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Protocol Title:

A Phase II, Randomized, Sham-Controlled Dose-Finding Study of the RD-X19 Treatment Device in Individuals with Mild to Moderate COVID-19

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Sponsor:

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STATISTICAL ANALYSIS PLAN

Protocol EB-P20-01

Version 2.0
February 2, 2022

A Phase II Randomized, Sham Controlled Dose Finding Study of the RD-X19 Treatment Device in Individuals with Mild to Moderate COVID-19

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Statistical Analysis Plan

1 Purpose of Statistical Analysis Plan

The purpose of the statistical analysis plan is to describe in detail all the data, statistical methods, and summary tables required to implement the statistical analysis of Clinical Study Protocol EB-P20-01 (Section 10 in the study protocol version 5.0, dated January 17, 2021).

2 Study Objectives

To evaluate multiple doses of the RD-X19 treatment device and establish evidence for safety and efficacy for each of the RD-X19 doses compared to sham in SARS-CoV-2 infected individuals with outpatient COVID-19.

3 Study Design, Efficacy Endpoints, and Sample Size Determination

3.1 Study Design

For the purpose of exploring the above objectives, the study will be conducted as a randomized, double-blind, sham-controlled dose finding study in SARS-CoV-2 infected outpatients with mild-to-moderate COVID-19.

This dose ranging portion of the study plans to enroll a minimum of 60 volunteers who are seronegative for SARS-CoV-2 Spike IgG antibody at baseline with 30 in each of at least two dosing cohorts (20 assigned to RD-X19 and 10 assigned to sham per cohort, 2:1 randomization).

Cohort A will begin with 24 J/cm^2 per treatment, administered 2X/Day for duration of 7 days. Once 80% of subjects (n=24) in Cohort A complete the Day 8 visit and no predefined safety signals as outlined in the study pausing/stopping criteria have been observed, Cohort B, 32 J/cm^2 per treatment will start enrollment. In the event device-related serious adverse events or patterns of device-related adverse events, including application site reactions, are observed in Cohort A, and based on the review and recommendation of the external safety monitoring committee (SMC) of unblinded data, the study may proceed with enrollment and dosing in Cohort C, 16 J/cm^2 per treatment in keeping with SMC recommendations. An illustration of the ascending (or descending) dose finding design is provided below.

Cohort A: RD-X19 24 J/cm^2 vs. Sham

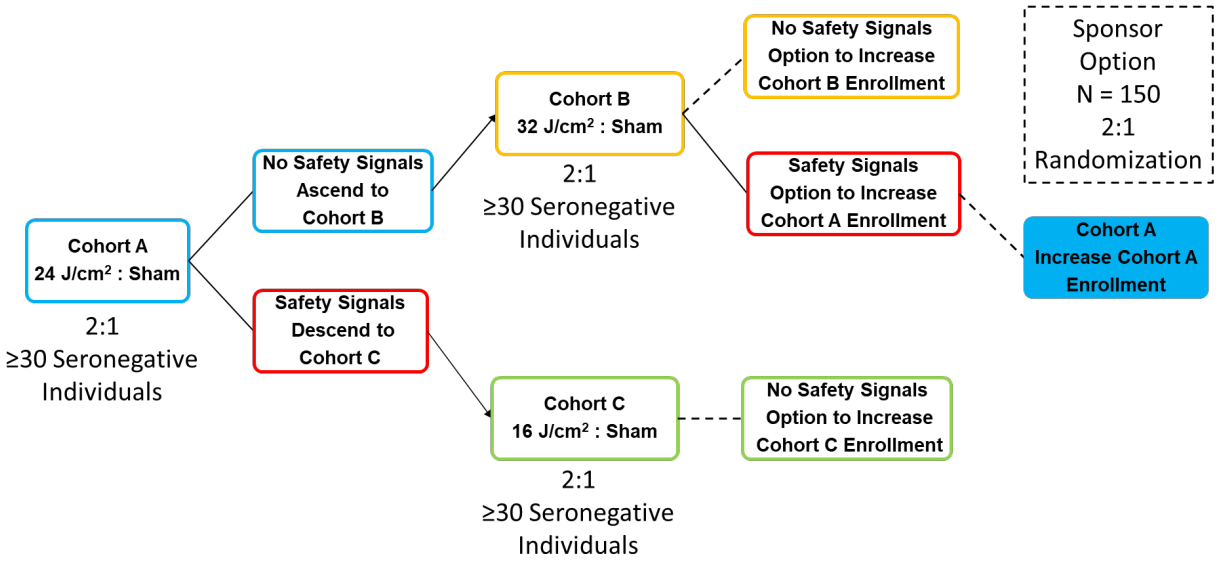
(5 minute treatment, 2X/Day for a duration of 7 days)

Cohort B: RD-X19 32 J/cm^2 vs. Sham

(5 minute treatment, 2X/Day for a duration of 7 days)

Cohort C: RD-X19 16 J/cm^2 vs. Sham

(5 minute treatment, 2X/Day for a duration of 7 days)



During the investigation of Cohort B , once 80% of the subjects complete the Day 8 visit without observation of safety signals meeting the definition of predefined pausing/stopping criteria, a blinded review of available safety data for Cohort A and Cohort B was conducted along with a blinded assessment of the proportion of 'success' events on the first primary endpoint of sustained symptom resolution for the subjects within each Cohort. At the sponsors option, the final cohort enrollment was increased in sample size, targeting up to an additional 150 subjects (2:1 randomization). This option to increase overall enrollment is intended to provide better resolution of the point estimate between a safe, well tolerated dose and sham treatment in a broader population, including subjects who are SARS-CoV-2 Anti-Spike IgG antibody positive at baseline, either through natural infection or immunization, in preparation for future trials.

Note: The Cohort which has the optional additional enrollment will be considered the 'Final Cohort'. In the event that the sponsor elects to not proceed with the optional additional enrollment then the last Cohort investigated will be defined to be the 'Final Cohort'. As such, the Final Cohort is defined as the cohort including the final randomized subject.

Subjects meeting all inclusion criteria and none of the exclusion criteria will be randomized in a 2:1 ratio within each dosing cohort.

The clinic visits will occur at:

- Visit 1 / Screening, Enrollment & Randomization
- Visit 2 / Day 3
- Visit 3 / Day 5 (± 1 day)
- Visit 4 / Day 8 (± 1 day)
- Visit 5 / Day 14 (± 2 day) / Early Termination (ET)

Assessments of study subjects will occur on study days 1, 3, 5, 8, with the final assessment visit on Day 14. Telephonic outreach by study personnel will occur on days 2 and 4 for additional safety monitoring and to enhance compliance with at-home study procedures. Study subjects

requiring hospitalization will be tracked until discharge or death and the date and time of these events will be captured in the study data.

Study Pausing Criteria

If observations of a device-related SAE or patterns of discrete or non-resolving device-related TEAEs grade 2 or higher in the same System Order Classified (SOC) Preferred Term (PT), based on the Medical Dictionary for Regulatory Activities (MedDRA) coding, are observed in a single subject, dosing will be discontinued for that subject and observed at regularly scheduled follow up visits.

EB-P20-01 enrollment in any Cohort will be paused if any of the following events occur:

- Any subject experiences a device related SAE.
- Any subject experiences laryngospasm, bronchospasm or anaphylaxis within 2 hours after treatment.
- Two (2) or more subjects experience an allergic reaction such as generalized urticaria (defined as occurring at three or more body parts) within 72 hours after treatment.
    - Potential photoallergy or phototoxicity to one or more photosensitizing drugs in the subject's medical history should be investigated in all cases. See "Medications that Increase Sensitivity to Light: A 1990 Listing (Levine 1990)."
- Three (3) or more subjects experience a Grade 2 or higher TEAE (including local, systemic and/or clinical laboratory abnormalities), in the same SOC PT based on the Medical Dictionary for Regulatory Activities (MedDRA) coding, considered to be related to RD-X19.

While the study enrollment is paused, attribution will be determined and assigned and the SMC will be notified that a consultation is required. Given the frequency of visits and the duration of the protocol, study device use may continue in unaffected subjects within a cohort until a recommendation is provided to unpause or terminate cohort enrollment by the SMC.

The SMC, when convened by the sponsor, will not only make a recommendation to unpause enrollment or discontinue dosing in a given cohort, but will also make a recomendation to the sponsor for ascending or descending from Cohort A in the event safety/tolerability signals are observed within the first dosing cohort (24 J/cm^2 RD-X19 device).

A study volunteer may elect to discontinue participation in the trial at any time. Investigative staff will ask the volunteer to return for an early termination evaluation, but they are under no obligation to do so. All study subjects must return the RD-X19 device at study termination and study staff must verify that the device serial number matches the study subject to whom it was assigned.

Study Stopping Criteria

When a device-related SAE or two or more device-related severe TEAEs (grade 3) in the same SOC PT are observed within a given cohort, further enrollment and treatment in that Cohort will be discontinued.

3.2 Efficacy Endpoints

The primary efficacy endpoints are:

- Time to sustained resolution of COVID-19 signs and symptoms (in all subjects) as measured by the time from baseline (in hours) when cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea (with or without vomiting) have been assessed by the subject as none (0) or mild (1) and all symptoms remain at or below 1 until the Day 14 visit. Subjects reporting a persistent fever (100.5 degrees for 36 hours or more) and/or SpO_2 levels <96% with any shortness of breath are considered not to have met the success criterion on that day even if all other symptoms are reported as none (0) or mild (1).

- Time to sustained resolution of COVID-19 signs and symptoms (in subjects with mild disease at baseline) as measured by the time from baseline (in hours) when cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea (with or without vomiting) have been assessed by the subject as none (0) or mild (1) and all symptoms remain at or below 1 until the Day 14 visit. Subjects reporting a persistent fever (100.5 degrees for 36 hours or more) and/or SpO_2 levels <96% with any shortness of breath are considered not to have met the success criterion on that day even if all other symptoms are reported as none (0) or mild (1).

Note: The second primary endpoint is defined in the same way as the first primary endpoint, but is evaluated only in subjects with mild disease at baseline.

