STATISTICAL ANALYSIS PLAN

Study Title:	Efficacy, Safety, and Tolerability of GLS-1200 Topical Nasal Spray in the Prevention of Incident Confirmed SARS-CoV-2 Infection
Name of Test Drug:	GLS-1200
Study Number:	T2R-002
Protocol Version:	7.0
Protocol Date:	26 February 2021
Analysis Plan Version:	2.0
Analysis Plan Date:	21 January 2022
Analysis Plan Author:	Catalyst Clinical Research, LLC

SIGNATURE PAGE

DocuSigned by:
Joel Maslow
Signer Name: Joel Maslow
Signing Reason: I approve this document
Signing Time: 21-Jan-2022 | 12:48:44 PM PST
04EA2860227C41CB95FDE4D9283AF2C9

21-Jan-2022

Signature Date

Dr. Joel Maslow

Chief Medical Officer

GeneOne Life Science Inc.

DocuSigned by:
Susan E. Spruill
Signer Name: Susan E. Spruill
Signing Reason: I approve this document
Signing Time: 21-Jan-2022 | 4:07:34 PM CST
6B44CB45B7954FD5B700ED25E98AB084

21-Jan-2022

Signature Date

Susan E. Spruill, MS, PStat®

Statisticial Consultant

Applied Statistics and Consulting

DocuSigned by:
Ahmed Tariq
Signer Name: Ahmed Tariq
Signing Reason: I approve this document
Signing Time: 21-Jan-2022 | 2:48:35 PM EST
8A9AFFC7511B48049134C7E9728C3D84

21-Jan-2022

Signature Date

Ahmed Tariq, MS

Biostatistician

Catalyst Clinical Research, LLC

LIST OF ABBREVIATIONS

AE	adverse event
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
bpm	beats per minute
CRF	case report form
CSR	Clinical Study Report
DBP	diastolic blood pressure
ECG	electrocardiogram
ET	early termination
FDA	Food and Drug Administration
GI	gastrointestinal
HBsAg	hepatitis B surface antigen
HCV	hepatitis C virus
ICH	International Conference on Harmonisation
IP	Investigational Product
ITT	Intent-to-Treat
MedDRA	Medical Dictionary for Regulatory Activities
OTC	over-the-counter
PT	preferred term
SAE	serious adverse event
SBP	systolic blood pressure
SD	standard deviation
SOC	system organ class
TFLs	tables, figures, and listings
ULN	upper limit of normal
WHO	World Health Organization

1. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of GeneOne Life Science Inc.'s Protocol T2R-002 [Efficacy, Safety, and Tolerability of GLS-1200 Topical Nasal Spray in the Prevention of Incident Confirmed SARS-CoV-2 Infection]. The purpose of this plan is to provide specific guidelines from which the statistical analyses will proceed. Any deviations from this plan will be documented in the clinical study report (CSR).

The reader is referred to the following complementary documents:

- Protocol T2R-002, version 7.0, dated 26Feb2021
- Case Report Form (CRF), version 1.017, dated 04Jun2020
- Symptom Diary, version 2, dated 16Apr2020
- Treatment Diary, version 1, dated 28 Mar2020
- DMP, version 1.0, dated 19Jun2020

2. STUDY OBJECTIVES

2.1. Primary Objectives

The primary objectives of the study are to evaluate the safety and tolerability of GLS-1200 topical nasal spray as well as the incidence in the diagnosis of PCR-confirmed SARS-CoV-2 infection by treatment group.

2.2. Secondary Objective

The secondary objective is to assess the documentation of symptoms consistent with SARS-CoV-2 infections relative to treatment group.

2.3. Exploratory Objective

The exploratory objective of the study is to assess the incidence of seroconversion in serum and the relationship of taste receptor genetics to incidence of SARS-CoV-2 infection relative to treatment group.

3. STUDY DESIGN AND PLAN

This is a Phase II, placebo-controlled, double-blind study of GLS-1200 topical nasal spray to assess the safety, tolerability, and ability to reduce the incidence of confirmed SARS-CoV-2 infection. Following recruitment and informed consent, those meeting enrollment criteria will be randomized 2:1 (GLS-1200:Placebo). Participants will initiate topical nasal spray applications immediately after randomization and will continue for 4 weeks. Participants will self-administer drug three times daily. Follow-up will continue through 6 weeks since some cases of SARS-CoV-2 infection may not be apparent until after the primary treatment period has concluded. The primary outcome measurements are safety, tolerability, and reduction in the diagnosis of PCR-confirmed SARS-CoV-2 infection. Secondary measures will assess the incidence of symptoms

between each visit, by treatment group. In addition the average number of days subjects experience each symptom will be summarized by treatment group. Exploratory measures will assess the incidence of seroconversion in serum and the relationship of taste receptor genetics to incidence of SARS-CoV-2 infection both relative to treatment group.

Table 1: Schedule of Assessments

Tests and Observations	Day 0	Week 2	Week 4	Week 6	Unscheduled
Permitted window (days)		±3d	±3d	±3d	N/A
Clinical Evaluations					
Obtain Written Informed Consent	X				
Confirm Eligibility Criteria	X				
Demographics	X				
Medical History and Concomitant Medications	X	X	X	X	
Physical Exam, height, weight, and Vital Signs[1]	X	X	X	X	X
Safety Evaluations					
Record Adverse Events		X	X	X	X
Provide participant diary	X				
Collect and review participant diary		X[2]	X	X	
Perform 12-lead ECG	X		X		
Pregnancy test[3]	X	X	X		
Blood for Hematology: CBC with differential	X		X		
Blood for Chemistry: Sodium, potassium, bicarbonate, glucose, BUN, Cr	X		X		
Study Related Procedures					
Dispense study drug & device, provide training	X				
Collect nasopharyngeal swabs for viral PCR	X	X	X	X	X
Collect serum for viral antibodies	X	X	X	X	
Collect plasma for measurement of quinine		X			
Collect saliva for TAS2R genotyping	X				
Estimated Blood Volume per Visit (mL)	40	25	40	20	

[1] A targeted physical exam will be performed at Weeks 2, 4 and 6 and at unscheduled visits.
[2] The participant diary will only be reviewed at Weeks 2 and 4; it will be reviewed and collected at Week 6.
[3] A urine pregnancy test will be administered.

4. DETERMINATION OF SAMPLE SIZE

The sample size for this study assumes an infection rate in the placebo group of 10%. A 2:1 randomization of 225 subjects would have a power of 80.8% to detect a difference of 9% between groups at alpha = 0.05 assuming 1% of individuals in the treatment group are confirmed to be infected with SARS-CoV-2.

5. GENERAL ANALYSIS CONSIDERATIONS

The statistical analysis results will be reported using tables, listings, and figures (TLFs). Summaries of continuous variables will display means, standard deviations (SDs), medians, minimums, maximums and the number of observations. Summaries of categorical variables will display frequency counts and percentages.

All analyses will be performed using SAS® Version 9.4 or higher.

6. ANALYSIS POPULATIONS

6.1. Intent-to-treat (ITT) Population

The ITT Population will include all randomized to treatment allocation.

6.2. Safety Population

The Safety Population will include all subjects who received at least one dose of study treatment.

6.3. Per-protocol (PP) Population

The PP Population will include all subjects who complete the trial and who receive ≥ 90% of the study treatments through to either diagnosis of SARS-CoV-2 infection (study end point) or to end of study (4 weeks), based on subject's completed doses on the treatment diary form, and who have no significant protocol deviations.

7. STUDY POPULATION

7.1. Subject Disposition

The number and percentage of subjects in each analysis population, who completed the study and who discontinued prior to study completion will be presented by treatment (GLS-1200 and placebo) and overall. Disposition will also by summarized by site. Subjects who discontinued prior to completing the study will also be summarized by reason for discontinuation.

Subject disposition will also be listed.

7.2. Protocol Deviations

Protocol deviations with significance will be listed.

7.3. Demographics and Baseline Characteristics

Demographics, baseline data, vital signs, medical history, prior and concomitant medications and treatments will be summarized by means of descriptive statistics: continuous variables as mean, median, SD, minimum/maximum ranges and categorical variables as frequencies and percentages, stratified by treatment arms and overall, based on the ITT population. These summaries will also by provided by site. Demographic and baseline characteristics will be listed.

