STATISTICAL ANALYSIS PLAN

Study Title:	Safety, Tolerability, Efficacy and Dose Response of GLS-1027 in the Prevention of Severe Pneumonitis caused by SARS-CoV-2 Infection
Name of Test Drug:	GLS-1027
Study Number:	GLS27-005
Protocol Version:	5.0
Protocol Date:	11 Aug 2021
Analysis Plan Version:	1.0
Analysis Plan Date:	03 Dec 2021
Analysis Plan Author:	Catalyst Clinical Research, LLC

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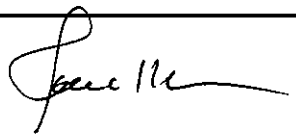
SIGNATURE PAGE

Signature  Date 3 December 2021

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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
PEEP	Positive End-Expiratory Pressure
PT	preferred term
SAE	serious adverse event
SBP	systolic blood pressure
SD	standard deviation
SOC	system organ class
TLFs	tables, listings, and figures
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 GLS27-005 [Safety, Tolerability, Efficacy and Dose Response of GLS-1027 in the Prevention of Severe Pneumonitis caused by 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 GLS27-005, version 5.0, dated 11 Aug 2021
- Case Report Form (CRF), version 1.05, dated 08 Feb 2021
- Data Management Plan, version 1.0, dated 04 Feb 2021

2. STUDY OBJECTIVES

2.1. Primary Objectives

The primary objectives of the study are to evaluate the following:

- Incidence of serious adverse events relative to treatment group
- Incidence of treatment failure within 28 days from enrollment

2.2. Exploratory Objectives

The exploratory objectives are:

- Assess the number of days requiring ICU care relative to treatment group.
- Assess the number of days of NIV, high-flow O2 or mechanical ventilation relative to treatment group.
- Assess incidence of WHO COVID-19 Classification levels relative to baseline serum IL-6 level.
- Assess incidence of WHO COVID-19 Classification levels relative to baseline serum ferritin level.
- Assess incidence of WHO COVID-19 Classification levels relative to baseline CRP
- Assess trough level of GLS-1027 relative to serum creatinine.
- Assess the maximal level of Positive End-Expiratory Pressure (PEEP) for subjects who are intubated relative to treatment group.
- Assess the number of days of PEEP > 5 cm H2O for subjects who are intubated relative to treatment group.
- Assess change in WHO COVID-19 Classification level at Day 28 from enrollment, relative to group.
- Assess SARS-CoV-2 IgM antibody responses relative to treatment group.

3. STUDY DESIGN AND PLAN

This is a Phase II, randomized, double-blind, placebo-controlled study to assess 2 dose levels of GLS-1027 for the prevention of treatment failure among participants admitted to the hospital with PCR confirmed infection with SARS-CoV-2 (WHO classification 3 or 4). Subjects can be enrolled up to 72 hours from the time of hospital admission.

Participants will be randomized to placebo or GLS-1027 at either 120 mg or 360 mg daily in a 1:1:1 ratio as adjunctive to standard of care based on the hospital COVID-19 treatment algorithm and/or local COVID-19 treatment practices. Participants will be administered study drug for a maximum treatment period of 14 days or until discharge or death, whichever comes first. Primary outcome will be assessment at day 28, with follow-up to continue to Day 56 to document AEs and outcome as to discharge, death, or WHO COVID-19 classification level if subject remains hospitalized.

All subjects will be considered to have completed the study except for the following circumstances:

- Withdrawal of consent from study
- Loss to follow-up
- Stopped study treatment for any reason other than discharge, pregnancy, or decreased renal function

Table 1: Schedule of Assessments

Tests and Observations	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	28	56[m]
Clinical Evaluations																	
Obtain written Informed Consent	X																
Confirm Eligibility Criteria	X																
Demographics	X																
Medical History	X																
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review Medical Record	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
WHO COVID-19 Classification (Appendix B)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Safety Evaluations																	
Record Adverse Events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Record AM Vital Signs [a]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record Hematology [b]	X	X	X			X			X			X			X		
Record Basic Metabolic Panel [c]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record liver function studies (LFTs) [c]	X					X			X			X			X		
Record other labs [d] (for days available)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record Procalcitonin (baseline value) [e]	X																
Record admission CXR	X																
Record if care given in ICU setting	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record whether nasal O_2 prescribed and dose level (L/min) [f]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record whether CPAP prescribed and expiratory pressure [g]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record if mechanically ventilated and level of PEEP, % FiO_2 [h]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record if treated by ECMO	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Record admission ECG	X																
Study Related Procedures																	
Administer assigned study drug [i]	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Perform urine pregnancy test	X																
Perform ECG (12-lead) [j]		X					X										
Collect serum for CPK, GGT [k]	X						X										
Collect blood for plasma for PK assessment [l]		X															
Collect blood for plasma for trough drug measurement (AM blood draw)		X	X	X			X										
Collect blood for serum (10mL red top,3 tubes)	X						X							X			
Collect blood for PBMCs (10mL ACD; 3 tubes) [n]	X						X							X			
Blood volume for serum, PBMCs	60						70							60			

[a] Vital signs to be recorded daily to include: temperature, respiratory rate, heart rate, systolic and diastolic blood pressure
[b] Hematology labs to be recorded (as collected as part of clinical care) and recorded: Hemoglobin, hematocrit, platelets, neutrophils, band forms, lymphocytes, eosinophils
[c] Basic metabolic panel labs: Sodium, potassium, creatinine, BUN, glucose, liver function tests; LFTs include AST, ALT, bilirubin (direct), alkaline phosphatase, LDH, albumin. .
[d] Other labs to be recorded if performed: Ferritin, CRP, IL-6, troponin, D-dimer
[e] Procalcitonin: record only initial measurement or within 48 hours of admission and/or SARS-CoV-2 diagnosis (may be performed prior to date of enrollment)
[f] Record maximal daily level of O2 by nasal cannula prescribed, if participant is receiving O2 by nasal cannula
[g] Record maximal daily level of end expiratory pressure delivered by CPAP prescribed, if participant is receiving CPAP