Secondary clinical endpoints:

- Proportion of study subjects who achieve 'Composite Resolution' at Day 8 defined as both a negative SARS-CoV-2 antigen test within the window for Visit 4 (Days 7 – 9) and all eight symptoms assessed by the subject as none (0) or mild (1), absence of fever and SpO2 $\geqslant$96% without shortness of breath at study day 8 (as reported on the Diary Card Day 8-Assessment 1).
- Proportion of study subjects who experience progression of COVID-19 as defined by an increase of the composite COVID-19 severity score greater than baseline at any point in the study on or after Day 3.
- Proportion of study subjects who answer yes to either of the following patient-reported global impression assessments independently at each of the Day 8 and Day 14 visits,
    a) In the past 24 hours, have you returned to your usual health (before your COVID-19 illness)?
    b) In the past 24 hours, have you returned to your usual activities (before your COVID-19 illness)?
- Proportion of study subjects with any one or more of the following severe clinical outcomes (including proportions of study subjects for each individual outcome):

1) who require medical attention or intervention attributed to COVID-19
2) who progress to severe systemic illness with respiratory rate ≥30/minute, heart rate ≥125, O_2 saturation ≤93% on room air or PaO2/FiO2 ≤300 mm Hg, or lung infiltrates upon imaging >50%.
3) who require hospitalization for severe COVID-19
4) who require endotracheal ventilation or ECMO with or without the use of solumedrol
5) who die

Secondary virologic endpoints:

- Mean change in nasopharyngeal viral load on days 3, 5, 8, and 14
- Geometric mean nasopharyngeal viral load at baseline and on days 3, 5, 8, and 14
- Proportion of subjects demonstrating clearance of viral infection, defined as a negative nasopharyngeal swab via RT-qPCR as assessed on Days 3, 5, 8 and 14

Exploratory assessments of effects of RD-X19 in saliva viral load include:

- Mean change in saliva viral load on days 3, 5, 8, and 14
- Geometric mean saliva viral load at baseline and on days 3, 5, 8, and 14

Exploratory assessment of effects of RD-X19 in oral micorbiome includes:

- Change in α and β diversity in microbial flora from baseline on day 8 and day 14 as analyzed by 16S rRNA subunit analysis from frozen saliva samples

3.3 Sample Size Determination

The target number of subjects to be randomized per cohort is 30 individuals seronegative for SARS-CoV-2 Spike IgG antibodies (20 subjects to the RD-X19 treatment arm and 10 subjects for Sham control), for a minimum total of 60 subjects. At the sponsors option, the total number of subjects can be increased by an additional 150 total subjects to include all serostatuses after a dose has been selected based on adequate safety/tolerability observed for the final dose cohort.

Based on findings in the EB-P12-01, the hazard ratio observed for the time to sustained symptom resolution in that early feasibility trial was HR=0.4 between active RD-X19 and Sham.

The increased sample size in the Final Cohort (up to 180 total), with an anticipated roughly equal number of antibody positive to negative individuals enrolled during the option, will lead to approximately 90 seropositive and 90 seronegative subjects. The modified Full Analysis Set (mFAS) population containing only antibody negative subjects (as defined in Section 4, 60 RD-X19: 30 Sham) has at least 90% power to detect meaningful changes in SARS-CoV-2 symptom resolution from baseline (Hazard ratio of 0.4) for the first primary endpoint. These power calculations assume that testing will be carried out using $\alpha = 0.025$ one-sided, up to a 20% dropout rate due to discontinuations or hospitalizations, as well as an assumption that the proportions of subjects having the event (for the first primary endpoint) by Day 14 is 85% for the RD-X19 arm and 75% for the Sham arm.

In the Full Analysis Set (FAS) for the Final Cohort, the primary analysis population including all randomized subjects receiving at least one treatment, the increased sample size (increase by a minimum of 100 RD-X19: 50 Sham) has at least 90% power to detect a Hazard ratio of 0.5 between RD-X19 and Sham for the first primary endpoint. These power calculations assume that testing will be carried out using $\alpha = 0.025$ one-sided, as well as an assumption that the proportions of subjects having the event (for the first primary endpoint) by Day 14 is 90% for the RD-X19 arm and 85% for the Sham arm, with adjustment for multiple endpoints as described in Section 5.1.1.

Note: The two primary endpoints will be tested using a maximum experimentwise type 1 error of 0.025 1-sided and using a maximum experimentwise type 1 error of 0.050 1-sided. In section 5.1.1, under the procedure for multiple endpoint adjustment, the significance levels for testing each of the two individual primary endpoints are derived so that the maximum experimentwise type 1 error is 0.025 one-sided, and significance levels are also derived so that the maximum experimentwise type 1 error is 0.050 one-sided.

4 Populations To Be Analyzed

Three subject populations are defined as follows:

(1) Safety/Full Analysis Set (FAS): This population will include all randomized subjects who receive at least 1 study treatment. This Population will be used for all analysis of safety data, and is also the primary analysis population for efficacy. Subjects will be analyzed based on actual treatment received.

(2) Modified Full Analysis Set (mFAS): This population will include all randomized subjects who received at least one treatment and who tested negative for SARS-CoV-2 antibodies at baseline. Subjects will be analyzed based on actual treatment received.

(3) Per-Protocol Population (PP): This population will include all randomized subjects in the FAS population who complete the study and did not have a major protocol deviation (MPD). The PP population will be used for supportive analysis of the clinical and virological endpoints. MPDs are those that could have interfered with the administration of treatment or the precise evaluation of treatment efficacy.

MPDs may include but will not be limited to the following:

- Violation of inclusion/exclusion criteria
- Use of prohibited concomitant medications during the treatment period
- Missed Visit 4 (Day 8) or Visit 4 outside of window
- Did not complete 100% (6 out of 6) of scheduled doses in the first 3 days, or at least 75% (11 out of 14), regardless of the time of enrollment on Day 1
- Returned for Day 14 Visit outside the designated visit window

All MPDs will be identified and documented in the Protocol Violation and Protocol Deviation Log before the database lock and study unblinding for analysis.

5 Planned Analyses

All study data will be presented in by-subject data listings. Tabulations will be displayed separately for RD-X19 and Sham from the Final cohort for the primary analysis, and, RD-X19

from each cohort individually, Pooled RD-X19 from both Cohorts and Pooled Sham from both Cohorts for supportive/secondary analyses.

5.1 Methodological Considerations

General Conventions

SAS software (version 9.4 or higher) will be used for all data analyses and tabulations.

Data for all investigational centers will be pooled for analysis. The sham groups from different cohorts will not be combined for the analyses unless otherwise specified. For all analyses, subjects will be analyzed based on actual treatment received.

Unless specified elsewhere, baseline is defined as the last available measurement prior to administration of study treatment. Change from baseline will be calculated as the post-baseline value minus the baseline value.

Summary tables will include the data based upon the protocol scheduled time points. For subjects who are early discontinued from the study or have visits outside of the allowed window, all efficacy assessments captured at the visit will be assigned to the protocol scheduled time point as follows:

Visit of Treatment Period	**Range for ET / Visit Re-allocation***
Visit 2 / Day 3	Study Day 1 to 3
Visit 3 / Day 5 (± 1 day)	Study Day 4 to 6
Visit 4 / Day 8 (± 1 day)	Study Day 7 to 9
Visit 5 / Day 14 (± 2 day)	Study Day >=10

*Study day = date of visit - date of first treatment + 1

Descriptive statistics of continuous variables will include n, mean, standard deviation (SD), median, and range. Generally, the minimum and maximum values will be presented to the same decimal precision as the raw values, the mean and median values to one additional decimal, and the SD, to two more decimal places than the raw values. Summaries for categorical data will include frequencies and percentages. Percentages will be presented to one decimal place.

5.1.1 Significance Levels and Adjustment for Multiple Endpoints

The trial will be viewed as positive as regards to efficacy if statistical significance is obtained in the primary analysis for either primary endpoint. To adjust for multiple endpoints the Hochberg[1] procedure will be used. As the two primary endpoints evaluate the same outcome, in all study subjects for the first primary endpoint and in subjects with mild disease for the second primary endpoint, then they are highly correlated. If for example in the primary analyses of the two primary endpoints there are 98 mild subjects and 76 moderate subjects then the correlation is $[98/174]^{0.5}$, and then as shown by Spiessens & Debois (2010)[2] a higher significance level can be used while still maintaining the maximum experimentwise type 1 error at the target α.

The Hochberg procedure (allowing for this correlation) proceeds as follows when the overall α =0.025 one-sided: (i) If both (one-sided) p-values for the two primary endpoints are < 0.025 then both primary endpoints are declared statistically significant; or (ii) If the largest (one-sided) p-value is ≥ 0.025 and the smallest (one-sided) p-value < 0.0144 then statistical significance can be declared for this one primary endpoint.

Testing for the primary endpoints is also carried out using an overall α =0.050 one-sided. In this case the Hochberg procedure (allowing for this correlation) proceeds as follows: (iii) If both

(one-sided) p-values for the two primary endpoints are < 0.050 then both primary endpoints are declared statistically significant; or (iv) If the largest (one-sided) p-value is ≥ 0.050 and the smallest p-value < 0.0297 then statistical significance can be declared for this one primary endpoint.

Note: The value of 0.0144 has been determined numerically (using the SAS PROBBNRM function) under the Hochberg procedure to control the maximum experimentwise type 1 error at 0.025 one-sided. Similarly, the value of 0.0297 has been determined numerically under the Hochberg procedure to control the maximum experimentwise type 1 error at 0.050 one-sided. Each value has been derived based on the assumption of 98 subjects with mild disease at baseline, and 76 with moderate disease at baseline in the FAS population for the Final Cohort. However, these α values will be re-calculated if the final counts differ from these values.

P-values for the one or both primary endpoints where for their primary analysis have statistical significance from (i) or (ii) under the Hochberg procedure (where the overall α =0.025 one-sided) will be flagged with "**". If p-values for the primary analysis of one or both primary endpoints are only statistically under (iii) or (iv) of the Hochberg procedure (where the overall α =0.050 one-sided) then they will be flagged with "*".

5.2 Handling of Missing Data and Data Handling Rules

5.2.1 Missing Efficacy Endpoints

In general, missing data will not be imputed with the exception that for the missing viral load results post baseline (nasopharyngeal and saliva biospecimens) will be imputed using the multiple imputation (MI) methodology as described in Section 5.5.2.

For derivation of resolution of COVID-19 symptoms, scenarios of missing diary data (8 symptoms: cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, nausea) in conjunction with vital signs of fever, SpO_2 levels, and shortness of breath will be handled as follows:

- Scenario 1: For Day x assessment y (am or pm) with missing severity for some among the 8 symptom(s), if there is at least one symptom scored 2 (moderate) or 3 (severe), subject will be considered failure for Day x assessment y.
- Scenario 2: For Day x assessment y with missing severity for some among the 8 symptom(s), if all non-missing values are 0 or 1, any other symptoms left blank on Day x assessment y will be considered with severity of 0 (none) for the purposes of derivation of resolution of COVID-19 symptoms. Subject's success or failure for Day x assessment y will then be determined by the vital sign data on fever and/or SpO_2 level/shortness of breath as follows:
    - If fever of ⩾ 100.5 and is persistent for ≥36 hours or SpO_2 levels <96% with shortness of breath, the subject will be considered a failure.
    - If SpO_2 levels <96% and data is missing for shortness of breath, the subject will be considered a failure.
    - If SpO_2 levels ≥96% and data is missing for shortness of breath, the subject will be considered a success.
    - If shortness of breath is "Yes" and SpO_2 levels are missing, the subject will be considered a failure.

- If shortness of breath is "No", and SpO_2 levels are missing, the subject will be considered a success.
- If temperature data is missing, the subject will be considered a success if fever was <100.5 on the previous assessment and a failure if the previous two assessments were both ≥100.5.

