum, maximum, geometric mean and geometric CV%) will be calculated for each time point. Geometric CV% will be calculated as the square root of the exponentiated SD of the natural log transformed data (SQRT(exp(sln2)-1), where appropriate.

Pharmacokinetic parameters for each monoclonal antibodies (NX01, NX02, NX11, XB10, XB18, and XB23) and serotypes (A and B) will be listed and summarized descriptively, including n, arithmetic mean, SD, minimum, median, maximum, CV(%), geometric mean, geometric CV%. For T_{max}, only n, minimum, median, and maximum will be reported.

7.18 Pharmacodynamic Analysis

Not Applicable

7.19 Efficacy Analyses

Not Applicable

7.20 Biomarker Analysis

Not Applicable

7.21 Immunogenicity Analysis

Antidrug antibodies titers will be summarized by dose levels using descriptive statistics for each monoclonal antibodies (NX01, NX02, NX11, XB10, XB18, and XB23), separately. PK Analysis Population will be used for all listings, summary tables and graphical presentation.

The frequency and percentage of positive immunogenicity response will be summarized by dose levels. Anti-drug antibody status will be listed by subject over time, and percentage of subjects determined to be positive or negative summarized by dose levels at each available time point.

7.22 Safety Analyses

All Safety analyses will be performed using the Safety Population.

Tables will be presented by dose levels. All subjects who received placebo in each of the cohorts will be combined and presented along with the other dose levels.

Unscheduled visits data for all safety variables (vitals, ECG and clinical laboratory) will be listed only and will not be summarized.

7.22.1 Adverse Events

All AEs will be classified by Primary System Organ Class (SOC) and Preferred Term (PT) according to the MedDRA, Version 23 or later. Only treatment-emergent AEs (TEAEs) will be included, ie, AEs that begin or worsen after dose of study drug has been received.

The following AE summaries will be presented (where applicable the number of patients (%) and number of events will be summarized) by dose cohort and control group:

- Overall summary of TEAEs
- TEAEs by SOC and PT
- TEAEs by maximum severity
- TEAEs by closest relationship

The overall incidence of TEAEs (number and percentage of subjects) as well as the number of events will be summarized by study drug; severity of TEAE; SAE; relation to study drug of TEAE and SAE; TEAEs leading to study or study drug discontinuation; and TEAEs leading to death will be tabulated for each study drug.

Study drug related AEs are those which were determined by the investigator to be study drug-related. The incidence of study drug related AEs (as recorded in the CRF) will be summarized using descriptive statistics by SOC and PT, categorized by severity and relationship to study

drug as recorded in CRF. The frequency of treatment emergent AEs (AE burden) will be summarized using descriptive statistics by SOC and PT.

For the incidence at the subject level by SOC and PT, if a subject experience more than 1 event within the same SOC and PT, only 1 occurrence will be included in the incidence. Although all the occurrences will be included in the counting of events.

For the incidence at the subject level by SOC, PT, and severity, if a subject experience more than 1 event within the same SOC and PT, only the most severe occurrence will be included in the incidence. Although all the occurrences will be included in the counting of events.

For the incidence at the subject level by SOC, PT, and relationship to study drug; if a subject experience more than 1 event within the same SOC and PT, only the most closely related occurrence will be included in the incidence. Although all the occurrences will be included in the counting of events.

Relative day of AE onset = AE onset date – date of dosing of study product + 1

Treatment Related AEs are those AEs which can be categorized under the relation “POSSIBLY RELATED” and/or “DEFINITELY RELATED”.

All AE data will be listed for all patients. Both the Investigator’s verbatim terms and the MedDRA preferred terms will be listed for each patient. AEs listings will also include start and end date, relationship to study drug, severity, action taken for the AEs and if the AE is serious.

Any SAEs, AEs with outcome of death, or AEs resulting in discontinuation of study or study drug will be listed separately.

AEs recorded as Reactogenicity will be listed by each subject and summarized by dose level and control group similarly as described above. Summaries will be provided for severity and closest relationship.

7.22.2 Clinical Laboratory Assessments

Safety Population will be used to present summaries and listings. Clinical laboratory data will be listed and summarized using System International (SI) units.

Laboratory data will be listed by subject at each time point. Clinical laboratory values that are out of normal ranges will be presented in a separate listing.

Observed and change from baseline of continuous clinical laboratory values (serum chemistry, coagulation panel, hematology, and urinalysis) for each parameter will be summarized by dose cohort and control group at each scheduled nominal time point. Categorical Urinalysis will be presented in the listing.

The number and percentage of subjects with shift from baseline based on the laboratory normal ranges will be tabulated.

For female subjects, urine/ serum pregnancy test results will be presented in the individual subject data listings for each visit.

