NOVOTECH
The Asia Pacific CRO

STATISTICAL ANALYSIS PLAN

A Phase 1b/2a, Double-blind, Placebo-controlled, Dose-escalation Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Recombinant Human Plasma gelsolin (rhu-pGSN) Added to Standard of Care in Subjects Hospitalized for Acute Community-acquired Pneumonia (CAP)

Protocol No.: BT-201

Product Code: rhu-pGSN

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SUMMARY OF CHANGES FROM SAP VERSION 1.0

Section 11.2.2 page 25, the following text has been added:

Additionally, counts (%) of number subjects with values out of normal range at each scheduled time point will also be presented along with shift tables that will represent the changes in normal range categories across post-baseline time points.

Section 17, the following tables have been added:

No.	Title	Analysis Population
14.3.4.1.2.1	SD: Summary of CBC Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.1.2.2	MAD: Summary of CBC Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.2.2.1	SD: Summary of Coagulation Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.2.2.2	MAD: Summary of Coagulation Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.3.2.1	SD: Summary of Comprehesive Metabolic Profile Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.3.2.2	MAD: Summary of Comprehesive Metabolic Profile Shifts from Baseline (Low, Normal, High)	Safety

Section 18, the following listings have been added:

No.	Title	Analysis Population
16.2.8.1.2.1	SD: Abnormal CBC	Intent-to-Treat
16.2.8.1.2.2	MAD: Abnormal CBC	Intent-to-Treat
16.2.8.2.2.1	SD: Abnormal Coagulation	Intent-to-Treat
16.2.8.2.2.2	MAD: Abnormal Coagulation	Intent-to-Treat
16.2.8.3.2.1	SD: Abnormal Comprehensive Metabolic Profile	Intent-to-Treat
16.2.8.3.2.2	MAD: Abnormal Comprehensive Metabolic Profile	Intent-to-Treat

SAP APPROVAL

By my signature, I confirm that this SAP has been reviewed by BioAegis Therapeutics, Inc., and has been approved for use on the BT-201 study:

Name	Title / Company	Signature	Date
Mark DiNubile	CMO. BioAegis		Dec. 3, 2018
Jan Steyn	Principal Biostatistician/ Novotech		3DEC2018

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List of Abbreviations

Abbreviation	Description
AUC_{0-t}	The area under the plasma concentration-time curve, from time 0 (time of dosing) to the last time point with measurable analyte concentration, calculated by the log down, linear up trapezoidal method.
AE	Adverse Event
ATC	Anatomical Therapeutic Class
AUC_{0-inf}	The area under the plasma concentration-time curve from time 0 extrapolated to infinity. AUC_{0-inf} is calculated as the sum of AUC_{0-t} plus the ratio of the last measurable plasma concentration to the elimination rate constant (k_{el}).
AUC_{0-8}	The area under the plasma concentration-time curve, from time 0 (time of dosing) to the 8 hours concentration, calculated by the log down, linear up trapezoidal method.
BLQ	Below the quantitation limit
CAP	Community-Acquired Pneumonia
CBC	Complete Blood Count
C_{max}	Maximum observed concentration
C_{min}	Minimum observed concentration over the dosing interval.
CL/F	Apparent clearance calculated as Dose/AUC_{0-inf}.
CS	Clinically Significant
CSR	Clinical Study Report
CV	Coefficient of variation
DLT	Dose Limiting Toxicity
DN_AUC_{0-inf}	Dose-normalized AUC_{0-inf}, calculated as AUC_{0-inf} divided by dose.
DN_AUC_{0-t}	Dose-normalized AUC_{0-t}, calculated as AUC_{0-t} divided by dose.
DN_AUC_{0-8}	Dose-normalized AUC_{0-8}, calculated as AUC_{0-8} divided by dose.
DN_C_{max}	Dose-normalized C_{max}, calculated as C_{max} divided by dose.
EKG	Electrocardiogram
eCRF	Electronic Case Report Form
EOS	End of Study
GCP	Good Clinical Practice
geo CV	Geometric Coefficient of Variation
HIV	Human Immunodeficiency Virus
ITT	Intention-to-treat
IV	Intravenous
IWRS	Interactive web response system
k_{el}	Apparent terminal elimination rate constant, calculated by linear regression of the terminal linear portion of the log concentration vs. time curve.
LLQ	Lower Limit of Quantification
MAD	Multiple-Ascending Dose
MedDRA	Medical Dictionary for Regulatory Activities
MMSE	Mini-Mental State Exam
N/A	Not Applicable
NCS	Not Clinically Significant

Abbreviation	Description
NK	Not Known
PE	Physical Examination
PI	Principal Investigator
PK	Pharmacokinetic
PP	Per Protocol
PSI	Pneumonia Severity Index
PT	Preferred Term
rhu-pGSN	Recombinant human plasma Gelsolin
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Single Dose
SD*	Standard Deviation
S.I.	International System of Units
SOC*	Standard of Care
SOC	System Organ Class
SOP	Standard Operating Procedure
$t_{½}$	Apparent elimination half-life, calculated as ln(2)/k_{el}.
TEAE	Treatment Emergent Adverse Event
T_{max}	Time to maximum observed drug concentration. If the maximum value occurs at more than one time point, T_{max} is defined as the first time point with this value.
V_z/F	Apparent volume of distribution at the terminal phase, calculated as Dose/ (k_{el} × $AUC_{0\text{-}inf}$).
WHO-DD	World Health Organization Drug Dictionary

1. INTRODUCTION

The following Statistical Analysis Plan (SAP) provides the outline for the statistical analysis of the data from the BT-201 study.