- Scenario 3: For Day x (pm), if severity is missing for all 8 symptoms, the diary entries from the previous completed entry, either Day x (am) or Day x-1 (pm), will be carried forward for Day x (pm). For Day x (am), if severity is missing for all 8 symptoms, the diary entries from the previous completed entry, either Day x-1 (pm) or Day x-1 (am) will be carried forward for Day x (am). Same applied to fever and SpO_2 level/shortness of breath.
- Scenario 4: For Day x assessment y where all 8 symptoms are scored 0 or 1, if fever or SpO_2 level is missing, subject's success or failure for Day x assessment y will be determined in the same way as in Scenario 2.

For derivation of the primary efficacy endpoints, subjects who were hospitalized due to COVID-19 will be designated as treatment failures, and right censored at 384 hours (16 days), i.e., censored at the end of the Visit 5 window.

For subjects who discontinued the study early for any reason other than hospitalization for COVID-19, only diary data up to subject's discontinuation date will be used. For derivation of the primary efficacy endpoints such subjects will be considered censored at the time of their last assessment.

Note: Subjects discontinuing for any reason are ineligible to meet the success criteria on either primary efficacy endpoint because "success" requires the conditions to be met until the Day 14 visit.

The COVID-19 Composite Severity Score (CSS) at baseline is defined as the sum of the eight individual COVID-19 signs and symptoms severity scores divided by eight. For purposes of calculating the COVID-19 composite severity score in the secondary endpoint of worsening disease from baseline, subjects with missing diary card entries (reporting none of eight symptoms scored) will not be considered to have met the criteria for worsening of disease at that assessment timepoint. Subjects with incomplete diary card entries (reporting from 1 to 7 of the eight symptoms scored), will be handled by dividing the sum of all scores reported by the number of scores reported, and compared to the baseline CSS.

5.2.2 Missing or Incomplete Dates for Adverse Events and Concomitant Medications

Adverse Events

Handling of partial dates is only considered for the start date. An adverse event with a partial start date is considered treatment emergent if:

- only the day is missing and the start month/year is the same or after the month/year of the first treatment
- the day and month are missing and the start year is the same or greater than the year of the first treatment date
- the start date is completely missing

Concomitant Medications

Handling of partial dates is only considered for the stop date. A medication with a partial stop date is considered concomitant if:

- only the day is missing and the stop month/year is the same or after the month/year of the first treatment
- the day and month are missing and the stop year is the same or greater than the year of the first treatment date
- the stop date is completely missing or the medication is ongoing.

5.3 Demographics and Baseline Characteristics

Demographics and baseline characteristics will be summarized descriptively for the Safety population.

5.4 Subject Accountability

A summary of subject disposition will be provided for all subjects descriptively, including reason for discontinuation and analysis populations.

5.5 Efficacy Analyses

The primary analysis population for all primary and secondary efficacy endpoints is the FAS population. Supportive analyses will be carried out on the mFAS and PP populations for the primary endpoints and for all secondary endpoints.

5.5.1 Analysis of Primary Efficacy Endpoint

The primary analysis for each of the two primary endpoints will be the comparison via an unstratified log-rank test between the RD-X19 treatment arm and sham from the Final Cohort and is based on the FAS population. This analysis will be supplemented with a graphical display and medians derived by the Kaplan Meier method.

All time-to-event analyses will be measured starting from the time of randomization. The data handling rules as described in Section 5.2.1 will be applied before analyses of the primary efficacy endpoints. These data handling rules cover cases related to subjects discontinuing the study early due to hospitalization for COVID-19, and cases related to subjects discontinuing the study early due to other reasons. Subjects that did not discontinue early but who did not achieve sustained resolution will be censored at the date of their Visit 5.

The Kaplan-Meier derived medians will be presented from the FAS population for the Final Cohort together with 95% CIs using the Brookmeyer & Crowley (1982) method and will include values for the RD-X19 treatment arm and the Sham arm. 25^{th} and 75^{th} percentiles will also be provided together with their 95% CIs using this same method.

Cox proportional hazards regression models (with a single term for treatment) will be employed to analyze the primary efficacy endpoints to derive a hazard ratio in each case between the RD-X19 treatment arm and the sham arm from the Final Cohort and will be based on the FAS population. Two-sided 95% confidence intervals and two-sided 90% confidence intervals will also be derived for the hazard ratios from the above models.

In addition, to evaluate the potential impact of subject baseline characteristics to the treatment effect estimation, the Cox proportional hazards regression will be performed for the Final Cohort based on the FAS population adjusting for the following set of covariates:

1) the COVID-19 Composite Severity Score at baseline defined as the sum of the eight individual COVID-19 signs and symptoms severity scores divided by eight (grouping of <1.25, ⩾1.25)
2) baseline disease status of mild vs. moderate disease (subjects meeting entry criteria are considered to be mild unless the physical/vital signs examination documents clinical signs suggestive of moderate illness)
   All subjects are designated as Mild with the exception of subjects:
   - Who have RR ⩾20 at Baseline
   - Who report Shortness of Breath at Baseline, or
   - Who have clinical signs suggestive of lower airway involvement.
3) gender
4) age (grouping of <50, ≥50)
5) baseline antibody status (positive, negative)

Note: For the second primary efficacy endpoint the term for baseline disease status of mild vs. moderate will not be included.

Two-sided 95% confidence intervals and two-sided 90% confidence intervals will also be derived for the hazard ratios from the above models.

Supportive analyses in each case for the two primary efficacy endpoints will be produced for the mFAS and the Per Protocol population. For the mFAS population the Cox proportional hazards regression model will not include the covariate related to baseline antibody status.

All of the above analyses of the primary endpoints will also be produced for pooled RD-X19 doses vs. pooled Sham, and for RD-X19 low dose (i.e., the dose not expanded to produce the Final Cohort) vs. Pooled Sham, but where in all cases these p-values will be viewed as descriptive only. For the analyses of pooled RD-X19 vs. pooled Sham the log-rank test and the Cox proportional hazards models will each be stratified by cohort.

Following notations are used in the sample SAS code:

- TRT: treatment group with values 1 for RD-X19 from Final Cohort, 2 for RD-X19 from Cohort A, and 3 for Sham from Final Cohort, 4 for Sham from Cohort A
- TRTpool: value 12 for pooled RD-X19 from both cohorts, 3 for pooled Sham
- COHORT: A for first cohort, B for Final cohort
- HOURS: time to sustained resolution of COVID-19 signs and symptoms
- CNSR: the censoring variables, 1 for censored, 0 for not censored
- COVIDSEV: grouping of COVID-19 Composite Severity Score at baseline, 1 for score <1.25, 2 for score ≥1.25
- DSSTATUS: baseline disease status, 1 for mild, 2 for moderate
- SEX: 1 for males, 2 for females
- AGEGRP: grouping of age, 1 for age <50, 2 for age ≥50
- ANTIBODY: grouping of baseline antibody status, 1 for positive, 2 for negative

Sample SAS Code for Main Analysis

1. Unstratified analysis of Primary Endpoint 1: Time to sustained resolution of COVID-19 signs and symptoms (in mild and moderate subjects)

   a) RD-X19 from Final Cohort vs Sham from Final Cohort, log-rank test (unstratified)

```
PROC LIFETEST DATA=datain CONFTYPE=LINEAR;
    WHERE trt in (1,3);
    TIME hours*cnsr(1);
    STRATA trt/ TEST=LOGRANK;
RUN;
```

   b) RD-X19 from Final Cohort vs Sham from Final Cohort, Cox proportional hazards regression model (unstratified)

```
PROC PHREG DATA=datain;
    WHERE trt in (1,3);
    CLASS trt(ref='3') / PARAM=ref;
    MODEL hours*cnsr(1) = trt /RL;
    HAZARDRATIO trt / ALPHA=0.05;
    HAZARDRATIO trt / ALPHA=0.10;
RUN;
```

   c) RD-X19 from Final Cohort vs Sham from Final Cohort, Cox proportional hazards regression model adjusting for pre-specified covariates

```
PROC PHREG DATA = datain;
    WHERE trt in (1,3);
    CLASS trt(ref='3') / PARAM=ref;
    MODEL hours*cnsr(1) = trt COVIDSEV DSSTATUS SEX AGEGRP
ANTIBODY /RL;
    HAZARDRATIO trt / ALPHA=0.05;
    HAZARDRATIO trt / ALPHA=0.10;
RUN;
```

   Note: For mFAS analysis, variable ANTIBODY is not included as a covariate.

2. Unstratified analysis of Primary Endpoint 2: Time to sustained resolution of COVID-19 signs and symptoms (in mild subjects)

   Same SAS code for Primary Endpoint 1 will be used for Primary Endpoint 2 with two changes: (i) the WHERE statement in each case will now include 'and DSSTATUS=1'; and (ii) for analysis c) of Primary Endpoint 2, the variable DSSTATUS is not included as a covariate.

3. For graphical display of survival function by the Kaplan-Meier method:

RD-X19 from Final Cohort vs Sham from Final Cohort

```
PROC LIFETEST DATA=datain PLOTS=SURVIVAL(FAILURE);
    WHERE trt in (1,3);
    TIME hours*cnsr(1);
    STRATA trt;
RUN;
```

5.5.2 Analysis of Secondary and Exploratory Endpoints

All secondary clinical, virologic, and exploratory efficacy endpoints will be summarized using descriptive statistics by visit (as appropriate) for each treatment group.

For virologic outcome assessments, subjects without a Baseline biospecimen collected and/or the Baseline biospecimen determined to NOT be an analysis-qualified sample, will be excluded from these analyses.

Analysis-qualified samples are defined as nasopharyngeal and saliva SARS-CoV-2 biospecimen samples that have no sample Violations as outlined in the Biospecimen Violation and Biospecimen Deviation (BVBD) Log. Any samples that are not analysis-qualified, designated by "Valid biospecimen = N" will be replaced by missing values (prior to the multiple imputation described below).

Viral load (log base 10 copies/mL) and cycle threshold (Ct) data are continuous in nature but may be reported as "undetermined" or "inconclusive" or "<LOQ".

For analysis-qualified samples, results of "undetermined" and "<LOQ" for N1 copies/mL will be handled as follows for data summary purpose:

- For viral load reported as "Undetermined", value 1 will be used to calculate descriptive statistics. This will support the need for logarithm transformation.
- For viral load reported as "<LOQ", value $5x10^1$ will be used to calculate descriptive statistics.

Sample values reported as either "Inconclusive" N1 Ct viral load or with an "Undetermined" RNase P (RP) internal control Ct value will be replaced by missing values prior to the multiple imputation (MI) described below.

MI will be performed separately for saliva samples and nasopharyngeal samples and for each treatment via a two-step process for subjects with non-missing baseline. Viral load values will be log10-transformed before MI. Missing data occurring for an intermediate visit will be imputed first using a Markov Chain Monte Carlo (MCMC) method. As a result, a monotone missingness pattern will be obtained for the data to be fully imputed. The subsequent imputation will use Monotone Regression to produce 100 imputed datasets where the remaining missing data are filled in.

The SAS code for MI is as follows:

- Saliva samples: random number = 184962 as the seed for the first Step and 64849 as the seed for the second step.

- Nasopharyngeal samples: random number = 133274 as the seed for the first Step and 485044 as the seed for the second step.