7.4. Medical History

Medical history verbatim terms collected from the CRF will be mapped to system organ classes (SOCs) and preferred terms (PTs) using the Medical Dictionary for Regulatory Activities (MedDRA) (version 23.0).

Summaries (number and percentage of subjects) of medical history by SOC and PT will be provided by treatment and overall.

A listing of medical history will be provided.

7.5. Prior and Concomitant Medications

Medication verbatim names collected from the CRF will be mapped to Anatomical Therapeutic Chemical (ATC) Classes and Preferred Names using the World Health Organization's WHODrug Global March 2020 version. Preferred Names will consist of only the base compounds and not the salts (e.g., Naproxen Sodium will be listed only as Naproxen). Concomitant medications will be summarized for each treatment by ATC class and preferred name. Prior and concomitant medications will be listed.

A prior medication is defined as a medication that was administered up to 8 weeks prior to first dose of study treatment. All other medications will be considered concomitant.

7.6. Drug Exposure

Exposure summaries of duration of exposure, total number of doses taken, and total number of doses missed, will be provided by treatment. Duration of exposure is defined as the date of last dose minus the date of first dose, regardless if any doses were missed in between.

Dosing data collected from treatment diaries will be listed along with any treatment side effects or device issues, and the number of known or suspected exposures to SARS-CoV-2.

7.7. Treatment Compliance

Treatment compliance is defined as the total number of administered doses, as recorded in the treatment diary, divided by the total number of planned doses. Each recorded dose will be considered to be a complete dose of study drug. Descriptive statistics of treatment compliance as well as the proportion of subjects falling into different treatment compliance categories (<50%, 50%-80%, and >80%) will be summarized by treatment group.

Unless differences are observed between sites in the baseline characteristics and demographics that would confound interpretation of efficacy and safety results, all efficacy and safety will be summarized over both sites. If there are concerns for confounded results due to site differences in demographic or baseline characteristics, then all efficacy and safety results will be subset by sites as well as overall. However, no treatment comparisons within sites will be made since the study is not powered to assess treatment effect within sites.

8. EFFICACY ANALYSES

8.1. Definition of the Primary Efficacy Endpoint

The primary efficacy endpoint is the incidence of SARS-CoV-2 infection, confirmed by PCR at any time within four weeks of treatment initiation. Participants will be queried as to any new diagnosis of SARS-CoV-2 infection, defined as a positive PCR test for SARS-CoV-2. Subjects who test negative for SARS-CoV-2 infection at Weeks 2 and 4 will be considered treatment successes. Subjects who are lost to follow-up, require rescue therapy, discontinue the study prior to completion of Week 4, or test positive for SARS-CoV-2 infection at at any point within four weeks of treatment initiation will be considered treatment failures. All deaths will be considered as treatment failures.

8.2. Analysis of the Primary Efficacy Endpoint

The number and percentage of treatment failures as well as treatment successes will be presented by treatment and compared using Fisher's exact test. Additionally, the number and percentage of subjects who test positive as well as those who test negative for SARS-CoV-2 infection will be provided by treatment at each visit (Weeks 2, 4 and 6). This summary and analysis will be performed for both the ITT and PP populations.

8.3. Definition of the Secondary Efficacy Endpoint

The secondary efficacy endpoint is the documentation of symptoms consistent with SARS-CoV-2 infections. Subjects will be instructed to maintain a symptom diary that includes those symptoms considered common for SARS-CoV-2. The diary is inclusive of symptoms identified by the World Health Organization for a diagnosis of SARS-CoV-2 as well as more recently identified symptoms such as conjunctivitis, diarrhea, and loss of taste or smell. Each symptom will be scored as present (score of 1) or absent (score of 0) and will be recorded in the symptom diary on a daily basis.

8.4. Analysis of the Secondary Efficacy Endpoint

The incidence of each symptom will be summarized by treatment group for each two week interval. In addition, the average number of days subjects had each symptom throughout the study period (6 weeks) will be summarized by treatment group. Summaries will be presented noncumulatively by visit as well as cumulatively over 4 weeks of treatment. The secondary analysis will be performed for the ITT population.

8.5. Definition of the Exploratory Efficacy Endpoint

The exploratory efficacy endpoint is the incidence of SARS-CoV-2 seroconversion.

8.6. Analysis of the Exploratory Efficacy Endpoint

The cumulative number and percentage of subjects who seroconvert at each post-baseline visit will be presented by treatment for the ITT population. The relationship of taste receptor genetics to incidence of SARS-CoV-2 infection relative to treatment group will be examined on an adhoc basis and is outside the scope of this document.

9. SAFETY ANALYSES

All safety analyses will be based on the Safety Population.

9.1. Adverse Events

An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body, or worsening of a pre-existing condition, temporally associated with the use of a product whether or not considered related to the use of the product. In this study, such changes will be monitored, classified, and summarized, as Clinical or Laboratory AEs. Medical conditions/diseases present before starting the investigational drug will be considered adverse events only if they worsen after starting study treatment. Verbatim terms on CRFs will be mapped to preferred terms (PTs) and system organ classes (SOCs) using the Medical Dictionary for Regulatory Activities (MedDRA) (version 23.0).

9.1.1. Severity

AEs are graded by the investigator as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (potentially life threatening) or Grade 5 (death) according to the NCI Common Terminology Criteria for Adverse Events version 5.0.

9.1.2. Relationship

Based on the criteria described below, AEs will be classified according to one of the following categories:

- Related – the investigator considers that there is a causal relationship between the event and study drug
- Probably related – the investigator considers that there is a probability of a causal relationship of the event to the study drug
- Possibly related – the investigator considers that there is a possible causal relationship of the event to the study drug
- Unlikely related – the investigator considers that there is an unlikely causal relationship of the event to the study drug
- Not related – the investigator considers that the event has no relationship to administration of the study drug

For the purpose of analysis, related AEs are those reported as “Related,” “Probably related,” “Possibly related” and unrelated AEs are those reported as "Unlikely related" or “Not related.” Events for which the investigator did not record relationship will be considered related for analysis. Data listings will show relationship as missing.

9.1.3. Serious Adverse Events

An SAE is any adverse drug experience occurring at any dose that results in any of the following outcomes:

- Death during the period of surveillance defined by the protocol;
- Is immediately life-threatening (e.g., participant was, in the view of the Investigator, at immediate risk of death from the event as it occurred). This does not include an AE that, had it occurred in a more serious form, might have caused death;
- An event requiring inpatient hospitalization or prolongation of existing hospitalization during the period of protocol defined surveillance (including any overnight stay in the hospital, regardless of the length of stay, even if the hospitalization is only a precautionary measure to allow continued observation. However, hospitalization (including hospitalization for an elective procedure) for continued treatment or assessment of a pre-existing condition that has not worsened, does not constitute an SAE. NOTE: Evaluation in a physician’s office, or at a hospital or other urgent care setting in an observational, non-admitted status regardless of the time period of observation, does not constitute an SAE;
- Results in congenital anomaly or birth defect;
- Results in persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions;
- Is an important medical event that may not result in death, be life threatening, or require hospitalization, but based upon appropriate medical judgment, may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization;
- Is medically significant or requires intervention to prevent one or other of the outcomes listed above.

9.1.4. Treatment-Emergent Adverse Events (TEAEs)

9.1.4.1. Definition of Treatment-Emergent

TEAEs are events that either:

a) began on or after the date and time of first dose or

b) had no recorded start date and the stop date is not before the date and time of first dose.

9.1.4.2. Incomplete Dates

If the date of onset is incomplete, then the month and year (or year alone if month is not recorded) of onset determine treatment emergence as follows. The event is treatment emergent if the month and year of onset (or year of onset) of the event is the same as or after the month and year (or year) of date of first dose.

9.1.5. Summaries of Adverse Events

An overall summary of AEs will display, by treatment, the number and percentage (with 95% exact binomial confidence interval) of subjects who had any TEAE, whose strongest TEAE relationship to study drug is related or not related, whose maximum TEAE severity is mild, moderate, or severe, who had any SAE, any Serious TEAE, any TEAE leading to study discontinuation, and any TEAE leading to death.