The planned analyses identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post hoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data. Any post hoc, or unplanned, exploratory analyses performed will be clearly identified as such in the final CSR.

2. PROJECT OVERVIEW

2.1 Study Design

Study BTI-201 is a Phase 1b/2a, double-blind, placebo-controlled, dose-escalation study to evaluate the safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of recombinant human plasma gelsolin (rhu-pGSN) added to standard of care (SOC*) in subjects hospitalized for acute community-acquired pneumonia (CAP). Each dosing cohort will include 8 subjects randomized 3:1 rhu-pGSN:placebo (6 rhu-pGSN subjects:2 placebo subjects).

There will be 1 single dose cohort (Cohort 1) and 3 multiple dose cohorts (Cohorts 2, 3 and 4).

Dose will be based on actual body weight. Dose escalation will involve 3 dose levels of rhu-pGSN (6, 12, and 24 mg/kg) in patients admitted for CAP. Dose escalation will only occur after post-therapy safety information on all subjects in the prior cohort has been reviewed at Day 7 for the single-dose (SD) and multiple-ascending dose (MAD*) arms.

The MAD portion of the study will commence once single doses of 6 mg/kg of rhu-pGSN are shown to be acceptably safe. The first 2 doses must be administered in the hospital, but the third dose can be given in a monitored outpatient setting where appropriate.

Discharged subjects will return for follow-up 7 days after the initiation of therapy (Day 7) and on Day 28 for the End-of-Study (EOS) Visit.

To assess safety and tolerability, subjects will undergo physical examinations (PE; including vital sign measurements), AE assessments, concomitant medication assessments, safety laboratory testing and Electrocardiogram (EKGs - completed locally), and other testing as per local custom.

2.2 Objectives

2.2.1 Primary objective

The primary objective of the study will be to evaluate the safety and tolerability of single and multiple ascending doses of rhu-pGSN administered by once-daily intravenous (IV) push to hospitalized subjects with a primary admitting diagnosis of CAP.

2.2.2 Secondary objectives

The secondary objective of the study will be to characterize the PK profile of rhu-pGSN after single or multiple IV doses

2.2.3 Exploratory objective.

The exploratory objectives of the study will be to investigate the following:

- To assess the quantitative relationship of pGSN levels at baseline with clinical outcomes, changes in prognostic indices and inflammatory biomarkers, and etiologic pathogen type.
- To assess the relationship between rhu-pGSN dose and clinical response and changes in surrogate biomarkers of efficacy.

2.2.4 Immunogenicity objective.

The immunogenicity objective of the study will be to investigate the post-treatment development of antibodies against rhu-pGSN by Day 28.

2.3 Sample Size

The sample size of N=6 rhu-pGSN recipients per dose level and combined placebo in the SD and MAD portions of the trial were chosen based on limiting exposure to pGSN in this initial study in the current development program. The sample sizes in this trial have the following properties in relation to interpretation of Adverse Events (AEs) incidence rates (Table 1).

Table 1 presents the Minimum Sample Size such that there is 90% probability of observing at least 1 AE of a certain type if the TRUE underlying AE rate.

Table 1: Minimum Sample Size Calculations

Sample Size	TRUE underlying AE rate
6 (each pGSN dose level)	32%
8 (pooled placebo)	21%
24 (pooled pGSN)	10%

With each sample size presented in the table above, if zero AEs of a certain type are observed, one could be "90% confident" the TRUE underlying rate for that AE is at most the rate indicated above.

2.4 Randomization

Following screening, subjects qualified for study entry will be randomized to receive rhu-pGSN or placebo during the treatment period. Randomization will be done centrally using the Interactive web response system (IWRS). All eligible subjects will be assigned a randomization number.

There will be 1 single dose cohort (Cohort 1) and 3 multiple dose cohorts (Cohorts 2, 3 and 4). Eight subjects will be sequentially randomized to each cohort for a total number randomized of 32 subjects.

Subjects will be randomized in a 3:1 ratio to rhu-pGSN or placebo (6 rhu-pGSN subjects:2 placebo subjects).

The investigational site team and the subject will be kept blinded to the treatment allocation of each participant. Only the designated pharmacist(s) will be unblinded to the treatment allocation. The unblinded pharmacist will utilize the IWRS system to randomly assign a treatment allocation. The treatment allocation will be available to the unblinded pharmacist(s).

3. STATISTICAL CONSIDERATIONS

Data will be handled and processed per the sponsor's representative (Novotech) Standard Operating Procedures (SOPs), which are written based on the principles of good clinical practice (GCP).