Where notation of main variables:

- Log_dayX: log10-transformed viral load at Day X visit, where X=1, 3, 5, 8 and 14.

```
*Step 1: MCMC fills interim missingness to make monotone;
 PROC MI data=datain out=step1 seed= XXXXX nimpute=100;
    mcmc impute=monotone;
    var log_day1 log_day3 log_day5 log_day8 log_day14;
 run;

*Step 2: MI regression;
PROC MI data=step1 out=step2 seed= XXXXX nimpute=1
  var log_day1 log_day3 log_day5 log_day8 log_day14;
  monotone reg(log_day3 = log_day1); *for D3;
  monotone reg(log_day5 = log_day1 log_day3); *for D5;
  monotone reg(log_day8 = log_day1 log_day3 log_day5); *for D8;
  monotone reg(log_day14 = log_day1 log_day3 log_day5 log_day8);
  by _imputation_;
run;
```

If either of the above multiple imputation procedures fails to converge, then multiple imputation (for both calls to PROC MI) will only be carried out for the Final Cohort, in which case only one of the 3 dummy variables for treatment will be needed in the first call to PROC MI.

The imputed values will be converted back to original scale by raising 10 to the power. For each missing value, its geometric mean of the 100 MI copies will be derived prior to the calculation of the summary statistics.

For log10-transformed viral load data, geometric means will be computed by exponentiating (base 10) the group means of the log10-transformed viral load.

In conjuncture with above handling of the viral data scenarios, for purposes of this protocol, clearance of viral infection post baseline visit is defined as achievement of: [1] RP Ct ≥0, AND [2] Average N1 Ct = "Undetermined".

Subjects with missing nasopharyngeal samples at any post baseline visit will not be imputed for the purposes of determining the proportion of subjects demonstrating clearance of viral infection. Such cases will be determined to be a 'failure' at this visit/assessment as having not achieved the endpoint of clearance of viral infection**.** If a subject's nasopharyngeal SARS-CoV-2 biospecimen sample at Visit X had a Violation as outlined in the Biospecimen Violation and Biospecimen Deviation Log, the subject will also be considered 'FAILURE' at Visit X.

The sponsor may decide if oral microbiome samples for the exploratory oral microbiome assessment will be analyzed after database lock. Summary of microbial flora will not be included in this analysis plan.

5.6 Safety and Tolerability Variables and Analyses

Safety and tolerability analyses will be performed for the Safety Population. All safety tables will include summary statistics for each RD-X19 dose group, Pooled RD-X19 dose groups, and Pooled Sham.

5.6.1 Adverse Events

All adverse events (AEs) occurring during the study will be recorded and coded in the Medical Dictionary for Regulatory Activities (MedDRA), version 24.0. TEAEs are defined as AEs recorded during or at any point after the first application of the study treatment. Exacerbations or worsening of any conditions during the trial that were present at screening and documented as part of medical history will also be recorded as TEAEs.

Frequency and percent of subjects reporting TEAEs will be tabulated for each treatment by system organ class (SOC) and preferred terms (PT) for the following:

- all TEAEs
- all TEAEs by severity
- all TEAEs by relationship to study treatment

In the summaries of incidence (frequencies and percentages) of all TEAEs, whether solicited or unsolicited, subjects who report more than one event that are mapped to the same PT will be counted only once. In the summaries of incidence of TEAEs by severity and by relationship to study treatment, subjects who report more than one event that are mapped to the same PT will be counted only once under the strongest severity and strongest relationship, accordingly. Incidence of TEAEs will also be tabulated by SOC and PT and further by what study day the 'most severe' observation was made.

Treatment-Emergent Serious Adverse Events (TESAEs) will be discussed within the clinical study report. TEAEs, TESAEs and TEAEs that led to treatment interruption or discontinuation will be presented in a tabular listing with attribution (device related, non-device related).

5.6.2 Reactogenicity Assessments

Tabulations will be generated by study visit for reactogenicity with number and percentage of subjects who experienced illumination site reactions (pain, erythema, edema/induration, and other pain, redness, swelling, or lesion of the oral mucosa).

5.6.3 Oropharyngeal Assessment

Oropharyngeal assessment results (Normal, Abnormal) will be summarized by number and percentage of subjects by study visit.

5.6.4 Vital Signs

For each vital sign (systolic and diastolic blood pressure, heart rate, breaths per minute, oral temperature and oxygen saturation via a pulse co-oximeter), actual values and change from baseline values will be summarized using descriptive statistics for each treatment group by visit.

5.6.5 Methemoglobin

Actual values of methemoglobin at baseline and Day 14/ET as well as change from baseline values will be summarized using descriptive statistics for each treatment group.

5.6.6 Other Assessments

Following assessment results will be presented in subject data listing: medical history, physical examination, clinical laboratory evaluations, concomitant medications.

5.7 References

1. Hochberg Y. (1988) A sharper Bonferroni procedure for multiple tests of significance. *Biometrika* 75: 800-802.

2. Spiessens B. & Debois M. (2010). Adjusted significance levels for subgroup analyses in clinical trials. *Contemporary Clinical Trials* 31: 647-656.

6 Tables and Listings

The following is an example of tables, listings and figures that will be included in the clinical study report. They may be modified as needed during the data analyses.

7 Appendices

7.1 Study Schedule of Activities

The schedule of visits and procedures to be conducted at each visit are summarized in the Study Schedule of Activities.

Study Procedures	**Screening, Enrollment & Randomization**	**Follow-up Period (Visit Window)**					
@ Each Study Day	**1**	**2**	**3**	**4**	**5 (-1 to +1)**	**8 (-1 to +1)**	**14/ET (-2 to +2)**
Informed Consent	**X**						
COVID-19 Testing - SARS-CoV-2 Rapid Antigen Test*	**X**					**X**	**X**
Medical History & Physical Examination	**X**		**Changes since last visit only**		**Changes since last visit only**	**X**	**X**
Oropharyngeal Assessment	**X****		**Changes since last visit only**		**Changes since last visit only**	**X**	**X**
Urine Pregnancy Test	**X**						
Concomitant Medication History/New	Baseline		**Changes since last visit only**		**Changes since last visit only**	**Changes since last visit only**	**Changes since last visit only**
Blood Draw (CMP, CBC, SARS-COV-2 antibody)	**X**						**X**
Methemoglobin	**X**						**X**
Vital Signs	**X**		**X**		**X**	**X**	**X**
Adverse Event Assessment / Reactogenicity	Baseline		**X**		**X**	**X**	**X**
Demographics, Inclusion / Exclusion Review	**X**						
Diary Dispensation (Diary Card Training) / Collection	**X**					**X**	**X**
Dispense RD-X19 Device / Treatment at Site***	**X**		**X**		**X**		
SARS-CoV-2 Biospecimen collection for viral assays (2 specimens – saliva and nasopharyngeal swab)****	**X**		**X**		**X**	**X**	**X**
Extra saliva specimen collection for exploratory oral microbiome assessment	**X**					**X**	**X**
COVID-19 Disease Assessment	**X**					**X**	**X**
Telephone Call for Safety Monitoring and Compliance		**X**		**X**			
Collect RD-X19 Device						**X**	

* Subjects presenting at the time of screening that have tested positive via a SARS-CoV-2 rapid antigen test at or within the past 24 hours of the screening visit and can provide documentation confirming proper identification, the date of the test and testing location, positivity of the result, and name/identity of the assay used to generate the result, are also eligible for enrollment and the rapid antigen test does not have to be repeated at the site.

** On Day 1 to be evaluated 30 minutes after first illumination at site.

*** For scheduling purposes, the recommended interval between treatment is not < 6 hours.
Only one treatment of the twice daily regimen will be done on site on Day**s** 1, 3 and 5, the second treatment will be done at home. For Day 1, the subject will be instructed to complete two treatments regardless of time of enrollment (e.g. 4 pm and 10 pm).

**** At Baseline and days 3, 5, 8, and 14, subjects will provide one saliva specimen and one nasopharyngeal swab for virology endpoint assessments. Biospecimens will be collected, preserved, and shipped to a central lab for assessment of SARS-CoV-2 mRNA via RT-qPCR. Optionally, the sponsor may perform additional genetic sequencing on one or both baseline specimens to obtain incidence of CDC classified variants of concern in the study population.

7.2 List of Summary Tables, Data Listings and Figures

List of Summary Tables

Number	Description	Analysis Set	Source Listing(s)
14.1	**Demographic and Baseline Data Summaries**		
14.1.1	Subject Final Study Disposition	All Randomized Subjects	16.2.1
14.1.2	Subject Analysis Population	All Randomized Subjects	16.2.1, 16.2.2.1
14.1.3	Demographic and Baseline Characteristics	Safety Population	16.2.4.1, 16.2.9.5
14.2	**Efficacy Data Summary Tables**		
14.2.1.1	Primary Analysis and Supportive Analyses of the First Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms for the Final Cohort	FAS & mFAS & PP Populations	16.2.6.4
14.2.1.2	Primary Analysis and Supportive Analyses of the Second Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms in Subjects with Mild Disease at Baseline for the Final Cohort	FAS & mFAS & PP Populations	16.2.6.4
14.2.1.3	Additional Supportive Analysis of First Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms for Both Cohorts Combined and for RD-X19 from Cohort A	FAS & mFAS & PP Populations	16.2.6.4
14.2.1.4	Additional Supportive Analysis of Second Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms in Subjects with Mild Disease at Baseline for Both Cohorts Combined and for RD-X19 from Cohort A	FAS & mFAS & PP Populations	16.2.6.4
14.2.2.1	Summary of Secondary Efficacy Endpoints: Proportion of Subjects Who Achieve Composite Resolution at Day 8	FAS & mFAS & PP Populations	16.2.6.4
14.2.2.2	Summary of Secondary Efficacy Endpoints: Proportion of Subjects Who Returned to Usual Health and Proportion Who Returned to Usual Activities	FAS & mFAS & PP Populations	16.2.6.4
14.2.2.3	Summary of Secondary Efficacy Endpoints: Proportion of Subjects with Progression of COVID-19 and Proportion of Subjects with Severe Clinical Outcomes	FAS & mFAS & PP Populations	16.2.6.4
14.2.3.1.1	Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild or Moderate Disease at Baseline	FAS Population	16.2.6.2
14.2.3.1.2	Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for subjects with Mild Disease at Baseline	FAS Population	16.2.6.2