[h] Record maximal daily level of PEEP and delivered FiO2 by mechanical ventilation, if participant is receiving mechanical ventilation
[i] Study drug administration will commence on the day of enrollment if treatment can be administered before 10 pm and then with AM medications thereafter, If, study drug cannot be administered prior to 10 pm on the day of enrollment, then the 1st day of treatment will occur on the day after enrollment.
[j] Perform a 12-lead ECG on the 2nd day of treatment with study drug between 75 and 90 minutes post-administration on day 2; and on day 15 (± 2 days)
[k] Serum is collected for CPK and GGT on day 1 and day 7, and weekly thereafter, if values on day 7 are abnormal until return to normal
[l] PK assessment will be performed for the initial 15 subjects enrolled. Blood (5 ml) will be collected for plasma collection at baseline (pre-treatment), and then at 1, 2, 4, and 8 hr. Trough measurements will be obtained as indicated for all study participants
[m] The clinical record should be reviewed at Day 28 and Day 56 as relevant to denote date of discharge, date of death, or clinical status (WHO COVID-19 Classification Level); if discharged, subjects should be contacted by telephone to ascertain clinical status.
[n] PBMCs will be collected at specified sites only

4. DETERMINATION OF SAMPLE SIZE

Based on the initial data obtained to date and data in the literature, it is anticipated that approximately 50% of subjects hospitalized with PCR-positive SARS-CoV-2 infections (WHO COVID-19 Classification level 3 or 4) will experience treatment failure at day 28 from enrollment. Treatment failure is defined as progression to WHO COVID-19 classification level of 6 or greater as defined by one or more of the following: the need for high-flow oxygen or non-invasive ventilation, the need for intubation or mechanical ventilation (level 6), the need for ECMO (level 7), or any cause death (level 8); the initiation of a non-study immune modulator; withdrawing consent from the study; becoming lost to follow-up; or discontinuation of treatment for any reason other than renal function or pregnancy. The sample size estimate for this proof of concept is based on Fisher's Exact two-sided test for 2 proportions using NQuery 8 (www.statsols.com). Estimates of admitted patients requiring salvage therapy is unknown, however, the clinical data set who require intubation is a likely subset of those whose condition worsens but do not progress to respiratory compromise.

Although the interim analysis will utilize masked treatment assignments, the O'Brien Fleming group sequential sample size estimation confirms that a single interim look would retain a cumulative exit probability of 70% with a cumulative alpha =0.05 after the final analysis using the target enrollment of 132 (44 per group) to detect a reduction of those reaching the endpoint of treatment failure. This study is not powered to assess statistically significant differences between GLS-1027 doses. A gate-keeping method will be used to compare the highest dose to placebo first and then compare the lower dose if the higher dose shows significant benefit.

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.

A masked interim analysis will be performed when 22 subjects in each group have been assessed for the primary endpoint of treatment failure. The primary goals of this analysis are to review blinded safety to ensure that GLS-1027 has no concerns or causes worsening conditions. Unless safety is of concern, the study will not be stopped for futility and enrollment will continue to the targeted sample size of 132.

6. ANALYSIS POPULATIONS

6.1. Intent-to-treat (ITT) Population

The ITT Population will include all subjects randomized to a treatment allocation. The ITT population will be used for the summary of all demographic and baseline characteristics and for analysis of the primary outcome of treatment failure. Subjects will be grouped in analyses and summaries based on their randomization allocation.

6.2. Modified Intent-to-treat (mITT) Population

The modified intention to treatment (mITT) population includes all participants who are randomized to a treatment allocation, and who have received at least one dose of study drug. The mITT population will be used for the summary and analysis of the primary outcome of treatment failure. Participants will be grouped based on the treatment allocation.

6.3. Safety Population

The Safety Population will include all participants in the mITT population. Subjects will be grouped in analyses and summaries based on their actual treatment.

6.4. Per-protocol (PP) Population

The PP Population includes all safety subjects who complete the trial by meeting the endpoint of treatment failure or being discharged within 14 days without meeting the endpoint. Subjects will be grouped in analyses and summaries based on their actual treatment. This set will be used as a sensitivity analysis to summarize the primary and other efficacy outcomes.

7. STUDY POPULATION

7.1. Subject Disposition

The number and percentage of subjects who were screened and failed screening, who were in each analysis population, who completed the study and who discontinued prior to study completion will be presented by treatment group (GLS-1027 120 mg, GLS-1027 360 mg, and placebo) and overall. 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 and 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, grouped by treatment arms and overall, based on ITT population. Demographic and baseline characteristics will also 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 also be provided.

7.5. Prior and Concomitant Medications

A prior medication is defined as a medication that was administered up to 4 months prior to time of enrollment. All other medications will be considered concomitant.

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.

7.6. Study 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 + 1, regardless of if any doses were missed in between. Exposure data will be listed.

7.7. Blood Collection for Pharmacokinetic and PBMC Results

Blood collection information (date/time and volume of blood) for PK assessments, trough drug measurements, serum, and PBMCs will be listed.