All data collected on the eCRFs will be presented in the data listings and will be listed and sorted by SD/MAD, treatment, subject number and visit, where applicable. All summaries will present the data by SD/MAD (apart from PK summaries), treatment group and overall (total subjects), as applicable. In addition, all placebo subjects will be combined into a single placebo group for purposes of summarizing the data.

- Continuous variables: Descriptive statistics will include the number of non-missing values (N), mean, standard deviation (SD*), median, minimum, maximum.

  The minimum and maximum values will be displayed to the same decimal precision as the source data, the arithmetic mean, SD* and median values will be displayed to one more decimal than the source data for the specific variable.

  The appropriate precision for derived variables will be determined based on the precision of the data on which the derivations are based, and statistics will be presented in accordance with the abovementioned rules.

- PK data: For PK data the arithmetic mean, standard deviation, median, minimum, maximum, coefficient of variation (CV%), geometric mean and geometric coefficient of variation (geo CV%) values will be presented. For the ratio of concentration data to the (within 30 minutes) pre-dose concentration on Day 1, the ln(SD*) will also be presented.

- Categorical variables: Descriptive statistics will include frequency counts and percentages per category. Percentages will be rounded to one decimal place, with the denominator being the number of subjects in the relevant population with non-missing data, unless otherwise specified.

- Time to Event Analysis: Through the Kaplan-Meier method, nonparametric estimates of the survivor function will be represented by quartile estimates (Q1, Median and Q3) along with 95 CIs. Product limit estimates will be presented as part of appendices to the study outputs (SAS output).

- Imputation: No missing data will be imputed.

- Baseline: Baseline values will be defined as the last valid, non-missing observation for each subject prior to the first dose of study medication. For the PK analysis, baseline will be defined as the pre-dose value for each study day.

- Repeat assessments (Safety): No repeat assessments will be included in summary presentations (Tables, Figures). Only the original values will be used in summary presentations. All repeat assessments captured in the Electronic Data Capture (EDC) system will be presented in the data listings.

- Assessment windows: All assessments will be included in the data listings and no visit windows will be applied to exclude assessments that were performed outside of the protocol specified procedure windows.

- Date and time display conventions: The following display conventions will be applied in all outputs where dates and/or times are displayed:

  - Date only: DDMMMYYYY
  - Date and time: DDMMMYYYY /HH:MM

If only partial information is available, unknown components of the date or time will be presented as 'NK' (not known), i.e., '2016-NK-NK'. Times will be reported in military time.

In the summary tables and figures, treatment groups will be summarized separately for SD/MAD, each cohort, combined placebo and overall (all subjects). Study outcomes will be summarized as follows:

- For each active dose level (overall):
    - SD Phase:
        - rhu-pGSN 6 mg/kg
        - Placebo
        - Overall
    - MAD Phase
        - rhu-pGSN 6 mg/kg
        - rhu-pGSN 12 mg/kg
        - rhu-pGSN 24 mg/kg
        - Combined Active
        - Combined Placebo
        - Overall

4. ANALYSIS POPULATIONS

In this study, four analysis populations are defined: Intention-to-treat (ITT), Safety, Pharmacokinetic and the Per Protocol populations (PP).

Furthermore, any additional exploratory analysis not identified in the SAP will be identified in the final CSR as exploratory post hoc analyses. This may include the addition of additional study populations or subgroups of interest.

The number and percentage of subjects in each analysis population will be summarized.

4.1 Population Descriptions

4.1.1 Intention-to-treat (ITT) population

The ITT population will be defined as all randomized subjects. Subjects will be analyzed per the randomized treatment they received if different from the actual treatment received.

All disposition, demographic and pharmacodynamic (PD) analyses will be based on the ITT population. All listings will be presented by the ITT population.

4.1.2 Safety population

The safety population will be defined as all enrolled subjects who received at least one dose of the study drug and will be based on actual treatment received.

If the safety population differs from the ITT population in that subjects received a different treatment to that they were randomized, or did not receive treatment whatsoever after randomization, the demographic and pharmacodynamic analyses will be repeated for the safety population.

All safety analyses will be based on the safety population.

4.1.3 Pharmacokinetic (PK) population

The PK population will comprise all subjects in the safety population who provide adequate PK samples to calculate the PK parameters. Subjects with important protocol deviations will be assessed on a subject-by-subject basis for inclusion in the PK Population. The PK analysis will be conducted using the Pharmacokinetic population.

4.1.4 Per Protocol (PP) population

The PP population will comprise all subjects in the safety population excluding subjects who missed doses and/or randomly discontinued the study before the primary Day 7 Visit. Furthermore, subject that had any relevant important protocol deviations will be excluded from the PP population.

5. PROTOCOL DEVIATIONS

In case protocol deviations/violations are reported, all protocol deviations/violations will be listed for each subject in the by-subject data listings. Prior to database lock and during the blinded review of database, all protocol deviations/violations will be reviewed and assigned a status of important or not.

