Biomedical Statistical Consulting

QUALITY IN DESIGN, IMPLEMENTATION, & PRESENTATION SINCE 1986

Statistical Analysis Plan

Protocol No.:

NI03-CV19-001

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of the Efficacy of Camostat mesilate for the Treatment of Confirmed COVID-19 in Outpatients

Sponsor:

Sagent Pharmaceuticals
1901 N. Roselle Road, Suite 450
Schaumburg, IL 60195

Version 2.0
March 31, 2021

Author:

David Maislin
Brendan Keenan
Greg Maislin

TABLE OF CONTENTS

Approval for Statistical Analysis Plan

Title:	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of the Efficacy of Camostat mesilate for the Treatment of Confirmed COVID-19 in Outpatients
Reference:	NI03-CV19-001
Version:	2.0
Author:	David Maislin

Author signature: _____ Date: 2021-03-31

The Statistical Analysis Plan has been reviewed by the CRO (Criterium Inc.):

Name of Reviewer/Approver: John M Hudak
Position: President

Signature: _____ Date: 31 MAR 2021

The Statistical Analysis Plan has been reviewed and approved by the Sponsor:

Name of Reviewer/Approver: Bob Szurgot
Position: VP Specialty Pharma

Sponsor signature: _____ Date: 3/31/2021

1 PURPOSE AND SCOPE OF STATISTICAL ANALYSIS PLAN

The purpose of this Statistical Analysis Plan (SAP) is to provide details regarding the analyses sets, endpoints, and statistical analysis methods to be used to meet the objectives of the NI03-CV19-001 trial. When differences exist in descriptions or explanations provided in the Clinical Study Protocol and this SAP, the SAP prevails. This SAP will be finalized prior to unblinding of the treatment allocations codes.

This document is designed to be a stand-alone document in terms of conveying essential statistical approaches to the analysis of the data. More definitions and details regarding variables collected are provided in the Clinical Study Protocol (version 4.0 at time of writing).

Statistical approaches were developed to be consistent with accepted statistical and clinical trial principles including ICH E9, Statistical principals for clinical trials[1].

[1] ICH E9 Expert Working Group. Statistical Principles for Clinical Trials: ICH Harmonized Tripartite Guideline. Statistics in Medicine 1999; 18:1905–1942.

2 STUDY OBJECTIVES AND ENDPOINTS

Section 2.1, 2.2, and 2.3 summarize the sections of the Clinical Trial protocol NI03-CV19-001 Version 4.0 and have been edited to provide additional clarity. As noted above in Purpose and Scope of Statistical Analysis Plan, this document was updated prior to the unblinding of treatment allocations and submitted to the FDA before database lock.

2.1 STUDY OBJECTIVES

2.1.1 Primary Objective

The primary objective of this study is:

To evaluate the clinical efficacy of Camostat mesilate (200 mg orally 4 times a day) in ambulatory subjects with confirmed COVID-19.

2.1.2 Secondary Objectives

The secondary objective of this study is:

Evaluate the safety profile of Camostat mesilate (200 mg orally 4 times a day) in ambulatory subjects with confirmed COVID-19.

2.2 PRIMARY ENDPOINT

Proportion of subjects requiring COVID-19 related hospitalization (including emergency room visit) or who die due to any cause within 28 days of randomization.

2.3 SECONDARY ENDPOINTS

2.3.1 Survival/Mortality

The overall survival rate (the proportion of randomized subjects who survive up to Day 15 and Day 28).

2.3.2 Clinical Improvement

- (Protocol) Time to resolution of fever from randomization up to Day 28 among subjects presenting with Fever (Day 0 fever >= 100.4° F / 38.0° C, oral)
- (Protocol) Time to hospitalization/ER visit or death following randomization up to Day 28 (defined as time to disease progression from randomization to either hospitalization/ER visit or death).
- (Protocol) Proportion of subjects with no viral shedding using RT-PCR at Day 7, Day 15, and at early termination.

2.3.3 Safety/Tolerability

- Incidence of AEs and SAEs of any grade from randomization up to Day 28.

- Cumulative incidence of grade 3 and 4 AEs from randomization up to Day 28.
- Incidence of discontinuation from study due to an AE/SAE (discontinued subjects will be followed up until Day 28).
- Change from baseline in clinical laboratory parameters (including platelet counts, liver function tests, and potassium levels, etc.).
- Change from baseline in vital signs (heart rate, blood pressure, peripheral capillary oxygen saturation [SpO2]).

2.4 RANDOMIZATION

Subjects will be randomized in a 2:1 ratio of Camostat mesilate: placebo. Approximately 300 subjects are planned to be enrolled (200 subjects to Camostat mesilate and 100 subjects to placebo).

One global computer generated, blocked randomization list with 2/3's of the assignments will be to Camostat mesilate and 1/3 to placebo, in random order. Randomization block sizes will randomly vary in size 3 and 6. Labeling will be randomly varied as an additional masking feature.

2.5 ANALYSIS SETS

2.5.1 Intent-to-Treat Population (ITT)

The Intent-to-Treat (ITT) population will include all subjects who are randomized. Subjects will be analyzed according to their study treatment assignment, not according to the treatment actually received. The ITT population is the primary population and will be used for evaluating primary and secondary efficacy endpoints and subject baseline characteristics.

2.5.2 Per-Protocol Population #1 (PP1)

The first Per-Protocol population (PP1) will include all subjects in the ITT population who complete the 14-day treatment period with 80% compliance with drug. Subjects will be analyzed according to the treatment actually received. 80% compliance of drug is determined by counting the number of pills returned at the end of the study. Subjects who do not return a bottle are assumed to have taken all doses. The primary and secondary efficacy endpoints will be evaluated in the PP1 population.

2.5.3 Per-Protocol Population #2 (PP2)

A second Per-Protocol population (PP2) will include all subjects in the ITT population who do not have major protocol deviations or clinically important intercurrent events thought to confound assessment of primary outcomes. The PP2 population will be provided for primary and secondary efficacy endpoints.

2.5.4 Safety Population (SP)

The Safety Population (SP) will consist of ITT subjects who receive at least 1 dose of study medication (Camostat mesilate or placebo). Subjects will be analyzed according to the study treatment received. The Safety population will be used for all summaries of safety and tolerability data.

2.6 BLINDING

This is randomized, double-blind, placebo-controlled study. Subjects will be randomized in a 2:1 ratio to Camostat mesilate:placebo. None of the investigators, study site personnel, Sponsor, or subjects will know to which treatment the subjects were randomized. Additional details of the blinding are provided in the Clinical Study Protocol (NI03-CV19-001 Version 4.0).

3 DESCRIPTION OF OUTCOME MEASURES

This section provides definitions of specific variables and concepts relevant to this Statistical Analysis Plan for primary and second efficacy outcomes. Please refer to the Clinical Trial Protocol for additional details.

3.1 PRIMARY ANALYSIS

Disease Progression (Hospitalization): The Primary Efficacy Endpoint is defined as status changing from ambulatory care to COVID-19 related hospitalization, ER visit, or death due to any cause on or prior to Day 28. Presenting to the emergency room is considered hospitalization. Hospitalization/ER visit and Death are recorded on the End of Study (EOS) form and will support the primary endpoint analysis. All subjects who have an End of Study form with any Hospitalization/ER Visit or Death are assumed to be COVID-related and therefore analyzed as a failure of the primary endpoint. Subjects failing the primary endpoint will be described within the Clinical Study Report.

3.2 SECONDARY ANALYSIS (PROTOCOL SPECIFIED)

Time to Resolution of fever (existing at day 0): This analysis will be conducted in the subjects with Day 0 temperature >= 100.4° F/ 38.0° C. Time to resolution of fever is defined as the time (in days) from initiation of study treatment (active or placebo) until normalization of fever (< 100.4° F / 38.0° C oral) and sustained for at least 72 hours; this will only be assessed in subjects who experienced a fever within 24 hours of enrollment. In the analysis of time to resolution of fever, temperature is recorded everyday up to day 14. Occurrence of fever is recorded as a binary (yes/no) a fever (>= 100.4° F/ 38.0° C) was recorded on the following day using the e-diary.

Time to Disease Progression (Hospitalization/ER visit or Death): Defined as time to disease progression from randomization to either COVID-19 related hospitalization/ER visit or death through Day 28. The primary endpoint is a binary endpoint of Disease Progression, this protocol specified analysis captures the temporal occurrence of the event.

Viral shedding (Resolution): Participants will have Viral Shedding characterized and evaluated as having Viral shedding or not having Viral shedding for this secondary endpoint. Viral shedding will be collected using reverse transcriptase-polymerase chain reaction (RT-PCR) at Day 7, Day 15, and at Day 28 or Early Termination. Subjects will have mid-turbinate nasal samples taken using flocked swabs at onsite study visits. The same nostril should be used for sampling each time it is done, and the nostril (right or left) should be recorded on the eCRF. Use of both nostrils is not to be a Major Protocol Deviation and therefore will have no bearing on the analysis populations. Details of collection method and laboratory requirements are defined in the Clinical Protocol.

3.3 EXPLORATORY ANALYSIS

Time to Resolution of Existing fever (existing by day 3): This analysis will be conducted in the subjects with a fever on Day 0 or those who have a fever within 72 hours of first treatment with fever defined as temperature >= 100.4° F / 38.0° C. Time to resolution of fever is defined as the time (in days) from 72 hours of study treatment (active or placebo) until normalization of fever (< 100.4° F / 38.0° C oral) and sustained for at least 72 hours. In the analysis of time to resolution of fever, temperature is recorded everyday up to day 14.

Time to Incidence of new fever: This analysis will be conducted in the subjects with Day 0 temperature < 100.4° F/38.0° C. Time to incidence of new fever is defined as the time (in days) from initiation of study treatment (active or placebo) until a daily maximum fever >= 100.4° F/38.0° C (oral). Daily fever is recorded dichotomously (yes/no) whether a fever of at least >= 100.4° F/38.0° C is measured in the e-diary. In the analysis of Time to Incidence of new fever, temperature is recorded everyday up to Day 14.

