Statistical Analysis Plan: Mock-up Tables and Figures

Version 1.0, 25-JAN-2022

Protocol Number: CX4945-AV01-IIT

A Phase II, Randomized and Controlled Investigator Initiated Trial Evaluating Safety, Pharmacokinetics and Clinical Benefit of Silmitasertib (CX-4945) in Outpatient Adult Subjects with Moderate Coronavirus Disease 2019 (COVID-19)

Protocol version: Amendment 1.0, 11MAY2021
Sponsor-Investigator: Dr. Chris Recknor, MD
Drug Provider: Senhwa Biosciences, Inc.

Table of Contents

1 Statistical Changes from Study Protocol

The statistical analysis methods will follow study protocol version amendment 1.0 (11-MAY-2021, exceptions and clarifications are described below:

1.1 Visit Adjustment

Visit 6 is End of Treatment (EOT) Visit, Treatment Discontinuation Visit or Early Withdrawal Visit at/before EOT. Data of visit 6 not in its visit window will be shifted to corresponding scheduled visit for analysis as in table below (marked '*'). Visit name will be presented as 'Adjusted Visit' for the visits reallocated to its original scheduled visit or the next visit after preceding scheduled visit.

	Visit 6 to Visit 3~6
COVID-19-Related Symptoms	*
Clinical Status - NIAID 8-Point Clinical Progression Outcomes Scale	*
Laboratory Examination	*
Vital Signs, Pulse Oxygen Saturation (SpO2) and COVID-19-Related Clinical Signs	*

1.2 Per-Protocol (PP) Population

According to the protocol, subject with major protocol violation shall be excluded from PP population. The definition shall be revised to 'The PP population is defined as the set of patients who meet the ITT population requirements and are not associated with any major protocol violations *relevant to efficacy analysis*'.

> **14.1.1.1 9.7.1.2. Per Protocol (PP) Population**
> The PP population is defined as the set of patients who meet the ITT population requirements and are not associated with any major protocol violations. This population will be identified before the database lock. This population will be used as the supportive analysis population for analysis of the primary and secondary efficacy endpoints.

1.3 Treatment Compliance of CX-4945

There is no definition of compliance in the protocol, it's defined as below.

$$\text{Treatment Compliance [\%]} = \frac{\text{\# of times of CX-4945 actually administered}}{\text{(Treatment Duration) * (2 times of administration/day)}} * 100\%$$

Treatment Duration [days] = the last administration date – the first administration + Adjustment

The first administration time	The last administration time	Adjustment
Morning	Morning	+0.5
Morning	Evening	+1
Evening	Morning	+0
Evening	Evening	+0.5

1.4 Analysis Method

1.4.1 Inferential Statistics

According to the protocol, no inferential statistics was planned. In the SAP, the inferential testing will be done as appropriate for treatment comparison.

9.8.4. Study Outcome Assessment

For continuous variables data will be summarized by treatment using n, mean, SD, minimum and maximum values. For categorical variables data will be summarized by treatment using frequency and percentage. **No inferential statistics are planned.** The Safety population will be used for the analysis of safety outcomes.

1.4.2 Method for Time to Event Data

The endpoints about time to event data as below table will be compared between treatment groups by using log-rank test, and corresponding response proportion will be presented by using Kaplan-Meier methods.

- Time to COVID-19-Related Clinical Signs Normalization
- Time to Oxygen Saturation Level Normalization
- Time to moderate COVID-19-Related Symptoms Resolution
- Time to SARS-COV-2 Viral Clearance
- Time to Improvement on NIAID 8-Point Clinical Progression Outcomes Scale (additional analysis, not mentioned in the protocol)
- Time to Improvement on EQ-5D-5L Imaginable Health Status (additional analysis, not mentioned in the protocol)

Considering the early censor on time to response (Normalization / Recovery / Viral Clearance / Improvement) data will result in over optimistic in statistical results, two data estimation methods below will be used for the sensitive analyses. Results will be claimed as robust if the results of both methods are consistent.

Time to Response (days), Best Case Scenario
= Days to first response for responder,
= Days to last observation for non-responder (censored)

Time to Response (days), Worst Case Scenario
= Days to first response for responder,
= Days to planned last observation date (31 for EQ-5D-5L and SARS-COV-2 Viral Clearance at visit 7, 45 for others at visit 8) for non-responder (censored)

Days to first response = date of first response – the first treatment date/time + 1
Days to last observation = date of last evaluation – the first treatment date/time + 1
For Arm SOC, the first treatment date is the date of visit 2

1.4.3 Method for Continuous Data

Demographics, baseline characteristics and continuous efficacy data will be analyzed by using two sample t test or Wilcoxon rank-sum test as appropriate. Net changes from pre-treatment laboratory test results and vital signs will be analyzed by using ANCOVA model with baseline value as covariate or Wilcoxon rank-sum test as appropriate.

1.4.4 Method for Categorical Data

Categorical data will be analyzed by using the Fisher's exact test or Chi-square test as

appropriate. Ordinal data will be analyzed by using Mantel-Haenszel chi-square test on given scores.

1.5 Method for Handling Missing Value

According to protocol, multiple imputation methods were planned to be done for efficacy evaluations using PROC MI of SAS. Since the sample size is relative small for both treatments, predictive model for multiple imputation is not realistic. Additional statistics on LOCF (Last Observation Carry Forward) data will be presented for by-visit efficacy analysis.

> 9.7.3. Missing Data
> The method for handling missing data will be included in the statistical analysis plan. Every effort will be made to obtain required data at each scheduled evaluation from all patients who have been randomized in the study to minimize missing data. However, in the event when there are missing data the following imputation methods will be used.
> For efficacy evaluations, multiple imputation methods will be used to handle missing data and will be detailed in the SAP. This imputation method is a robust method to impute potential missing measurements. The imputation will be carried out in SAS version 9.4 or later using PROC MI.

1.6 Pharmacokinetics Analyses

Pharmacokinetics data will not be provided, and PK parameters will not be analyzed per sponsor's decision, and therefore it is not covered in the SAP.

2 Protocol Versions and Protocol Amendments

The first subject was enrolled on 3-Dec-2020, and the last subject is expected to be dismissed on 7-Oct-2021. All applied protocol and CRF versions are listed as below.

No.	Protocol Version	CRF Version	IRB Approval	FDA Approval
1	3.0, 20OCT2020	1.1, 12OCT2021	5-Nov-2020	3-Nov-2020
2	Amendment 1.0, 11MAY2021	1.0, 06SEP2021	24-May-2021	24-Jun-2021

3 Mock-up Tables and Figures

The Mock-up "TABLES and FIGURES" is planned according to ICH E3, in which relevant Clinical Study Report (CSR) section is 14. The words shadowed below are to be adjusted or repeated upon real data, or just for notification.