Important protocol deviations/violations may include the following, depending on the timing and nature of the deviation:

- INFORMED CONSENT DEVIATION: Subject not consented prior to study procedures being performed or subject not re-consented to study at next scheduled study visit following local approval of an updated PIS-CF.
- ENTRY DEVIATION: Subject enrolled in violation of eligibility criteria.
- WITHDRAWAL DEVIATION: Subject developed withdrawal criteria during the study, but were not withdrawn.
- DOSING DEVIATION: Subject received the wrong treatment or incorrect dose of investigational product or comparator; Subject received treatment at incorrect timepoint in study; Subject received treatment that had not been stored per protocol.
- OPERATIONAL DEVIATION: Informed consent deviations (other than consent not being obtained prior to study entry, which would be considered an Entry Deviation), IRB/IEC expired approval, significant visit window deviations, or other issues that may significantly impact subject safety or data integrity.

6. SUBJECT DISPOSITION

Outcomes will be summarized by the treatment groups as specified in section 3.

6.1.1 Subject disposition

Subject disposition will be summarized using counts and percentages and will be based on the ITT Population. The number of screened subjects, number and percentage of randomized subjects, subjects discontinued from the study as well as the primary reason for discontinuation will also be summarized.

All disposition information collected will be listed together with the date that the subject provided informed consent and the date and time of the first study drug administration.

If the there is a difference between the ITT, Safety populations or the PP population, the disposition summary tables will be repeated for that population.

6.1.2 Analysis Populations

The number of subjects included in of each of the defined analysis populations will be summarized using counts and percentages and will be based on the ITT Population.

In addition, the inclusion/exclusion of each subject into/from each of the defined analysis populations will be listed.

7. DEMOGRAPHIC AND BASELINE INFORMATION

Demographic and baseline body measurements will be summarized using the ITT Population and may be repeated for the safety population and per protocol populations if different from the ITT population.

All information will be presented by the treatment groups as specified in section 3.

7.1 Demographics

7.1.1 Definition of variables

- Age (years);
- Sex;
- Child Bearing Potential;
- Method of Birth Control;
- Race;
- Height (cm);
- Weight (kg);

7.1.2 Biostatistical methods

Quantitative and categorical summaries will be presented for demographic variables at the screening visit.

A by-subject data listing for demographic and baseline characteristics will be generated.

7.2 Medical history

Past medical history will be coded using the Medical Dictionary for Regulatory Activities, (MedDRA - latest version), and will be presented in the by-subject data listings including the MedDRA codes.

7.3 Pregnancy Test (Serum and Urine)

Pregnancy test results will be included in the by-subject data listings. This includes the pregnancy test results at Screening and Day 28/End of Study.

7.4 Serology

The following viral detection results (serologies) at Screening will be listed for each subject when available: Hepatitis B, Hepatitis C and HIV status.

7.5 Other baseline characteristics

Confirmation of CAP (both clinical and radiographic) will be presented in the by-subject data listings.

8. STUDY DRUG ADMINISTRATION

Study drug administration results will be presented using the ITT Population.

A by-subject data listing will be generated for study medication administration. These listings will include randomized dose assignment, Date/Time of Injection, Study Drug Administered (mL), duration of administrations, reason whole study drug dose was not administered, injection interruptions, re-start and reason for any interruptions. Subjects who receive the wrong IP (rhu-pGSN vs. placebo) will be flagged.

9. PHARMACOKINETICS (PK)

All PK summary tables and figures will be based on the PK Population. All listings will be based on the Safety Population (Actual Treatment). All analyses will be done by treatment group.

For the 1 dose in the SD arm and the first 2 doses in the MAD arms, blood will be drawn within 30 minutes pre-dose, and 5-10 minutes after the end of administration, as well as 2, 8, 12 and/or 16, and 24 hours after the end of administration (± 30 minutes) for analysis. Identical PK sampling is encouraged on Day 3 where feasible (but not required) in the multiple-dose arms.

In this section (section 9):

- The rhu-pGSN treatment group will be referred to the Active treatment group.
- Exogenous pGSN concentrations will be referred to as rhu-pGSN concentrations.
- Endogenous pGSN + Exogenous pGSN (total) will be referred to as pGSN

9.1 Definition of variables

The following PK parameters for pGSN will be estimated For Day 1(SD/MAD), Day 2 (MAD) and Day 3 (MAD). PK Parameters will only be calculated for the Active (rhu-pGSN) treatment group. No PK parameters will be calculated for the Placebo treatment group:

Day 1: SD/MAD & Day 2/3: MAD

AUC_{0-t}	The area under the plasma concentration-time curve, from time 0 (time of dosing) to the last time point (24 hours) with measurable analyte concentration, calculated by the log down, linear up trapezoidal method. AUC_{0-t} will additionally be calculated for the estimated rhu-pGSN profile for both the change from pre-dose on each study day and the double-delta method.
AUC_{0-8}	The area under the plasma concentration-time curve, from time 0 (time of dosing) to the 8 hours concentration, calculated by the log down, linear up trapezoidal method. AUC_{0-8} will additionally be calculated for the estimated rhu-pGSN profile for both the change from pre-dose on each study day and the double-delta method.
AUC_{0-inf}	The area under the plasma concentration-time curve from time 0 extrapolated to infinity. AUC_{0-inf} is calculated as the sum of AUC_{0-t} plus the ratio of the last measurable plasma concentration to the elimination rate constant (k_{el}).
C_{max}	Maximum observed concentration. C_{max} will additionally be calculated for the estimated rhu-pGSN profile for both the change from pre-dose on each study day and the double-delta method.
T_{max}	Time to maximum observed drug concentration. If the maximum value occurs at more than one time point, T_{max} is defined as the first time point with this value.