Time to Resolution of new fever (occurring by Day 11): This analysis will be conducted in the subjects with a new fever defined as temperature >= 100.4° F / 38.0° C by Day 11. Time to resolution of new fever is defined as the time (in days) from 72 hours of study treatment (active or placebo) until normalization of fever (< 100.4° F / 38.0° C oral) and sustained for at least 72 hours. Occurrence by Day 11 is necessary to capture 72 hours of resolution within the data captured.

Incidence of Fever (any Fever) after Day 0: This analysis will be conducted in the subjects with Day 0 temperature < 100.4° F/38.0° C. New fever is defined as a daily maximum fever >= 100.4° F/38.0° C (oral). Daily fever is recorded dichotomously (yes/no) whether a fever of at least >= 100.4° F/38.0° C is measured in the e-diary up to Day 14.

Days with Fever: This analysis will be conducted in all subjects in the ITT population through day 14 completing 14 days. For each subject, the occurrence of fever (>= 100.4° F / 38.0° C) will be recorded, 1 for yes, 0 for no. For any missing days of temperature data, the probability of fever on the missing data will be imputed as the mean of the non-missing days. For example, if a subject has 10 (of 14) days of temperature data, and 3 of those days had fever, each of the 4 missing days will be given a value of 0.3. Summary statistics (number of subjects, mean, SD, median, min and max) for the number of days with fever will be characterized. This analysis aims to explore the amount of fever present in time between subjects on IP and not on IP.

Severity of Fever: Shift tables will be provided for the severity of Fever among subjects with a fever at Day 0 using the following classification scheme[2]:

[2] The grading for fever was adapted according to FDA categories used in COVID-19 vaccine studies ("U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. September 2007. Guidance for Industry. Toxicity Grading Scale for Healthy Adult and Adolescent

- None: < 100.4
- Mild (Grade 1): >=38–38.4°C (>=100.4–101.1°F)
- Moderate (Grade 2): >=38.5–38.9°C (>=101.2–102.0°F)
- Severe (Grade 3): >=39–40°C (>=102.1–104.0°F)
- Potentially Life Threatening (Grade 4): Over 40°C (>=104.0°F)

A secondary descriptive analysis will be provided in which the status of fever at all points in time will be classified using the among Fever classifications without restricting to Fever at Day 0.

Volunteers Enrolled in Preventive Vaccine Clinical Trials. https://www.fda.gov/media/73679/download Accessed 30 March 2021

4 ANALYSIS APPROACH

4.1 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT

4.1.1 Primary Efficacy Endpoint

The primary endpoint (the proportion of subjects requiring COVID-19 related hospitalization/ER visit or who died due to any cause within 28 days of randomization) will be analyzed using an unadjusted Pearson chi-squared test. If the expected number of events in either group is less than five (5), a Fisher's exact test will be used.

4.1.2 Primary Efficacy Hypotheses

The primary efficacy hypothesis is that the probability of experiencing a COVID-19 related hospitalization/ER visit or death from any cause within 28 days of randomization is smaller among subjects randomized to the study drug relative to those subjects randomized to placebo. Symbolically, these hypotheses may be represented as follows.

Ho: $\boldsymbol{\pi_{cm} - \pi_{pl} \geq 0}$

Ha: $\boldsymbol{\pi_{cm} - \pi_{pl} < 0}$

Where $\boldsymbol{\pi_{cm}}$ and $\boldsymbol{\pi_{pl}}$ are the probabilities of experiencing the primary endpoint as defined above among subjects randomized to Camostat mesilate and placebo, respectively.

4.1.3 Testing of Primary Efficacy Hypothesis

Primary results will include the numbers and percentages of subjects in each treatment group requiring COVID-19 related hospitalization/ER visit or who died due to any cause within 28 days of randomization.

As noted in the next section, the study is statistically powered by assuming that $\boldsymbol{\pi_{cm}} = 0.15$ and $\boldsymbol{\pi_{pl}} = 0.30$ and the number of subjects to be randomized are 186 and 93, in the active and placebo arms, respectively. Consequently, the expected number of subjects to experience the event is nearly 28 for both arms, with 158 and 65 subjects in the active and placebo arms, respectively, not expected to experience the primary endpoint. Therefore, an unadjusted chi-squared test (or exact test, if expected cell counts are < 5 in either group) will be used to test the primary efficacy hypotheses using a two-sided type 1 error of 0.05. Superiority will be concluded if $p<0.05$ and the proportion of subjects experiencing the event is smaller among subjects randomized to the active treatment. This is tantamount to specifying a one-sided type 1 error rate of $\alpha=0.025$.

In addition to determining the p-value for the primary efficacy hypothesis, results will also be expressed in terms of a two-sided normal based (asymptomatic) 95% confidence interval estimating the treatment group difference in 28-day COVID hospitalization or death. The upper bound of the confidence interval will be interpreted as the smallest treatment effect consistent with the study results.

If the expected number of events in either group is less than five (5), a Fisher's exact test and exact binomial intervals will be provided.

4.1.4 Sample Size Determination for the Primary Efficacy Hypothesis

Sample size determination assumed event rates of 15% and 30% in the active and placebo groups, respectively, 2:1 randomization, and a two-sided type 1 error rate of α=0.05. Under these assumptions, an adjusted chi-square test will have 80% power for sample sizes of 186 and 93 in the investigational and placebo arms, respectively (total sample size = 279). The sample size is increased by approximately 7.5% to allow for up to 200 and 100, respectively, to account for loss-to-follow-up.

4.1.5 Heterogeneity of Treatment Effects

Heterogeneity of treatment effects will be evaluated for the subgroups (see Subgroup Analyses). To this end, the estimated group difference in the probability of experiencing the event on the probability scale, along with its 95% confidence interval (CI) will be estimated within each subgroup. These results will be graphically displayed in a forest plot.

4.1.6 Handling of Baseline Differences

Group differences in baseline characteristics will be evaluated. Analyses will be performed to evaluate the treatment effect controlling for baseline covariates found to have clinically meaningful baseline differences. Clinically meaningful will be determined by the Sponsor Study Safety Monitor or Primary Investigator. This will be done using a generalized linear model with parameters estimated using SAS PROC GENMOD with distribution set to ***binomial*** and link set to ***logit***. The adjusted probabilities and their standard errors are determined on the probability scale using the ***ilink*** option in a ***lsmeans*** statement with a ***diff*** option. This statement produces a test for the treatment group difference controlling for other covariates in the model. The model will include treatment group and each identified covariate one-at-a-time. The standard error on the probability scale for the difference in event rates will be determined as the square root of the sum of the treatment group specific squared standard errors and used in the determination of the 95% CI.

As requested by FDA, multivariable analyses will be provided to the degree that sample size and number of observed events in each group allow. It is understood that a total of 10 events per covariate is necessary for this modeling approach, which limits the number of covariates the model can support. The full model will consist of age, BMI, sex, and the number of days since first COVID-19 symptom (=<5 or >5 days), in addition to treatment group (sample size permitting). In addition to the full model, a forward stepwise procedure will be used to identify a set of covariates that each provide some independent association with the primary outcome.

The totality of evidence (i.e., the clinical and statistical interpretations) will provide support for decision making regarding Phase III investigation.

4.1.7 Handling of Missing Data for the Primary Efficacy Test

To provide a true ITT efficacy test, subjects lost-to-follow-up prior to Day 28 must be imputed. A multiple imputation (MI) (Rubin and Schenker 1991)[3] strategy will be used in the primary efficacy test followed by a completers analysis and a tipping point analysis as sensitivity analyses that examine the robustness of the Missing at Random (MAR) assumption necessary for valid application of MI.

To implement the MI for primary efficacy testing, 20 imputed data sets will be constructed. If the pattern of missing data is not monotonic, a fully conditional (FCS) approach as implemented in SAS PROC MI (SAS Institute)[4] will be utilized. If the pattern of missing data is monotonic, a regression approach may be used. The MI model will include age, BMI, sex, and the number of days since first COVID-19 symptom (<=5 or >5 days), as well as temperature at Day 7 and 14 taken at the clinic. Should the pattern of missing data be non-monotonic, an FCS model will be utilized. The estimated treatment group difference and standard error will be determined for each imputed data set and combined using Rubin's rule as implemented in SAS PROC MIANALZE. The final treatment group difference will be the average of the multiple imputed datasets. The standard error, p-value, and width of the confidence interval will account for both within and between imputation error.

The validity of the MI depends on the assumption of Missing at Random (MAR). MAR means that the likelihood of missingness does not depend on the unobserved event status. A tipping point analysis will be performed to evaluate the robustness of this assumption. First a completer's analysis will be performed in which only subjects with complete endpoint status (that is, did not withdraw early or discontinue) are included. Then, all subjects with missing data are included in the analysis varying the numbers of subjects assumed to have experienced the event in both groups separately. This analysis includes the worst-case scenario in which all missing treated subjects are assumed to have experienced the event and all placebo subjects are assumed to have not experienced the event. It also includes the best-case scenario, in which all missing treated subjects are assumed to have not experienced the event and all placebo subjects are assumed to have experienced the event. All other scenarios are similarly evaluated. Assuming superiority has been demonstrated, the percentage of scenarios in which the results change from rejecting the null hypothesis to not rejecting the null hypothesis is determined.

If this percentage of scenarios in which study conclusions change is small (for example, less than 20%), then the superiority conclusion has been shown to be robust with regard to missing data.

As requested by FDA, an additional sensitivity will be provided in which all missing data are treated as failures.

If an exact test is necessary for the primary endpoint due to expected cell counts < 5 in either group, only the tipping point analysis based on the exact tests will be provided.