3.1 Analysis of Continuous Data

For ANOVA / ANCOVA / T test (two sample t test) noted in the mock-up table, Wilcox_t (Wilcoxon rank-sum test in t approximation) will be applied if normality assumption is not valid (p-value of Shapiro-Wilk normality test ≤0.05).

3.2 Analysis of Categorical Data

C/F noted in the mock-up table, Chi-Square test is applied when no cell have expected count < 1 and <=20% of the cells are with expected count < 5, otherwise Fisher's exact test will be applied.

Instructions and Abbreviations:

(1) Site ID □□□::

Site ID	Site Name	Site Code
001	Center for Advanced Research & Education	CARE
002	CA' Research	CAR

(2) Treatment Group:
CX-4945: The best supportive / standard of care + CX-4945 1000 mg BID ,
SOC : The best supportive / standard of care

(3) Population

- ITT (Intention-To-Treat):
  All randomized patients
- Safety Population:
  Receiving at least one dose of CX-4945 or being randomized to the standard of care arm.
- PP (Per-Protocol):
  A subset of ITT and Safety population who are not associated major protocol deviation relevant to efficacy analysis.

  If Safety Population and ITT are the same, these two populations will be combined as 'Safety Population and Intention-To-Treat' if results of both populations are to be presented in the same table.

(4) For Visit Name (in Tables and Figures) and Visit Code (in Subject Data Listing):

Visit No.	Visit Description	Visit Day	Visit Name	Visit Code
1	Screening Visit	-7 ~ -1	Visit 1 (Screening)	V01
2	Treatment Visit (Day 1)	1	Visit 2 (Day 1)	V02D01T
3	Treatment Visit (Day 4)	4 ± 1	Visit 3 (Day 4)	V03D04T
4	Treatment Visit (Day 8)	8 ± 1	Visit 4 (Day 8)	V04D08T
5	Treatment Visit (Day 11)	11 ± 1	Visit 5 (Day 11)	V05D11T
6	End of Treatment (EOT)Visit (Day 14)	14 ± 1	Visit 6 (Day 14, EOT)	V06D14E
7	Follow-up 1 Visit (Day 28)	28 ± 3	Visit 7 (Day 28, F1)	V07D28F
8	Follow-up 2 Visit (Day 45)	45 ± 3	Visit 8 (Day 45, F2)	V08D45F
9	Follow-up 3 Visit (Day 60)	60 ± 3	Visit 9 (Day 60, F3)	V09D60F
	Unscheduled Visit	-	-	UV

(5) Efficacy Endpoints:

- **Time to COVID-19-Related Clinical Signs Normalization**: **Normal when all below are met**
  (1) Fever is <36.6°C from axillary site, or < 37.2°C from oral site, or < 37.8°C from rectal or tympanic site, or <37.2°C from forehead by using non-contact infrared thermometers
  (2) Respiratory rate is < 20 bpm while breathing room air
  (3) SpO2 ≥ 96% in room air without shortness of breath or dyspnea caused by COVID-19
  (4) Heart rate < 90 beats per minute
  If some signs listed above were caused by other conditions documented in the medical history and started before COVID-19, the patient can be considered as recovered, when these signs return to the previous (pre-COVID-19) values

- **Oxygen Saturation Level Normalization: Normal when SpO2 ≥ 96%**

- **Resolution of moderate COVID-19-Related Symptoms when all below are met:**
  - No key COVID-19-related symptoms scored higher than 1.
  - If some symptoms were caused by other conditions documented in the medical history and started before COVID-19 (e.g, insomnia), the patient can be considered as recovered, when these symptoms return to the previous (pre-COVID-19) value.

- **SARS-COV-2 Viral Clearance: negative RT-PCR**

- **NIAID 8-Point Clinical Progression Outcomes Scale:**
  1 - Death
  2 - Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO)
  3 - Hospitalized, on non-invasive ventilation or high flow oxygen devices
  4 - Hospitalized, requiring supplemental oxygen
  5 - Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise)
  6 - Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care
  7 - Not hospitalized, limitation on activities and/or requiring home oxygen
  8 - Not hospitalized, no limitations on activities

- **EQ-5D-5L Imaginable Health Status Improvement: Imaginable Health Status <90 at baseline and ≥ 90 after baseline**

- **Time to Response (Normalization / Resolution / Viral Clearance / Improvement)**
  Time to Response (days), Best Case Scenario
  = Days to first response for responder,
  = Days to last observation for non-responder (censored)

  Time to Response (days), Worst Case Scenario
  = Days to first response for responder,
  = Days to planned last observation date (31 for EQ-5D-5L and SARS-COV-2 Viral Clearance at visit 7, 45 for others at visit 8) for non-responder (censored)

  Days to first response = date of first response – the first treatment date/time + 1
  Days to last observation = date of last evaluation – the first treatment date/time + 1
  For Arm SOC, the first treatment date is the date of visit 2

(6) For Clinical Relevance

CS: abnormal and clinically significant	LLN: lower limit of normal range
NCS: abnormal but not clinically significant	ULN: upper limit of normal range

(7) For Transition of Clinical Relevance

Relieved	CS (Medical History or Adverse Event) at baseline to Normal / NCS at visit.
Unchanged	Including Normal at baseline to NCS at visit, NCS at baseline to Normal at visit.
Worsened (Medical History)	Normal / NCS at baseline to CS (Medical History) at visit
Worsened (Adverse Event)	Normal / NCS / CS (Medical History) at baseline to CS (Adverse Event) at visit

If both 'Medical History' and 'Adverse Event' are checked for 'CS', it will be counted as 'Adverse Event' only.