8. EFFICACY ANALYSES

8.1. Definition of the Primary Efficacy Endpoint

The primary endpoint is treatment failure within 28 days of enrollment. Treatment failure is defined as:

- Progression to WHO classification level 6 or greater including the need for high-flow oxygen or non-invasive ventilation
- Receiving salvage therapy with a non-study immune-modulator (Appendix A).
- Lost to follow-up through hospital transfer, within the 14-day primary treatment period.
- Discontinuation of study drug for any cause prior to day 14 or hospital discharge will be considered as a treatment failure, except for those for whom study drug was temporarily suspended due to a decrease in renal function (creatinine clearance of < 60 mL/min), other reasons for temporary cessation of treatment listed in Section 7.3.2 of the protocol, or for discontinuation in the case of pregnancy. These subjects will be followed for the primary endpoint at 28 days with long-term follow-up at day 56.

Subjects who complete 14 days of treatment but remain hospitalized but do not meet the criteria for treatment failure, will not considered be as treatment failures with respect to the primary endpoint.

8.2. Analysis of the Primary Efficacy Endpoint

The proportion of subjects in each treatment group who reach the study endpoint of treatment failure by 28 days will be compared to placebo using Fisher's Exact 2-sided test of proportions. Additionally, the frequency for each outcome (intubation, ECMO, death) will be determined within each group. The ITT, mITT and PP analysis populations will be used to analyze the primary endpoint.

8.3. Definition of the Exploratory Efficacy Endpoints

Exploratory endpoints include the following which will be summarized using the PP populations by treatment group received:

- Assess the number of days of hospitalization relative to treatment group
- Assess the number of days requiring ICU care relative to treatment group. If a subject does not require ICU care, the number of days will be set to zero for the group summary. The number of ICU days will be summarized for all subjects in each group and for the proportion of those who are actually in ICU.
- Assess the number of days of non-invasive or mechanical ventilation relative to treatment group. If a subject does not require non-invasive or mechanical ventilation, the number of days will be set to zero for the group summary. The number of mechanical ventilation

days will be summarized for all subjects in each group and for the proportion of those who are actually on mechanical ventilation.

- Assess incidence of WHO COVID-19 Classification levels relative to baseline serum IL-6 level
- Assess incidence of WHO COVID-19 Classification levels relative to baseline serum ferritin level
- Assess incidence of WHO COVID-19 Classification levels relative to baseline CRP
- Assess trough level of GLS-1027 relative to serum creatinine
- Assess the maximal level of Positive End-Expiratory Pressure (PEEP) for subjects who are intubated relative to treatment group.
- Assess the number of days of PEEP > 5 cm H2O for subjects who are intubated relative to treatment group
- Assessment of WHO COVID-19 Classification at 28 day relative to treatment group
- Assess SARS-CoV-2 IgM antibody responses relative to treatment group

No adjustments or imputations will be made for deaths or other forms of missingness except those already described above.

Corticosteroids will be recorded as a prior or concomitant medication. Subgroup analysis will be performed to compare outcomes relative to treatment group and relative to use or non-use of corticosteroids. Primary treatment outcomes will be determined from the time of enrollment through to Day 28.

8.4. Analysis of the Exploratory Efficacy Endpoints

PEEP values during intubation will be plotted separately by treatment over time. Assessment of WHO COVID-19 Classification at 28 day relative to treatment group is discussed in Sections 8.1 and 8.2. Shift tables for worst (most extreme) values of serum IL-6 level, serum ferritin level, and CRP relative to baseline will be presented for each WHO COVID-19 Classification level.

The number of days in ICU, requiring mechanical ventilation and of PEEP > 5 cm H_2O will be summarized by treatment using descriptive statistics (sample size, mean, median, SD, minimum, maximum).

The number and percentage of subjects will be summarized by treatment according to their SARS-CoV-2 IgM antibody response. The above exploratory endpoint analyses will be presented for the PP population and individual results will be listed by treatment and study day. No formal statistical analysis is planned.

The relationship of trough level of GLS-1027 to serum creatinine 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 AE that meets one of the following conditions:

- 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);
- Requires or prolongs hospitalization;
- Results in congenital anomaly or birth defect;
- Results in persistent or significant disability/incapacity;
- Is an important medical event that may not result in death or be life threatening, 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;
- Results in death.

9.1.4. Treatment-Emergent Adverse Events (TEAEs)

9.1.4.1. Definition of Treatment-Emergent

TEAEs include the following:

a) Post-treatment complications that occur as a result of protocol mandated procedure.
b) Any pre-existing condition that increases in severity, or changes in nature during or as a consequence of the study drug phase of a human clinical trial, will also be considered an AE.
c) Complications and termination of pregnancy; see protocol v5.0 section 7.1.7 for additional information.
d) Non-elective medical or surgical procedures.

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 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 Related 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

Continuous response variables per time point will be summarized with mean, median, minimum, and maximum values. Categorical response variables will be summarized per time point with percentages. Shift from baseline in laboratory parameter results (indicated as Low, Normal, or High) will be summarized for the worse (most extreme) post-baseline assessment. Mean (+/- SD) laboratory parameter values of interest 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 interpretation (results are Normal, Abnormal Not Clinically Significant (NCS), or Abnormal Clinically Significant (CS)) will be summarized at each post-baseline study day 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 study day 15 by treatment:

- <=450 msec (males) or <=470 msec (females)
- >450 msec (males) or >470 msec (females)

- Change from baseline <=60 msec (only applies to post-baseline visits)
- Change from baseline >60 msec (only applies to post-baseline visits)

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.

9.6. Urine Pregnancy Test

Pregnancy test results will be listed.

9.7. Other Data

Chest x-ray scores, nasal oxygen (O_2) administration and flow rate, and CPAP usage and PEEP, % FiO2 if mechanically ventilated, ECMO treatment will be presented in listings. The number of days of nasal oxygen (O_2) administration and flow rate, level of PEEP, % of FiO2 if mechanically ventilated, ECMO treatment and CPAP usage, will be summarized by treatment using descriptive statistics (sample size, mean, median, SD, minimum, maximum).