Number	Description	Analysis Set	Source Listing(s)
14.2.3.2.1	Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild or Moderate Disease at Baseline	mFAS Population	16.2.6.2
14.2.3.2.2	Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild Disease at Baseline	mFAS Population	16.2.6.2
14.2.3.3.1	Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild or Moderate Disease at Baseline	PP Population	16.2.6.2
14.2.3.3.2	Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild Disease at Baseline	PP Population	16.2.6.2
14.2.4.1	Summary of Secondary Virologic Outcomes: Proportion of Subjects with Clearance of Viral Infection by Visit for Subjects with Mild or Moderate Disease at Baseline	FAS & mFAS & PP Populations	16.2.6.2
14.2.4.2	Summary of Secondary Virologic Outcomes: Proportion of Subjects with Clearance of Viral Infection by Visit for Subjects with Mild Disease at Baseline	FAS & mFAS & PP Populations	16.2.6.2
14.2.5.1	Summary of Exploratory Virologic Outcomes: Log10-Transformed Saliva Viral Load by Visit	FAS Population	16.2.6.2
14.2.5.2	Summary of Exploratory Virologic Outcomes: Log10-Transformed Saliva Viral Load by Visit	mFAS Population	16.2.6.2
14.2.5.3	Summary of Exploratory Virologic Outcomes: Log10-Transformed Saliva Viral Load by Visit	PP Population	16.2.6.2
14.3	**Safety Data Summaries**		
14.3.1.1	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Safety Population	16.2.7
14.3.1.2	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity	Safety Population	16.2.7
14.3.1.3	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Causality to Study Device	Safety Population	16.2.7
14.3.1.4	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Study Day of Most Severe Observation	Safety Population	16.2.7
14.3.2	Reactogenicity by Visit	Safety Population	16.2.9.3
14.3.3	Oropharyngeal Assessment by Visit	Safety Population	16.2.9.4
14.3.4.1	Vital Signs (Systolic Blood Pressure (mmHg)) by Visit	Safety Population	16.2.9.3
14.3.4.2	Vital Signs (Diastolic Blood Pressure (mmHg)) by Visit	Safety Population	16.2.9.3
14.3.4.3	Vital Signs (Heart Rate (beats/min)) by Visit	Safety Population	16.2.9.3

Number	Description	Analysis Set	Source Listing(s)
14.3.4.4	Vital Signs (Temperature (F)) by Visit	Safety Population	16.2.9.3
14.3.4.5	Vital Signs (Oxygen saturation) by Visit	Safety Population	16.2.9.3
14.3.4.6	Vital Signs (Respiratory (breaths/min)) by Visit	Safety Population	16.2.9.3
14.3.5	Methemoglobin by Visit	Safety Population	16.2.9.1

List of Data Listings

Number	Description
16.2.1	Subject Disposition
16.2.2.1	Protocol Deviations
16.2.2.2	Informed Consent, Eligibility Criteria, and Randomization
16.2.2.3	General Comments
16.2.4.1	Demographics
16.2.4.2	Medical/Surgical History
16.2.4.3	COVID-19 Symptom Assessment at Visit 1/Day 1
16.2.5.1	Subject Dosing Diary, Study Device Dispensing at Visit 1/Day 1, and Illumination Treatment at Site
16.2.5.2	Subject Dosing Diary and Study Device Collection
16.2.5.3	Treatment Record at End of Study
16.2.5.4	Treatment Application Log
16.2.6.1	COVID-19 Symptom Assessment and Severity Score from Subject Diary
16.2.6.2	Viral Load via Saliva and Nasopharyngeal Swab Collection
16.2.6.3	Derived Primary and Secondary Clinical Outcomes
16.2.7	Adverse Events
16.2.8.1	Biospecimen Lab Collection
16.2.8.2	Pregnancy Test (Female Subjects Only)
16.2.9.1	SARS-CoV-2 Rapid Antigen Test and Methemoglobin Measurement
16.2.9.2	COVID-19 Disease Assessment
16.2.9.3	Reactogenicity Assessment and Medical Encounter/Hospitalization
16.2.9.4	Oropharyngeal Assessment
16.2.9.5	Vital Signs
16.2.9.6	Physical Examination
16.2.9.7	Prior and Concomitant Medications
16.2.9.8.1	Medical Encounter Questionnaire (Part 1)
16.2.9.8.2	Medical Encounter Questionnaire (Part 2)
16.2.9.8.3	Medical Encounter Questionnaire (Part 3)

List of Figures

Number	Description	Analysis Set
15.1.1a	Kaplan-Meier Plot for Primary Endpoint 1 (Time to Sustained Resolution of COVID-19 Signs and Symptoms), Final Cohort RD-X19 and Final Cohort Sham	FAS Population
15.1.1b	Kaplan-Meier Plot for Primary Endpoint 1 (Time to Sustained Resolution of COVID-19 Signs and Symptoms), Each RD-X19 Dose Group and Pooled Sham	FAS Population
15.1.2a	Kaplan-Meier Plot for Primary Endpoint 1 (Time to Sustained Resolution of COVID-19 Signs and Symptoms), Final Cohort RD-X19 and Final Cohort Sham	mFAS Population
15.1.2b	Kaplan-Meier Plot for Primary Endpoint 1 (Time to Sustained Resolution of COVID-19 Signs and Symptoms), Each RD-X19 Dose Group and Pooled Sham	mFAS Population
15.1.3a	Kaplan-Meier Plot for Primary Endpoint 1 (Time to Sustained Resolution of COVID-19 Signs and Symptoms), Final Cohort RD-X19 and Final Cohort Sham	PP Population

Number	Description	Analysis Set
15.1.3b	Kaplan-Meier Plot for Primary Endpoint 1 (Time to Sustained Resolution of COVID-19 Signs and Symptoms), Each RD-X19 Dose Group and Pooled Sham	PP Population

Summary Tables

Table 14.1.1 – Subject Final Study Disposition

	RD-X19 from Final Cohort n (%)	RD-X19 from Cohort A n (%)	Pooled RD-X19 n (%)	Pooled Sham n (%)	Total n (%)
Subjects Randomized	XX	XX	XX	XX	XX
Subjects Completed Study	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Subjects Discontinued	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for Discontinuations:					
Withdrawal by Subject	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-Up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Investigator Discretion	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Failure to Meet Entry Criteria	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Clinically Significant Lab Findings	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Source: Listing 16.x.x
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Table 14.1.2 – Subject Population

	RD-X19 from Final Cohort n (%)	RD-X19 from Cohort A n (%)	Pooled RD-X19 n (%)	Pooled Sham n (%)	Total n (%)
Randomized	XX	XX	XX	XX	XX
Safety/Full Analysis Set (FAS)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exclusion from FAS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for exclusion from FAS:					
No record of first dose	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Modified Full Analysis Set (mFAS)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exclusion from mFAS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for exclusion from mFAS:					
No record of first dose	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Tested positive for SARS-CoV-2 antibodies	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Per-Protocol (PP) population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exclusion from PP population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for exclusion from PP population					
No record of first dose	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued due to a significant abnormality from the baseline CMP and CBC tests	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Major Protocol Deviation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…					

Subjects with multiple exclusion reasons are presented under each category of Reason for Exclusion as appropriate.
For all analysis populations subjects are summarized under the treatment received
Source: Listing 16.x.x
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Table 14.1.3 – Demographic and Baseline Characteristics for Safety/Full Analysis Set

		RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham	Total
Age (Years)						
	N	XX	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Gender n (%)						
	Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity n (%)						
	Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Willing to Provide	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Race n (%)						
	American-Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Black or African-American	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	White or Caucasian	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Body Mass Index (kg/m^2)						
	N	XX	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
COVID-19 Composite Severity Score[1]						
	N	XX	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Lab confirmed SARS-CoV-2 in nasopharyngeal sample n (%)						
	Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Baseline Disease Severity n (%)						
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Baseline Serostatus n (%)						
	Antibody (+)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Antibody (-)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Nasopharyngeal viral load						
	N	XX	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
	Geometric Mean on Original Scale[2]	XX.X	XX.X	XX.X	XX.X	XX.X

Source: Listing 16.x.x
[1] COVID-19 Composite Severity Score (CSS) is defined as the sum of the eight individual COVID-19 signs and symptoms severity scores divided by eight. Subjects with scores missing for one or more symptoms will have CSS calculated as the sum of all scores reported divided by the number of scores reported.
[2] Geometric Means are computed by exponentiating (base 10) the Means of the log10-transformed viral load.
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Table 14.2.1.1 – Primary Analysis and Supportive Analyses of the First Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms for the Final Cohort

Population	Statistics	Final Cohort RD-X19	Final Cohort Sham
Full Analysis Set (FAS)[#]			
	N	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	1-sided P-value for treatment comparison from Log-rank Test[1]	0.XXXX	
	2-sided P-value for treatment comparison from Log-rank Test[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio [1]	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio adjusted for Covariates	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	
	90% CI[2]	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[2]	0.XXX	
Modified Full Analysis Set (mFAS)			
	N	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	P-value for treatment comparison from Log-rank Test[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio[1]	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio adjusted for Covariates[2]	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	

90% CI[2]	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[2]	0.XXX	
Per Protocol (PP) Population		
N	XX	XX
n (%) Censored	XX (XX.X)	XX (XX.X)
Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
P-value for treatment comparison from Log-rank Test[1]	0.XXX	
Final CohortRD-X19 to Final Cohort Sham Hazard Ratio [1]	X.XXX	
95% CI[1]	(X.XXX, X.XXX)	
90% CI[1]	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[1]	0.XXX	
Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio adjusted for Covariates[2]	0.XXX (0.XXX, 0.XXX)	
95% CI[2]	(X.XXX, X.XXX)	
90% CI[2]	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[2]	0.XXX	

Abbreviation: CI = Confidence Interval, PH = Proportional Hazards

#The primary analysis of the endpoint is the log-rank test performed for the Full Analysis Set. For the p-values for the primary analysis, ** denotes statistically significant using the procedure for multiple endpoint adjustment with an overall α =0.025 one-sided; * denotes statistically significant using the procedure for multiple endpoint adjustment with an overall α =0.050 one-sided.

Note: Sustained resolution of COVID-19 signs and symptoms is defined as all 8 signs and symptoms (cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea) have been assessed by the subject as none (0) or mild (1) and all remain at or below 1 until study Day 14. Subjects reporting a persistent fever (100.5 degrees for 36 hours or more) and/or SpO2 levels <96% with any shortness of breath are considered not to have met the success criterion on that day even if all other symptoms are reported as none (0) or mild (1). Subjects who were hospitalized due to COVID-19 are designated as treatment failures, and right censored at 384 hours (16 days). Subjects discontinued for other reasons are censored at their time of discontinuation. Other subjects who did not achieve sustained resolution at the last assessment of the study are considered censored at the time of the last assessment.

[1] Log-Rank Test and Cox PH Regression analyses were performed unstratified

[2] The Cox PH regression model included pre-specified covariates: COVID-19 Composite Severity Score at Baseline (<1.25, ≥1.25), Baseline Disease Status (mild, moderate), Sex (male, female), Age (<50, ≥50), Baseline Antibody Status (positive, negative). For mFAS, the Cox PH regression model does not include the covariate related to baseline antibody status.