7.22.3 Vital Signs

Vital signs data will be listed by subject at each nominal time point. Observed and change from baseline vital signs values will be summarized by dose cohort and control group at each nominal timepoint.

7.22.4 Electrocardiograms

ECG data will only be listed.

7.22.5 Physical Examinations

Physical examination findings will be listed individually for each nominal timepoint. Shift from baseline and table describing finding as normal/abnormal will be presented for each nominal timepoint.

7.22.6 Prior and Concomitant Medications

All prior and concomitant medications will be listed. A separate listing will be provided for concomitant procedures.

7.22.7 Other Observations Related to Safety

Hypersensitivity panel data if available will be listed. Reactogenicity data will be listed and summarized as described in Section 7.22.1.

7.23 Planned Interim Analysis

A blinded interim safety and PK analysis is planned for this study to analyze all PK, ADA, and MNA samples for Cohorts 1-3 through Day 60 and Day 120. This will include all subjects in all cohorts through Day 60 and Day 120. A second blinded interim safety analysis is planned to analyze all PK, ADA, and MNA samples for Cohort 4 through Day 90. Stopping criteria are for safety and are defined in Section 9.5 of the protocol.

The ICON PK scientist will be unblinded to the treatment assignment for that particular cohort to facilitate a more detailed assessment of the PK and ADA data, which may include individual patient demographic and safety data. The ICON PK scientist will provide a summary of the PK and ADA analysis, including individual patient data, but will not include the unique patient number to ensure the Investigators and Sponsor remain blinded or any other individual data that may unblind.

7.24 Statistical Software

PK parameters will be calculated using Phoenix™ WinNonlin®, version 8.0 or later. All data listings, summaries, and statistical analyses will be generated using SAS GRID Linux/SAS Studio.

7.25 General Conventions for Tables, Listings and Figures

Tables and listings will be presented in landscape mode with minimum of 3/4" bound edge margin and 3/8" other margins on 8.5" x 11" paper.

Times new roman font size of no less than 8 point will be used for tables and listings.

A source line will be included on the bottom of each page of all tables and listings. It will contain the SAS code program name and the run date and time.

Each variable is recorded to a specific number of decimal places. If the raw data is presented with varying precision, then the least precise value will be considered as the data precision.

For summary tables, unless otherwise specified, the number of decimal places provided in the tables and listings will be based on the accuracy of the least accurate value in the raw data as follows:

n	integer
Arithmetic mean	1 decimal place more than the least accurate number in the raw data
SD	2 decimal place more than the least accurate number in the raw data
CV(%)	2 decimal places
Geometric mean	1 decimal place more than the least accurate number in the raw data
Geometric CV	2 decimal places
Median	1 decimal place more than the least accurate number in the raw data
Minimum	same number of decimal places as raw data
Maximum	same number of decimal places as raw data
Percentage	1 decimal place

8. LIST OF TABLES, FIGURES, AND LISTINGS

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Table 14.1.2	Summary of Analysis Populations
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Section 14.2	**Pharmacokinetic and Immunogenicity Data Summaries**
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	Note: separate for each monoclonal antibody and serotype
Table 14.2.1.2	Summary of Pharmacokinetic Parameters (PK Analysis Population)
	Note: separate for each monoclonal antibody and serotype
Figure 14.2.1.1	Plot of Mean (SD) Serum Concentration-Time Profile (PK Analysis Population)
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Section 14.2.2	**Immunogenicity Data Summaries**
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Table 14.3.1.6	Summary of Reactogenic Adverse Events by System Organ Class, Preferred Term, and Maximum Reported Severity Grade (Safety Population)
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Section 14.3.2	**Listings of Deaths, Other Serious and Certain Significant Adverse Events**
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Table 14.3.4.1	Individual Subjects with Abnormal Clinical Laboratory Values (Safety Population)
	Note: Please provide reference to Listing 16.2.8.3
Section 14.3.5	**Additional Safety Data Summaries**
Table 14.3.5.1	Absolute and Change from Baseline of Clinical Laboratory Results by Category and Test (Safety Population)
	Note: please include only continuous tests
Table 14.3.5.2	Shift from Baseline in Clinical Laboratory Results (Safety Population)
Table 14.3.5.3	Absolute and Change from Baseline for Vital Signs (Safety Population)
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Listing Number	**Listing Name**
Section 16.2.1	**Discontinued Subjects**
Listing 16.2.1	Subject Disposition (Enrolled Subjects)
Section 16.2.2	**Protocol Deviations**
Listing 16.2.2	Protocol Deviations (Safety Population)
Section 16.2.3	**Subjects Excluded from Analysis**
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Listing 16.2.4.1	Demographics and Baseline Characteristics (Safety Population)
	Note: Including Screening Height and Weight
Listing 16.2.4.2	Screening Outcome (All Subjects)