The following summaries (number and percentage of subjects) of AEs (by SOC and PT) will be provided by treatment:

- All TEAEs
- All TEAEs by strongest relationship
- All TEAEs by maximum severity grade
- All Serious AEs
- All Serious TEAEs
- All TEAEs leading to study discontinuation
- All TEAEs leading to death

These summaries will present the number and percentage of subjects with at least one qualifying AE. Subjects may have more than one AE per SOC and PT. Each summary will be ordered by descending order of incidence of SOC and PT within each SOC.

In addition to the by-treatment summaries, data listings will be provided for the following:

- All AEs (with a flag indicating whether the event is treatment emergent)
- SAEs
- AEs leading to study discontinuation
- Deaths

9.2. Clinical Laboratory Evaluations

Shift from baseline in laboratory parameter results (indicated as Low, Normal, or High) will be summarized for each post-baseline visit. Mean (+/- SD) laboratory parameter values will be graphically presented over time by treatment. All laboratory parameters will be listed and include indicators for low/high and clinical significance as determined by the investigator.

9.3. Vital Signs

Vital signs (temperature, heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP)) will be summarized using descriptive statistics (sample size, mean, SD, median, minimum, and maximum) at baseline and at each post-baseline time point by treatment. Change from baseline will also be summarized at each post-baseline time point. Mean (+/- SD) Vital Sign values will be graphically presented over time by treatment. All vital signs results will be listed.

9.4. ECG Results

Shift from baseline in 12-Lead ECG overall interpretion (results are Normal, Abnormal Not Clinically Significant (NCS), or Abnormal Clinically Significant (CS)) will be summarized at each post-baseline visit by treatment. Mean (+/- SD) continuous ECG parameter values will be graphically presented over time by treatment.

Additionally, the number and percentage of subjects will be summarized for the following QTcF Interval result categories at baseline and each post-baseline visit by treatment:

- <=450 msec (males) or <=470 msec (females)
- >450 msec (males) or >470 msec (females)
- Change from baseline <=60 msec (only applies to Week 4)
- Change from baseline >60 msec (only applies to Week 4)

A listing of ECG results will present the interpretations of abnormalities and whether these are considered clinically significant by the investigator.

9.5. Physical Exam

Physical exam findings will be listed.

APPENDIX A: PRESENTATION OF DATA AND PROGRAMMING SPECIFICATIONS

Tables

- Formal organization of tabulations may be changed during programming if appropriate, e.g., tables for the different variables may be combined into a single table, or tables with more than one variable may be split into several tables.
- Means, medians, and quartiles will be presented to one more decimal place than the raw data. SDs will be presented to two more decimal places than the raw data. Minimums and maximums will be reported with the same number of decimal places as the raw data.
- Percentages will be presented to the tenths place.
- For frequency counts of categorical variables, categories whose counts are zero will be displayed for the sake of completeness. For example, if none of the subjects discontinue due to "lost to follow-up," this reason will be included in the table with a count of 0. Categories with zero counts will not have zero percentages displayed.
- The last footnote will be "Reference: xxx", where xxx indicates the source listing number(s).

Listings

- Formal organization of the listing may be changed during programming if appropriate, e.g., additional variables may be included, change in the column order, or the listing may be split into multiple parts due to space constraints, etc.
- If not otherwise specified, all data listings will be sorted by treatment, subject number, visit, and date/time as appropriate.
- All date values will be presented in a ISO 8601 date (e.g., 2001-08-29) format.
- All observed time values will be presented using a 24-hour clock HH:MM:SS format (e.g., 01:35:45 or 11:26). Seconds will only be reported if they were measured as part of the study.

Missing or incomplete dates, i.e., AEs and concomitant medications

The most conservative approach will be systematically considered. If the AE onset date is missing or incomplete, it is assumed to have occurred during the study treatment phase (i.e., considered a TEAE) except if the partial onset date or other data such as the stop date, indicates differently. Similarly, a medication with partial start and stop dates could be considered as a concomitant treatment.

The following algorithms will be applied to missing and incomplete start and stop dates:

Start Dates

- If the day portion of the start date is missing, then the start date will be estimated to be equal to the date of IP administration, provided the start month and year are the same as IP administration and the stop date is either after IP administration or completely missing. Otherwise, the missing day portion will be estimated as '01'.

- If both the day and month portions of the start date are missing, then the start date will be estimated to be equal to the date of IP administration, provided the start year is the same as IP administration and the stop date is either after IP administration or completely

missing. Otherwise, the event will be assumed to start on the first day of the given year, e.g., 2013-??-?? is estimated as 2013-01-01.

- If the start date is completely missing and the stop date is either after IP administration or completely missing, the start date will be estimated to be the day of IP administration. Otherwise, the start date will be estimated to be the first day of the same year as the stop date. All other non-AE and non-concomitant medication day calculations where only partial dates are available will be handled as follows: the first day of the month will be used in the calculations if the day part of a start date is missing while January 1 will be employed if both the month and day parts of a start date are missing.

- For treatment start dates, if patients are randomized and have non-missing visit data for Week 4 as well as non-missing treatment diary data, then start date is set to earliest treatment diary date. If patient's treatment diary data is missing or Week 4 visit is missing, then treatment start date is set to earliest recorded exposure date. Drug dispensation date is used as treatment start date if no other data is available.

Stop Dates

- If only the day of resolution is unknown, the day will be assumed to be the last of the month, e.g., 2013-01-?? will be treated as 2013-01-31.

- If both the day and month of resolution are unknown, the event will be assumed to have ceased on the last day of the year, e.g., 2013-??-?? will be treated as 2013-12-31.

- If the stop date is completely missing or the event is continuing, the event will be assumed to be after IP administration and will be left as missing.

- For treatment stop dates, if patient has non-missing treatment diary data but has data gaps of more than 3 days, then treatment stop date is set to start date + 28 days. If treatment diary data is non-missing and there are no data gaps of 3 days or more then treatment stop date is set to last treatment diary date. If treatment diary data is missing but patient is recorded to have completed study, then treatment stop date is set to start date + 28 days. Finally, if treatment diary data is missing and patient has not completed the study, then treatment stop date is set to study withdrawal date.

Standard Calculations

Variables requiring calculation will be derived using the following formulas:

- Study Day – The day in relation to the first dose date (Day 0), calculated as date – first dose date.

- Days – A duration expressed in days between two dates (start date and end date) is calculated using the formulas noted below:

- duration in days = end date – start date + 1, where end date ≥ start date

- duration in days = end date – start date, where end date < start date

- Months – A duration expressed in months is calculated as the number days divided by 365.25/12 (~30.4).

- Years – A duration expressed in years between one date (date1) and another later date (date2) is calculated using the formula: duration in years = (date2-date1+1)/365.25

- Height – Height entries made in inches (in) are converted to centimeters (cm) using the following formula: height (cm) = height (in) × 2.54

- Weight – Weight entries made in pounds (lb.) are converted to kilograms (kg) using the following formula: weight (kg) = weight (lb.) / 2.2046

- Temperature – Temperature entries in degrees Fahrenheit are converted to degrees centigrade using the following formula: temp (degrees centigrade) = 5/9 × [temp (degrees Fahrenheit) - 32]

- Change from baseline – Change from baseline will be calculated as: Change = post baseline value – baseline value

- Percent change from baseline – Change from baseline will be calculated as: percent change from baseline = [(post baseline value – baseline value) / baseline value] × 100

APPENDIX B: TABLE OF CONTENTS FOR STATISTICAL TABLES AND LISTINGS

The following TL numbering is completed according to ICH guidelines. The ICH heading number and description are in **bold**. Minor changes from this planned index do not need to be amended in the SAP. Formal organization of tabulations may be changed during programming if appropriate, e.g., tables for the different variables may be combined into a single table, or tables with more than one variable may be split into several tables.