k_{el}	Apparent terminal elimination rate constant calculated by linear regression of the terminal linear portion of the log concentration vs. time curve.
$t_{½}$	Apparent elimination half-life, calculated as ln(2)/kel
$\%AUC_{ext}$	Percentage of the extrapolated area under the plasma concentration-time curve, calculated as 100% * [AUC0-inf - AUC0-t]/ AUC0-inf
C_L/F	Apparent clearance calculated as Dose/$AUC_{0\text{-}inf}$.
V_z/F	Apparent volume of distribution at the terminal phase, calculated as Dose/ (k_{el} × $AUC_{0\text{-}inf}$).
DN_C_{max}	Dose-normalized C_{max}, calculated as C_{max} divided by dose DN_C_{max} will additionally be calculated for the estimated rhu-pGSN profile for both the change from pre-dose day 1 and the double-delta method..
DN_$AUC_{0\text{-}inf}$	Dose-normalized $AUC_{0\text{-}inf}$, calculated as $AUC_{0\text{-}inf}$ divided by dose
DN_$AUC_{0\text{-}t}$	Dose-normalized $AUC_{0\text{-}t}$, calculated as $AUC_{0\text{-}t}$ divided by dose DN_$AUC_{0\text{-}t}$ will additionally be calculated for the estimated rhu-pGSN profile for both the change from pre-dose on each study day and the double-delta method.
DN_$AUC_{0\text{-}8}$	Dose-normalized $AUC_{0\text{-}24}$, calculated as $AUC_{0\text{-}24}$ divided by dose DN_$AUC_{0\text{-}8}$ will additionally be calculated for the estimated rhu-pGSN profile for both the change from pre-dose on each study day and the double-delta method.

9.2 Biostatistical methods

Plasma pGSN

Individual plasma pGSN concentrations will be summarized by nominal sampling time.

Plasma pGSN concentrations that are below the quantitation limit (BQL) will be set to 0 if before the first quantifiable concentration, and to ½ the lower level of quantification elsewhere for calculation of summary statistics for concentration data at each time point.

The actual blood sampling dates and times relative to dosing time will be listed by subject and nominal sampling time, with time deviations calculated for all subjects with available plasma concentration data, including subjects excluded from the PK Population.

Individual (for each subject) and mean plasma pGSN concentration over time will be displayed graphically in linear and semi-logarithmic plot of pGSN concentration versus time. The actual collection time will be used for individual plasma pGSN concentration curve and the nominal time will be used for plot of mean plasma pGSN concentration curve.

Plasma concentrations vs. time data will be analyzed using validated PK software (Phoenix WinNonlin version 6.3 or higher), by standard non-compartmental model. Actual collection time will be used in the calculation of plasma PK parameters. For the calculation of the PK parameters, all plasma concentrations that are BLQ prior to the first measurable

concentration will be set to ½ the lower level of quantification. The BLQ values that are between measurable concentrations will be set to ½ LLOQ. The BLQ values that occur at the end of the profile (after the last quantifiable concentration) will also be set to ½ the lower level of quantification.

Ratio of Plasma pGSN

For subjects that do not have quantifiable pre-dose concentration values on each day, the pre-dose value will be set to ½ lower limit of quantification (LLQ).

Individual plasma pGSN: Day 1, 2 and Day 3 pGSN concentration ratios from each day's pre-dose will be summarized by nominal sampling time.

Plasma pGSN concentrations that are below the quantitation limit (BQL) will be set to ½ the lower level of quantification post dose for calculation of summary statistics for concentration ratio data at each time point.

Ratio of Pre-dose and Placebo Adjusted Plasma pGSN

For the active treatment groups, plasma concentration of pGSN will further be evaluated (adjusted) in terms of the mean Placebo pGSN at each time point as well as the pre-dose (baseline value) for each study day:

- Pre-dose values on each study day will be presented as recorded;
- Pre-dose values on each study day that are BLQ will be set to ½ LLQ;
- Subsequent BLQ values (post the first quantifiable concentration on each day) will be set to ½ LLQ.
- Pre-dose and Placebo Adjusted Concentration

  = (Active Treatment Group natural log Concentration on Day z at Time Point y – Day z Pre-dose natural log Concentration) - (Placebo Treatment Group natural log Concentration on Day z at Time Point y – Placebo Day z Pre-dose natural log Concentration) [results will be back-transformed to the ratio of ratios scale.]

Baseline and Placebo corrected Individual plasma pGSN concentrations will be summarized by nominal sampling time.