[3] Rubin DB and Schenker N. Multiple imputation in health-care databases: an overview and some applications. Statistics in Medicine 10: 585-598, 1991.
[4] Version 9.4, SAS Institute Inc, Cary, NC

4.1.8 Handling of Missing Data for the Secondary Endpoint of Fever resolution

Three days of non-fever are required for the confirmation of fever resolution. If after a non-fever is observed and the next 2 days are missing in the e-diary, then fever status (not the same day temperature) on the first non-missing will be used in the confirmation. That is, resolution of fever requires 3 sequential days of non-fever recorded in the e-diary, which may not be consecutive days, if there is missing data.

4.2 ANALYSES OF SECONDARY EFFICACY ENDPOINTS

4.2.1 Survival/Mortality

The overall survival rate (the proportion of randomized subjects who survive up to Day 15 and Day 28) will be summarized using the same approach as the primary outcome.

4.2.2 Clinical Improvement

Time to resolution of fever from randomization up to Day 28 will be analyzed with Kaplan Meier[5] survival analyses. A log-rank test will be used to compare this time-to-event outcome between groups. The median event time and their corresponding 2-sided 95% CIs will be provided for each treatment arm. The analysis will treat subjects who die and have not yet had a fever resolve as having their fever having not been resolved at Day 28. A sensitivity analysis of this analytical approach will be performed, and the interpretation discussed in the Clinical Study Report.

Time to COVID-19 related Hospitalization/ER visit or Death (disease progression) will be provided using a similar approach as to time to fever resolution.

If needed, between group comparisons will be made accounting for covariates that may be associated with outcome which clinically significant baseline differences were observed despite randomization as determined by the Sponsor Safety Monitor and Principal Investigator using a proportional hazard (Cox) regression[6].

Proportion of subjects with no viral shedding (yes/no) using RT-PCR at Day 7, Day 15, and at early termination will be analyzed using the approach specified for the primary endpoint.

4.3 ANALYSES OF SAFETY/TOLERABILITY

As stated in the Clinical Protocol NI03-CV19-001 Version 4.0, all reported AEs will be coded using the latest version of the Medical Dictionary for Regulatory Activities (MedDRA). The incidence of Treatment Emergent Adverse Events (TEAEs) will be included in incidence tables. Events with missing onset dates will be included as treatment emergent. If a subject experiences more than 1 occurrence of the same AE, the occurrence

[5] Kaplan EL and Meier P. Nonparametric estimation from incomplete observations, Journal of the American Statistical Association, 53:457-481, 1959.
[6] Cox DR. Regression models with life-tables (with discussion), Journal of the Royal Statistical Society, B. 66:188-90, 1972.

with the greatest severity and the closest association with the study drug will be used in the summary tables. SAEs, Common Terminology Criteria for Adverse Events (CTCAE) grades 3, 4, or 5 TEAEs, and TEAEs causing discontinuation will be summarized using discrete summaries by system organ class and preferred term for each treatment group. All AEs will be listed by subject, along with information regarding onset (study day), duration, relationship and severity to study drug, action taken with study drug, treatment of event, and outcome.

Treatment emergent adverse events (TEAEs) are defined as all adverse events that occur after first study treatment (either active or placebo). TEAEs will be summarized by severity and relationship separately.

All adverse events that lead to death or are life threatening will be recorded as Serious Adverse Events in the SDTM datasets. Only non-COVID related Serious Adverse Event (SAE's) will be included in the summaries provided below.

4.3.1 Summary of Adverse Events

All analyses of adverse events will be based on the Safety Population. A summary of the numbers and percentages of patients within each treatment group experiencing at least one treatment emergent-adverse event (TEAE) will be provided in tables. A treatment emergent-adverse event is any AE that occurs after any exposure to treatment.

A Relative Risk comparison of the incidence in Camostat mesilate to Placebo will also be provided including a 95% Binomial Exact Confidence Interval when at least 3 subjects in both groups experienced the event.

TEAEs will be defined as an AE occurring from Day 1 to end of study which is defined as Day 28. 'Drug-related' is defined as 'possibly,' 'probably,' or 'definitely' caused by the study medication.

The AE endpoints summarized in this table are:

- With one or more TEAE
- With one or more drug-related TEAE
- With one or more serious TEAEs
- With one or more serious drug-related TEAE
- With one or more severe TEAE
- With one or more moderate or severe TEAE
- TEAE with outcome of death
- TEAE with outcome of drug related death
- Discontinued study drug due to AE/SAE
- Discontinued from study due to AE/SAE

4.3.2 Specific Adverse Events

The incidence rates (%) and event counts of TEAEs by system organ class (SOC) and by preferred term (PT) will be summarized by treatment group. The table will be organized

so that adverse event categories (SOC) are reported in upper case letters and specific adverse events (PT) are reported in lowercase.

The incidence rates (%) and event counts of TEAEs by system organ class (SOC) and by preferred term (PT) will be summarized by treatment group restricted to events with at least 5% incidence in either group.

Tables will summarize the incidence rates (%) of specific TEAE PTs, sorted by descending incidence of PT in the active drug group.

The incidence rates (%) and event counts of drug related TEAEs by SOC and by PT will be summarized by treatment group.

The incidence rates (%) and event counts of serious drug related TEAEs by SOC and by PT will be summarized by treatment group.

Tables will summarize the incidence rates (%) of serious TEAE PTs, sorted by descending incidence of PT in the active drug group.

The incidence rates (%) and event counts of serious drug related TEAEs by SOC and by PT will be summarized by treatment group.

4.3.3 Severity of Adverse Events

The incidence rates (%) and event counts of severe TEAEs by SOC and by PT will be summarized by treatment group.

Tables will summarize the incidence rates (%) of severe TEAE PTs, sorted by descending incidence of PT in the active drug group.

Counts of drug related TEAEs in the active drug group will be summarized by severity, SOC and PT will be provided. Similarly, counts of drug related TEAEs in the placebo group will be summarized by severity, SOC and PT.

4.3.4 Comparisons Between Subjects with and without a TEAE

Tables will provide a comparison of demographic and baseline disease characteristics between patients in the active treatment group experiencing and not experiencing at least one Treatment Emergent Adverse Event.

4.3.5 Safety Listings

A comprehensive set of safety listings will be provided for all subjects in the Safety Analysis Set. Adverse event listings will include SOC, PT, relationship, severity, onset and resolution dates (and study days), and action taken.

4.3.6 Clinical Laboratory Values

Clinical Laboratory data at each timepoint and change from baseline will be summarized using descriptive statistics and shift tables (based on normative ranges). (See Protocol NI03-CV19-001 Section 12.3 Laboratory Assessments and PPD Lab Manual for normative ranges.)

4.3.7 Vital Signs

Vital signs at each timepoint and change from baseline will be summarized using descriptive statistics. The Vital Signs collected include: Systolic/Diastolic Blood Pressure, pulse, temperature, and oxygen saturation.

Temperature is collected in two ways within the e-diary. One involved a dichotomous variable indicating a fever the previous day was >= 100.4 degrees F, and if so, the temperature. In addition, the current temperature was recorded. The e-diary was only collected through Day 15 (i.e., maximum temperature reported is Day 14). In addition, temperature was collected on Day 15, 21, and 28 at clinic or phone visits.

4.3.8 Compliance of Drug

Subjects are instructed to take 112 of the Camostat mesilate 100 mg/Placebo tablets, 2 tablets, 4 times per day, for 14 days. At the end of the study, subjects will return their bottle and the number of tablets returned will be counted. Subjects who do not return the bottle are assumed to have taken all the tablets, and therefore, return 0.

Exposure to the drug will be characterized as number of tablets taken using descriptive statistics including number of subjects, mean, SD, Q1, median, Q3, minimum and maximum.

4.4 SUBGROUP ANALYSES

Exploratory pre-specified subgroup analysis will be performed. For these exploratory analyses, primary efficacy endpoint, selected secondary efficacy endpoints, and selected safety endpoints will be repeated and stratified according to the following classifications:

1. Days from first COVID-19 symptom to the start of treatment, ≤ 5 days or > 5 days
2. Age, <55 and >=55 years
3. Age, <65 and >=65 years
4. Age, >=75 years
5. Sex at birth
6. Race, White vs. non-white
7. Ethnicity, Hispanic vs. non-Hispanic
8. Number of Risk Factors
9. Site (see Site Poolability)
10. Region (see Region Poolability)

4.5 EXPLORATORY ANALYSES

, The following analysis will be performed as exploratory e

- Time to Resolution of fever (existing by day 3)
- Time to Incidence of new fever

- Incidence of Fever (any Fever) after Day 0
- Days with Fever
- Severity of Fever

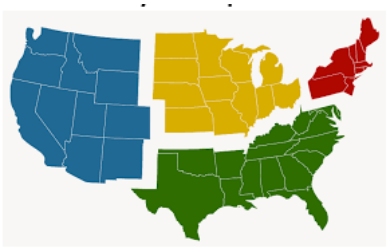
4.6 POOLABILITY

4.6.1 Site Poolability

Site poolability of the primary endpoint will be evaluated using a random effects meta-analysis approach using the R package ***metafor*** to implement the analysis[7]. Sites contributing less than 8 subjects will be pooled. After pooling (if needed), sites with 100% success will be given 0.5 subjects with failure and sites with 100% failure will be given 0.5 subjects success. The True Effects will be evaluated on the logit scale and are assumed to be normally distributed with mean μ and variance τ^2. By imposing a specified distribution on the site-to-site variability, i.e., a normal distribution with mean μ and variance τ^2, sensitivity to small sample sizes in individual sites is reduced and the parameters reflecting the magnitude of site-to-site variability are naturally derived. The quantitative measure of the magnitude of heterogeneity is I^2 [8]. I^2 is the fraction of $\boldsymbol{\tau^2}$ that is due to effect size heterogeneity (among sites), as opposed to sampling variance (within site). Fractions 25% and less are considered small (see reference 8). If there is significant site to site variability, the impact on this variability will be evaluated using a random effects logistic regression to test the null hypothesis that the likelihood of achieving the primary endpoint is the same for treated and placebo patients accounting for site-to-site heterogeneity in treatment effects.