List of Tables

ICH Heading	Table Number	Table Description
14.1		**DEMOGRAPHIC/BASELINE DATA**
	14.1.1.1	Subject Disposition (All Subjects)
	14.1.1.2	Reason For Screen Failure (All Screen Failure Subjects)
	14.1.2	Demographic and Baseline Characteristics (Safety Population)
	14.1.3	Medical History (Safety Population)
	14.1.4	Concomitant Medications (Safety Population)
	14.1.5	Exposure and Treatment Compliance (Safety Population)
14.2		**EFFICACY DATA**
	14.2.1.1	Incidence of SARS-CoV-2 Infection by Visit (ITT Population)
	14.2.1.2	Incidence of SARS-CoV-2 Infection by Visit (PP Population)
	14.2.2	Incidence of Individual Symptoms and Average Number of Days with Symptoms by Visit Interval (ITT Population)
	14.2.3	Cumulative Incidence of SARS-CoV-2 Seroconversion by Visit (ITT Population)
14.3		**SAFETY DATA**
14.3.1		**Displays of Adverse Events**
	14.3.1.1	Overall Summary of Adverse Events (Safety Population)
	14.3.1.2	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
	14.3.1.3	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Strongest Relationship to Study Drug (Safety Population)
	14.3.1.4	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Grade (Safety Population)
	14.3.1.5	Related Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Grade (Safety Population)
14.3.2		**Serious and Significant Adverse Events**
	14.3.2.1	Serious Adverse Events by System Organ Class and Preferred Term (Safety Population)
	14.3.2.2	Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

ICH Heading	Table Number	Table Description
	14.3.2.3	Treatment-Emergent Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term (Safety Population)
	14.3.2.4	Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term (Safety Population)
14.3.4		**Laboratory**
	14.3.4.1	Shift from Baseline in Hematology Results by Test and Visit (Safety Population)
	14.3.4.2	Shift from Baseline in Chemistry Results by Test and Visit (Safety Population)
	14.3.4.3	Observed and Change from Baseline in Vital Sign Results by Test and Visit (Safety Population)
	14.3.4.4.1	Shift from Baseline in 12-Lead ECG Overall Interpretation by Visit (Safety Population)
	14.3.4.4.2	Summary of QTcF Interval (msec) by Visit and Result Category (Safety Population)

List of Figures

ICH Heading	Figure Number	Figure Description
14.3.4		**Laboratory**
	14.3.4.1	Line Plots of Mean (+/- SD) Hematology Results vs. Time by Test (Safety Population)
	14.3.4.2	Line Plots of Mean (+/- SD) Chemistry Results vs. Time by Test (Safety Population)
	14.3.4.3	Line Plots of Mean (+/- SD) Vital Sign Results vs. Time by Test (Safety Population)
	14.3.4.4	Line Plots of Mean (+/- SD) 12-Lead ECG Results vs. Time by Test (Safety Population)

List of Data Listings

ICH Heading	Listing Number	Listing Description
16.2		**SUBJECT DATA LISTINGS**
16.2.1		**Discontinued Subjects**
	16.2.1	Subject Disposition
16.2.2		**Protocol Deviations**
	16.2.2	Protocol Deviations
16.2.3		**Subjects Excluded from the Safety Analysis**
	16.2.3	Inclusion/Exclusion Criteria
16.2.4		**Demographic and Baseline Data**
	16.2.4.1	Demographic and Baseline Characteristics
	16.2.4.2	Medical History
	16.2.4.3	Prior and Concomitant Medications
16.2.5		**Compliance and/or Drug Concentration Data**
	16.2.5.1	Exposure and Treatment Compliance
	16.2.5.2	Treatment Diary
	16.2.5.3	Plasma Collection for Measurement of Quinine
16.2.6		**Individual Efficacy Response Data**
	16.2.6.1	PCR Results
	16.2.6.2	Symptom Scores
	16.2.6.3	Seroconversion
16.2.7		**Adverse Events listings**
	16.2.7.1	Adverse Events
	16.2.7.2	Serious Adverse Events
	16.2.7.3	Adverse Events Leading to Study Discontinuation
	16.2.7.4	Deaths
16.2.8		**Laboratory and Other Data**
	16.2.8.1	Hematology
	16.2.8.2	Chemistry
	16.2.8.3	Vital Signs
	16.2.8.4	12-Lead Electrocardiogram
	16.2.8.5	Physical Examination
	16.2.8.6	Pregnancy Test

APPENDIX C: TABLE LAYOUTS

Table 14.1.1.1
Subject Disposition
(All Subjects)

Study Site Subject Status	GLS-1200	Placebo	Overall
Overall			
Screened			xx
Screen Failures			xx
ITT Population [1]	xx	xx	xx
Safety Population [2]	x (xx.x%)	x (xx.x%)	x (xx.x%)
PP Population [3]	x (xx.x%)	x (xx.x%)	x (xx.x%)
Completed the study [4]	x (xx.x%)	x (xx.x%)	x (xx.x%)
Discontinued the study	x (xx.x%)	x (xx.x%)	x (xx.x%)
Reason for discontinuation			
<Reason #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Reason #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Reason #3>	x (xx.x%)	x (xx.x%)	x (xx.x%)
Site 101			
.			
.			
.			
Site 108			
.			
.			
.			

Percentages are based on the ITT Population.
[1] The Intent-to-treat (ITT) Population includes all randomized to treatment allocation.
[2] The Safety Population includes all subjects who received at least one dose of study treatment.
[3] The Per-protocol (PP) Population includes all subjects who completed the trial, received >=90% of the study treatments, and have no significant protocol deviations. Trial completion is defined as either completing Week 4 or meeting the study endpoint of PCR confirmed SARS-CoV-2 infection.
[4] Study completion is defined as completing all visits regardless of drug compliance.
Reference: Listing 16.2.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming note: Sort discontinuation reasons by descending overall frequency. List all reasons per CRF page.

Table 14.1.1.2
Reason for Screen Failure
(All Screen Failure Subjects)

Study Site Reason	Overall (xx)
Overall	
<Reason #1>	x (xx.x%)
<Reason #2>	x (xx.x%)
<Reason #3>	x (xx.x%)
Site 101	
<Reason #1>	x (xx.x%)
<Reason #2>	x (xx.x%)
<Reason #3>	x (xx.x%)
Site 108	
<Reason #1>	x (xx.x%)
<Reason #2>	x (xx.x%)
<Reason #3>	x (xx.x%)

Reference: Listing 16.2.3 and Listing 16.2.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming note: Sort screen failure reasons by descending overall frequency. List all reasons per CRF page.

Table 14.1.2
Demographic and Baseline Characteristics
(Safety Population)

Study Site Characteristic	GLS-1200 (N=XX)	Placebo (N=XX)	Overall (N=XX)
Overall			
Age (years)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<65 years	x (xx.x%)	x (xx.x%)	x (xx.x%)
>=65 years	x (xx.x%)	x (xx.x%)	x (xx.x%)
Sex			
Male	x (xx.x%)	x (xx.x%)	x (xx.x%)
Female	x (xx.x%)	x (xx.x%)	x (xx.x%)
Race			
American Indian or Alaskan Native	x (xx.x%)	x (xx.x%)	x (xx.x%)
Asian	x (xx.x%)	x (xx.x%)	x (xx.x%)
Black or African American	x (xx.x%)	x (xx.x%)	x (xx.x%)
Native Hawaiian or Other Pacific Islander	x (xx.x%)	x (xx.x%)	x (xx.x%)
White	x (xx.x%)	x (xx.x%)	x (xx.x%)
Other	x (xx.x%)	x (xx.x%)	x (xx.x%)
Ethnicity			
Hispanic or Latino	x (xx.x%)	x (xx.x%)	x (xx.x%)
Not Hispanic or Latino	x (xx.x%)	x (xx.x%)	x (xx.x%)

Baseline is the last non-missing value prior to first dose of study treatment.
Reference: Listing 16.2.4.1 and Listing 16.2.1

Table 14.1.2
Demographic and Baseline Characteristics
(Safety Population)

Characteristic	GLS-1200 (N=XX)	Placebo (N=XX)	Overall (N=XX)
Height (cm)			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg)			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Site 101			
.			
.			
.			
Site 108			
.			
.			
.			

Baseline is the last non-missing value prior to first dose of study treatment.
Reference: Listing 16.2.4.1 and Listing 16.2.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.3
Medical History
(Safety Population)

Study Site System Organ Class Preferred Term	GLS-1200 (N=XX)	Placebo (N=XX)	Overall (N=XX)
Overall			
Subjects with at least one medical history	x (xx.x%)	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
.			
.			
Site 101			
.			
.			
.			
Site 108			
.			
.			
.			