Source: Listing 16.x.x

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Table 14.2.1.2 – Primary Analysis and Supportive Analyses of the Second Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms in Subjects with Mild Disease at Baseline for the Final Cohort

Population	Statistics	Final Cohort RD-X19	Sham
Full Analysis Set (FAS)[#]			
	N	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	1-sided P-value for treatment comparison from Log-rank Test[1]	0.XXXX	
	2-sided P-value for treatment comparison from Log-rank Test[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio [1]	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio adjusted for Covariates	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	
	90% CI[2]	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[2]	0.XXX	
Modified Full Analysis Set (mFAS)			
	N	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	P-value for treatment comparison from Log-rank Test[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio[1]	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	
	Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio adjusted for Covariates[2]	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	

90% CI[2]	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[2]	0.XXX	
Per Protocol (PP) Population		
N	XX	XX
n (%) Censored	XX (XX.X)	XX (XX.X)
Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
P-value for treatment comparison from Log-rank Test[1]	0.XXX	
Final CohortRD-X19 to Final Cohort Sham Hazard Ratio [1]	X.XXX	
95% CI[1]	(X.XXX, X.XXX)	
90% CI[1]	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[1]	0.XXX	
Final Cohort RD-X19 to Final Cohort Sham Hazard Ratio adjusted for Covariates[2]	0.XXX (0.XXX, 0.XXX)	
95% CI[2]	(X.XXX, X.XXX)	
90% CI[2]	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[2]	0.XXX	

Abbreviation: CI = Confidence Interval, PH = Proportional Hazards

#The primary analysis of the endpoint is the log-rank test performed for the Full Analysis Set. For the p-values for the primary analysis, ** denotes statistically significant using the procedure for multiple endpoint adjustment with an overall α =0.025 one-sided; * denotes statistically significant using the procedure for multiple endpoint adjustment with an overall α =0.050 one-sided.

Note: Sustained resolution of COVID-19 signs and symptoms is defined as all 8 signs and symptoms (cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea) have been assessed by the subject as none (0) or mild (1) and all remain at or below 1 until study Day 14. Subjects reporting a persistent fever (100.5 degrees for 36 hours or more) and/or SpO2 levels <96% with any shortness of breath are considered not to have met the success criterion on that day even if all other symptoms are reported as none (0) or mild (1). Subjects who were hospitalized due to COVID-19 are designated as treatment failures, and right censored at 384 hours (16 days). Subjects discontinued for other reasons are censored at their time of discontinuation. Other subjects who did not achieve sustained resolution at the last assessment of the study are considered censored at the time of the last assessment.

[1] Log Rank Test and Cox PH Regression analyses were performed unstratified

[2] The Cox PH regression model included pre-specified covariates: COVID-19 Composite Severity Score at Baseline (<1.25, ≥1.25), Sex (male, female), Age (<50, ≥50), Baseline Antibody Status (positive, negative). For mFAS, the Cox PH regression model does not include the covariate related to baseline antibody status.

Source: Listing 16.x.x

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Table 14.2.1.3 – Additional Supportive Analysis of the First Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms, Both Cohorts Combined and for RD-X19 from Cohort A

Population	Statistics	Pooled RD-X19	RD-X19 from Cohort A	Pooled Sham
Full Analysis Set (FAS)				
	N	XX	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	P-value for treatment comparison from Log-rank Test[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio[1]	X.XXX	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio adjusted for Covariates[2]	0.XXX	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[2]	0.XXX	0.XXX	
Modified Full Analysis Set (mFAS)				
	N	XX	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	P-value for treatment comparison from Log-rank Test[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio[1]	X.XXX	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio adjusted for Covariates[2]	0.XXX	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[2]	0.XXX	0.XXX	

Per Protocol (PP) Population

N	XX	XX	XX
n (%) Censored	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
75th Percentile of Time to Sustained Resolution (95% CI) [1]	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
P-value for treatment comparison from Log-rank Test[1]	0.XXX	0.XXX	
RD-X19 to Pooled Sham Hazard Ratio[1]	X.XXX	X.XXX	
95% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
90% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[1]	0.XXX	0.XXX	
RD-X19 to Pooled Sham Hazard Ratio adjusted for Covariates [2]	0.XXX	0.XXX	
95% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
90% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[2]	0.XXX	0.XXX	

Abbreviation: CI = Confidence Interval, PH = Proportional Hazards

Note: Sustained resolution of COVID-19 signs and symptoms is defined as all 8 signs and symptoms (cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea) have been assessed by the subject as none (0) or mild (1) and all remain at or below 1 until study Day 14. Subjects reporting a persistent fever (100.5 degrees for 36 hours or more) and/or SpO2 levels <96% with any shortness of breath are considered not to have met the success criterion on that day even if all other symptoms are reported as none (0) or mild (1). Subjects who were hospitalized due to COVID-19 are designated as treatment failures, and right censored at 384 hours (16 days). Subjects discontinuing for other reasons are censored at their time of discontinuation. Other subjects who did not achieve sustained resolution at the last assessment of the study are considered censored at the time of the last assessment.

[1] Log-Rank Test and Cox PH Regression analyses were performed unstratified for RD-X19 from Cohort A vs. Pooled Sham, and stratified by cohort for Pooled RD-X19 vs. Pooled Sham.

[2] The Cox PH regression model included pre-specified covariates: COVID-19 Composite Severity Score at Baseline (<1.25, ≥1.25)), Baseline Disease Status (mild, moderate), Sex (male, female), Age (<50, ≥50), Baseline Antibody Status (positive, negative). For mFAS, the Cox PH regression model does not include the covariate related to baseline antibody status. Analyses were performed unstratified for RD-X19 from Cohort A vs. Pooled Sham, and stratified by cohort for Pooled RD-X19 vs. Pooled Sham.

Source: Listing 16.x.x

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Table 14.2.1.4 – Additional Supportive Analysis of the Second Primary Efficacy Endpoint: Time (Hours) to Sustained Resolution of COVID-19 Signs and Symptoms in Subjects with Mild Disease at Baseline, Both Cohorts Combined and RD-X19 from Cohort A

Population	Statistics	Pooled RD-X19	RD-X19 from Cohort A	Pooled Sham
Full Analysis Set (FAS)				
	N	XX	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	P-value for treatment comparison from Log-rank Test[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio[1]	X.XXX	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio adjusted for Covariates[2]	0.XXX	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[2]	0.XXX	0.XXX	
Modified Full Analysis Set (mFAS)				
	N	XX	XX	XX
	n (%) Censored	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	75th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
	P-value for treatment comparison from Log-rank Test[1]	0.XXX#	0.XXX#	
	RD-X19 to Pooled Sham Hazard Ratio[1]	X.XXX	X.XXX	
	95% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[1]	0.XXX	0.XXX	
	RD-X19 to Pooled Sham Hazard Ratio adjusted for Covariates[2]	0.XXX	0.XXX	
	95% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	90% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
	P-value for treatment comparison from Cox PH Regression[2]	0.XXX	0.XXX	

Per Protocol (PP) Population

N	XX	XX	XX
n (%) Censored	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
25th Percentile of Time to Sustained Resolution (95% CI)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
75th Percentile of Time to Sustained Resolution (95% CI) [1]	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
P-value for treatment comparison from Log-rank Test[1]	0.XXX#	0.XXX#	
RD-X19 to Pooled Sham Hazard Ratio[1]	X.XXX	X.XXX	
95% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
90% CI[1]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[1]	0.XXX	0.XXX	
RD-X19 to Pooled Sham Hazard Ratio adjusted for Covariates [2]	0.XXX	0.XXX	
95% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
90% CI[2]	(X.XXX, X.XXX)	(X.XXX, X.XXX)	
P-value for treatment comparison from Cox PH Regression[2]	0.XXX	0.XXX	

Abbreviation: CI = Confidence Interval, PH = Proportional Hazards

Note: Sustained resolution of COVID-19 signs and symptoms is defined as all 8 signs and symptoms (cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea) have been assessed by the subject as none (0) or mild (1) and all remain at or below 1 until study Day 14. Subjects reporting a persistent fever (100.5 degrees for 36 hours or more) and/or SpO2 levels <96% with any shortness of breath are considered not to have met the success criterion on that day even if all other symptoms are reported as none (0) or mild (1). Subjects who were hospitalized due to COVID-19 are designated as treatment failures, and right censored at 384 hours (16 days). Subjects discontinuing for other reasons are censored at their time of discontinuation. Other subjects who did not achieve sustained resolution at the last assessment of the study are considered censored at the time of the last assessment.

[1] Log-Rank Test and Cox PH Regression analyses were performed unstratified for RD-X19 from Cohort A vs. Pooled Sham, and stratified by cohort for Pooled RD-X19 vs. Pooled Sham.

[2] The Cox PH regression model included pre-specified covariates: COVID-19 Composite Severity Score at Baseline (<1.25, ≥1.25), Sex (male, female), Age (<50, ≥50), Baseline Antibody Status (positive, negative). For mFAS, the Cox PH regression model does not include the covariate related to baseline antibody status. Analyses were performed unstratified for RD-X19 from Cohort A vs. Pooled Sham, and stratified by cohort for Pooled RD-X19 vs. Pooled Sham.

Source: Listing 16.x.x

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Table 14.2.2.1 – Summary of Secondary Efficacy Endpoints: Proportion of Subjects Who Achieve Composite Resolution

Population	Statistics	RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham
Full Analysis Set					
	N of subjects at Visit 4/Day 8	XX	XX	XX	XX
	n (%) Subjects with negative SARS-CoV-2 antigen test at Visit 4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects with all symptoms none (0) or mild (1) on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects achieving success on Composite Resolution	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Modified Full Analysis Set					
	N of subjects at Visit 4/Day 8	XX	XX	XX	XX
	n (%) Subjects with negative SARS-CoV-2 antigen test at Visit 4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects with all symptoms none (0) or mild (1) on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects achieving success on Composite Resolution	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Per Protocol Population					
	N of subjects at Visit 4/Day 8	XX	XX	XX	XX
	n (%) Subjects with negative SARS-CoV-2 antigen test at Visit 4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects with all symptoms none (0) or mild (1) on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects achieving success on Composite Resolution	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note 1: Composite Resolution at Visit 4/Day 8 is defined as: [1] a negative SARS-CoV-2 antigen test within the window for Visit 4 (Days 7 – 9); [2] all symptoms assessed by the subject as none (0) or mild (1) at study day 8 (as reported on the Diary Card Day 8-Assessment 1); and [3] absence of fever and SpO2 ≥96% without shortness of breath.
Note 2: Subjects who did not have assessment values for [1] are counted as failures for the corresponding component and for Composite Resolution.
Source: Listing 16.x.x
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Table 14.2.2.2 – Summary of Secondary Efficacy Endpoints: Proportion of Subjects Who Returned to Usual Health and Usual Activities

Population	Statistics	RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham
Full Analysis Set					
	N of subjects at Visit 4/Day 8	XX	XX	XX	XX
	n (%) Subjects who returned to usual health on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects who returned to usual activities on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	N of subjects at Visit 5/Day 14/ET	XX	XX	XX	XX
	n (%) Subjects who returned to usual health on Day 14/ET	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects who returned to usual activities on Day 14/ET	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Modified Full Analysis Set					
	N of subjects at Visit 4/Day 8	XX	XX	XX	XX
	n (%) Subjects who returned to usual health on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects who returned to usual activities on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	N of subjects at Visit 5/Day 14/ET	XX	XX	XX	XX
	n (%) Subjects who returned to usual health on Day 14/ET	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects who returned to usual activities on Day 14/ET	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Per Protocol Population					
	N of subjects at Visit 4/Day 8	XX	XX	XX	XX
	n (%) Subjects who returned to usual health on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects who returned to usual activities on Day 8	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	N of subjects at Visit 5/Day 14/ET	XX	XX	XX	XX
	n (%) Subjects who returned to usual health on Day 14/ET	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects who returned to usual activities on Day 14/ET	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Return to usual health and Return to usual activities are defined by an answer yes to following patient-reported global impression assessments, respectively: (1) In the past 24 hours, have you returned to your usual health (before your COVID-19 illness)? (2) In the past 24 hours, have you returned to your usual activities (before your COVID-19 illness)?
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.2.2.3 – Summary of Secondary Efficacy Endpoints: Proportion of Subjects with Progression of COVID-19 and Proportion of Subjects with Severe Clinical Outcomes