(8) Abbreviations of Statistics

N: number of non-missing values	ANOVA: analysis of variance
M: missing, not available	ANCOVA: analysis of covariance
Missing: number of missing values	CHISQ: Chi-Square test
Mean: mean of values	FISHER: Fisher's exact test
SD: standard deviation of values	MHCHISQ: Mantel-Haenszel chi-square test on given scores
Q1: 25% quartile of values	T: two sample t test
Q3: 75% quartile of values	W: Wilcoxon rank-sum test
Median: median of values	Diff.: difference
IQR: inter-quartile-range (IQR=Q3-Q1)	
Min: minimum of values	
Max: maximum of values	
CI: confidence interval	
LS-mean: least-square mean	

For CI and p-value (WI, within group):
t denotes by using one sample t-test
w denotes wilcoxon sign rank test
(determined by Shapiro-Wilk normality test)

For CI and p-value (between groups):
Wilcox_t denotes Wilcoxon rank-sum test (Mann-Whitney U Test) in t approximation
Wilcox_z denotes Wilcoxon rank-sum test (Mann-Whitney U Test) in z approximation
ANOVA denotes Treatment effect in ANOVA model
ANCOVA denotes Treatment effect in ANCOVA model
For 95% CI (HL), HL denotes CI using Hodges-Lehman for median

14 TABLES AND FIGURES

- *The texts in shaded Italic are for programming note.*
- *Column of Study Site includes columns of {001-CARE, 002-CAR, Total}*
- *Column of Treatment Group includes columns of {CX-4945, SOC, Total}*
- *Column 'Difference' denotes pairwise comparison statistics.*
- *Multi-Selection means 'A subject may be counted in more than one category'*
- *Description in <…> will be presented according to data values.*
- *For column p-value: refer to Abbreviations of statistics in [Instructions and Abbreviations] above.*
- *For Groups Diff., §C = CX-4945, §S = SOC,*
  T denotes two sample t test, W denotes Wilcox_t (Wilcoxon rank-sum test in t approximation), C denotes Chi-Square test, F denotes Fisher's exact test

14.1 DEMOGRAPHIC DATA AND BASELINE CHARACTERISTICS

14.1.1 Screen Failures and Subject Disposition by Study Site

Population: All Screened Subjects / Randomized Subjects

Characteristics	Study Site
. All Screened Subjects	
N	XXX
~Randomized Subjects	XXX (XXX.X%)
. Population of Randomized Subjects	
N	XXX
ITT	XXX (XXX.X%)
~ Safety	XXX (XXX.X%)
~ PP	XXX (XXX.X%)
~ Non-PP	XXX (XXX.X%)
~ <Reason 1>	XXX (XXX.X%)
~ <Reason 2>	XXX (XXX.X%)
…	XXX (XXX.X%)
. Treatment Arm of Randomized Subjects	
N	XXX
CX-4945	XXX (XXX.X%)
SOC	XXX (XXX.X%)
. Protocol Deviation of Randomized Subjects (Multi-Selection by Major/Minor & Category)	
N	XXX
~ Any Protocol Deviation	XXX (XXX.X%)
~ Major Protocol Deviation	XXX (XXX.X%)
~ <Reason 1>	XXX (XXX.X%)
~ <Reason 2>	XXX (XXX.X%)
...	
~ Minor Protocol Deviation	XXX (XXX.X%)
~ <Reason 1>	XXX (XXX.X%)
~ <Reason 2>	XXX (XXX.X%)
...	

14.1.2 Study Termination, Subject Disposition and Protocol Deviation

Population: Intention-to-Treat Population

Characteristics	Treatment Group	
. Study Termination		
N	XXX	
Study Completed	XXX (XXX.X%)	
Study Not Completed	XXX (XXX.X%)	
~ Withdrew consent	XXX (XXX.X%)	
~ Protocol issue	XXX (XXX.X%)	
…	XXX (XXX.X%)	
. Study Duration [days]		TW
N (Missing)	XXX	0.XXXX
Mean (SD)	XXX (XXX)	
Median (IQR)	XXX (XXX)	
Q1~Q3	XXX~XXX	
Min~Max	XXX~XXX	
. Population		
N	XXX	
Safety	XXX (XXX.X%)	
~ PP	XXX (XXX.X%)	
~ Non-PP	XXX (XXX.X%)	
~ <Reason 1>	XXX (XXX.X%)	
~ <Reason 2>	XXX (XXX.X%)	
...	XXX (XXX.X%)	
. Protocol Deviation (Multi-Selection)		
N	XXX	
~ Any Protocol Deviation	XXX (XXX.X%)	
~ Major Protocol Deviation	XXX (XXX.X%)	
~ <Reason 1>	XXX (XXX.X%)	
~ <Reason 2>	XXX (XXX.X%)	
...	XXX (XXX.X%)	
~ Minor Protocol Deviation	XXX (XXX.X%)	
~ <Reason 1>	XXX (XXX.X%)	
~ <Reason 2>	XXX (XXX.X%)	
...	XXX (XXX.X%)	

Study Duration [days] = Date of Termination - Visit 1, or alternatively as the last visit date - Visit 1

14.1.3 Study Visits

Population: Intention-to-Treat Population

Characteristics	Treatment Group
. Repeat Variable: Study Visits Completed on ITT Population (Multi-Selection by Visit), Study Visits Completed on Safety Population (Multi-Selection by Visit) Study Visits Completed on PP Population (Multi-Selection by Visit),	
Adjusted Visits Completed on ITT Population (Multi-Selection by Visit), Adjusted Visits Completed on Safety Population (Multi-Selection by Visit) Adjusted Visits Completed on PP Population (Multi-Selection by Visit)	
N	XXX
Visit 1 (Screening)	XXX (XXX.X%)
Visit 2 (Day 1)	XXX (XXX.X%)
Visit 3 (Day 4)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)
Visit 4 (Day 8)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)
Visit 5 (Day 11)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)
Visit 6 (Day 14, EOT)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)
Visit 7 (Day 28, F1)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)
Visit 8 (Day 45, F2)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)
Visit 9 (Day 60, F3)	XXX (XXX.X%)
~In-Person	XXX (XXX.X%)
~Remote (Phone/Telehealth)	XXX (XXX.X%)

14.1.4 Demographic Data

Population: Intent-to-Treat Population

Characteristics	Treatment Group	P-value
. Study Site		
N (Missing)	XXX (XXX)	
001-CARE	XXX (XXX.X%)	
002-CAR	XXX (XXX.X%)	
. Repeat Variable:		
Age [Y/O], Baseline Body Weight [kg], Body Height [cm],		
Baseline BMI [kg/m^2]		T/W
N (Missing)	XXX (XXX)	0.XXXX
Mean (SD)	XXX (XXX)	
Median (IQR)	XXX (XXX)	
Q1~Q3	XXX~XXX	
Min~Max	XXX~XXX	
. Gender		C/F
N (Missing)	XXX (XXX)	0.XXXX
Male	XXX (XXX.X%)	
Female	XXX (XXX.X%)	
. Race		
N (Missing)	XXX (XXX)	
Black /African American	XXX (XXX.X%)	
American Indian or Alaska Native	XXX (XXX.X%)	
Asian	XXX (XXX.X%)	
Native Hawaiian or Other Pacific Islander	XXX (XXX.X%)	
White	XXX (XXX.X%)	
…	…	
. Ethnicity		C/F
N (Missing)	XXX (XXX)	0.XXXX
Hispanic or Latino	XXX (XXX.X%)	
Not Hispanic or Latino	XXX (XXX.X%)	
…	…	

Age [years old]= (Date of informed consent obtained – birth date)/365.25 rounded down to the nearest integer
BMI [kg/m^2]= Weight [kg] / (Height [cm])^2 * 10000
Baseline is Visit 2 or alternatively as Visit 1 if Visit 2 data is not available.