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 and medians 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 an 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.

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.

Standard Calculations

Variables requiring calculation will be derived using the following formulas:

- 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 ≥ treatment start date

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

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APPENDIX C: TABLE LAYOUTS

Table 14.1.1.1
Subject Disposition
(All Subjects)

Subject Status	GLS-1027 120 mg	GLS-1027 360 mg	Placebo	Overall
Screened				xx
Screen Failure				xx
ITT Population [1]	xx	xx	xx	xx
mITT Population [2]	xx	xx	xx	xx
Safety Population [3]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PP Population [4]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Completed the study	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Discontinued the study	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Reason for discontinuation				
<Reason #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Reason #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Reason #3>	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

Percentages are based on the ITT Population, unless otherwise noted.
[1] The Intent-to-treat (ITT) Population includes all randomized to treatment allocation.
[2] The modified intention to treatment (mITT) population includes all participants who are randomized to a treatment allocation, and who have received at least one dose of study drug.
[3] The Safety Population includes all subjects in the ITT population who received at least one dose of study drug.
[4] The PP Population includes all safety subjects who complete the trial by meeting the endpoint or being discharged within 14 days without meeting the endpoint.
Reference: Listing 16.2.1

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

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

Reason	Overall (xx)
<Reason #1>	x (xx.x%)
<Reason #2>	x (xx.x%)
<Reason #3>	x (xx.x%)

Reference: Listing 16.2.3

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

Table 14.1.2
Demographic and Baseline Characteristics
(ITT Population)

Characteristic	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Age (years)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
<65 years	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
>=65 years	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Sex				
Male	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Female	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Race				
American Indian or Alaskan Native	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Asian	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Black or African American	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Native Hawaiian or Other Pacific Islander	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
White	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Other	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Ethnicity				
Hispanic or Latino	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Not Hispanic or Latino	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Not Reported	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Unknown	x (xx.x%)	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

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

Table 14.1.2
Demographic and Baseline Characteristics
(ITT Population)

Characteristic	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Height (cm)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

BMI = Body Mass Index
Baseline is the last non-missing value prior to first dose of study treatment.
Note: Body mass index (BMI) calculated as weight (kg) / [[height (cm)/100]^2].
Reference: Listing 16.2.4.1

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

Table 14.1.3
Medical History
(ITT Population)

System Organ Class Preferred Term	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Subjects with at least one medical history event	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%)
.				
.				

MedDRA = Medical Dictionary for Regulatory Activities.
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

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

Table 14.1.4
Prior and Concomitant Medications
(ITT Population)

ATC Class Preferred Name	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Subjects who received any prior or concomitant medications	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects who received any prior or concomitant corticosteroids	x (xx.x%)	x (xx.x%)	x (xx.x%)
<ATC Class # 1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Name #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Name #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Name #3>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<ATC Class # 2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Name #1>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Name #2>	x (xx.x%)	x (xx.x%)	x (xx.x%)
<Preferred Name #3>	x (xx.x%)	x (xx.x%)	x (xx.x%)
.			
.			

A concomitant medication is any medication that was ongoing or started on or after the date of first dose. A prior medication is defined as a medication that was administered up to 4 months prior to time of enrollment.
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

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
Treatment Exposure
(Safety Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Duration of exposure (days) [1]			
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
Total number of doses taken			
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
Total number of doses missed			
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

[1] Duration of exposure is defined as the date of last dose minus the date of first dose + 1.
Reference: Listing 16.2.5.1.

Table 14.2.1.1
Analysis of Overall Treatment Failure
(ITT Population)

Overall/Subjects with prior or concomitant corticosteroids/Subjects without prior or concomitant corticosteroids

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Treatment Failure [1]	x (xx.x%)	x (xx.x%)	x (xx.x%)
Achieved WHO level >=6	x (xx.x%)	x (xx.x%)	x (xx.x%)
Lost to follow-up	x (xx.x%)	x (xx.x%)	x (xx.x%)
Withdrawal of informed consent	x (xx.x%)	x (xx.x%)	x (xx.x%)
Required salvage therapy	x (xx.x%)	x (xx.x%)	x (xx.x%)
Discontinued study drug prior to discharge	x (xx.x%)	x (xx.x%)	x (xx.x%)
Had missing assessment of WHO level classification	x (xx.x%)	x (xx.x%)	x (xx.x%)
p-value [2]	0.xxxx	0.xxxx	
Maximum WHO Level = 6 (Intubation or Mechanical Ventilation)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Maximum WHO Level = 7 (Requirement for ECMO)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Maximum WHO Level = 8 (Death)	x (xx.x%)	x (xx.x%)	x (xx.x%)

[1] Subjects who met any of the reasons listed are considered treatment failures. Subjects who failed treatment for multiple reasons are counted once for each reason.
[2] P-value is calculated using a Fisher’s exact test and compares the active treatment to placebo. Will only be provided for the 120 mg group if the 360 mg group is significant.
Reference: Listing 16.2.6.1

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

Programming note: Repeat for Table 14.2.1.2 Analysis of Overall Treatment Failure (mITT Population).
Programming note: Repeat for Table 14.2.1.3 Analysis of Overall Treatment Failure (PP Population).
Programming note: P-values will not be provided for corticosteroid use/non-use subset pages.

Table 14.2.2.1.1
Summary of the Number of Days Requiring ICU Care
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days Requiring ICU Care			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Reference: Listing xxxxx

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

Programming note: Repeat for Table 14.2.2.1.2 Summary of the Number of Days Requiring ICU Care (PP Population).

Table 14.2.2.2.1
Summary of the Number of Days on Mechanical Ventilation
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days on Mechanical Ventilation			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Reference: Listing 16.2.6.2

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

Programming note: Repeat for Table 14.2.2.2.2 Summary of the Number of Days on Mechanical Ventilation (PP Population).