4.6.2 Region Poolability

The distributions of regions will be summarized in the Baseline Demographic table According to the following four region breakdown:



4.7 PROTOCOL DEVIATIONS

The following Protocol Deviations (PD) will be captured for all subjects and recorded in the Protocol Deviation Log. The protocol Deviation log will capture deviations into the buckets

[7] Viechtbauer W. Bias and efficiency of meta-analytic variance estimators in the random-effects model. J Educ Behav Stat. 2005;30(3):261-293.
[8] Higgins JP, Thompson SG, Deeks JJ. Altman DG. Measuring inconsistency in meta-analyses. BMJ: 327(7414):557

shown in the 'Deviation' column of the following table. The bucketed deviations will be provided to the Sponsor Study Safety Monitors for review and classification per the Classification system outlined in Protocol Deviation Classifications. If a PD falls out of these categories, they will be handled on a case-by-case basis by sponsor medical monitors.

Table 1: Protocol Deviation Classifications

Deviation	Classification	Note
Required procedure performed incorrectly	Minor if not primary endpoint	
Required procedure not performed	Minor if not primary endpoint	This will not include missing e-diary temperatures. This will be addressed in the section in missing data for secondary endpoint of fever.
Out of window visit	Minor	
Missed Visit/Visit not performed	Minor	The window around the 72 hours from notification of positive COVID is +4 hours. Therefore, if notification occurs up to and including 76 hours, the deviation will be minor, otherwise, Major.
Specimen temperature excursion	Requires case by case via Sponsor	
Study product temperature excursion	Requires case by case via Sponsor	
Study product not stable	Requires case by case via Sponsor	
Blood not collected	Minor	
Nasal swab not collected	Minor	
Did not meet Inclusion/Exclusion criteria	Major	
Informed consent deviations	Major	
Incorrect study drug given per randomization:	Major	
Subject fails to take 80% of study drug	Major	Subject is included in ITT and Safety Population (if at least one dose was taken)

4.8 PATIENT DISPOSITION

Patient disposition will be summarized according to Table 14.1.1.1.

4.9 CHANGES TO THE ANALYSIS PLAN

All revisions to the Analysis Plan will be documented in the Clinical Study Report.

5 APPENDIX: SHELL TABLES AND FIGURES

This section displays mock-ups of the tables, listings, and figures that will be provided in the clinical study report.

SAP TLF's are provided to describe data presentations including examples of the Tables, Listings, and Figures.

The following is a DRAFT set of Tables, Listings, and Figures. Table numbers, layouts, and units are subject to revision.

Table 2: Listing of Tables, Listings, and Figures

TLF Name	TLF Number	Popu-lation
Accounting		
Table 14.1.1 - Subject Disposition by Treatment	Table 14.1.1	ITT
Figure 14.1.1 – Subject Disposition by Treatment – Consort Diagram	Figure 14.1.1	ITT
Baseline Demographics		
Table 14.1.2.1 - Summary of Demographic Characteristics by Treatment	Table 14.1.2.1	ITT
Table 14.1.2.2 - Summary of Demographic Characteristics by Treatment	Table 14.1.2.2	PP1
Table 14.1.2.3 - Summary of Demographic Characteristics by Treatment	Table 14.1.2.3	PP2
Table 14.1.2.4 - Summary of Demographic Characteristics by Treatment	Table 14.1.2.4	SP
Table 14.1.3 - Summary of Baseline Clinical Laboratory Data by Treatment	Table 14.1.3	ITT
Table 14.1.4 - Summary of Baseline Vital Signs by Treatment	Table 14.1.4	ITT
Primary/Secondary		
Table 14.2.1.1 - Primary Efficacy – Proportion of Subjects Requiring COVID-19 Hospitalization/ER visit	Table 14.2.1.1	ITT
Table 14.2.1.2 - Secondary Efficacy – Proportion of Subjects Requiring COVID-19 Hospitalization/ER visit	Table 14.2.1.2	PP1
Table 14.2.1.3 - Secondary Efficacy – Proportion of Subjects Requiring COVID-19 Hospitalization/ER visit	Table 14.2.1.3	PP2
Table 14.2.1.4 – General Linear Model of COVID-19 Hospitalization/ER visit Adjusted by Covariates	Table 14.2.1.4	ITT
Table 14.2.1.5 – General Linear Model of COVID-19 Hospitalization/ER visit Adjusted by Covariates	Table 14.2.1.5	PP1
Table 14.2.1.6 – General Linear Model of COVID-19 Hospitalization/ER visit Adjusted by Covariates	Table 14.2.1.6	PP2
Table 14.2.1.7 – Forest Plots of Group Difference in Primary Endpoint with 95% Confidence Intervals Stratified by Categorical Baseline Characteristics	Table 14.2.1.7	ITT
Table 14.2.1.8 – Forest Plots of Group Difference in Primary Endpoint with 95% Confidence Intervals Stratified by Categorical Baseline Characteristics	Table 14.2.1.8	PP1
Table 14.2.1.9 – Forest Plots of Group Difference in Primary Endpoint with 95% Confidence Intervals Stratified by Categorical Baseline Characteristics	Table 14.2.1.9	PP2
Table 14.2.2.1 – Counts and Percentages Surviving to Days 15 and 28 Days by Treatment Group in ITT	Table 14.2.2.1	ITT
Table 14.2.2.2 – Counts and Percentages Surviving to Days 15 and 28 Days by Treatment Group in PP1	Table 14.2.2.2	PP1
Table 14.2.2.3 – Counts and Percentages Surviving to Days 15 and 28 Days by Treatment Group in PP2	Table 14.2.2.3	PP2
Table 14.2.3.1 – Time to Resolution of Fever by Treatment in ITT Analysis Set	Table 14.2.3.1	ITT
Table 14.2.3.2 – Time to Resolution of Fever by Treatment in PP1 Analysis Set	Table 14.2.3.2	PP1
Table 14.2.3.3 – Time to Resolution of Fever by Treatment in PP2 Analysis Set	Table 14.2.3.3	PP2
Figure 14.2.4.1 – Kaplan-Meier Time to Resolution of Fever in ITT	Figure 14.2.4.1	ITT
Figure 14.2.4.2 – Kaplan-Meier Time to Resolution of Fever in PP1	Figure 14.2.4.2	PP1
Figure 14.2.4.3 – Kaplan-Meier Time to Resolution of Fever in PP2	Figure 14.2.4.3	PP2
Table 14.2.5.1 – Time to COVID-19 Hospitalization/ER visit or Death by Treatment in ITT	Table 14.2.5.1	ITT
Table 14.2.5.2 – Time to COVID-19 Hospitalization/ER visit or Death by Treatment in PP1	Table 14.2.5.2	PP1