Population	Statistics	RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham
Full Analysis Set					
	N	XX	XX	XX	XX
	n (%) Subjects who experience progression of COVID-19[1]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects with severe clinical outcomes (at least one of following)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require medical attention or intervention attributed to COVID-19	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who progress to severe disease[2]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require hospitalization for severe COVID-19	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require endotracheal ventilation or ECMO	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who die	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Modified Full Analysis Set					
	N	XX	XX	XX	XX
	n (%) Subjects who experience progression of COVID-19[1]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects with severe clinical outcomes (at least one of following)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require medical attention or intervention attributed to COVID-19	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who progress to severe disease[2]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require hospitalization for severe COVID-19	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require endotracheal ventilation or ECMO	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who die	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Per Protocol Population					
	N	XX	XX	XX	XX
	n (%) Subjects who experience progression of COVID-19[1]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) Subjects with severe clinical outcomes (at least one of following)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require medical attention or intervention attributed to COVID-19	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who progress to severe disease[2]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require hospitalization for severe COVID-19	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who require endotracheal ventilation or ECMO	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	-- n (%) subjects who die	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1]: Progression of COVID-19 is defined by increase of composite COVID-19 severity score (> baseline score) at any point in the study on or after Day 3.
[2]: Subjects will be designated as Severe having any one of the following: Respiratory Rate ≥30, Heart Rate ≥125, SpO2 ≤93%, or lung infiltrates upon imaging >50%.

Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.2.3.1.1 – Summary of Secondary Virologic Outcomes: Log10-Transformed Nasopharyngeal Viral Load by Visit for Subjects with Mild and Moderate Disease at Baseline, Full Analysis Set

Study Visit	Statistics	RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham
Visit 1 / Day 1	N	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
	Geometric Mean on Original Scale	XX.X	XX.X	XX.X	XX.X
Visit 2 / Day 3	N	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
	Geometric Mean on Original Scale	XX.X	XX.X	XX.X	XX.X
Visit 3 / Day 5					
Visit 4 / Day 8					
Visit 5 / Day 14					

To deal with missing data multiple imputation (MI) has been carried out on the Log10 scale. The mean of the 100 MI copies is used in each case to replace the missing value. Summary statistics are calculated after this imputation for missing data.
Note: Geometric Means are computed by exponentiating (base 10) the Means of the log10-transformed viral load.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Repeat Table 14.2.3.1.1 for the following:

Table 14.2.3.1.2 – Summary of Secondary Virologic Outcomes: Log10-Transformed Nasopharyngeal Viral Load by Visit for Subjects with Mild Disease at Baseline, Full Analysis Set

Repeat Tables 14.2.3.1.1 and 14.2.3.1.2 for the following:

Table 14.2.3.2.1 – Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild and Moderate Disease at Baseline, Modified Full Analysis Set

Table 14.2.3.2.2 – Summary of Secondary Virologic Outcomes: Log10-Transformed nasopharyngeal Viral Load by Visit for Subjects with Mild Disease at Baseline, Modified Full Analysis Set

Table 14.2.3.3.1 – Summary of Secondary Virologic Outcomes: Log10-Transformed Nasopharyngeal Viral Load by Visit for Subjects with Mild and Moderate Disease at Baseline, Per-Protocol Population

Table 14.2.3.3.2 – Summary of Secondary Virologic Outcomes: Log10-Transformed Nasopharyngeal Viral Load by Visit for Subjects with Mild Disease at Baseline, Per-Protocol Population

Table 14.2.4.1 – Summary of Secondary Virologic Outcomes: Proportion of Subjects with Clearance of Viral Infection by Visit for Subjects with Mild and Moderate Disease at Baseline

Population Visit	Statistics	RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham
Full Analysis Set					
Visit 2 / Day 3	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 3 / Day 5	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 4 / Day 8	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 5 / Day 14	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Modified Full Analysis Set					
Visit 2 / Day 3	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 3 / Day 5	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 4 / Day 8	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 5 / Day 14	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Per-Protocol Population					
Visit 2 / Day 3	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 3 / Day 5	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 4 / Day 8	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 5 / Day 14	N	XX	XX	XX	XX
	n (%) Subjects who have clearance of viral infection	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note 1: Clearance of viral infection is defined as a negative nasopharyngeal swab via RT-qPCR. Subjects with missing nasopharyngeal samples at a visit were determined to be a 'failure' at the visit as having not achieved the endpoint of clearance of viral infection.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Repeat Table 14.2.4.1 for the following:

Table 14.2.4.2 – Summary of Secondary Virologic Outcomes: Proportion of Subjects with Clearance of Viral Infection by Visit for Subjects with Mild Disease at Baseline

Table 14.2.5.1 – Summary of Exploratory Virologic Outcomes: Log10-Transformed Saliva Viral Load by Visit for Full Analysis Set

Study Visit	Statistics	RD-X19 from Final Cohort	RD-X19 from Cohort A	Pooled RD-X19	Pooled Sham
Visit 1 / Day 1	N	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
	Geometric Mean on Original Scale	XX.X	XX.X	XX.X	XX.X
Visit 2 / Day 3	N	XX	XX	XX	XX
	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
	Geometric Mean on Original Scale	XX.X	XX.X	XX.X	XX.X
Visit 3 / Day 5					
Visit 4 / Day 8					
Visit 5 / Day 14					

To deal with missing data multiple imputation (MI) has been carried out on the Log10 scale. The mean of the 100 MI copies is used in each case to replace the missing value. Summary statistics are calculated after this imputation for missing data.
Note: Geometric Means are computed by exponentiating (base 10) the Means of the log10-transformed viral load.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Repeat Table 14.2.5.1 for the following:

Table 14.2.5.2 – Summary of Exploratory Virologic Outcomes: Log10-Transformed Saliva Viral Load by Visit for Modified Full Analysis Set

Table 14.2.5.3 – Summary of Secondary Virologic Outcomes: Log10-Transformed Saliva Viral Load by Visit for Per-Protocol Population

Table 14.3.1.1 - Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Safety Population

System Organ Class Preferred Term	RD-X19 from Final Cohort (N=XX) n (%)	RD-X19 from Cohort A (N=XX) n (%)	Pooled RD-X19 (N=XX) n (%)	Pooled Sham (N=XX) n (%)
Subjects Reporting at Least One Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…				
System Organ Class #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…				

Counts reflect numbers of subjects reporting one or more TEAE that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one TEAE are counted only once.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.1.2 - Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity for Safety Population

System Organ Class Preferred Term	Severity	RD-X19 from Final Cohort (N=XX) n (%)	RD-X19 from Cohort A (N=XX) n (%)	Pooled RD-X19 (N=XX) n (%)	Pooled Sham (N=XX) n (%)
Subjects Reporting at Least One Adverse Event	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…					
…					

Counts reflect numbers of subjects reporting one or more TEAE that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one TEAE are counted only once (under the greatest reported severity).
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.1.3 - Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Causality to Study Device for Safety Population

System Organ Class Preferred Term	Causality	RD-X19 from Final Cohort (N=XX) n (%)	RD-X19 from Cohort A (N=XX) n (%)	Pooled RD-X19 (N=XX) n (%)	Pooled Sham (N=XX) n (%)
Subjects Reporting at Least One Adverse Event	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…					
…					
…					

Counts reflect numbers of subjects reporting one or more TEAE that map to the MedDRA system organ class/preferred term. At each level of summarization (overall system organ class, or preferred term), subjects reporting more than one TEAE are counted only once (under the greatest reported causality).
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.1.4 –Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Study Day of Most Severe Observation for Safety Population

System Organ Class Preferred Term	Study Day*	RD-X19 from Final Cohort (N=XX) n (%)	RD-X19 from Cohort A (N=XX) n (%)	Pooled RD-X19 (N=XX) n (%)	Pooled Sham (N=XX) n (%)
Subjects Reporting at Least One Adverse Event	Day 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Day 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	…				
System Organ Class #1	Day 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Day 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	…				
Preferred Term #1	Day 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Day 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…	…				
…					
…					

*Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment. For the summary, Study Day is the day number when the most severe observation was made of an event.
Counts reflect numbers of subjects reporting one or more TEAE that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one TEAE are counted only once under the earliest Study Day when the event of greatest severity was reported.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.2 – Reactogenicity by Visit for Safety Population

Study Visit	Category	RD-X19 from Final Cohort (N=XX)	RD-X19 from Cohort A (N=XX)	Pooled RD-X19 (N=XX)	Pooled Sham (N=XX)
Visit 1 / Day 1	N	XX	XX	XX	XX
	n (%) subject with any findings on reactogenicity assessment	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with illumination site pain	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with illumination site erythema	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with illumination site Edema/Induration	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with other pain, redness, swelling, lesion of the oral mucosa	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 2 / Day 3	N	XX	XX	XX	XX
	n (%) subject with any findings on reactogenicity assessment	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with illumination site pain	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with illumination site erythema	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with illumination site Edema/Induration	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	n (%) subject with other pain, redness, swelling, lesion of the oral mucosa	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 3 / Day 5	…				
Visit 4 / Day 8	…				
Visit 5 / Day 14/ ET	…				

Note: Reactogenicity assessed after illumination for treatments performed at the site on Visits 1, 2, and 3.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.3 – Oropharyngeal Assessment by Visit for Safety Population

Study Visit	Category	RD-X19 from Final Cohort n (%)	RD-X19 from Cohort A n (%)	Pooled RD-X19 n (%)	Pooled Sham n (%)
Overall*	N	XX	XX	XX	XX
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 1 / Day 1	N	XX	XX	XX	XX
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 2 / Day 3	N	XX	XX	XX	XX
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Visit 3 / Day 5	…				
Visit 4 / Day 8	…				
Visit 5 / Day 14/ET	…				

*For Overall, Normal category includes subjects with a normal result for all visits; Abnormal category includes subjects with an abnormal result at any visit. Note: Oropharyngeal assessments performed within 30 minutes after exposure for treatments performed at the site on Visits 1, 2, and 3.
Source: Listing 16.x.x
O:\Studies\EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.4.1 – Vital Signs (Systolic Blood Pressure (mmHg)) by Visit for Safety Population

Study Visit	Category	Statistics	RD-X19 from Final Cohort (N=XX)	RD-X19 from Cohort A (N=XX)	Pooled RD-X19 (N=XX)	Pooled Sham (N=XX)
Visit 1 / Day 1 (Baseline)	Actual Value	N	XX	XX	XX	XX
		Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
Visit 2 / Day 3	Actual Value	N	XX	XX	XX	XX
		Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
	Change from Baseline	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
Visit 3 / Day 5						
Visit 4 / Day 8						
Visit 5 / Day 14/ET						