Table 14.2.2.3.1
Summary of the Number of Days Requiring Nasal Oxygen (O_2) Administration
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days Requiring Nasal Oxygen (O_2)			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Reference: Listing 16.2.6.3

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Programming note: Repeat for Table 14.2.2.3.2 Summary of the Number of Days Requiring Nasal Oxygen (O2) Administration (PP Population).

Table 14.2.2.4.1
Summary of the Number of Days Requiring CPAP Usage
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days Requiring CPAP Usage			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Reference: Listing 16.2.6.4

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Programming note: Repeat for Table 14.2.2.4.2 Summary of the Number of Days Requiring CPAP Usage (PP Population).

Table 14.2.2.5.1
Summary of the Number of Days Requiring ECMO Administration
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days Requiring ECMO Administration			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Reference: Listing 16.2.6.5

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

Programming note: Repeat for Table 14.2.2.5.2 Summary of the Number of Days Requiring ECMO Administration (PP Population).

Table 14.2.2.6.1
Summary of the Number of Days with PEEP > 5 cm H2O
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days with PEEP > 5 cm H_2O			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Note: Only subjects who were intubated are included in this endpoint analysis.
Reference: Listing 16.2.6.2

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

Programming note: Repeat for Table 14.2.2.6.2 Summary of the Number of Days with PEEP > 5 cm H2O (PP Population).

Table 14.2.2.7.1
Summary of Maximal Levels of PEEP Values
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Maximal Level of PEEP			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Note: Only subjects who were intubated are included in this endpoint analysis.
Reference: Listing 16.2.6.2

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

Programming note: Repeat for Table 14.2.2.7.2 Summary of Maximal Levels of PEEP Values (PP Population).

Table 14.2.2.8.1
Summary of the Number of Days in Hospital
(ITT Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)
Number of Days in Hospital			
n	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	x.xx	x.xx	x.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Reference: Listing xxxxx

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

Programming note: Repeat for Table 14.2.2.8.2 Summary of the Number of Days in Hospital (PP Population).

Table 14.2.3.1
Cumulative Incidence of SARS-CoV-2 IgM Antibody Response by Study Day
(PP Population)

Study Day Responded	GLS-1027 120 mg (N=XX)	GLS-1027 120 mg (N=XX)	Placebo (N=XX) n(%)
Day 1			
n	x	x	x
Yes	x (xx.x%)	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)	x (xx.x%)
Day 2			
n	x	x	x
Yes	x (xx.x%)	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)	x (xx.x%)
Day 3			
n	x	x	x
Yes	x (xx.x%)	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)	x (xx.x%)
Day 4			
n	x	x	x
Yes	x (xx.x%)	x (xx.x%)	x (xx.x%)
No	x (xx.x%)	x (xx.x%)	x (xx.x%)
...			

The incidence of antibody response is summarized based on results obtained at or prior to the study day.
Reference: Listing 16.2.6.3

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

Table 14.2.4.1
WHO COVID-19 Classification Levels Relative to Baseline Serum Ferritin Level
(PP Population)

WHO Classification Level	Serum Ferritin [1]	GLS-1027 120 mg (N=XX) Post-Baseline			GLS-1027 360 mg (N=XX) Post-Baseline			Placebo (N=XX) Post-Baseline			Overall (N=XX) Post-Baseline		
	Baseline	Low	Normal	High	Low	Normal	High	Low	Normal	High	Low	Normal	High
5	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
8	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Worst (most extreme) values presented for serum ferritin.
Reference: Listing xx.x.x.x

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

Table 14.2.4.2
WHO COVID-19 Classification Levels Relative to Baseline Serum IL-6 Level
(PP Population)

WHO Classification Level	Serum IL-6 [1]	GLS-1027 120 mg (N=XX) Post-Baseline			GLS-1027 360 mg (N=XX) Post-Baseline			Placebo (N=XX) Post-Baseline			Overall (N=XX) Post-Baseline		
	Baseline	Low	Normal	High	Low	Normal	High	Low	Normal	High	Low	Normal	High
5	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
8	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Worst (most extreme) values presented for serum IL-6.
Reference: Listing xx.x.x.x

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

Table 14.2.4.3
WHO COVID-19 Classification Levels Relative to Baseline CRP
(PP Population)

WHO Classification Level	CRP [1]	GLS-1027 120 mg (N=XX) Post-Baseline			GLS-1027 360 mg (N=XX) Post-Baseline			Placebo (N=XX) Post-Baseline			Overall (N=XX) Post-Baseline		
	Baseline	Low	Normal	High	Low	Normal	High	Low	Normal	High	Low	Normal	High
5	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
8	n	x	x	x	x	x	x	x	x	x	x	x	x
	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Worst (most extreme) values presented for CRP.
Reference: Listing xx.x.x.x

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

Table 14.3.1.1
Overall Summary of Treatment-Emergent Adverse Events
(Safety Population)

	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Subjects with any TEAE	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects whose strongest TEAE relationship to study drug is related [1]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects whose strongest TEAE relationship to study drug is not related [2]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects whose maximum TEAE severity grade is grade 1 [3]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects whose maximum TEAE severity grade is grade 2 [3]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects whose maximum TEAE severity grade is grade 3 [3]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects whose maximum TEAE severity grade is grade 4 [3]	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with any SAE	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with any Serious TEAE	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with any TEAE leading to study discontinuation	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with any TEAE leading to death	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

AE = Adverse Event; SAE = Serious Adverse Event; TEAE = Treatment-Emergent Adverse Event;
[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-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
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%)
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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-1027 120 mg (N=XX)		GLS-1027 360 mg (N=XX)		Placebo (N=XX)		Overall (N=XX)	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
Subjects with at least one related TEAE	x (xx.x%)	x (xx.x%)	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%)	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%)	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%)	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%)	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%)	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%)	x (xx.x%)	x (xx.x%)
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.								