14.1.5 Coronavirus Disease 2019 (COVID-19) History

Population: Intent-to-Treat Population

Characteristics	Treatment Group	P-value
. Repeat Variable:		
Disease Duration [days],		
Symptom Duration [days],		
Symptom Duration up to Randomization [days]		TW
N (Missing)	XXX (XXX)	0.XXXX
Mean (SD)	XXX (XXX)	
Median (IQR)	XXX (XXX)	
Q1~Q3	XXX~XXX	
Min~Max	XXX~XXX	
. COVID-19 Vaccination History		
N	XXX	
At least one below [Event#:Subj#]	XXX : XXX (XXX.X%)	
~ AstraZeneca	XXX : XXX (XXX.X%)	
~ Johnson & Johnson	XXX : XXX (XXX.X%)	
~ Pfizer	XXX : XXX (XXX.X%)	
~ Moderna	XXX : XXX (XXX.X%)	
…	…	

Disease Duration [days] =(date of screening visit – date of first positive RT-PCR for testing COVID-19),
Symptom Duration [days] =(date of screening visit – start date of COVID-19 self-reported by patient),
missing day is estimated as 15, missing month is estimated as Jul-01, full unknown is missing

14.1.6 General Medical History and Concurrent Disease/Status

Population: Intent-to-Treat Population

Characteristics	Treatment Group
. General Medical History	
N	XXX
At least one below	XXX (XXX.X%)
~ <Body System 1>	XXX (XXX.X%)
~ <Body System 2>	XXX (XXX.X%)
~ <Body System 3>	XXX (XXX.X%)
~ <Body System 4>	XXX (XXX.X%)
…	…
. Current Condition (Multi-Selection)	
N	XXX
At least one below	XXX (XXX.X%)
~ <Body System 1>	XXX (XXX.X%)
~ <Body System 2>	XXX (XXX.X%)
~ <Body System 3>	XXX (XXX.X%)
~ <Body System 4>	XXX (XXX.X%)
…	…

Current condition lists the medical histories that are ongoing or with end date ≥ date of visit 2

14.1.7 Concomitant Medications

Population: Intent-to-Treat Population / Safety Population

Characteristics	Treatment Group
--Repeat Population: <See populations above>	
Repeat Variable: Prior Medication, Concomitant Medication	
(Multi-Selection by Highest ATC Level Class and ATC Preferred Term)	
N	XXX
At least one below	XXX (XXX.X%)
~ <Highest ATC Level Class 1>	XXX (XXX.X%)
~ <ATC Preferred Term 1>	XXX (XXX.X%)
~ <ATC Preferred Term 2>	XXX (XXX.X%)
…	…
~ <Highest ATC Level Class 2>	XXX (XXX.X%)
~ <ATC Preferred Term 1>	XXX (XXX.X%)
~ <ATC Preferred Term 2>	XXX (XXX.X%)
…	…

WHODrug Global B3-format September 1, 2020 is used for coding
Prior Medication: medications onset prior to Day 1
Concomitant Medication: medications applied on / after Day 1

14.1.8 Best Supportive / Standard Of Care Procedures

Population: Intent-to-Treat Population

Characteristics	Treatment Group	P-value
- Repeat Duration:		
Prior Procedure, Concomitant Procedure, Post Procedure		
. Repeat Variable:		
Subject with Best Supportive / Standard Of Care Procedures (Multi-Selection by Highest ATC Level Class and ATC Preferred Term)		
N	XXX	C/F
At least one below [Day#:Subj#]	XXX : XXX (XXX.X%)	0.XXXX
Extracorporeal Membrane oxygenation	XXX : XXX (XXX.X%)	0.XXXX
Fluid management	XXX : XXX (XXX.X%)	0.XXXX
Mechanical Ventilation	XXX : XXX (XXX.X%)	0.XXXX
~ High-flow oxygen	XXX : XXX (XXX.X%)	0.XXXX
~ Supplemental oxygen	XXX : XXX (XXX.X%)	0.XXXX
~ Noninvasive ventilation	XXX : XXX (XXX.X%)	0.XXXX
~ Extracorporeal membrane oxygenation (ECMO)	XXX : XXX (XXX.X%)	0.XXXX
~ Other	XXX : XXX (XXX.X%)	0.XXXX
Prone position	XXX : XXX (XXX.X%)	0.XXXX
. Days with Mechanical Ventilation [days]		TW
N (Missing)	XXX (XXX)	0.XXXX
Mean (SD)	XXX (XXX)	
Median (IQR)	XXX (XXX)	
Q1~Q3	XXX~XXX	
Min~Max	XXX~XXX	

Prior Procedure: procedures onset prior to Day 1
Concomitant Procedures: procedures from Day 1 to End of Treatment Visit
Post Procedure: procedures after End of Treatment Visit to End of Study
Day# = End date/time – Start date/time, rounded up to the nearest integer

14.1.9 Study Drug Administration, Compliance and Exposure

Population: Intent-to-Treat Population

Characteristics	CX-4945
. Repeat Variable: Treatment Duration [days], Total CX-4945 Dose [caps], Mean Daily Dose [caps / day] Total CX-4945 Administration [Times], Treatment Compliance [%], Mean Daily Administration [times / day]	
N (Missing)	XXX
Mean (SD)	XXX (XXX)
Median (IQR)	XXX (XXX)
Q1~Q3	XXX~XXX
Min~Max	XXX~XXX
. Treatment Compliance	
N (Missing)	XXX (XXX)
<50%	XXX (XXX.X%)
50 ~ <75%	XXX (XXX.X%)
75 ~ <100%	XXX (XXX.X%)
100 ~ <125%	XXX (XXX.X%)
≥125%	XXX (XXX.X%)
. CX-4945 Completion	
N	XXX
CX-4945 Completed	XXX (XXX.X%)
CX-4945 Not Completed	XXX (XXX.X%)
~ Drug Interruption	XXX (XXX.X%)
~ Drug Discontinuation	XXX (XXX.X%)
~ <Reason 1>	XXX (XXX.X%)
~ <Reason 2>	XXX (XXX.X%)
…	…

Treatment Duration [days] = the last administration date – the first administration + Adjustment

The first administration time	The last administration time	Adjustment
Morning	Morning	+0.5
Morning	Evening	+1
Evening	Morning	+0
Evening	Evening	+0.5