MedDRA = Medical Dictionary for Regulatory Activities; SOC = System Organ Class; PT = Preferred Term.
Medical history terms are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one medical history term are counted only once.
Reference: Listing 16.2.4.2 and Listing 16.2.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.4
Concomitant Medications
(Safety Population)

Study Site ATC Class Preferred Name	GLS-1200 (N=XX)	Placebo (N=XX)
Overall		
Subjects who received any concomitant medications	x (xx.x%)	x (xx.x%)
<ATC Class # 1>	x (xx.x%)	x (xx.x%)
<Preferred Name #1>	x (xx.x%)	x (xx.x%)
<Preferred Name #2>	x (xx.x%)	x (xx.x%)
<Preferred Name #3>	x (xx.x%)	x (xx.x%)
<ATC Class # 2>	x (xx.x%)	x (xx.x%)
<Preferred Name #1>	x (xx.x%)	x (xx.x%)
<Preferred Name #2>	x (xx.x%)	x (xx.x%)
<Preferred Name #3>	x (xx.x%)	x (xx.x%)
.		
.		
Site 101		
.		
.		
.		
Site 108		
.		
.		
.		

A concomitant medication is any medication that was ongoing or started on or after the date of first dose.
Medications are coded using WHODrug Global (March 2020) and ordered by descending order of overall incidence of ATC class and overall incidence of preferred name within each class. At each level of summation (overall, ATC class, preferred name), subjects reporting more than one medication are counted only once.
Reference: Listing 16.2.4.3 and Listing 16.2.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Sort table by descending overall count of ATC class and descending overall count of preferred name within each class.

Table 14.1.5
Exposure and Treatment Compliance
(Safety Population)

	GLS-1200 (N=XX)	Placebo (N=XX)
Overall		
Duration of exposure (days) [1]		
n	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Total number of doses taken		
n	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Total number of doses missed		
n	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Treatment compliance [2]		
n	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
<50%	x (xx.x%)	x (xx.x%)
50%-80%	x (xx.x%)	x (xx.x%)
>80%	x (xx.x%)	x (xx.x%)
Site 101		
.		
.		
Site 108		
.		
.		

[1] Duration of exposure is defined as the date of last dose minus the date of first dose + 1.
[2] Treatment compliance is defined as the total number of doses taken divided by the total number of planned doses times 100.
Reference: Listing 16.2.5.1 and Listing 16.2.1

Table 14.2.1.1
Incidence of SARS-CoV-2 Infection by Visit
(ITT Population)

	GLS-1200 (N=XX)	Placebo (N=XX)	p-value [1]
Treatment Success [2]	x (xx.x%)	x (xx.x%)	x.xxx
Treatment Failure [3]	x (xx.x%)	x (xx.x%)	
Lost to follow-up	x (xx.x%)	x (xx.x%)	
Required recue therapy	x (xx.x%)	x (xx.x%)	
Discontinued study prior to completion of Week 4	x (xx.x%)	x (xx.x%)	
Tested positive for SARS-CoV-2 infection at any time up to Week 4	x (xx.x%)	x (xx.x%)	
Had missing PCR result at any visit up to Week 4	x (xx.x%)	x (xx.x%)	
Died	x (xx.x%)	x (xx.x%)	
Week 0 PCR Result			
n	x	x	
Negative	x (xx.x%)	x (xx.x%)	
Positive	x (xx.x%)	x (xx.x%)	
Missing	x (xx.x%)	x (xx.x%)	
Week 2 PCR Result			
n	x	x	
Negative	x (xx.x%)	x (xx.x%)	
Positive	x (xx.x%)	x (xx.x%)	
Missing	x (xx.x%)	x (xx.x%)	

...

[1] The p-value is calculated using a Fisher's exact test.
[2] Subjects who test negative for SARS-CoV-2 infection at Weeks 2 and 4 are considered treatment successes.
[3] Subjects who met any of the reasons listed are considered treatment failures. Subjects who fail treatment for multiple reasons are counted once for each reason.
Reference: Listing 16.2.6.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming note: Continue for remaining visits. Repeat for Table 14.2.1.2 Incidence of SARS-CoV-2 Infection (PP Population).

Table 14.2.2
Incidence of Individual Symptoms and Average Number of Days with Symptoms by Visit Interval
(ITT Population)

Symptom	GLS-1200 (N=XX)	Placebo (N=XX)
Subjects who reported Body Aches at least once from Day 1 to Week 2	x (xx.x%)	x (xx.x%)
Subjects who reported Body Aches at least once from Week 2 to Week 4	x (xx.x%)	x (xx.x%)
Subjects who reported Body Aches at least once from Week 4 to Week 6	x (xx.x%)	x (xx.x%)
Subjects who reported Body Aches at least once during the overall treatment phase [1]	x (xx.x%)	x (xx.x%)
Number of days subjects reported Body Aches from Day 1 to Week 2		
n	x	x
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Number of days subjects reported Body Aches from Week 2 to Week 4		
n	x	x
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Number of days subjects reported Body Aches from Week 4 to Week 6		
n	x	x
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Number of days subjects reported Body Aches during the overall treatment phase [1]		
n	x	x
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx

Percentages are based on the ITT Population.
Number of days summaries include subjects who experienced no symptoms, reported as 0 days.
[1] Includes the time from Day 1 to Week 4.
Reference: Listing 16.2.6.2.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Continue for each individual symptom.

Table 14.2.3
Cumulative Incidence of SARS-CoV-2 Seroconversion by Visit
(ITT Population)

Visit Seroconverted	GLS-1200 (N=XX)	Placebo (N=XX)
Week 2		
n	x	x
Yes	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)
Week 4		
n	x	x
Yes	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)
Week 6		
n	x	x
Yes	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)

The incidence of seroconversion is summarized based on results obtained at or prior to the visit.
Reference: Listing 16.2.6.3

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.1
Overall Summary of Adverse Events
(Safety Population)

	GLS-1200 (N=XX) n (%) [95% CI]	Placebo (N=XX) n (%) [95% CI]
Subjects with any TEAE	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects whose strongest TEAE relationship to study drug is related [1]	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects whose strongest TEAE relationship to study drug is not related [2]	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects whose maximum TEAE severity grade is Mild [3]	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects whose maximum TEAE severity grade is Moderate [3]	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects whose maximum TEAE severity grade is Severe [3]	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects with any SAE	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects with any serious TEAE	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects with any TEAE leading to study discontinuation	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]
Subjects with any TEAE leading to death	x (xx.x%) [xx.x% - xx.x%]	x (xx.x%) [xx.x% - xx.x%]

AE = adverse event; SAE = Serious Adverse Event; TEAE = Treatment-Emergent Adverse Event; CI = Confidence Interval
The 95% CIs for the subject percentages are calculated using an exact binomial distribution.
[1] Related TEAEs are those with a relationship of related, possibly related, or probably related. If the relationship is missing, it is considered related.
[2] Not related TEAEs are those with a relationship of unlikely related or not related.
[3] Severity grades are determined according to the NCI Common Terminology Criteria for Adverse Events version 5.0.
Reference: Listing 16.2.7.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)	Placebo (N=XX)
Subjects with at least one TEAE	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
.		
.		

AE=adverse event; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one TEAE are counted only once.
Reference: Listing 16.2.7.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Strongest Relationship to Study Drug
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)		Placebo (N=XX)	
	Related	Not Related	Related	Not Related
Subjects with at least one TEAE	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
.				
.				

AE=adverse event; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one TEAE are counted only once using the strongest relationship.
Related TEAEs are those with a relationship of related, possibly related, or probably related. If the relationship is missing, it is considered related. Not Related TEAEs are those with a relationship of unlikely related or not related.
Reference: Listing 16.2.7.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.4
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Grade
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)			Placebo (N=XX)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Subjects with at least one TEAE	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
.						
.						

AE=adverse event; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one TEAE are counted only once using the highest grade.
Severity grades are determined according to the NCI Common Terminology Criteria for Adverse Events version 5.0.
Reference: Listing 16.2.7.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Repeat Table 14.3.1.4 layout for:

Table 14.3.1.5
Related Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Grade
(Safety Population)

Table 14.3.2.1
Serious Adverse Events by System Organ Class and Preferred Term
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)	Placebo (N=XX)
Subjects with at least one SAE	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
.		
.		