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)

Treatment Group: xxxx

System Organ Class Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4
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%)
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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 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-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Subjects with at least one serious AE	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%)
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.				

AE=Adverse Event; Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
AEs are coded using MedDRA v23.0 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-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Subjects with at least one serious 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 v23.0 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-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Subjects with at least one TEAE leading to study discontinuation	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 v23.0 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 14.3.2.4
Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term
(Safety Population)

System Organ Class Preferred Term	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Subjects with at least one TEAE leading to death	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 v23.0 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 14.3.4.1
Hematology
(Safety Population)

Test	Time Point	GLS-1027 120 mg (N=xx)		GLS-1027 360 mg (N=xx)		Placebo (N=xx)		Total (N = xx)	
		Result	Change from Baseline	Result	Change from Baseline	Result	Change from Baseline	Result	Change from Baseline
<Test #1> (<unit>)	Baseline								
	n	xx		xx		xx		xx	
	Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
	Median	xx.x		xx.x		xx.x		xx.x	
	Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
	Day 2								
	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Etc.								

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

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
Chemistry
(Safety Population)

Table 14.3.4.3
Shift from Baseline in Hematology Results by Test
(Safety Population)

Test [1]	GLS-1027 120 mg (N=XX) Baseline			GLS-1027 360 mg (N=XX) Baseline			Placebo (N=XX) Baseline			Overall (N=XX) Baseline		
	Low	Normal	High	Low	Normal	High	Low	Normal	High	Low	Normal	High
<Test #1> (units)												
n		x			x			x			x	
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

...

[1] Worst (most extreme) values presented for each test.
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 study day.
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 14.3.4.4
Shift from Baseline in Chemistry Results by Test and Study Day
(Safety Population)

Table 14.3.4.5
Observed and Change from Baseline in Vital Sign Results by Test and Study Day
(Safety Population)

Test Study Day	GLS-1027 120 mg (N=XX)		GLS-1027 360 mg (N=XX)		Placebo (N=XX)		Overall (N=XX)	
	Observed	Change from Baseline	Observed	Change from Baseline	Change from Baseline		Change from Baseline	
<Test #1> (units)								
Baseline								
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	
Day 2								
n	x	x	x	x	x	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	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	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	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Day 3								
n	x	x	x	x	x	x	x	x
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	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	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	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 14.3.4.6.1
Shift from Baseline in 12-Lead ECG Overall Interpretation by Study Day
(Safety Population)

Study Day	GLS-1027 120 mg (N=XX) Baseline			GLS-1027 360 mg (N=XX) Baseline			Placebo (N=XX) Baseline			Overall (N=XX) Baseline		
	Normal	Abnormal NCS	Abnormal CS	Normal	Abnormal NCS	Abnormal CS	Normal	Abnormal NCS	Abnormal CS	Normal	Abnormal NCS	Abnormal CS
Day 2												
n		x			x			x			x	
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal NCS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 15												
n		x			x			x			x	
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal NCS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

(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 study day.
Reference: Listing 16.2.8.4

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

Table 14.3.4.6.2
Summary of QTcF Interval (msec) by Study Day and Result Category
(Safety Population)

Study Day Result Category	GLS-1027 120 mg (N=XX)	GLS-1027 360 mg (N=XX)	Placebo (N=XX)	Overall (N=XX)
Baseline				
n	x	x	x	x
<=450 msec (males) or <=470 msec (females)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>450 msec (males) or >470 msec (females)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2				
n	x	x	x	x
<=450 msec (males) or <=470 msec (females)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>450 msec (males) or >470 msec (females)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change from baseline <=60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change from baseline >60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 15				
n	x	x	x	x
<=450 msec (males) or <=470 msec (females)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>450 msec (males) or >470 msec (females)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change from baseline <=60 msec	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change from baseline >60 msec	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 a baseline and post-baseline (for Week 4) result at the study day.
Reference: Listing 16.2.8.4

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

APPENDIX D: FIGURE LAYOUTS

Figure 14.2.2.1
Line Plot of Mean (+/- SD) PEEP Results During Intubation by Study Day
(ITT Population)

Figure 14.2.2.2
Line Plot of Mean (+/- SD) PEEP Results During Intubation by Study Day
(PP Population)

Figure 14.3.4.1
Line Plots of Mean (+/-SD) Vital Sign Results by Test and Study Day
(Safety Population)

Figure 14.3.4.2
Line Plots of Mean (+/-SD) 12-Lead ECG Results by Test and Study Day
(Safety Population)

APPENDIX E: LISTING LAYOUTS

Listing 16.2.1
Subject Disposition

Treatment: GLS-1027 120 mg

Subject ID	Informed Consent Date	Randomization Date	ITT Population [1]	mITT Population [2]	Safety Population [3]	PP Population [4]	First Dose Date/Time	Study Completion Status	Study Completion or Discontinuation Date (Study Day)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)
xxxxx	yyyy-mm-dd	yyyy-mm-dd	Yes/No	Yes/No	Yes/No	Yes/No	yyyy-mm-dd hh:mm	xxxxxxxxxx	yyyy-mm-dd (xx)

[1] The Intent-to-treat (ITT) Population includes all randomized to treatment allocation.
[2] The modified intention to treatment (mITT) population includes all participants who are randomized to a treatment allocation, and who have received at least one dose of study drug.
[3] The Safety Population includes all subjects who received at least one dose of study drug.
[4] The PP Population includes all safety subjects who complete the trial by meeting the endpoint or being discharged within 14 days without meeting the endpoint.