TLF Name	TLF Number	Popu-lation
Table 14.2.5.3 – Time to COVID-19 Hospitalization/ER visit or Death by Treatment in PP2	Table 14.2.5.3	PP2
Figure 14.2.6.1 – Kaplan-Meier Time to COVID-19 Hospitalization/ER visit by Treatment in ITT	Figure 14.2.6.1	ITT
Figure 14.2.6.2 – Kaplan-Meier Time to COVID-19 Hospitalization/ER visit by Treatment in PP1	Figure 14.2.6.2	PP1
Figure 14.2.6.3 – Kaplan-Meier Time to COVID-19 Hospitalization/ER visit by Treatment in PP2	Figure 14.2.6.3	PP2
Table 14.2.7.1 – Proportion of Subjects with No Viral Shedding at Days 7, 15, and at Early Termination in ITT	Table 14.2.7.1	ITT
Table 14.2.7.2 – Proportion of Subjects with No Viral Shedding at Days 7, 15, and at Early Termination in PP1	Table 14.2.7.2	PP1
Table 14.2.7.3 – Proportion of Subjects with No Viral Shedding at Days 7, 15, and at Early Termination in PP2	Table 14.2.7.3	PP2
Table 14.2.8.1 – Shift Table of Fever Severity Categories	Table 14.2.8.1	ITT
Table 14.2.8.2 – Shift Table of Fever Severity Categories	Table 14.2.8.2	PP1
Table 14.2.8.3 – Shift Table of Fever Severity Categories	Table 14.2.8.3	PP2
Tables Safety		
Table 14.3.1.1 - Overall Summary of Adverse Events by Treatment	Table 14.3.1.1	SP
Table 14.3.1.2 – Adverse Events Occurring in 5% of Subjects in Either Treatment Group by MedDRA System Organ Class and Preferred Term	Table 14.3.1.2	SP
Table 14.3.1.3– Adverse Events Occurring in all Subjects by MedDRA System Organ Class and Preferred Term	Table 14.3.1.3	SP
Table 14.3.1.4 - Incidence of Treatment Emergent Adverse Events	Table 14.3.1.4	SP
Table 14.3.1.5 - Incidence of Treatment Emergent Serious Adverse Events	Table 14.3.1.5	SP
Table 14.3.1.6 - Incidence of Related Treatment Emergent Adverse Events	Table 14.3.1.6	SP
Table 14.3.1.7 - Incidence of Related Treatment Emergent Serious Adverse Events	Table 14.3.1.7	SP
Table 14.3.1.8 - Incidence of Non-Serious Grade 3 or Grade 4 Treatment Emergent Adverse Events	Table 14.3.1.8	SP
Table 14.3.1.9 - Incidence of Treatment Emergent Adverse Events Leading to Study Drug Discontinuation	Table 14.3.1.9	SP
Table 14.3.1.10 to 29 Overall Summary of Adverse Events by Treatment by Subgroup	Table 14.3.1.10 to 29	SP
Listing 14.3.2.1 – Listing of Deaths	Listing 14.3.2.1	SP
Listing 14.3.2.2 – Listing of Serious Adverse Events	Listing 14.3.2.2	SP
Listing 14.3.2.3 – Listing of Non-Serious Grade 3 or Grade 4 Adverse Events	Listing 14.3.2.3	SP
Listing 14.3.2.4 – Listing of Adverse Events Leading to Study Drug Discontinuation	Listing 14.3.2.4	SP
Laboratory Assessment		
Table 14.3.4.1.1 - Summary of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment	Table 14.3.4.1.1	ITT
Table 14.3.4.1.2 - Summary of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment	Table 14.3.4.1.2	SP
Table 14.3.4.1.3 – Shift of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment	Table 14.3.4.1.3	ITT
Table 14.3.4.1.4 – Shift of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment	Table 14.3.4.1.4	SP
Figure 14.3.4.1.5 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alanine Aminotransferase (ALT) (U/L)	Figure 14.3.4.1.5	ITT
Figure 14.3.4.1.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alanine Aminotransferase (ALT) (U/L)	Figure 14.3.4.1.6	SP
Table 14.3.4.2.1 - Summary of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment	Table 14.3.4.2.1	ITT
Table 14.3.4.2.2 - Summary of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment	Table 14.3.4.2.2	SP
Table 14.3.4.2.3 - Shift of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment	Table 14.3.4.2.3	ITT
Table 14.3.4.2.4 - Shift of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment	Table 14.3.4.2.4	SP
Figure 14.3.4.2.5 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alanine Aminotransferase (ALT) (U/L)	Figure 14.3.4.2.5	ITT
Figure 14.3.4.2.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alanine Aminotransferase (ALT) (U/L)	Figure 14.3.4.2.6	SP
Table 14.3.4.3.1 - Summary of Alkaline Phosphatase (U/L) by Study Day and Treatment	Table 14.3.4.3.1	ITT
Table 14.3.4.3.2 - Summary of Alkaline Phosphatase (U/L) by Study Day and Treatment	Table 14.3.4.3.2	SP
Table 14.3.4.3.3 - Shift of Alkaline Phosphatase (U/L) by Study Day and Treatment	Table 14.3.4.3.3	ITT
Table 14.3.4.3.4 - Shift of Alkaline Phosphatase (U/L) by Study Day and Treatment	Table 14.3.4.3.4	SP
Figure 14.3.4.3.5 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alkaline Phosphatase (U/L)	Figure 14.3.4.3.5	ITT
Figure 14.3.4.3.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alkaline Phosphatase (U/L)	Figure 14.3.4.3.6	SP
Table 14.3.4.4.1 - Summary of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment	Table 14.3.4.4.1	ITT

TLF Name	TLF Number	Popu-lation
Table 14.3.4.4.2 - Summary of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment	Table 14.3.4.4.2	SP
Table 14.3.4.4.3 – Shift of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment	Table 14.3.4.4.3	ITT
Table 14.3.4.4.4 – Shift of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment	Table 14.3.4.4.4	SP
Figure 14.3.4.4.5 - Boxplots of Laboratory Parameters by Study Day and Treatment: Gamma-glutamyl Transpeptidase (GGT) (U/L)	Figure 14.3.4.4.5	ITT
Figure 14.3.4.4.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Gamma-glutamyl Transpeptidase (GGT) (U/L)	Figure 14.3.4.4.6	SP
Table 14.3.4.5.1 - Summary of Potassium (mmol/L) by Study Day and Treatment	Table 14.3.4.5.1	ITT
Table 14.3.4.5.2 - Summary of Potassium (mmol/L) by Study Day and Treatment	Table 14.3.4.5.2	SP
Table 14.3.4.5.3 - Shift of Potassium (mmol/L) by Study Day and Treatment	Table 14.3.4.5.3	ITT
Table 14.3.4.5.4 - Shift of Potassium (mmol/L) by Study Day and Treatment	Table 14.3.4.5.4	SP
Figure 14.3.4.5.5 - Boxplots of Laboratory Parameters by Study Day and Treatment: Potassium (mmol/L)	Figure 14.3.4.5.5	ITT
Figure 14.3.4.5.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Potassium (mmol/L)	Figure 14.3.4.5.6	SP
Table 14.3.4.6.1 - Summary of Platelets (109/L) by Study Day and Treatment	Table 14.3.4.6.1	ITT
Table 14.3.4.6.2 - Summary of Platelets (109/L) by Study Day and Treatment	Table 14.3.4.6.2	SP
Table 14.3.4.6.3 - Shift of Platelets (109/L) by Study Day and Treatment	Table 14.3.4.6.3	ITT
Table 14.3.4.6.4 - Shift of Platelets (109/L) by Study Day and Treatment	Table 14.3.4.6.4	SP
Figure 14.3.4.6.5 - Boxplots of Laboratory Parameters by Study Day and Treatment: Platelets (109/L)	Figure 14.3.3.6.5	ITT
Figure 14.3.4.6.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Platelets (109/L)	Figure 14.3.3.6.6	SP
Table 14.3.5.1.1 - Summary of Systolic Blood Pressure (mmHg) by Study Day and Treatment	Table 14.3.5.1.1	ITT
Table 14.3.5.1.2 - Summary of Systolic Blood Pressure (mmHg) by Study Day and Treatment	Table 14.3.5.1.2	SP
Figure 14.3.5.1.3 - Boxplots of Vital Signs by Study Day and Treatment: Systolic Blood Pressure (mmHg)	Figure 14.3.5.1.3	ITT
Figure 14.3.5.1.4 - Boxplots of Vital Signs by Study Day and Treatment: Systolic Blood Pressure (mmHg)	Figure 14.3.5.1.4	SP
Table 14.3.5.2.1 - Summary of Diastolic Blood Pressure (mmHg) by Study Day and Treatment	Table 14.3.5.2.1	ITT
Table 14.3.5.2.2 - Summary of Diastolic Blood Pressure (mmHg) by Study Day and Treatment	Table 14.3.5.2.2	SP
Figure 14.3.5.2.3 - Boxplots of Vital Signs by Study Day and Treatment: Diastolic Blood Pressure (mmHg)	Figure 14.3.5.2.3	ITT
Figure 14.3.5.2.4 - Boxplots of Vital Signs by Study Day and Treatment: Diastolic Blood Pressure (mmHg)	Figure 14.3.5.2.4	SP
Table 14.3.5.3.1 - Summary of Pulse Rate (beats/minute) by Study Day and Treatment	Table 14.3.5.3.1	ITT
Table 14.3.5.3.2 - Summary of Pulse Rate (beats/minute) by Study Day and Treatment	Table 14.3.5.3.2	SP
Figure 14.3.5.3.3 - Boxplots of Vital Signs by Study Day and Treatment: Pulse Rate (beats/min)	Figure 14.3.5.3.3	ITT
Figure 14.3.5.3.4 - Boxplots of Vital Signs by Study Day and Treatment: Pulse Rate (beats/min)	Figure 14.3.5.3.4	SP
Table 14.3.5.4.1 - Summary of Temperature (°C) by Study Day and Treatment	Table 14.3.5.4.1	ITT
Table 14.3.5.4.2 - Summary of Temperature (°C) by Study Day and Treatment	Table 14.3.5.4.2	SP

DRAFT Table 14.1.2.1
Subject Disposition by Treatment
All Randomized Subjects

	Camostat mesilate (N=xxx)		Placebo (N=xxx)		All Subjects (N=xxx)	
Subject Disposition	**n**	**%**	**n**	**%**	**n**	**%**
Enrolled/Randomized	xxx	xxx	xxx	xxx	xxx	xxx
Received Treatment	xxx	xxx	xxx	xxx	xxx	xxx
Compliant with Study Drug (Received 80%)	xxx	xxx	xxx	xxx	xxx	xxx
Died	xxx	xxx	xxx	xxx	xxx	xxx
Completed 28 Day Study Visit[b]	xxx	xxx	xxx	xxx	xxx	xxx
Did not Complete 28 Day Study Visit						
Withdraw Reason 1						
…						
Withdraw Reason 10						
Analysis Populations	xxx	xxx	xxx	xxx	xxx	xxx
Intent-to-Treat Population (ITT)	xxx	xxx	xxx	xxx	xxx	xxx
Per-Protocol Population #1 (PP1)	xxx	xxx	xxx	xxx	xxx	xxx
Per-Protocol Population #2 (PP2)	xxx	xxx	xxx	xxx	xxx	xxx
Safety Population	xxx	xxx	xxx	xxx	xxx	xxx

Notes: N=Number of randomized subjects; n=Number of subjects with the specified event; NA = Not applicable.
[a]A complete dose is 2 tablets 4 times a day for 14 days or 112 tablets. Compliance with study drug is subjects who finished the 14 days of treatment and took 90 or more tablets over 14 days.
[b]The 28-day visit is a telephone call.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

DRAFT Table 14.1.2.1.1
Summary of Categorical Demographic Characteristics by Treatment
Intent-to-Treat Population