Mean Daily Dose [caps / day] = Total CX-4945 Dose [caps] / Treatment Duration [days]

$$\text{Treatment Compliance [\%]} = \frac{\text{\# of times of CX-4945 actually administered}}{\text{(Treatment Duration) * (2 times of administration/day)}} * 100\%$$

Mean Daily Administration [times / day] = Total CX-4945 Administration [Times] / Treatment Duration [days]

14.2 EFFICACY DATA

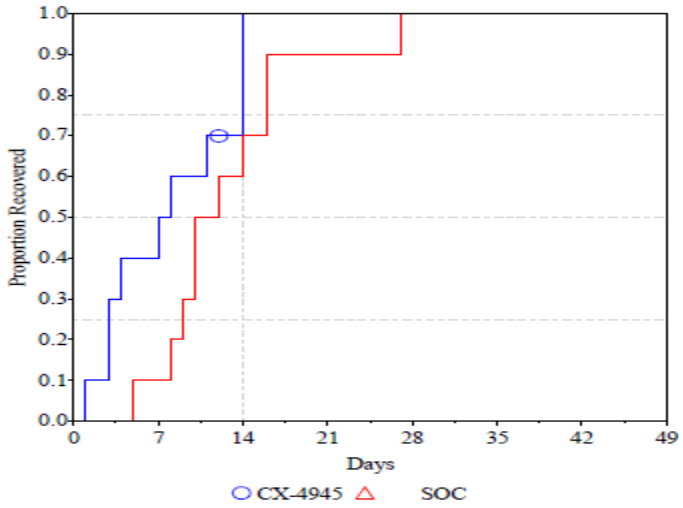
<TTR Layout: For Time to Response Data>

Population: Intent-to-Treat Population / Per-Protocol Population

Characteristics	Treatment Group	Difference	P-value
--Repeat Population: <See populations above>			
- Variable per table title: Time to COVID-19-Related Clinical Signs Normalization [days] Time to COVID-19-Related Symptoms Resolution [days] Time to SARS-COV-2 Viral Clearance [days]			
. Repeat Scenario: Best Case Scenario, Worst Case Scenario			
N (Missing)	XXX (XXX)		LOGRANK
Censored No.	XXX (XXX%)		0.XXXX
Observed No.	XXX (XXX%)		
Q1 [95% CI]	XXX [XX~XX]		
Median [95% CI]	XXX [XX~XX]		
Q3 [95% CI]	XXX [XX~XX]		
Mean (SE)	XXX (XXX)		
Min	XXX		
Max (Observed)	XXX		
Max	XXX		

Footnote the definition according to [Instructions and Abbreviations] of title pages.

<TTR Figure Layout: For Response Proportion>



14.2.1 COVID-19-Related Clinical Signs

14.2.1.1 Time to COVID-19-Related Clinical Signs Normalization

Use TTR Layout

Footnote: refer to table 14.3.8 for the normal status of each symptom by visit

14.2.1.2 Figure of Normalization Proportion on COVID-19-Related Clinical Signs (Best Case Scenario)

14.2.1.3 Figure of Normalization Proportion on COVID-19-Related Clinical Signs (Worst Case Scenario)

Use TTR Figure Layout

14.2.1.4 Time to Oxygen Saturation Level Normalization

Use TTR Layout

14.2.1.5 Figure of Normalization Proportion on Oxygen Saturation Level (Best Case Scenario)

14.2.1.6 Figure of Normalization Proportion on Oxygen Saturation Level (Worst Case Scenario)

Use TTR Figure Layout

14.2.2 Covid-19-Related Symptoms

14.2.2.1 Time to COVID-19-Related Symptoms Resolution

Use TTR Layout

14.2.2.2 Figure of Recovery Proportion on COVID-19-Related Symptoms (Best Case Scenario)

14.2.2.3 Figure of Recovery Proportion on COVID-19-Related Symptoms (Worst Case Scenario)

Use TTR Figure Layout

14.2.3 Nasopharyngeal Swab RT-PCR Result and SARS-COV-2 Viral Load

14.2.3.1 SARS-COV-2 Viral Clearance and Viral Load [copies/µL]

Population: Intent-to-Treat Population / Per-Protocol Population

Characteristics	Treatment Group	Difference	P-value
--Repeat Population: <See populations above>			
. Repeat Visit: Visit 1 (Screening), Baseline, Visit 4 (Day 8), Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), LOCF			
N (Missing)	XXX (XXX)		
Negative	XXX (XXX.X%)		
Positive	XXX (XXX.X%)		
N (Missing)	XXX (XXX)		0.XXXX
Mean (SD)	XXX (XXX)		
Median (IQR)	XXX (XXX)		
Q1~Q3	XXX~XXX		
Min~Max	XXX~XXX		
Repeat [Baseline to Visit] except Visit 1 (Screening) and Baseline			C/F
N (Missing)	XXX (XXX)	0.XXXX	
Positive to Negative#	XXX (XX.X%)		
Positive to Positive	XXX (XX.X%)		
Diff. between groups		§C - §S	
Difference (#)		XXX%	
95% CI (#)		XXX% ~XXX%a	
Repeat [Visit - Baseline] except Visit 1 (Screening) and Baseline			TW
N (Missing)	XXX (XXX)		0.XXXX
Mean (SD)	XXX (XXX)		
Median (IQR)	XXX (XXX)		
Q1~Q3	XXX~XXX		
Min~Max	XXX~XXX		
For W, normality is not applied			
Groups Diff		§C - §S	
Median (Asymptotic SE)		XXX	
95% CI (HL)		XXX~XXX	
For T, normality is applied			
Groups Diff		§C - §S	
Mean (SD)		XXX (XXX)	
95% CI		XXX~XXX	

a denotes CI using normal approximation for binomial proportion of #
Viral Load > 25,000.00 copies/µL is estimated as 25,000.00 copies/µL.
Baseline is Visit 2 (Day 1) data, or is Visit 1 if Visit 2 (Day 1) is null