SAE=serious adverse event; MedDRA = Medical Dictionary for Regulatory Activities.
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one AE are counted only once.
Reference: Listing 16.2.7.2

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.2.2
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)	Placebo (N=XX)
Subjects with at least one serious TEAE	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
.		
.		

AE=adverse event; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one TEAE are counted only once.
Reference: Listing 16.2.7.2

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.2.3
Treatment-Emergent Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)	Placebo (N=XX)
Subjects with at least one TEAE leading to study discontinuation	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
.		
.		

AE=adverse event; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one TEAE are counted only once.
Reference: Listing 16.2.7.3

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.2.4
Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term
(Safety Population)

System Organ Class Preferred Term	GLS-1200 (N=XX)	Placebo (N=XX)
Subjects with at least one TEAE leading to death	x (xx.x%)	x (xx.x%)
<System Organ Class #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
<System Organ Class #2>	x (xx.x%)	x (xx.x%)
<Preferred Term #1>	x (xx.x%)	x (xx.x%)
<Preferred Term #2>	x (xx.x%)	x (xx.x%)
.		
.		

AE=adverse event; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities
AEs are coded using MedDRA version 23.0 and ordered by descending order of overall incidence of SOC and overall incidence of PT within each SOC. At each level of summation (overall, SOC, PT), subjects reporting more than one TEAE are counted only once.
Reference: Listing 16.2.7.4

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.4.1
Shift from Baseline in Hematology Results by Test and Visit
(Safety Population)

Test / Visit	GLS-1200 (N=XX) Baseline			Placebo (N=XX) Baseline		
	Low	Normal	High	Low	Normal	High
<Test #1> (units)						
Week 4						
n		x			x	
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Baseline is the last non-missing value prior to first dose of study treatment.
Percentages are based on n, the number of subjects with both a baseline and post-baseline result at the visit.
Shifts are based on local labs from each site.
Reference: Listing 16.2.8.1

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Continue for all hematology tests.

Repeat Table 14.3.4.1 layout for:

Table 14.3.4.2
Shift from Baseline in Chemistry Results by Test and Visit
(Safety Population)

Table 14.3.4.3
Observed and Change from Baseline in Vital Sign Results by Test and Visit
(Safety Population)

Test Visit	GLS-1200 (N=XX)		Placebo (N=XX)	
	Observed	Change from Baseline	Observed	Change from Baseline
<Test #1> (units)				
Baseline				
n	x		x	
Mean (SD)	xx.xx (xx.xxx)		xx.xx (xx.xxx)	
Median	x.xx		x.xx	
Min, Max	xx.x, xx.x		xx.x, xx.x	
Week 2				
n	x	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 4				
n	x	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 6				
n	x	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Baseline is the last non-missing value prior to first dose of study treatment.
Reference: Listing 16.2.8.3

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Continue for all vital sign tests.

Table 14.3.4.4.1
Shift from Baseline in 12-Lead ECG Overall Interpretation by Visit
(Safety Population)

	GLS-1200 (N=XX) Baseline			Placebo (N=XX) Baseline		
	Normal	Abnormal NCS	Abnormal CS	Normal	Abnormal NCS	Abnormal CS
Week 4						
n		x			x	
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal NCS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

(N)CS = (Not) Clinically Significant.
Baseline is the last non-missing value prior to first dose of study treatment.
Percentages are based on n, the number of subjects with both a baseline and post-baseline result at the visit.
Reference: Listing 16.2.8.4

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.4.4.2
Summary of QTcF Interval (msec) by Visit and Result Category
(Safety Population)

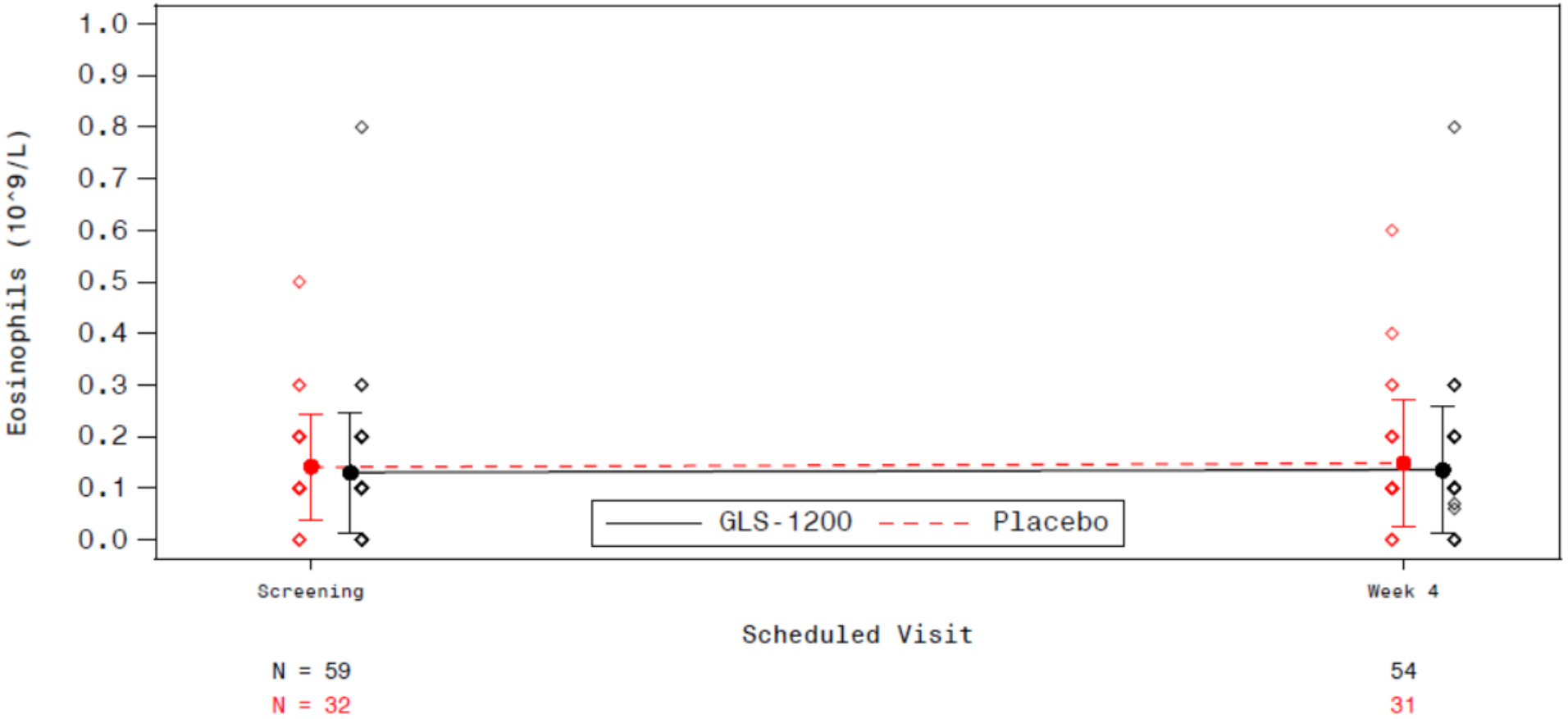
Visit Result Category	GLS-1200 (N=XX)	Placebo (N=XX)
Baseline		
n	x	x
<=450 msec (males) or <=470 msec (females)	xx (xx.x)	xx (xx.x)
>450 msec (males) or >470 msec (females)	xx (xx.x)	xx (xx.x)
Week 4		
n	x	x
<=450 msec (males) or <=470 msec (females)	xx (xx.x)	xx (xx.x)
>450 msec (males) or >470 msec (females)	xx (xx.x)	xx (xx.x)
Change from baseline <=60 msec	xx (xx.x)	xx (xx.x)
Change from baseline >60 msec	xx (xx.x)	xx (xx.x)

Baseline is the last non-missing value prior to first dose of study treatment.
Percentages are based on n, the number of subjects with a baseline and post-baseline (for Week 4) result at the visit.
Reference: Listing 16.2.8.4

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

APPENDIX D: FIGURE LAYOUTS

Figure 14.3.4.1
Line Plots of Mean (+/-SD) Hematology Results vs. Time by Test
(Safety Population)