		Camostat mesilate (N=xxx)		Placebo (N=xxx)		All Subjects (N=xxx)	
Variable	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**
Sex at Birth	Male	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Female	xxx	xx.x	xxx	xx.x	xxx	xx.x
Age Group 1	<55 Years	xxx	xx.x	xxx	xx.x	xxx	xx.x
	>=55 Years	xxx	xx.x	xxx	xx.x	xxx	xx.x
Age Group 2	<65 Years	xxx	xx.x	xxx	xx.x	xxx	xx.x
	>=65 Years	xxx	xx.x	xxx	xx.x	xxx	xx.x
Age Group 3	<75 Years	xxx	xx.x	xxx	xx.x	xxx	xx.x
	>=75 Years	xxx	xx.x	xxx	xx.x	xxx	xx.x
Time from Positive Covid-19 Test to Randomization	<= 5 days	xxx	xx.x	xxx	xx.x	xxx	xx.x
	>5 days	xxx	xx.x	xxx	xx.x	xxx	xx.x
Race	White	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Black or African American	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Asian	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Native American or Alaska Native	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Native Hawaiian or Other Pacific Islander	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Multi-racial	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Unknown	xxx	xx.x	xxx	xx.x	xxx	xx.x
Race Group 1[a]	White	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Non-White	xxx	xx.x	xxx	xx.x	xxx	xx.x

DRAFT Table 14.1.2.1.1
Summary of Categorical Demographic Characteristics by Treatment
Intent-to-Treat Population

Ethnicity	Hispanic or Latino	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Not Hispanic or Latino	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Unknown	xxx	xx.x	xxx	xx.x	xxx	xx.x
Risk Factors	Age 65 or Older	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Chronic Cardiac Conditions	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Chronic Liver Disease	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Chronic Lung Disease	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Diabetes Mellitus	xxx	xx.x	xxx	xx.x	xxx	xx.x
Risk Factors	Hypertension	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Severe Obesity	xxx	xx.x	xxx	xx.x	xxx	xx.x
Number of Risk Factors	1	xxx	xx.x	xxx	xx.x	xxx	xx.x
	2	xxx	xx.x	xxx	xx.x	xxx	xx.x
	3	xxx	xx.x	xxx	xx.x	xxx	xx.x
	4	xxx	xx.x	xxx	xx.x	xxx	xx.x
	5	xxx	xx.x	xxx	xx.x	xxx	xx.x
	6	xxx	xx.x	xxx	xx.x	xxx	xx.x
Northeast	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site …	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
South	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site …	xxx	xx.x	xxx	xx.x	xxx	xx.x

DRAFT Table 14.1.2.1.1
Summary of Categorical Demographic Characteristics by Treatment
Intent-to-Treat Population

	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site …	xxx	xx.x	xxx	xx.x	xxx	xx.x
West	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x
	Site …	xxx	xx.x	xxx	xx.x	xxx	xx.x
Central	Site xxx	xxx	xx.x	xxx	xx.x	xxx	xx.x

Note: Denominator for percentages is the number of subjects in the intent-to-treat population for a group.
[a]Subjects who did not report a race are not counted in Race Group 1.

Program Source: xxxxx.sas Database Lock Date: DDMMMYYYY : Run Date: DDMMMYYYY

DRAFT Table 14.1.2.1.2
Summary of Continuous Demographic Characteristics by Treatment
Intent-to-Treat Population

Variable	Statistic	Camostat mesilate (N=xxx)	Placebo (N=xxx)	All Subjects (N=xxx)
Age (yrs)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx
Height (cm)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx
Weight (kg)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx
Body Mass Index (kg/mm^2)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx

DRAFT Table 14.1.2.1.2
Summary of Continuous Demographic Characteristics by Treatment
Intent-to-Treat Population

Number of Risk Factors	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x
Time from Positive Covid-19 Test to Randomization (hrs)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx

Note: Denominator for percentages is the number of subjects in the safety population for a group.

Program Source: xxxxx.sas Database Lock Date: DDMMMYYYY : Run Date: DDMMMYYYY

DRAFT Table 14.2.1.1
Numbers and percentages of subjects in each treatment group
Requiring COVID-19 related hospitalization or who died due to any cause within 28 days of randomization
ITT Analysis Set[1]

	Number and Percentage with Endpoint									
	Camostat mesilate			Placebo				Difference and Confidence Interval (%)[3]		
Hospitalization/ER visit or death within 28 Days	**N**	**n**	**%**	**N**	**n**	**%**	**p-value[2]**	**Diff.**	**LB**	**UB**
Multiple Imputation		---			---					
Completers										
Best Case										
Worse Case										
All Missing as Failure										

Notes:
[1] The Intent-to-Treat (ITT) population will include all subjects who are randomized. Subjects will be analyzed according to their study treatment assignment, not according to the treatment actually received (N=xxx).
[2] Unadjusted chi-square test
[3] Two-sided 95% CI
Program Source [xxxxxxx.sas]

Programming Note: This table will be repeated for the Per-Protocol populations(s).

DRAFT Table 14.2.1.4
Numbers and percentages of subjects in each treatment group
Requiring COVID-19 related hospitalization or who died due to any cause within 28 days of randomization
ITT Analysis Set[1]

	Number and Percentage with Endpoint									
	Camostat mesilate			Placebo				Difference and Confidence Interval (%)[3]		
Hospitalization/ER visit or death within 28 Days	**N**	**n**	**%**	**N**	**n**	**%**	**p-value[2]**	**Diff.**	**LB**	**UB**
Adjusted for baseline covariates with clinically significant group differences[4]										
Adjusted for all covariates[5]										
Model identified by stepwise[6]										

Notes:
[1] The Intent-to-Treat (ITT) population will include all subjects who are randomized. Subjects will be analyzed according to their study treatment assignment, not according to the treatment actually received (N=295).
[2] Unadjusted chi-square test
[3] Two-sided 95% CI
[4] Variable list
[5] Variable list
[6] Variable list
Program Source [xxxxxxx.sas]

DRAFT Table 14.2.3
Time to Resolution of Fever
Intent-To-Treat Population

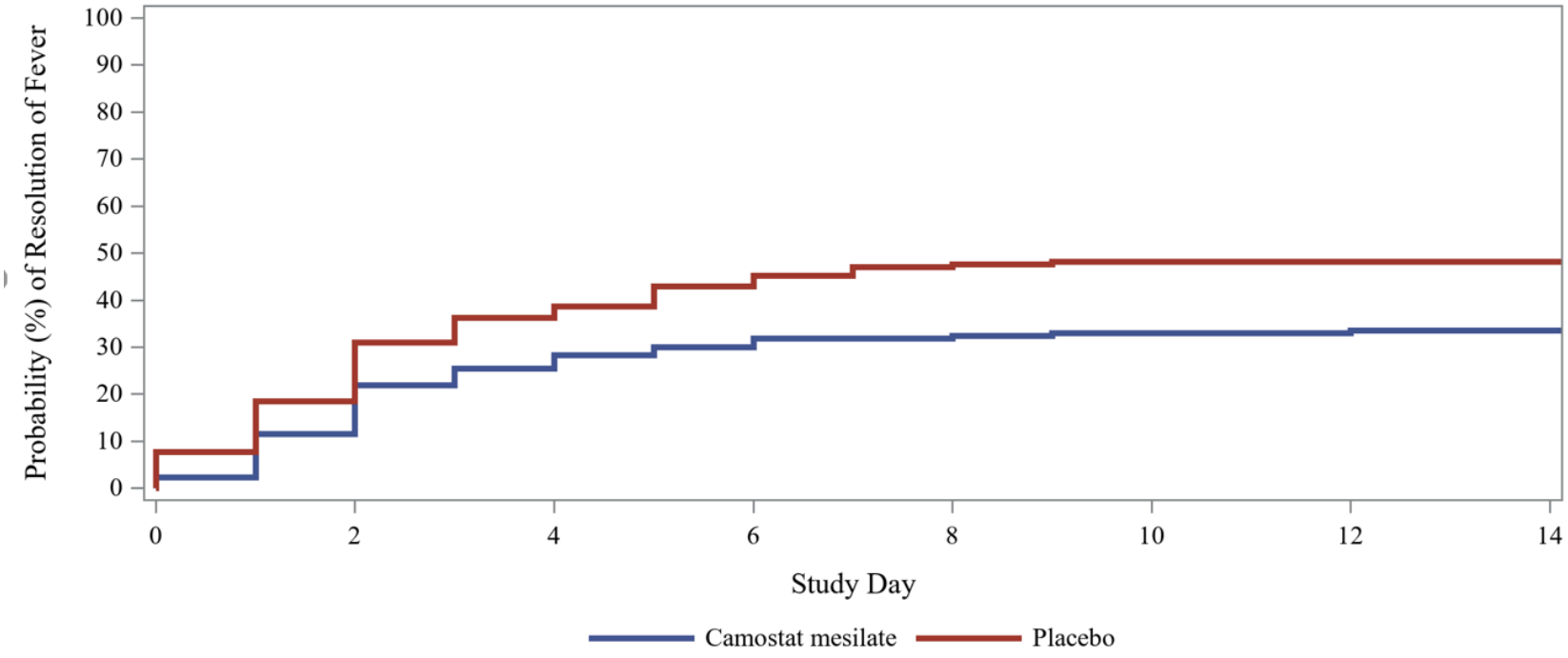
Interval	Pts at start	#with event	Censored	Cumulative Resolution Rate	SE‡
At Start					
Day 1					
…					
Day 14					

Notes:
‡ SE Errors computed using the Peto method. No subjects died on or before Day14.

Program source:

Programming Notes: Time to Resolution of New Fever will be displayed in a similar manner.

DRAFT Figure 14.2.4
Kaplan-Meier Time to Resolution of Fever
Intent-to-Treat Population



Program Name: XXXXXX.sas

Database lock date: 17JAN2020; Run Date: 30MAR2021

Note: This figure will include a number At-Risk Table detailing the number of subjects with events and censored for each day of the analysis. Day 0 will be included displaying the number of subjects in the analysis overall.

Programming Notes: Kaplan-Meier Time to COVID-19 Hospitalization/ER visit will be displayed in similar manner.

DRAFT Table 14.2.5
Time to COVID-19 Hospitalization/ER visit or Death
Intent-To-Treat Population

Interval	Pts at start	#with event	Censored	Cumulative Rate	SE‡
At Start					
Day 1					
…					
Day 28					

Notes:
‡ SE Errors computed using the Peto method.