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

Programming Note: Repeat for each treatment group.

Listing 16.2.2
Protocol Deviations

Treatment: GLS-1027 120 mg

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

Programming Note: Repeat for each treatment group.

Listing 16.2.3
Inclusion/Exclusion Criteria

Treatment: GLS-1027 120 mg

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: Repeat for each treatment group. If more than one criterion IDs are selected for a subject, list each one on a separate line.

Listing 16.2.4.1
Demographic and Baseline Characteristics

Treatment: GLS-1027 120 mg

Subject ID	Age (years)	Gender at Birth/ Current Gender	Taking Approved Form of Birth Control	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m^2)
xxxxxx	xx	Male/Female	Yes	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	No: Reason	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	N/A	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	Yes/No	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	Yes/No	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	Yes/No	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	Yes/No	xxxxxxxxxxxx	xxxxxxxxxxxx	xx.x	xx.x	xx.x
xxxxxx	xx	Male/Female	Yes/No	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

Programming Note: Repeat for each treatment group.

Listing 16.2.4.2
Medical History

Treatment: GLS-1027 120 mg

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

Programming Note: Repeat for each treatment group.

Listing 16.2.4.3
Prior and Concomitant Medications

Treatment: GLS-1027 120 mg

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
...								

Medications are coded using WHODrug Global (March 2020).
Prior medications are denoted by *. Prior corticosteroids are denoted by +.
A prior medication is defined as a medication that started and stopped 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
Programming Note: Repeat for each treatment group.

Listing 16.2.5.1
Treatment Exposure

Treatment: GLS-1027 120 mg

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

[1] Duration of exposure is defined as the date of last dose minus the date of first dose + 1.

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

Programming Note: Repeat for each treatment group.

Listing 16.2.5.2
Study Drug Administration

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Study drug administered	Date/time of administration	Full dose given	If partial dose, amount given	Number of pills administered
xxxxxx	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
xxxxxx	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
xxxxxx	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
xxxxxx	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx
	xxxxxx	Yes/No: Reason	yyyy-mm-dd hh:mm	Yes/No	xx	xx

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

Programming Note: Repeat for each treatment group.

Listing 16.2.5.3
Pharmacokinetic Assessment

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Blood for PK Assessment Collected	PK Timepoint	Date/Time of PK Collection	Result (unit)
xxxxxx	Day 2	Yes/No	Pre-Treatment	yyyy-mm-dd hh:mm	xx.x
			1 Hour Post-Dose	NOT DONE	
			2 Hours Post-Dose	yyyy-mm-dd hh:mm	xx.x
			4 Hours Post-Dose	yyyy-mm-dd hh:mm	xx.x
			8 Hours Post-Dose	yyyy-mm-dd hh:mm	xx.x
xxxxxx	Day 2	Yes/No	Pre-Treatment	yyyy-mm-dd hh:mm	xx.x
			1 Hour Post-Dose	NOT DONE	
			2 Hours Post-Dose	yyyy-mm-dd hh:mm	xx.x
			4 Hours Post-Dose	yyyy-mm-dd hh:mm	xx.x
			8 Hours Post-Dose	yyyy-mm-dd hh:mm	xx.x

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

Programming Note: Repeat for each active treatment group.

Listing 16.2.5.4
Blood Draw

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Blood for Trough Drug Measurement Collected/ Volume Collected	Date/Time of Trough Drug Measurement Collection	Blood for Serum Collected/ Volume Collected	Date/Time of Serum Collection	Blood for PBMCs Collected/ Volume Collected	Date/Time of PBMCs Collection
xxxxxx	Day 1	N/A		Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm
	Day 2	Yes/No/xx	yyyy-mm-dd hh:mm	N/A		N/A	N/A
	Day 3	Yes/No/xx	yyyy-mm-dd hh:mm	N/A		N/A	N/A
	Day 4	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm
	Day 9	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm
	Day 16	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm
	Day 23	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm
	Day 28	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm	Yes/No/xx	yyyy-mm-dd hh:mm

Programming Note: Repeat for each treatment group.

Listing 16.2.6.1
WHO Clinical Classification

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Date of Assessment	Score
xxxxxx	Day 1	yyyy-mm-dd	x
	Day 2	yyyy-mm-dd	x
	...		
xxxxxx	Day 1	yyyy-mm-dd	x
	Day 2	yyyy-mm-dd	x
	...		
xxxxxx	Day 1	yyyy-mm-dd	x
	Day 2	yyyy-mm-dd	x
	...		

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

Programming Note: Repeat for each treatment group.

Listing 16.2.6.2
Mechanical Ventilation

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Mechanical Ventilation Used	Date of Mechanical Ventilation	Maximal Daily Level of PEEP (cm)	Maximal Daily Level of Delivered FiO_2 (%)
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.x	xxx.x
	Day 2	Yes/No	yyyy-mm-dd	xxx.x	xxx.x
	...				
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.x	xxx.x
	Day 2	Yes/No	yyyy-mm-dd	xxx.x	xxx.x
	...				
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.x	xxx.x
	Day 2	Yes/No	yyyy-mm-dd	xxx.x	xxx.x
	...				

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

Programming Note: Repeat for each treatment group.

Listing 16.2.6.3
Nasal Oxygen (O_2) Administration

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Nasal 0_2 Prescribed	Date of Nasal 0_2 Administration	O_2 Flow Rate (L/min)
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.xx
	Day 2	Yes/No	yyyy-mm-dd	xxx.xx
	...			
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.xx
	Day 2	Yes/No	yyyy-mm-dd	xxx.xx
	...			
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.xx
	Day 2	Yes/No	yyyy-mm-dd	xxx.xx
	...			