Analysis of Estimated rhu-pGSN

This analysis will exclude the placebo treatment group:

- Pre-dose values on each study day will be presented as recorded;
- Pre-dose values on each study day that are BLQ will be set to ½ LLQ;
- Subsequent BLQ values (post the first quantifiable concentration on each day) will be set to ½ LLQ.
- Estimated rhu-pGSN concentration

  = concentration on Day z at Time Point y – Day z Pre-dose concentration

Individual estimated rhu-pGSN concentrations will be summarized by nominal sampling time. Geometric summary statistics will not be calculated for estimated rhu-pGSN concentrations, as these values could be lower than or equal to 0.

Estimated Individual (for each subject) and mean estimated plasma rhu-pGSN concentration over time will be displayed graphically in linear plots of estimated rhu-pGSN concentration versus time. The actual collection time will be used for individual estimated plasma rhu-pGSN concentration curve and the nominal time will be used for plot of mean estimated plasma rhu-pGSN concentration curve.

Estimated plasma concentrations vs. time data will be analyzed using SAS software. Actual collection time will be used in the calculation of plasma PK parameters. The following parameters (including dose normalized parameters) will be calculated for each study day:

- AUC_{0-t}
- AUC_{0-8h}
- C_{max}

Double Delta Analysis of Estimated rhu-pGSN

- Pre-dose values on each study day will be presented as recorded;
- Pre-dose values on each study day that are BLQ will be set to ½ LLQ;
- Subsequent BLQ values (post the first quantifiable concentration on each day) will be set to ½ LLQ.
- Estimated rhu-pGSN will be calculated as follows:

  = (Active Treatment Group Concentration on Day z at Time Point y – Day z Pre-dose Concentration) - (Mean Placebo Treatment Group Concentration on Day z at Time Point y – Mean Placebo Day z Pre-dose Concentration)

Estimated rhu-pGSN concentrations will be summarized by nominal sampling time. Geometric summary statistics will not be calculated for estimated rhu-pGSN concentrations, as these values could be lower than or equal to 0.

Estimated Individual (for each subject) and mean estimated plasma rhu-pGSN concentration over time will be displayed graphically in linear plots of estimated rhu-pGSN concentration versus time. The nominal time will be used for individual estimated plasma rhu-pGSN concentration curve and the nominal time will be used for plot of mean estimated plasma rhu-pGSN concentration curve.

Estimated rhu-pGSN plasma concentrations vs. time data will be analyzed using SAS software. Nominal time will be used in the calculation of plasma PK parameters. The following parameters (including dose normalized parameters) will be calculated for each study day:

- AUC_{0-t}
- AUC_{0-8h}
- C_{max}

10. PHARMACODYNAMICS (EFFICACY)

All PD summary tables, figures and listings will be based on the ITT Population. All analysis will be done by study part (SD/MAD) by each treatment group.

As a sensitivity analysis, the analysis will be repeated based on the PP population.

10.1 Definition of variables

The following biomarkers will be analyzed:

- Procalcitonin;
- pGSN;
- TNFα;
- TGFβ;
- IL1β;
- IL1ra;
- IL2;
- IL4;
- IL6;
- IL10;
- IL17a.`

10.2 Biostatistical methods

Biomarker will be summarized via counts and percentages of subjects for categorical variables, and by summary statistics for baseline, each observed time point, and ratio from baseline at each observed time point for continuous variables (as for the PK analysis with the exception of CV% and Geometric CV%) by treatment group and overall.

11. SAFETY

Safety endpoints will be analyzed using the Safety Population. All information will be presented by study part, for each treatment group and overall.

11.1 Adverse Events

11.1.1 Definition of variables

- Adverse event (AE)
- Serious adverse event (SAE)
- Treatment emergent adverse event (TEAE)

AEs and SAEs are defined in the study protocol. TEAEs are defined as adverse events that occurred or worsened following the first administration of study medication. Adverse events that have missing onset dates will be considered treatment-emergent, unless the stop date is known to be prior to the first administration of the study medication.

11.1.2 Biostatistical methods

All AEs will be coded using MedDRA.

All AE summaries will be restricted to TEAEs only. Summary tables will include the number of subjects (%) experiencing an event and the number of events. Subjects will be counted only once at each system organ class (SOC) and preferred term (PT) level of summary.

The TEAE summaries will include:

- TEAE summary by SOC and PT
- TEAE summary of serious events by SOC and PT
- TEAE summary of deaths by SOC and PT
- TEAE summary by severity (NCI-CTCAE) by SOC and PT
- TEAE summary by causality to Study Drug by SOC and PT
- TEAE summary by causality to Study Procedure by SOC and PT
- TEAE summary of events leading to treatment discontinuation (Drug withdrawn) by SOC and PT

All AEs will be listed and will include verbatim term, PT, SOC, treatment, severity, causality, seriousness, and action taken with regards to the study drug. Separate listings will be created for SAEs, deaths and events leading to treatment discontinuation (Drug withdrawn).