Program source:

DRAFT Table 14.2.7
Proportion of Subjects with No Viral Shedding at Days 7, 15, and at Early Termination
Intent to Treat Population

	Camostat mesilate (N=xxx)		Placebo (N=xxx)		
	n	**%**	**n**	**%**	**Diff**
Day 7	xxx	xxx	xxx	xxx	xxx
Day 15	xxx	xxx	xxx	xxx	xxx
Day 28 or Early Termination	xxx	xxx	xxx	xxx	xxx
Program Source: xxxxx.sas	database Lock Date: DDMMMYYYY : Run Date: DDMMMYYYY				

DRAFT Table 14.2.8.1
Shift Table of Fever Severity Categories by Study Day and Treatment

		Camostat mesilate												Placebo											
		(N=xxx)												(N=xxx)											
		None		Grade 1		Grade 2		Grade 3		Grade 4		Missing		None		Grade 1		Grade 2		Grade 3		Grade 4		Missing	
Study Day		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%			n			%
Day 0	--	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
Day 1	None	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Low grade	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Moderate	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	High-grade	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Hyperpyrexia	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Missing	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
…	None	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Low grade	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Moderate	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	High-grade	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Hyperpyrexia	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Missing	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
Day 14	None	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Low grade	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Moderate	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	High-grade	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Hyperpyrexia	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x
	Missing	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx	xx.x	xx.x

DRAFT Table 14.1.3
Summary of Baseline Clinical Laboratory Data by Treatment
Intent-to-Treat Population

Variable	Statistic	Camostat mesilate (N=xxx)	Placebo (N=xxx)	All Subjects (N=xxx)
Albumin (g/L)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx
Alkaline Phosphatase (U/L)	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x
Alanie Aminotransferase (U/L)	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x
Aspartate Aminotransferase (U/L)	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x

DRAFT Table 14.1.3
Summary of Baseline Clinical Laboratory Data by Treatment
Intent-to-Treat Population

Note: Continue for all Clinical laboratory tests: Bicarbonate, Chloride, Creatinine, Glucose, Direct Bilirubin, Total Bilirubin, GGT, LDH, Platelets, Potassium, Sodium, Urea Nitrogen, White Blood Cells, Red Blood Cells, Hemoglobin, Hematocrit, Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Immature Granulocytes , MCV, CRP
Program Source: xxxxx.sas database Lock Date: DDMMMYYYY : Run Date: DDMMMYYYY

Note: All units in the above Table are Subject to Change.

DRAFT Table 14.1.4
Summary of Baseline Vital Signs by Treatment
Intent to Treat Population

Variable	Statistic	Camostat mesilate (N=xxx)	Placebo (N=xxx)	All Subjects (N=xxx)
Temperature °C	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx
Systolic Blood Pressure (mmHg)	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x
Diastolic Blood Pressure (mmHg)	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x
Pulse (breaths/mins)	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	Standard Deviation	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x
	Minimum, Maximum	x, x	x, x	x, x

DRAFT Table 14.1.4
Summary of Baseline Vital Signs by Treatment
Intent to Treat Population

Oxygen Saturation (%)	n	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x
	Standard Deviation	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x
	Minimum, Maximum	xx, xx	xx, xx	xx, xx
Program Source: xxxxx.sas			database Lock Date: DDMMMYYYY : Run Date: DDMMMYYYY	

DRAFT Table 14.3.1.1
Overall Summary of Adverse Events by Treatment
Safety Population

	Camostat mesilate (N=xxx)		Placebo (N=xxx)	
	n	**%**	**n**	**%**
Subjects with at least one[a]:				
Treatment Emergent adverse event (TEAE)[b]	xxx	xx.x	xxx	xx.x
Drug related TEAE	xxx	xx.x	xxx	xx.x
Serious TEAE	xxx	xx.x	xxx	xx.x
Serious drug related TEAE	xxx	xx.x	xxx	xx.x
Severe TEAE	xxx	xx.x	xxx	xx.x
Moderate or Severe TEAE	xxx	xx.x	xxx	xx.x
TEAE with outcome of death	xxx	xx.x	xxx	xx.x
TEAE with outcome of drug related death	xxx	xx.x	xxx	xx.x
Adverse event causing study drug withdrawal	xxx	xx.x	xxx	xx.x
Adverse event causing discontinuation from study	xxx	xx.x	xxx	xx.x
Maximum severity for a subject[c]:				
Mild (Grade 1)	xxx	xx.x	xxx	xx.x
Moderate (Grade 2)	xxx	xx.x	xxx	xx.x

DRAFT Table 14.3.1.1
Overall Summary of Adverse Events by Treatment
Safety Population

	Camostat mesilate (N=xxx)		Placebo (N=xxx)	
	n	**%**	**n**	**%**
Severe (Grade 3)	xxx	xx.x	xxx	xx.x
Life-Threatening (Grade 4)	xxx	xx.x	xxx	xx.x
Death (Grade 5)	xxx	xx.x	xxx	xx.x

Notes: N=Number of subjects in the Safety Population; n=Number of subjects with the specified event.
[a]A subject is only counted once in each row category.
[b]A subject is counted once at the maximum severity observed over all treatment-emergent adverse events.
Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

DRAFT Table 14.3.1.2
Adverse Events Occurring in 5% of Subjects in Either Treatment Group by MedDRA System Organ Class and Preferred Term
Safety Population

SOC	PT	Camostat mesilate (N=xxx)			Placebo (N=xxx)			All Subjects (N=X)		
		n	%	Events	n	%	Events	n	%	Events
Serious Adverse Events										
SOC1	PT1	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
…	…	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
Other (Non-serious) Adverse Events										
SOC1	PT1	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
…	...	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx

N = number of subjects in the Safety Population.
n = number of subjects reporting event.
Events = total frequency of events reported.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Programming Notes:

Select all preferred terms/System organ classes where the % for any treatment group or overall is >= 5%. Sort preferred terms by descending order of frequency

DRAFT Table 14.3.1.3.1
Adverse Events Occurring in All Subjects by MedDRA System Organ Class and Preferred Term
Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Camostat mesilate (N=xxx)			Placebo (N=xxx)			All Subjects (N=X)		
		n	%	Events	n	%	Events	n	%	Events
Serious Adverse Events										
SOC1	PT1	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
…	...	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
Other (Non-serious) Adverse Events										
SOC1	PT1	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
…	…	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx

N = number of subjects in the Safety Population.
n = number of subjects reporting event.
Events = total frequency of events reported.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Programming Notes:

Select all preferred terms/System organ classes. Sort preferred terms by descending order of frequency

DRAFT Table 14.3.1.3.2
Adverse Events Occurring in All Subjects by MedDRA Preferred Term
Safety Population

MedDRA Preferred Term	Camostat mesilate (N=xxx)			Placebo (N=xxx)			All Subjects (N=X)		
	n	%	Events	n	%	Events	n	%	Events
PT1	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
...	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx
…	xx	xx.x	xxx	xx	xx.x	xxx	xx	xx.x	xxx

N = number of subjects in the Safety Population.
n = number of subjects reporting event.
Events = total frequency of events reported.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Programming Notes:

Select all preferred terms- Sort preferred terms by descending order of frequency in Active group.

DRAFT Table 14.3.1.4
Incidence of Treatment Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Camostat mesilate (N=xxx)		Placebo (N=xxx)		All Subjects (N=X)	
		n	%	n	%	n	%
Any System Organ Class	Any Preferred Term	xx	xx.x	xx	xx.x	xx	xx.x
SOC1	Any Preferred Term	xx	xx.x	xx	xx.x	xx	xx.x
	PT1	xx	xx.x	xx	xx.x	xx	xx.x
	PT2	xx	xx.x	xx	xx.x	xx	xx.x
	Continue for all PT	xx	xx.x	xx	xx.x	xx	xx.x
SOC2	Any Preferred Term	xx	xx.x	xx	xx.x	xx	xx.x
	PT1	xx	xx.x	xx	xx.x	xx	xx.x
	PT2	xx	xx.x	xx	xx.x	xx	xx.x
	Continue for all PT	xx	xx.x	xx	xx.x	xx	xx.x

N = number of subjects in the Safety Population.
n = number of subjects reporting event.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Programming Notes:

Sort by System organ class and preferred term

Table 14.3.1.5: Incidence of Treatment Emergent Serious Adverse Events

Programming Notes: Use the same layout as Table 14.3.1.4 – Select only Serious Adverse Events

Table 14.3.1.6: Incidence of Related Treatment Emergent Adverse Events

Programming Notes: Use the same layout as Table 14.3.1.4 – Select only Adverse Events Related to Study Drug

Table 14.3.1.7: Incidence of Related Treatment Emergent Serious Adverse Events

Programming Notes: Use the same layout as Table 14.3.1.4 – Select only Serious Adverse Events Related to Study Drug

Table 14.3.1.8: Incidence of Grade 3 or Grade 4 or Grade 5 Treatment Emergent Adverse Events

Programming Notes: Use the same layout as Table 14.3.1.4 – Select only Treatment Emergent Adverse Events Graded as Grade 3 or Grade 4 or Grade 5

Table 14.3.1.9: Incidence of Treatment Emergent Adverse Events Leading to Study Drug Discontinuation

Programming Notes: Use the same layout as Table 14.3.1.4 – Select only Treatment Emergent Adverse Events leading to study drug discontinuation