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

Programming Note: Repeat for each treatment group.

Listing 16.2.6.4
CPAP Use, ECMO Prescription, ICU Admission

Treatment: GLS-1027 120 mg

Subject ID	Study Day	CPAP Prescribed	Date of CPAP Use	Maximal Daily Level of End Expiratory Pressure Delivered by CPAP (cm)	Was ECMO prescribed?	Date of ECMO prescription	Was patient admitted to ICU?	Date of ICU Admission
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.xx	Yes/No	yyyy-mm-dd	Yes/No	yyyy-mm-dd
	Day 2	Yes/No	yyyy-mm-dd	xxx.xx	Yes/No	yyyy-mm-dd	Yes/No	yyyy-mm-dd
	...							
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.xx	Yes/No	yyyy-mm-dd	Yes/No	yyyy-mm-dd
	Day 2	Yes/No	yyyy-mm-dd	xxx.xx	Yes/No	yyyy-mm-dd	Yes/No	yyyy-mm-dd
	...							
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	xxx.xx	Yes/No	yyyy-mm-dd	Yes/No	yyyy-mm-dd
	Day 2	Yes/No	yyyy-mm-dd	xxx.xx	Yes/No	yyyy-mm-dd	Yes/No	yyyy-mm-dd
	...							

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

Programming Note: Repeat for each treatment group.

Listing 16.2.6.5
SARS-COV-2 IgM Antibody Titer and Response

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Date of Assessment	Titer
xxxxxx	Day 1	yyyy-mm-dd	xxx
	Day 7	yyyy-mm-dd	xxx
xxxxxx	Day 1	yyyy-mm-dd	xxx
	Day 7	yyyy-mm-dd	xxx
xxxxxx	Day 1	yyyy-mm-dd	xxx
	Day 7	yyyy-mm-dd	xxx

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

Programming Note: Repeat for each treatment group.

Listing 16.2.7.1
Adverse Events

Treatment: GLS-1027 120 mg

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

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

Programming Note: Repeat for each treatment group. 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-1027 120 mg

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\xxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming Note: Repeat for each treatment group. Sort by Treatment, Subject ID, AE start date and end date.

Listing 16.2.7.4
Deaths

Treatment: GLS-1027 120 mg

Subject ID	Death Date (Study Day)	If Death is Due to Adverse Event, AE #
xxxxxx	yyyy-mm-dd (xx)	xx
xxxxxx	yyyy-mm-dd (xx)	xx
xxxxxx	yyyy-mm-dd (xx)	xx
xxxxxx	yyyy-mm-dd (xx)	xx

Programming Note: Repeat for each treatment group. Sort by Treatment, Subject ID.

Listing 16.2.8.1
Hematology

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Date (Study Day)	Lab Test	Result
xxxxxx	Day 0	yyyy-mm-dd (xx)	xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
			xxxxxxxxxx	xx.x
	Study Day 4	yyyy-mm-dd (xx)	xxxxxxxxxx	xx.x
			xxxxxxxxxx	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

Programming Note: Repeat for each treatment group.

Repeat for Listing 16.2.8.2 Chemistry

Listing 16.2.8.3
Vital Signs

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Date/Time of Test	Min/Max Systolic BP (mmHg)	Min/Max Diastolic BP (mmHG)	Min/Max Heart Rate (beats/min)	Min/Max Respiratory Rate (breaths/min)	Min/Max Temperature (◦C)
xxxxxx	Day 1	yyyy-mm-dd hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 2	yyyy-mm-dd hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 3	yyyy-mm-dd hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 4	yyyy-mm-dd hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 5	yyyy-mm-dd hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 6	yyyy-mm-dd hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x
	...						

Baseline is defined as the last non-missing value prior to the first dose of study treatment.
SBP=Systolic Blood Pressure, DBP=Diastolic Blood Pressure.

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

Programming Note: Repeat for each treatment group.

Listing 16.2.8.4
12-Lead Electrocardiogram

Treatment: GLS-1027 120 mg

Subject ID	Study Day	ECG Date/Time	Parameter	Result	Overall Interpretation	Abnormal CS Findings
xxxxxx	Hospital Admission	yyyy-mm-dd hh:mm	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		
	Day 2	yyyy-mm-dd hh:mm	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

Programming Note: Repeat for each treatment group.

Listing 16.2.8.5
Physical Examination

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Exam Completed	Date	Any Clinically Significant Findings
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Yes/No
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Yes/No
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Yes/No
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Yes/No

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

Programming Note: Repeat for each treatment group.

Listing 16.2.8.6
Urine Pregnancy Test

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Test Completed	Date/Time of Test	Result
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Negative/Positive
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Negative/Positive
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Negative/Positive
xxxxxx	Day 1	Yes/No	yyyy-mm-dd	Negative/Positive

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

Programming Note: Repeat for each treatment group.

Listing 16.2.8.7
Chest X-Ray Score

Treatment: GLS-1027 120 mg

Subject ID	Study Day	Chest X-Ray Performed	Date of Chest X-Ray	CXR Score
xxxxxx	Hospital Admission	Yes/No	yyyy-mm-dd	xxx.xx
	xxxxx	Yes/No	yyyy-mm-dd	xxx.xx
xxxxxx	Hospital Admission	Yes/No	yyyy-mm-dd	xxx.xx
	xxxxx	Yes/No	yyyy-mm-dd	xxx.xx
xxxxxx	Hospital Admission	Yes/No	yyyy-mm-dd	xxx.xx
	xxxxx	Yes/No	yyyy-mm-dd	xxx.xx

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

Programming Note: Repeat for each treatment group.

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Initials: 0
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Envelope Sent	Hashed/Encrypted	12/3/2021 3:21:57 PM
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