14.2.3.2 Time to SARS-COV-2 Viral Clearance

Use TTR Layout

14.2.3.3 Figure of SARS-COV-2 Viral Clearance Proportion (Best Case Scenario)

14.2.3.4 Figure of SARS-COV-2 Viral Clearance Proportion (Worst Case Scenario)

Use TTR Figure Layout

14.2.4 Clinical Status - NIAID 8-Point Clinical Progression Outcomes Scale

14.2.4.1 Clinical Status - NIAID 8-Point Clinical Progression Outcomes Scale

Population: Intent-to-Treat Population / Per-Protocol Population

Characteristics	Treatment Group		P-value
--Repeat Population: <See populations above>			
N	XXX		
Subjects with any below [Event#:Subj#]	XXX : XXX (XXX.X%)		
~ Death *(NIAID item 1)*	XXX : XXX (XXX.X%)		
~ Respiratory Failure *(NIAID item 2~3 or from AE)*	XXX : XXX (XXX.X%)		
~ Hospitalized *(NIAID item 2~6)*	XXX : XXX (XXX.X%)		
. Repeat Visit: No 'Visit 1 (Screening)' for IL-6: Visit 1 (Screening), Baseline, Adjusted Visit 3 (Day 4), Adjusted Visit 4 (Day 8), Adjusted Visit 5 (Day 11), Adjusted Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), Visit 8 (Day 45, F2), LOCF			
N (Missing)	XXX (XXX)		0.XXXX
Item 1	XXX (XXX.X%)		
Item 2	XXX (XXX.X%)		
…	…		
Item 8	XXX (XXX.X%)		
Repeat [Baseline to Visit] except Visit 1 (Screening), Baseline		C/F	
N (Missing)	XXX (XXX)	0.X	
Improvement (Item 7 to Item 8)	XXX (XX.X%)	XX	
Progression (Item 7 to Item 1~6)	XXX (XX.X%)	X	

Respiratory failure required mechanical ventilation, oxygen delivered by high-flow nasal cannula, ESMO; shock or multi-organ dysfunction/failure

For NIAID 8-Point Clinical Progression Outcomes Scale:
Item 1 - Death
Item 2~3 - Hospitalized, respiratory failure
Item 4~6 - Hospitalized, non-respiratory failure
Item 7 - Not hospitalized, limitation on activities and/or requiring home oxygen
Item 8 - Not hospitalized, no limitations on activities
Refer to [Instructions and Abbreviations] of title pages for further definition

14.2.4.2 Time to Improvement on NIAID 8-Point Clinical Progression Outcomes Scale

Use TTR Layout

14.2.4.3 Figure of Improvement Proportion on NIAID 8-Point Clinical Progression Outcomes Scale (Best Case Scenario)

14.2.4.4 Figure of Improvement Proportion on NIAID 8-Point Clinical Progression Outcomes Scale (Worst Case Scenario)

Use TTR Figure Layout

14.2.5 EQ-5D-5L

14.2.5.1 EQ-5D-5L

Population: Intent-to-Treat Population / Per-Protocol Population

Characteristics	Treatment Group	Difference	P-value
--Repeat Population: <See populations above>			
. Repeat Visit: Visit 2 (Day 1), Visit 4 (Day 8), Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), LOCF			
. Repeat Variable:			TW
Total score of Q1~Q5, Imaginable Health Status			(Visit 2 (Day 1))
N (Missing)	XXX (XXX)		0.XXXX
Mean (SD)	XXX (XXX)		
Median (IQR)	XXX (XXX)		
Q1~Q3	XXX~XXX		
Min~Max	XXX~XXX		
For Imaginable Health Status only			
≥ 90	XXX (XXX.X%)		
< 90	XXX (XXX.X%)		
Repeat [Visit - Visit 2 (Day 1)] except Visit 2 (Day 1)			
N (Missing)	XXX (XXX)		TW
N (Missing)	XXX (XXX)		0.XXXX
Mean (SD)	XXX (XXX)		
Median (IQR)	XXX (XXX)		
Q1~Q3	XXX~XXX		
Min~Max	XXX~XXX		
For W, normality is not applied		§C - §S	
Groups Diff			
Median (Asymptotic SE)		XXX	
95% CI (HL)		XXX~XXX	
For T, normality is applied		§C - §S	
Groups Diff			
Mean (SD)		XXX (XXX)	
95% CI		XXX~XXX	

Q1. Mobility, Q2. Self-Care, Q3. Usual Activities, Q4. Pain/Discomfort, Q5. Anxiety/Depression

14.2.5.2 Time to Improvement on EQ-5D-5L Imaginable Health Status

Use TTR Layout

14.2.5.3 Figure of Improvement Proportion on EQ-5D-5L Imaginable Health Status (Best Case Scenario)

14.2.5.4 Figure of Improvement Proportion on EQ-5D-5L Imaginable Health Status (Worst Case Scenario)

Use TTR Figure Layout

14.3 SAFETY DATA

14.3.1 Treatment Emergent Adverse Event – Subject Based Analyses

14.3.1.1 Treatment Emergent AE – Summary

Population: Safety Population

Characteristics [Event#:Subj#]	Treatment Group
(Multi-Selection)	
N	XXX
Subjects with AE	XXX : XXX (XXX.X%)
~ Grade ≥3	XXX : XXX (XXX.X%)
~ Grade 4	XXX : XXX (XXX.X%)
~ Grade 5	XXX : XXX (XXX.X%)
Subjects with Treatment-Related AE	XXX : XXX (XXX.X%)
~ Grade ≥3	XXX : XXX (XXX.X%)
~ Grade 4	XXX : XXX (XXX.X%)
~ Grade 5	XXX : XXX (XXX.X%)
Subjects with AE Leading to Action Taken	XXX : XXX (XXX.X%)
~ Dose Reduced	XXX : XXX (XXX.X%)
~ Drug Interrupted	XXX : XXX (XXX.X%)
~ Drug Withdrawn by Subject	XXX : XXX (XXX.X%)
~ Drug Withdrawn Instructed by Investigator	XXX : XXX (XXX.X%)
Subjects with SAE	XXX : XXX (XXX.X%)
~ Requires or Prolongs Hospitalization	XXX : XXX (XXX.X%)
~ Life-Threatening SAE	XXX : XXX (XXX.X%)
~ Death SAE	XXX : XXX (XXX.X%)
~ SUSAR	XXX : XXX (XXX.X%)
~ Death SUSAR	XXX : XXX (XXX.X%)

Subject with multiple events are counted as one incidence.
Treatment Related is defined as Definitely Related, Probable Related, or Possibly Related

14.3.1.2 Treatment Emergent AE – Subjects with AE

14.3.1.3 Treatment Emergent AE – Subjects with Treatment-Related AE

Population: Safety Population

Characteristics	Treatment Group
(Multi-Selection by XXX, System Organ Class and Preferred Term)	
N	XXX
At least one below [Event#:Subj#]	XXX : XXX (XXX.X%)
~ <MedDRA Body System1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)
~ <MedDRA Body System2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)

For each MedDRA (version 23.1) SOC or Preferred Term, subject with multiple events are counted as one incidence.
[For 14.3.1.3] Treatment Related is defined as Definitely Related, Probable Related, or Possibly Related