DRAFT Table 14.3.2.1
Listing of Deaths

Subject ID	Treatment	Adverse Event Description	Onset Date/ Resolution Date	Study Day of Onset/ Duration	Severity	Relationship to Study Treatment	Outcome	Action Taken with Study Treatment	MedDRA® System Organ Class	MedDRA® Preferred Term
xxxxxx	**Camostat mesilate**	xxxxxxxxx	YYYY-MM-DD YYYY-MM-DD	YY/ YY	XXXXX	XXXXXX	XXXXXX	XXXXXXX	XXXXXXX	XXXXXXX
		xxxxxxxxx	YYYY-MM-DD YYYY-MM-DD	YY/ YY	XXXXX	XXXXXX	XXXXXX	XXXXXXX	XXXXXXX	XXXXXXX
xxxxxx	Placebo	xxxxxxxxx	YYYY-MM-DD YYYY-MM-DD	YY/ YY	XXXXX	XXXXXX	XXXXXX	XXXXXXX	XXXXXXX	XXXXXXX
		xxxxxxxxx	YYYY-MM-DD YYYY-MM-DD	YY/ YY	XXXXX	XXXXXX	XXXXXX	XXXXXXX	XXXXXXX	XXXXXXX

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Table 14.3.2.2: Listing of Serious Adverse Events

Programming Notes: Use the same layout as Table 14.3.2.1 – Select only Serious Adverse Events

Table 14.3.2.3: Listing of Grade 3 or Grade 4 or Grade 5 Adverse Events

Programming Notes: Use the same layout as Table 14.3.2.1 – Select only Grade 3 or Grade 4 or Grade 5 Adverse Events

Table 14.3.2.4: Listing of Adverse Events Leading to Study Drug Discontinuation

Programming Notes: Use the same layout as Table 14.3.2.1 – Select only Adverse Events leading to study drug discontinuation

DRAFT Table 14.3.4.1
Summary of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment
Intent-to-Treat Population

		Camostat mesilate (N=xxx)		Placebo (N=xxx)	
Study Day	**Statistic**	**Observed**	**Change**	**Observed**	**Change**
Baseline (Day 1)[a]	n	xxx	xxx	xxx	xxx
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	Std Deviation	xxx.x.	xxx.x.	xxx.x.	xxx.x.
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Day 7	n	xxx	xxx	xxx	xxx
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	Std Deviation	xxx.x.	xxx.x.	xxx.x.	xxx.x.
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Day 15	n	xxx	xxx	xxx	xxx
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	Std Deviation	xxx.x.	xxx.x.	xxx.x.	xxx.x.
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

Notes: N=Number of subjects in the Intent-toTreat Population; n=Number of subjects with an assessment at the specified time point.
Change=Change from Baseline; [a]Baseline is the last value prior to treatment for a subject. It is used in the change from baseline.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Table 14.3.4.1.2: Summary of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.2 – change population to the safety population

DRAFT Table 14.3.4.1.3
Shift of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment

		Camostat mesilate (N=xxx)								Placebo (N=xxx)							
		Low		Normal		High		Missing		Low		Normal		High		Missing	
Study Day		**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Baseline	---	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	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
	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
	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
	Missing	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x

Notes: N=Number of subjects in the Intent-to Treat Population;

n=Number of subjects with an assessment at the specified time point.
[a]Baseline is the last value prior to treatment for a subject.

Program: xxxxx.sas Database Lock Date: DDMMMYYYY: Run Date: DDMMMYYYY

Table 14.3.4.1.4: Shift of Alanine Aminotransferase (ALT) (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – change population to the safety population

DRAFT Figure 14.3.4.1.5
Boxplots of Laboratory Parameters by Study Day and Treatment: Alanine Aminotransferase (ALT) (U/L)
Intent-to-Treat Population

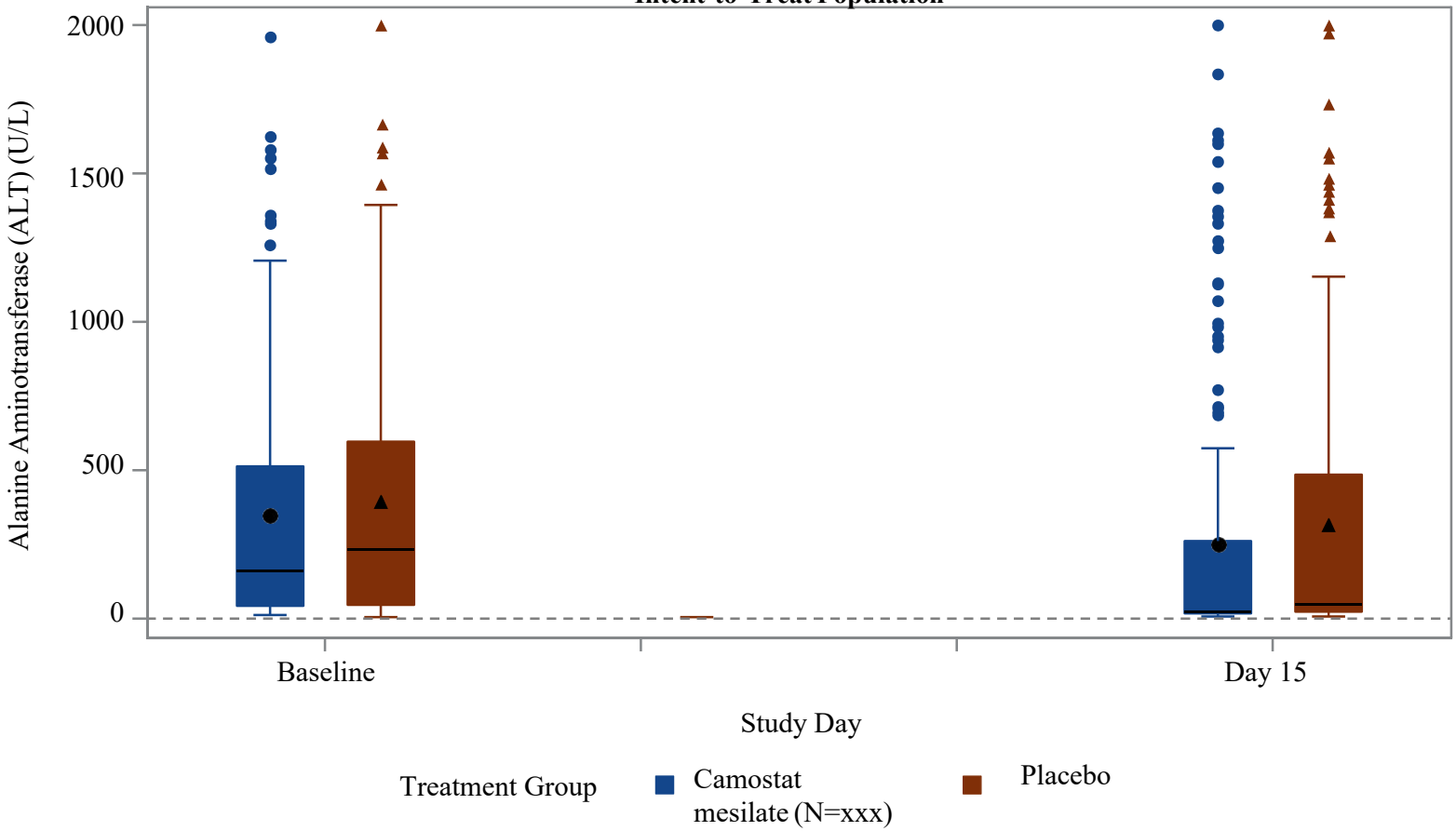


Figure 14.3.4.1.6: Boxplots of Laboratory Parameters by Study Day and Treatment: Alanine Aminotransferase (ALT) (U/L) – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.5 – change population to the safety population

Table 14.3.4.2.1 - Summary of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.1 – Change ALT to AST

Table 14.3.4.2.2 - Summary of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.1 – change ALT to AST and population to the safety population

Table 14.3.4.2.3 – Shift of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – Change ALT to AST

Table 14.3.4.2.4 - Shift of Aspartate Aminotransferase (AST) (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – change ALT to AST and population to the safety population

Figure 14.3.4.2.5 – Boxplots of Laboratory Parameters by Study Day and Treatment: Aspartate Aminotransferase (AST) (U/L) – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.5 – Change ALT to AST

Figure 14.3.4.2.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Aspartate Aminotransferase (AST) (U/L) – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1,5 – change ALT to AST and population to the safety population

Table 14.3.4.3.1 - Summary of Alkaline Phosphatase (U/L) by Study Day and Treatment – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.1 – Change ALT to AST

Table 14.3.4.3.2 - Summary of Alkaline Phosphatase (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.1 – change ALT to AST and population to the safety population

Table 14.3.4.3.3 – Shift of Alkaline Phosphatase (U/L) by Study Day and Treatment – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – Change ALT to AST

Table 14.3.4.3.4 - Shift of Alkaline Phosphatase (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – change ALT to AST and population to the safety population

Figure 14.3.4.3.5 – Boxplots of Laboratory Parameters by Study Day and Treatment: Alkaline Phosphatase (U/L) – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.5 – Change ALT to AST

Figure 14.3.4.3.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Alkaline Phosphatase (U/L) – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1,5 – change ALT to AST and population to the safety population

Table 14.3.4.3.1 - Summary of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.1 – Change ALT to AST

Table 14.3.4.3.2 - Summary of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.1 – change ALT to AST and population to the safety population

Table 14.3.4.3.3 – Shift of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – Change ALT to AST

Figure 14.3.4.3.4 - Shift of Gamma-glutamyl Transpeptidase (GGT) (U/L) by Study Day and Treatment – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1.3 – change ALT to AST and population to the safety population

Figure 14.3.4.3.5 – Boxplots of Laboratory Parameters by Study Day and Treatment: Gamma-glutamyl Transpeptidase (GGT) (U/L) – ITT Population
Programming Notes: Use the same layout as Table 14.3.4.1.5 – Change ALT to AST

Figure 14.3.4.3.6 - Boxplots of Laboratory Parameters by Study Day and Treatment: Gamma-glutamyl Transpeptidase (GGT) (U/L) – Safety Population
Programming Notes: Use the same layout as Table 14.3.4.1,5 – change ALT to AST and population to the safety population