Overall survival (time to death in days) will be analyzed through Kaplan-Meier methods and censored at the time of the study exit visit. Date of death will be taken as the SAE end date for which the outcome is stated to be fatal. Overall survival (days) = Date of event outcome of death/ Date of study exit - Date of first study drug administration + 1.

11.2 Safety Laboratory Assessments

Blood samples will be collected at the time points specified in the Schedule of Events (refer to the Protocol) to conduct Complete blood count (CBC), Coagulation and Comprehensive Metabolic Profile analyses.

11.2.1 Definition of variables

The following tests will be performed within each of the specified test panels:

Complete blood count (CBC):

- Hematocrit (HCT);
- Hemoglobin (HGB);
- Red Blood Cells (RBC)
- White Blood Cells (WBC) with differential (including Eosinophils (EOS), Neutrophils (NEUT), Basophils (BASO), Lymphocytes (LYM) and Monocytes (MONO);
- Platelets (PLAT);
- Reticulocyte count

Coagulation:

- Prothrombin Time (PT) / International Normalized Ratio (INR);
- Partial Thromboplastin Time (PTT).

Comprehensive Metabolic Profile:

- Albumin (ALB)
- Blood Urea Nitrogen (BUN)
- Creatinine (CREAT)
- C-Reactive Protein (CRP)
- Lactate Dehydrogenase (LDH)
- Creatine phosphokinase (CPK)
- Alanine Aminotransferase (ALT)
- Aspartate Aminotransferase (AST)
- Total Bilirubin (BILI)
- Alkaline Phosphatase (ALP)
- Amylase
- Lipase

11.2.2 Biostatistical Methods

All laboratory data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

Results for individual parameters may be reported in different units depending on the analyzing laboratory. If required, the results (and the corresponding normal range cut-off values) for individual parameters may be converted to International System of Units (S.I.) units to summarize the data.

For the all parameters where a unit value has been reported, the parameter names that will be used in the outputs will comprise of the test name and the unit of measure, for example, 'Albumin (g/L)'. Parameters will be sorted alphabetically within tables and listings.

For all parameters where a normal range limit value is reported, the normal range will be derived based on the available lower and upper limit values and any reported mathematical symbols. If both a lower and upper limit value is available, the normal range will be presented as '(Lower, Upper)'.

The reported results for each parameter with a defined normal range will be classified ('Low', 'Normal', 'High') in relation to the defined normal range limits. If a result is equal to the normal range cut-off value, the result will be considered 'Normal'.

The change from baseline values at each post-baseline visit will be calculated for all parameters with continuous results (except for specific gravity and pH).

The decimal precision for each parameter will be based on the maximum number of decimals to which the reported result or the normal range limits are presented to in the raw data. The results and normal ranges will be displayed to the same decimal precision in the listings.

If a result for a parameter that is normally considered continuous is reported as a range (i.e., the result for basophils is reported as '<0.01' for a single time point), the result may be converted to a numeric value that is smaller than the reported result to contribute to the derivations and the summary statistics. Any conversion rules that are applied will be highlighted in the footnotes of the affected tables and listings. The original reported result value will however be included in the listing.

The laboratory result tables will present summary statistics for each laboratory parameter within the specific test panel. For each parameter, summaries will be presented for the baseline and each scheduled post-baseline visit. In addition, summaries will be presented for the change from baseline values at each scheduled post-baseline visit.

Additionally, counts (%) of number subjects with values out of normal range at each scheduled time point will also be presented along with shift tables that will represent the changes in normal range categories across post-baseline time points.

The listings of laboratory parameters will include all the information (fields) collected. In addition, the observations that are used as the baseline record (value) for each parameter will be flagged, and the change from baseline values at each post-baseline visit will be presented.

For all parameters, standardized values will be reported.

11.3 Vital Signs Measurements

11.3.1 Definition of variables

The following vital signs measurements will be taken at the time points specified in the Schedule of Events (refer to the Protocol):

- Heart Rate (beats/min);
- Systolic blood pressure (SBP) (mmHg)
- Diastolic blood pressure (DBP) (mmHg)
- Respiratory rate (breaths/min)
- Temperature (ºC)
- Pulse Oximetry (%)
- Overall Investigator Interpretation

11.3.2 Biostatistical Methods

All vital signs data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

The parameter names that will be used in the outputs will comprise of the test name and the unit of measure, for example, 'Systolic Blood Pressure (mmHg)'. Parameters will be sorted in the order that the measurements were collected in on the Vital Signs eCRF page within the tables and listings.

The change from baseline to the pre-dose assessment at each post-baseline visit will be calculated for all parameters.

The decimal precision for each parameter will be based on the maximum number of decimals to which the results were reported on the eCRF.

Vital signs measurements will present summary statistics for the results at the baseline and each scheduled post-baseline visit for each of the parameters. In addition, summaries will be presented for the change from baseline values at each scheduled post-baseline visit.

The summary of overall interpretation results table will present counts and percentages for the reported results at baseline and each post-baseline visit/time point. Result categories will be ordered as 'Normal', 'Abnormal not clinical significant (NCS)' and 'Abnormal clinical significant (CS)'.