14.3.1.4 Treatment Emergent AE – Subjects with Grade ≥3 AE

14.3.1.5 Treatment Emergent AE – Subjects with Grade ≥3 Treatment-Related AE

Population: Safety Population

Characteristics	Treatment Group
(Multi-Selection by Severity Grade, System Organ Class and Preferred Term)	
N	XXX
At least one below [Event#:Subj#]	XXX : XXX (XXX.X%)
~ Repeat Severity Grade:	
Grade ≥3, Grade 4, Grade 5	XXX : XXX (XXX.X%)
~ <MedDRA Body System1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)
~ <MedDRA Body System2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)

[For 14.3.1.5] Treatment Related is defined as Definitely Related, Probable Related, or Possibly Related

14.3.1.6 Treatment Emergent AE – Subjects with AE Leading to Action Taken

Population: Safety Population

Characteristics	Treatment Group
(Multi-Selection by Action Taken, System Organ Class and Preferred Term)	
N	XXX
At least one below [Event#:Subj#]	XXX : XXX (XXX.X%)
~ Repeat Action Taken:	
Dose Increased, Dose Reduced, Drug Interrupted, Drug Withdrawn by Subject, Drug Withdrawn Instructed by Investigator	XXX : XXX (XXX.X%)
~ <MedDRA Body System1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)
~ <MedDRA Body System2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)

14.3.1.7 Treatment Emergent AE – Subjects with Serious Adverse Event (SAE)

14.3.1.8 Treatment Emergent AE – Subjects with Suspected Unexpected Serious Adverse Reaction (SUSAR)

SUSAR: Unexpected Treatment Related SAE

Population: Safety Population

Characteristics	Treatment Group
(Multi-Selection by SAE Criteria, System Organ Class and Preferred Term)	
N	XXX
At least one below [Event#:Subj#]	XXX : XXX (XXX.X%)
Repeat SAE Criterion: Any SAE Criterion, Requires or Prolongs Hospitalization, death, …	XXX : XXX (XXX.X%)
~ <MedDRA Body System1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)
~ <MedDRA Body System2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 1>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 2>	XXX : XXX (XXX.X%)
~ <MedDRA Preferred Term 3>	XXX : XXX (XXX.X%)

SAE Criteria 'F/L/H' and 'F/L' will be counted as 'F' only, and 'L/H' as 'L', where F=Fatal (Death), L=Life threatening, H=Require hospitalization or prolongation of existing hospitalization.

14.3.2 Laboratory Examination – Hematology

14.3.2.1 Hematology – <Item 1 and Unit>

14.3.2.2 Hematology – <Item 2 and Unit>

14.3.2.3 …. Refer to [Instructions and Abbreviations] of section 16 for the test terms

14.3.3 Laboratory Examination – Chemistry

14.3.3.1 Chemistry – <Item 1 and Unit>

14.3.3.2 Chemistry – <Item 2 and Unit>

14.3.3.3 …. Refer to [Instructions and Abbreviations] of section 16 for the test terms

14.3.4 Laboratory Examination – Inflammatory Marker

14.3.4.1 Inflammatory Marker – <Item 1 and Unit>

14.3.4.2 Inflammatory Marker – <Item 2 and Unit>

14.3.4.3 …. Refer to [Instructions and Abbreviations] of section 16 for the test terms

14.3.5 Laboratory Examination – Coagulation

14.3.5.1 Coagulation – <Item 1 and Unit>

14.3.5.2 Coagulation – <Item 2 and Unit>

14.3.5.3 …. Refer to [Instructions and Abbreviations] of section 16 for the test terms

14.3.6 Laboratory Examination – Urinalysis

14.3.6.1 Urinalysis – <Item 1 and Unit>

14.3.6.2 Urinalysis – <Item 2 and Unit>

14.3.6.3 …. Refer to [Instructions and Abbreviations] of section 16 for the test terms

<LB Layout 1: For Continuous Laboratory Test; Clinical relevance analyses will be excluded if not applicable>

Population: Safety Population

Characteristics	Treatment Group	Difference	p-value
. Repeat Visit: No 'Visit 1 (Screening)' for IL-6: Visit 1 (Screening), Baseline, Adjusted Visit 3 (Day 4), Adjusted Visit 4 (Day 8), Adjusted Visit 5 (Day 11), Adjusted Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), Visit 8 (Day 45, F2)			T/W <Baseline Only>
N (Missing)	XXX (XXX)		0.XXXX
Mean (SD)	XXX (XXX)		
Median (IQR)	XXX (XXX)		
Q1~Q3	XXX~XXX		
Min~Max	XXX~XXX		
For W, normality is not applied <Baseline Only>			
Groups Diff		§C - §S	
Median (Asymptotic SE)		XXX	
95% CI (HL)		XXX~XXX	

Characteristics	Treatment Group	Difference	p-value
For T, normality is applied <Baseline Only>			
Groups Diff		§C - §S	
Mean (SD)		XXX (XXX)	
95% CI		XXX~XXX	
N (Missing)	XXX (XXX)		
Normal	XXX (XX.X%)		
NCS	XXX (XX.X%)		
CS (Medical History)	XXX (XX.X%)		
CS (Adverse Event)	XXX (XX.X%)		
. Repeat [Visit – Baseline] excluding Visit 1 (Screening) and Baseline			ANCOVA/W
N (Missing)	XXX (XXX)		0.XXXX
Mean (SD)	XXX (XXX)		
Median (IQR)	XXX (XXX)		
Q1~Q3	XXX~XXX		
Min~Max	XXX~XXX		
95% CI (WI)	XXX~XXXwt		
For W, normality is not applied			
Groups Diff		§C - §S	
95% CI (HL)		XXX~XXX	
For ANOVA, normality is applied	XXX (XXX)		
LsMean (SE)	XXX~XXX		
95% CI of LsMean			
Groups Diff. (T)		§C- §S	
Difference of LsMean		XXX	
95% CI of LsMean		XXX~XXX	

ANCOVA Model (p-value 0.XXXX) with effect Treatment (p-value 0.XXXX), Baseline (p-value 0.XXXX), Treatment*Baseline (p-value 0.XXXX).