Reference: Listing 16.2.8.1
Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Display each hematology test on a separate page.
Repeat Figure 14.3.4.1 layout for:

Figure 14.3.4.2

Line Plots of Mean (+/-SD) Chemistry Results vs. Time by Test
Safety Population

Figure 14.3.4.3
Line Plots of Mean (+/-SD) Vital Sign Results vs. Time by Test
Safety Population

Figure 14.3.4.4
Line Plots of Mean (+/-SD) 12-Lead ECG Results vs. Time by Test
Safety Population

APPENDIX E: LISTING LAYOUTS

Listing 16.2.1
Subject Disposition

Treatment: GLS-1200, Placebo

Subject ID	Study Site	Informed Consent Date	Randomization Date	ITT Population [1]	Safety Population [2]	PP Population [3]	First Dose Date	Study Completion Status	Study Completion or Discontinuation Date (Study Day)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	yyyy-mm-dd	xxxxxxxxxx	yyyy-mm-dd (xx)

[1] The Intent-to-treat (ITT) Population includes all randomized to treatment allocation.
[2] The Safety Population includes all subjects who received at least one dose of study treatment.
[3] The Per-protocol (PP) Population includes all subjects who completed the trial, received >=90% of the study treatments, and have no significant protocol deviations. Trial completion is defined as either completing Week 4 or meeting the study endpoint of PCR confirmed SARS-CoV-2 infection.

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.2
Protocol Deviations

Treatment: GLS-1200, Placebo

Subject ID	Deviation Date (Study Day)	Deviation Category	Description
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx
xxxxxx	yyyy-mm-dd (xx)	Major/Minor	xxxxxx

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.3
Inclusion/Exclusion Criteria

Treatment: GLS-1200, Placebo

Subject ID	All eligibility criteria met	Criterion not met	Criterion Description
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx
xxxxxx	Yes/No	Inclusion xx/Exclusion xx	xxxxxxxx

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: If more than one criterion ID is selected for a subject, list each one on a separate line.

Listing 16.2.4.1
Demographic and Baseline Characteristics

Treatment: GLS-1200, Placebo

Subject ID	Age (years)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m^2)
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x

Baseline is the last non-missing value prior to first dose of study treatment.

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.4.2
Medical History

Treatment: GLS-1200, Placebo

Subject ID	Any medical history	System Organ Class/ Preferred Term/ Verbatim Term	Start Date	Ongoing	Stop Date
xxxxxx	Yes/No	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	yyyy-mm-dd	Yes/No	yyyy-mm-dd
		xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxx	yyyy-mm-dd	Yes/No	yyyy-mm-dd
xxxxxx	Yes/No	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	yyyy-mm-dd	Yes/No	yyyy-mm-dd
		xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxx	yyyy-mm-dd	Yes/No	yyyy-mm-dd
xxxxxx	Yes/No	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	yyyy-mm-dd	Yes/No	yyyy-mm-dd
		xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxx	yyyy-mm-dd	Yes/No	yyyy-mm-dd

MedDRA = Medical Dictionary for Regulatory Activities.
Medical history terms are coded using MedDRA version 23.0.

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.4.3
Prior and Concomitant Medications

Treatment: GLS-1200, Placebo

Subject ID	ATC Class/ Preferred Name/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)	Dose	Units	Route	Frequency	Indication
xxxxxx	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx
	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx*	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx
	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx
	xxxxxxxxxx/ xxxxxxxxx/ xxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx

Medications are coded using WHODrug Global (March 2020).
Prior medications are denoted by *.
A prior medication is defined as a medication that was administered up to 8 weeks prior to first dose of study treatment. A concomitant medication is any medication that is ongoing or started on or after the date of first dose.
Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.5.1
Exposure and Treatment Compliance

Treatment: GLS-1200, Placebo

Subject ID	Date of first dose	Date of last dose	Duration of Exposure (days) [1]	Number of Days with At Least One Dose Taken	Total Doses Taken	Total Doses Missed	Treatment Compliance [2]
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%
xxxxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx	xx	xx%

[1] Duration of exposure is defined as the date of last dose minus the date of first dose + 1.
[2] Treatment compliance is defined as the total number of doses taken divided by the total number of planned doses times 100.

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.5.2
Treatment Diary

Treatment: GLS-1200, Placebo

Subject ID	Day	Date (Study Day)	Dose 1 Taken	Dose 2 Taken	Dose 3 Taken	Diary Comments	SARS-CoV-2 Exposures: # Suspected	SARS-CoV-2 Exposures: # Known
xxxxxx	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx
	xx	yyyy-mm-dd (xx)	Yes/No	Yes/No	Yes/No	xxxxxxxx	xx	xx

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.5.3
Plasma Collection for Measurement of Quinine

Treatment: GLS-1200, Placebo

Subject ID	Visit	Plasma Collected	Collection Date/Time (Study Day)	Date of Last Spray Administration (Study Day)	Test Result (unit)
xxxxxx	Week 2	Yes/No	yyyy-mm-dd hh:mm (xx)	yyyy-mm-dd (xx)	xx.x
xxxxxx	Week 2	Yes/No	yyyy-mm-dd hh:mm (xx)	yyyy-mm-dd (xx)	xx.x
xxxxxx	Week 2	Yes/No	yyyy-mm-dd hh:mm (xx)	yyyy-mm-dd (xx)	xx.x
xxxxxx	Week 2	Yes/No	yyyy-mm-dd hh:mm (xx)	yyyy-mm-dd (xx)	xx.x

Listing 16.2.6.1
PCR Results

Treatment: GLS-1200, Placebo

Subject ID	Visit	Nasopharyngeal Swabs for Viral PCR Collected	Collection Date (Study Day)	Test Result
xxxxxx	Day 0	Yes/No	yyyy-mm-dd (xx)	Negative/Positive
	Week 2	Yes/No	yyyy-mm-dd (xx)	Negative/Positive
	Week 4	Yes/No	yyyy-mm-dd (xx)	Negative/Positive
	Week 6	Yes/No	yyyy-mm-dd (xx)	Negative/Positive

Listing 16.2.6.2
Symptom Scores

Treatment: GLS-1200, Placebo

Subject ID	Day	Date	Fever	Cough	Sore Throat	Headache	Shortness of Breath	Body Aches	Fatigue	GI Issues	Runny Nose	Sneezing	Loss of Smell	Loss of Taste	Red Eyes
xxxxxx	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1
	xx	yyyy-mm-dd	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1

0=No, 1=Yes
Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.3
Seroconversion

Treatment: GLS-1200, Placebo

Subject ID	Visit	Serum for Viral Antibodies Collected	Collection Date (Study Day)	Titer	Seroconversion
xxxxxx	Day 0	Yes/No	yyyy-mm-dd (xx)	xx	Yes/No
	Week 2	Yes/No	yyyy-mm-dd (xx)	xx	Yes/No
	Week 4	Yes/No	yyyy-mm-dd (xx)	xx	Yes/No
	Week 6	Yes/No	yyyy-mm-dd (xx)	xx	Yes/No

Listing 16.2.7.1
Adverse Events

Treatment: GLS-1200, Placebo

Subject ID	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)	Severity	Relationship	Action Taken	Serious	Outcome	Study Discontinuation	Treatment Required
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	Yes/No	xxxxxxxxxx	Yes/No	Yes/No
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	Yes/No	xxxxxxxxxx	Yes/No	Yes/No
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)/ yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	Yes/No	xxxxxxxxxx	Yes/No	Yes/No

Severity grades are determined according to the NCI Common Terminology Criteria for Adverse Events version 5.0.

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Sort by Treatment, Subject ID, AE start date and end date.

Repeat Layout of Listing 16.2.7.1 for:

Listing 16.2.7.3 Adverse Events Leading to Study Discontinuation

Listing 16.2.7.2
Serious Adverse Events

Treatment: GLS-1200, Placebo

Subject ID	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)	End Date (Study Day)	Severity	Relationship	Action Taken	SAE Criteria	Outcome	Study Discontinuation	Treatment Required
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	Yes/No	Yes/No
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	Yes/No	Yes/No
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	Yes/No	Yes/No
xxxxxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Grade x	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	Yes/No	Yes/No

SAE = Serious Adverse Event
Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Sort by Treatment, Subject ID, AE start date and end date.