Source: Listing 16.x.x
O:\Studies\ EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year

Repeat Table 14.3.4.1 for the following:

Table 14.3.4.2 – Vital Signs (Diastolic Blood Pressure (mmHg)) by Visit for Safety Population

Table 14.3.4.3 – Vital Signs (Heart Rate (beats/min)) by Visit for Safety Population

Table 14.3.4.4 – Vital Signs (Temperature (F)) by Visit for Safety Population

Table 14.3.4.5 – Vital Signs (Oxygen saturation) by Visit for Safety Population

Table 14.3.4.6 – Vital Signs (Respiratory (breaths/min)) by Visit for Safety Population

Table 14.3.5 – Methemolgobin by Visit for Safety Population

Study Visit	Category	Statistics	RD-X19 from Final Cohort (N=XX)	RD-X19 from Cohort A (N=XX)	Pooled RD-X19 (N=XX)	Pooled Sham (N=XX)
Visit 1 / Day 1 (Baseline)	Actual Value	N	XX	XX	XX	XX
		Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
Visit 5 / Day 14/ET	Actual Value	N	XX	XX	XX	XX
		Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
	Change from Baseline	Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX

Source: Listing 16.x.x
O:\Studies\ EmitBio\EB-P20-01\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year

Data Listings

Listing 16.2.1 - Subject Disposition

Subject	Cohort	Safety Population	mITT Population	PP Population	Date of First Treatment	Study Exit Date (Study Day)	Completed Study?	Primary Reason for Study Discontinuation
Treatment:								

Abbreviations: mITT, Modified Intent-to-Treat; PP, Per-Protocol
Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment.
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Listing 16.2.2.1 - Protocol Deviations

Subject	Cohort	Major (Significant) Protocol Deviation?	Description of Deviation
Treatment:			

Major (Significant) protocol deviations are those that exclude subjects from the per-protocol analysis.
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Listing 16.2.2.2 - Informed Consent, Eligibility Criteria and Randomization

		Informed Consent		Baseline/Randomization			Randomization		
Subject	Cohort	Signed?	Date	Subject met all Entry Criteria?	Unmet Entry Criterion Number	Description of Unmet Criterion	Randomized?	Number	Date

Treatment:

Listing 16.2.2.3 - General Comments

Subject	Cohort	Date of Comment	eCRF Form/Module	Comments	Author Initial
Treatment:					

Listing 16.2.4.1 - Demographics

Subject	Initial	Cohort	Date of Birth	Age	Sex	Ethnicity	Race
Treatment:							

Age is calculated relative to date of informed consent.
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Listing 16.2.4.2 - Medical/Surgical History

Subject	Cohort	Subject had medical or surgical history?	Condition or Procedure	Onset Date	Stop Date	Concomitant medications at V1?
Treatment:						

Listing 16.2.4.3 – COVID-19 Symptom Assessment at Visit 1/Day 1

Subject	Cohort	Symptoms within past 3 days?	Assessment		Cough	Sore Throat	Nasal Congestion	Headache	Chills/ Sweats	Muscle/ Joint Pain	Fatigue	Nausea	Fever	SpO2	COVID-19 Severity Score
			Date	Time											
Treatment:															

COVID-19 Symptom: 0=None, 1=Mild, 2=Moderate, 3=Severe. Study Day is calculated relative to date of first treatment.
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Listing 16.2.5.1 - Subject Dosing Diary, Study Device Dispensing at Visit 1/Day 1, and Illumination Treatment at Site

							Illumination treatment performed on site under supervision?		
Subject	Cohort	Dosing instructions reviewed and dosing diary dispensed?	Investigational device dispensed to the subject?	Device Dispenser	Diary dispensed/ instruction reviewed?	Diary Dispenser	Visit 1 /Day 1	Visit 2 /Day 3	Visit 3 /Day 5
Treatment:									

Listing 16.2.5.2 - Subject Dosing Diary and Study Device Collection

Subject	Cohort	Visit	Diary returned/ reviewed?	RD-X19 device collected?	Collected by	Diary dispensed/ instruction reviewed?	Diary Dispenser	Diary dispensed at V4 collected/ reviewed?	Collected by	Replacement device provided at any point in the study?	Dispenser by
Treatment:											

Listing 16.2.5.3 – Treatment Record at End of Study

Subject	Cohort	Subject applied at least one treatment?	Total Illumination Treatments	Total Treatments Missed
Treatment:				

Listing 16.2.5.4 – Treatment Application Log

Subject	Cohort	Dose Number	Date of Treatment	Time of Treatment	Missed Treatment	Dose Not Applicable	Unknown
Treatment:							

Listing 16.2.6.1- COVID-19 Symptom Assessment and Severity Score from Subject Diary

Subject	Cohort	ND/ NA/ UNK	Day	Study Day	Date:Time	Cough	Sore Throat	Nasal Congestion	Headache	Chills/ Sweats	Muscle or Joint pain	Fatigue	Nausea	Fever (F)	SpO2 (%)	COVID-19 Severity Score
Treatment:																
xxxx			Day 1- Assessment 1	1												
			Day 1- Assessment 2	1												
			Day 2- Assessment 1	2												

COVID-19 Symptom: 0=None, 1=Mild, 2=Moderate, 3=Severe. Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment.
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Listing 16.2.6.2 – Viral Load via Saliva and Nasopharyngeal Swab Collection

Place holder pending on receiving the vendor data

Listing 16.2.6.3- Derived Primary and Secondary Clinical Outcomes

			Time to sustained resolution of COVID-19		Progression of	Day 8 Returned to		Day 14 Returned to		Severe Clinical
Subject	Cohort	Analyses	Event Time (hrs)	Censor	COVID-19?	Usual Health	Usual Activities	Usual Health	Usual Activities	Outcomes?
Treatment:										

Abbreviation: mITT = Modified Intent-to-Treat, PP = Per-Protocol
Note: Sustained resolution of COVID-19 signs and symptoms is defined as all 8 signs and symptoms (cough, sore throat, nasal congestion, headache, chills and or sweats, myalgia, fatigue, and nausea) have been assessed by the subject as none (0) or mild (1) and all remain at or below 1 until study Day 14. Subjects who did not achieve sustained resolution at the last assessment of the study are considered censored at the time of the last assessment.
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Listing 16.2.7 - Adverse Events

Subject	Cohort	AE No.	System Organ Class / Preferred Term / Event Name	Occurred prior to first dose?	Start Date (Study Day)	Stop Date (Study Day)	Serious?	Severity	Relationship to Study Device	Action Taken	Outcome
Treatment:											

Note: Adverse events coded in MedDRA, version xx.x
Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment while Day -1 is the day prior to first treatment.
O:\Studies\ EmitBio\EB-P20-01\Biometrics\Programs\Listings\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year

Listing 16.2.8.1 – Biospecimen Lab Collection

Subject	Cohort	Visit	Saliva swab sample B obtained?	Nasopharyngeal swab sample R obtained?	Oral saliva specimen sample G obtained?	Date of Collection (Study Day)
Treatment:						

Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment.
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Listing 16.2.8.2 - Pregnancy Test (Female Subjects Only)

Subject	Cohort	Visit	Believe become pregnant?	Pregnancy Test Done?	If not done, subject is not of childbearing potential due to	Date of Test (Study Day)	Result
Treatment:							

Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment.
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Listing 16.2.9.1 – SARS-CoV-2 Rapid Antigen Test and Methemoglobin Measurement

			SARS-CoV-2 Rapid Antigen Test at Baseline		Methemoglobin	
Subject	Cohort	Visit	Performed?	Result of Antigen Test	Measured?	Result (%)
Treatment:						

Listing 16.2.9.2 – COVID-19 Disease Assessment

Subject	Cohort	Visit	Loss of Taste?	Loss of Smell?	Shortness of Breath on Exertion?	Returned to your usual heath in the past 24 hours?	Returned to your usual activities in the past 24 hours?
Treatment:							

Listing 16.2.9.3 - Reactogenicity Assessment and Medical Encounter/Hospitalization

Subject	Cohort	Visit	Illumination Site Pain?	Illumination Site Erythema?	Illumination Site Edema/ Induration?	Other pain, redness, swelling, or lesion of the oral mucosa?	Received medical care for COVID-19 since previous visit?	Hospitalized for COVID-19?
Treatment:								

Listing 16.2.9.4 - Oropharyngeal Assessment

Subject	Cohort	Visit	Oropharyngeal assessment performed?	Any changes since previous visit?	Assessment Result	Description of Abnormality
Treatment:						

Listing 16.2.9.5 - Vital Signs

Subject	Cohort	Visit	Height (in)	Weight (lb)	Body Mass Index (kg/m^2)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Heart Rate (beats/min)	Respiratory Rate (breaths/min)	Temperature (F)	SpO2 (%)
Treatment:									XX /NCS	XXX /NCS	

For out-of-range results, CS = clinically significant, NCS = not clinically significant.
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Listing 16.2.9.6 - Physical Examination

Subject	Cohort	Visit	PE Performed?	Subject requires a targeted PE?	Test Name	Description of Abnormality
Treatment:						

Listing 16.2.9.7 - Prior and Concomitant Medications

Subject	Cohort	WHO Class / WHO Drug Name / Medication Name	Start Date (Study Day)	End Date (Study Day)	Dose	Unit	Route	Frequency	Indication
Treatment:									

Abbreviations: ATC = anatomic therapeutic chemical; WHODDE, World Health Organization Drug Dictionary Enhanced
Medications are coded to ATC class and drug names using the WHODDE, version xxxxx.
Study Day is calculated relative to date of first treatment. Day 1 is the day of first treatment while Day -1 is the day prior to first treatment.
O:\Studies\ EmitBio\EB-P20-01\Biometrics\Programs\Listings\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year

Programming Note:

- *If specifications for indications are reported as an AE or MH #, merge with AE/MH data to present the actual reported event as the specification.*
- *When creating WHO Class, utilize ATC level 4 drug class; utilize level 3 term if level 4 is missing and level 2 if both level 3 and level 4 are missing in the dataset*

Listing 16.2.9.8.1 – Medical Encounter Questionnaire (Part 1)

Subject	Cohort	Type of Visit	Date of Admission	Reason for Admission	Outcome of Visit	Vital Signs					
						Unknown	Temperature	Respiration	Pulse	Systolic BP	Diastolic BP
Treatment:											

Listing 16.2.9.8.2 – Medical Encounter Questionnaire (Part 2)

Subject	Cohort	Abnormal Clinical Findings	Abnormal Lab Findings	Oxygen Required	Continue to use RD-X19?	What follow-up was recommended?	Initial of Study Staff
Treatment:							

Listing 16.2.9.8.3 – Medical Encounter Questionnaire (Part 3)

		Treatment Provided						
Subject	Cohort	No Treatment	Remdesivir	Other Antiviral Med.	Monoclonal Antibodies	Convalescent Plasma	Solumedrol	Other
Treatment:								