. Repeat [<Baseline> to <Visit>]			
N (Missing)	XXX (XXX)		
Relieved	XXX (XX.X%)		
Unchanged	XXX (XX.X%)		
Worsened (Medical History)	XXX (XX.X%)		
Worsened (Adverse Event)	XXX (XX.X%)		

For Item excluding IL-6 Baseline is Visit 2 (Day 1) data, or is Visit 1 if Visit 2 (Day 1) is null
For IL-6 Baseline is Visit 2 (Day 1) data
Refer to [Instructions and Abbreviations] of title pages for Transition of Clinical Relevance

<LB Layout 2: For Categorical Urinalysis Test, including pH; MHCHISQ for PH, C/F for else>

Population: Safety Population

Characteristics	Treatment Group	p-value
. Repeat Visit: Visit 1 (Screening), Baseline, Adjusted Visit 3 (Day 4), Adjusted Visit 4 (Day 8), Adjusted Visit 5 (Day 11), Adjusted Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), Visit 8 (Day 45, F2)		MHCHISQ / C/F <Baseline Only>
N (Missing)	XXX (XXX)	0.XXXX
<Value 1>	XXX (XX.X%)	
<Value 2>	XXX (XX.X%)	
<Value 3>	XXX (XX.X%)	
N (Missing)	XXX (XXX)	
Normal	XXX (XX.X%)	
NCS	XXX (XX.X%)	
CS (Medical History)	XXX (XX.X%)	
CS (Adverse Event)	XXX (XX.X%)	
. Repeat [<Visit> – <Baseline>] for pH Repeat [<Baseline> to <Visit>] for else For <Visit> excluding Visit 1 (Screening) and Baseline		MHCHISQ / C/F
N (Missing)	XXX (XXX)	0.XXXX
<Value 1>	XXX (XX.X%)	
<Value 2>	XXX (XX.X%)	
<Value 3>	XXX (XX.X%)	
. Repeat [<Baseline> to <Visit>]		
N (Missing)	XXX (XXX)	
Relieved	XXX (XX.X%)	
Unchanged	XXX (XX.X%)	
Worsened (Medical History)	XXX (XX.X%)	
Worsened (Adverse Event)	XXX (XX.X%)	

Baseline is Visit 2 (Day 1) data, or is Visit 1 if Visit 2 (Day 1) is null
Refer to [Instructions and Abbreviations] of title pages for Transition of Clinical Relevance
[For Color and Appearance] Data of normal values will be coded as 'Normal', and data not in normal values will be coded as 'Abnormal'.

14.3.7 Physical Examination

14.3.7.1 Physical Examination – All Abnormalities

Population: Safety Population

Characteristics	Treatment Group
. Repeat Visit: Visit 1 (Screening), Visit 2 (Day 1), Visit 4 (Day 8), Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), Visit 8 (Day 45, F2)	
N (Missing)	XXX (XXX)
At least one below	XXX (XXX.X%)
~ <Body System 1>	XXX (XXX.X%)
~ NCS	XXX (XXX.X%)
~CS (Medical History)	XXX (XXX.X%)
~CS (Adverse Event)	XXX (XXX.X%)
~ <Body System 2>	XXX (XXX.X%)
~ NCS	XXX (XXX.X%)
~CS (Medical History)	XXX (XXX.X%)
~CS (Adverse Event)	XXX (XXX.X%)
~ <Body System 3>	XXX (XXX.X%)
~ NCS	XXX (XXX.X%)
~CS (Medical History)	XXX (XXX.X%)
~CS (Adverse Event)	XXX (XXX.X%)
…	…

14.3.8 Vital Signs, Body Weight and SpO2

14.3.8.1 Vital Signs – Temperature [degree C]

14.3.8.2 Vital Signs – Respiratory Rate [breaths/min]

14.3.8.3 Vital Signs – Systolic Blood Pressure [mmHg]

14.3.8.4 Vital Signs – Diastolic Blood Pressure [mmHg]

14.3.8.5 Vital Signs – Heart Rate [beats/min]

14.3.8.6 Vital Signs – Weight [kg]

14.3.8.7 Vital Signs – Pulse Oxygen Saturation (SpO2) [%]

Population: Safety Population

Characteristics	Treatment Group	p-value
. Repeat Visit: Visit 1 (Screening), Baseline, Adjusted Visit 3 (Day 4), Adjusted Visit 4 (Day 8), Adjusted Visit 5 (Day 11), Adjusted Visit 6 (Day 14, EOT), Visit 7 (Day 28, F1), Visit 8 (Day 45, F2)		T/W <Baseline Only>
N (Missing)	XXX (XXX)	0.XXXX
Mean (SD)	XXX (XXX)	
Median (IQR)	XXX (XXX)	
Q1~Q3	XXX~XXX	
Min~Max	XXX~XXX	
For W, normality is not applied	§C - §S	
Groups Diff		
Median (Asymptotic SE)	XXX	
95% CI (HL)	XXX~XXX	
For T, normality is applied	§C - §S	
Groups Diff		
Mean (SD)	XXX (XXX)	
95% CI	XXX~XXX	
For Temperature, Respiratory Rate, Heart Rate, Pulse Oxygen Saturation (SpO2)		C/F
Normal	XXX (XXX.X%)	0.XXXX
Abnormal	XXX (XXX.X%)	
. Repeat [Visit – Baseline] excluding Visit 1 (Screening) and Baseline		ANCOVA/W
N (Missing)	XXX (XXX)	0.XXXX
Mean (SD)	XXX (XXX)	
Median (IQR)	XXX (XXX)	
Q1~Q3	XXX~XXX	
Min~Max	XXX~XXX	
95% CI (WI)	XXX~XXXwt	
For W, normality is not applied	<§C - §S>	
Groups Diff	XXX~XXX	
95% CI (HL)		
For ANCOVA, normality is applied	XXX (XXX)	
	XXX~XXX	
LsMean (SE)		
95% CI of LsMean		
Groups Diff. (T)	<§C- §S>	
Difference of LsMean	XXX	
95% CI of LsMean	XXX~XXX	

ANCOVA Model (p-value 0.XXXX) with effect Treatment (p-value 0.XXXX), Baseline (p-value 0.XXXX), Treatment*Baseline (p-value 0.XXXX).

Baseline is Visit 2 (Day 1) data, or is Visit 1 if Visit 2 (Day 1) is null
[Temperature] Normal: <36.6℃ from axillary site, or < 37.2℃ from oral site or < 37.8℃ from rectal or tympanic site
[Respiratory Rate] Normal: < 20 breaths/min
[Heart Rate] Normal: <90 beats/min
[Pulse Oxygen Saturation (SpO2)] Normal: ≥ 96%

14.3.9 Electrocardiogram (ECG)

14.3.9.1 Electrocardiogram - Overall interpretation

Population: Safety Population

Characteristics	Treatment Group
. Visit 1 (Screening), Visit 6 (Day 14, EOT),	
N (Missing)	XXX (XXX)
Normal	XXX (XX.X%)
NCS	XXX (XX.X%)
CS (Medical History)	XXX (XX.X%)
CS (Adverse Event)	XXX (XX.X%)
. Visit 1 (Screening) to Visit 6 (Day 14, EOT)	
N (Missing)	XXX (XXX)
Relieved	XXX (XX.X%)
Unchanged	XXX (XX.X%)
Worsened (Medical History)	XXX (XX.X%)
Worsened (Adverse Event)	XXX (XX.X%)