Listing 16.2.7.4
Deaths

Treatment: GLS-1200, Placebo

Subject ID	Death Date (Study Day)	If Death is Due to AE, AE Term/ Start Date (Study Day)
xxxxxx	yyyy-mm-dd (xx)	xxxxxxxxxxxx/ yyyy-mm-dd (xx)
xxxxxx	yyyy-mm-dd (xx)	xxxxxxxxxxxx/ yyyy-mm-dd (xx)
xxxxxx	yyyy-mm-dd (xx)	xxxxxxxxxxxx/ yyyy-mm-dd (xx)
xxxxxx	yyyy-mm-dd (xx)	xxxxxxxxxxxx/ yyyy-mm-dd (xx)

Programming Note: Sort by Treatment, Subject ID.

Listing 16.2.8.1
Hematology

Treatment: GLS-1200, Placebo

Subject ID	Visit	Date/Time (Study Day)	Lab Test	Result	Reference Range
xxxxxx	Day 0	yyyy-mm-dd hh:mm (xx)	xxxxxxxxxx	xx.x L, CS	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx
			xxxxxxxxxx	xx.x H, NCS	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx
	Visit 4	yyyy-mm-dd hh:mm (xx)	xxxxxxxxxx	xx.x	xxxx - xxxx
			xxxxxxxxxx	xx.x	xxxx - xxxx

L=Low, H=High, (N)CS=(Not) Clinically Significant

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Repeat for Listing 16.2.8.2 Chemistry

Listing 16.2.8.3
Vital Signs

Treatment: GLS-1200, Placebo

Subject ID	Visit	Date/Time (Study Day)	Diastolic Blood Pressure (mmHg)	Systolic Blood Pressure (mmHg)	Heart Rate (beats/min)	Temperature (C)	Height (cm)	Weight (kg)
xxxxxx	Day 0	yyyy-mm-dd hh:mm (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 2	yyyy-mm-dd hh:mm (xx)	xx.x	xx.x	xx.x	xx.x		
	Week 4	yyyy-mm-dd hh:mm (xx)	xx.x	xx.x	xx.x	xx.x		
	Week 6	yyyy-mm-dd hh:mm (xx)	xx.x	xx.x	xx.x	xx.x		

Listing 16.2.8.4
12-Lead Electrocardiogram

Treatment: GLS-1200, Placebo

Subject ID	Visit	ECG Date/Time (Study Day)	Parameter	Result	Overall Interpretation	Abnormal Findings
xxxxxx	Day 0	yyyy-mm-dd hh:mm (xx)	xxxxxxxxxxxx	xx.x	Normal/Abnormal NCS/Abnormal CS	xxxxxxxxxxxxxxxxxx
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
	Week 4	yyyy-mm-dd hh:mm (xx)	xxxxxxxxxxxx	xx.x	Normal/Abnormal NCS/Abnormal CS	xxxxxxxxxxxxxxxxxx
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		
			xxxxxxxxxxxx	xx.x		

N(CS)=(Not) Clinically Significant

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.8.5
Physical Examination

Treatment: GLS-1200, Placebo

Subject ID	Visit	Date (Study Day)	Exam Performed	Clinically Significant Findings
xxxxxx	Day 0	yyyy-mm-dd (xx)	Yes/No	Yes/No
	Week 2	yyyy-mm-dd (xx)	Yes/No	Yes/No
	Week 4	yyyy-mm-dd (xx)	Yes/No	Yes/No
	Week 6	yyyy-mm-dd (xx)	Yes/No	Yes/No
xxxxxx	Day 0	yyyy-mm-dd (xx)	Yes/No	Yes/No
	Week 2	yyyy-mm-dd (xx)	Yes/No	Yes/No
	Week 4	yyyy-mm-dd (xx)	Yes/No	Yes/No
	Week 6	yyyy-mm-dd (xx)	Yes/No	Yes/No

Source: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.8.6
Pregnancy Test

Treatment: GLS-1200, Placebo

Subject ID	Visit	Date (Study Day)	Test Performed	Result
xxxxxx	Day 0	yyyy-mm-dd (xx)	Yes/No	Negative/Positive
	Week 2	yyyy-mm-dd (xx)	Yes/No	Negative/Positive
	Week 4	yyyy-mm-dd (xx)	Yes/No	Negative/Positive
xxxxxx	Day 0	yyyy-mm-dd (xx)	Yes/No	Negative/Positive
	Week 2	yyyy-mm-dd (xx)	Yes/No	Negative/Positive
	Week 4	yyyy-mm-dd (xx)	Yes/No	Negative/Positive

DocuSign

Certificate Of Completion

Envelope Id: 067D38AAE50F442C8CF9E1EEE7672DB4
Status: Completed
Subject: Please DocuSign: GeneOne_T2R-002_SAP_v2.0_21JAN2022_final.docx
Source Envelope:
Document Pages: 69
Signatures: 3
Envelope Originator:
Certificate Pages: 5
Initials: 0
Ahmed Tariq
AutoNav: Enabled
5826 Fayetville Rd
EnvelopeId Stamping: Disabled
Suite 202
Time Zone: (UTC-05:00) Eastern Time (US & Canada)
Durham, NC 27713
ahmed.tariq@catalystcr.com
IP Address: 67.86.44.161

Record Tracking

Status: Original
1/21/2022 2:43:50 PM
Holder: Ahmed Tariq
ahmed.tariq@catalystcr.com
Location: DocuSign

Signer Events	Signature	Timestamp
Ahmed Tariq ahmed.tariq@catalystcr.com Catalyst Clinical Research - Part 11 Security Level: Email, Account Authentication (Required)	Ahmed Tariq Signature Adoption: Pre-selected Style Signature ID: 8A9AFFC7-511B-4804-9134-C7E9728C3D84 Using IP Address: 67.86.44.161 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/21/2022 2:47:14 PM Viewed: 1/21/2022 2:47:50 PM Signed: 1/21/2022 2:48:43 PM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Joel Maslow jmaslow@genels.us Security Level: Email, Account Authentication (Required)	DocuSigned by: Joel Maslow Signer Name: Joel Maslow Signing Reason: I approve this document Signing Time: 21-Jan-2022 | 12:48:44 PM PST 04EA2860227C41CB95FDE4D9283AF2C9 Signature Adoption: Pre-selected Style Signature ID: 04EA2860-227C-41CB-95FD-E4D9283AF2C9 Using IP Address: 71.25.109.173 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/21/2022 3:33:52 PM Viewed: 1/21/2022 3:47:44 PM Signed: 1/21/2022 3:48:48 PM
Electronic Record and Signature Disclosure: Accepted: 1/21/2022 3:47:44 PM ID: fb122045-6f6b-4297-9385-b5fe167eca46		

Signer Events	Signature	Timestamp
Susan E. Spruill sspruill@appstatsconsulting.com Security Level: Email, Account Authentication (Required)	Susan E. Spruill Signature Adoption: Pre-selected Style Signature ID: 6B44CB45-B795-4FD5-B700-ED25E98AB084 Using IP Address: 99.197.222.18 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/21/2022 2:47:15 PM Viewed: 1/21/2022 5:06:49 PM Signed: 1/21/2022 5:07:56 PM
Electronic Record and Signature Disclosure: Accepted: 1/21/2022 5:06:49 PM ID: d33f3acd-59af-4d13-a931-eeea026d5ce7		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	1/21/2022 2:47:15 PM
Certified Delivered	Security Checked	1/21/2022 5:06:49 PM
Signing Complete	Security Checked	1/21/2022 5:07:56 PM
Completed	Security Checked	1/21/2022 5:07:56 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Catalyst Clinical Research - Part 11 (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Catalyst Clinical Research - Part 11:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: shawnegerton@catalystcr.com

To advise Catalyst Clinical Research - Part 11 of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at shawnegerton@catalystcr.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Catalyst Clinical Research - Part 11

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to shawnegerton@catalystcr.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Catalyst Clinical Research - Part 11

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to shawnegerton@catalystcr.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Catalyst Clinical Research - Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Catalyst Clinical Research - Part 11 during the course of your relationship with Catalyst Clinical Research - Part 11.