The listings of vital signs measurements will include all the information collected. In addition, the observations that are used as the baseline record (value) for each parameter will be flagged, and the change from baseline values at each post-baseline visit will be presented.

11.4 12 - Lead Electrocardiogram (EKG)

11.4.1 Definition of variables

The following EKG measurements will be taken at the time points specified in the Schedule of Events (refer to the Protocol):

- Heart Rate (beats/min);
- PR Interval (ms)
- QRS Interval (ms)
- QT Interval (sec)
- QTcF Interval (ms) = QT interval /cube root of the RR interval
- Overall Investigator Interpretation

11.4.2 Biostatistical Methods

All EKG data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

The parameter names that will be used in the outputs will comprise of the test name and the unit of measure, for example, 'Heart Rate (beats/min)'. Parameters will be sorted in the order that the measurements were collected in on the EKG eCRF page within the tables and listings.

For study visits where, multiple EKG measurement are taken, the mean of the measurements will be summarized and the worst-case overall investigator interpretation for the multiple measurements will be presented.

The change from baseline to the pre-dose assessment at each post-baseline visit will be calculated for all parameters.

The decimal precision for each parameter will be based on the maximum number of decimals to which the results were reported on the eCRF.

EKG measurements will present summary statistics for the results at the baseline and each scheduled post-baseline visit for each of the parameters. In addition, summaries will be presented for the change from baseline values at each scheduled post-baseline visit.

The summary of overall interpretation results table will present counts and percentages for the reported results at baseline and each post-baseline visit/time point. Result categories will be ordered as 'Normal', 'Abnormal NCS' and 'Abnormal CS'.

The listings of EKG measurements will include all the information collected and calculated (mean results). In addition, the observations that are used as the baseline record (value) for each parameter will be flagged, and the change from baseline values at each post-baseline visit will be presented.

11.5 Physical Examinations

Physical Examination assessments will be listed for all time points.

11.6 Outcome Prediction Models

11.6.1 Definition of variables

The following outcome prediction models will be taken at the time points specified in the Schedule of Events (refer to the Protocol):

- CURB-65 Score;

- Pneumonia Severity Index (PSI) Score
- Pneumonia Severity Index (PSI) Risk Class
- SOFA Score
- Mini-Mental State Exam (MMSE) Score

11.6.2 Biostatistical Methods

All outcome prediction model data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

The change from baseline to the pre-dose assessment at each post-baseline visit will be calculated for all parameters.

The decimal precision for each parameter will be based on the maximum number of decimals to which the results were reported on the eCRF.

Outcome prediction model scores will present summary statistics for the results at the baseline and each scheduled post-baseline visit for each of the parameters. In addition, summaries will be presented for the change from baseline values at each scheduled post-baseline visit.

The summary of PSI Risk Class will present counts and percentages for the reported results at baseline and each post-baseline visit/time point. Result categories will be ordered by risk class.

The listings of outcome prediction model data will include all the information collected. In addition, the observations that are used as the baseline record (value) for each parameter will be flagged, and the change from baseline values at each post-baseline visit will be presented.

11.7 Concomitant Medications

Concomitant and prior medications will be coded using World Health Organization Drug Dictionary (WHO-DD, September 2015).

Prior medications are defined as any medication where the use was stopped prior to the first administration of the study medication. Prior medications will be listed only.

Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of the study medication. Medications that were stopped on the same date as the first study drug infusion will be analyzed as concomitant medications. If a clear determination cannot be made (partial medication end dates) the medication will be classified as concomitant.

Concomitant medications will be summarized by WHO-DD Anatomical Therapeutic Chemical (ATC) class Level 3, and preferred term using frequency counts and percentages by study part and treatment group. Subjects who take the same medication more than once will be counted only once for that preferred term. Subjects will also only be counted once for each ATC3 class, regardless of the number of medications they have taken within that class

11.8 Other safety evaluations

Hospitalization follow-up will be presented in by-subject listings by study part and treatment group. Length of stay in hospital defined as date and time of discharge or date of study exit if still hospitalized at the time of death or study exit (censored at 23:59) - date and time of Hospitalization admission due to CAP in hours, length of ICU stay and the period of intubation in days will be listed and presented through Kaplan-Meier (K-M) methods.

The length of stay in ICU and period of intubation analysis will be restricted to subjects that stayed in the ICU and were intubated. The event investigated will be the cessation of ICU stay and the cessation of intubation.

12. IMMUNOGENICITY ENDPOINTS

All Immunogenicity endpoints will be listed using the safety population by study part and treatment. Specimens from placebo recipients will serve as a negative control.

Antibodies against rhu-pGSN will be blindly assayed from frozen specimens to determine whether the investigational product induces an antibody response in recipients.

13. EXPLORATORY ENDPOINTS

Other analyses to be performed include:

- Blood, sputum, and other cultures as clinically indicated (note that a sputum culture is mandatory if a sputum specimen can be obtained and blood cultures are strongly encouraged at entry into the study).
- Sputum neutrophil elastase (where feasible at entry and near the conclusion of study therapy).

Exploratory endpoints will be listed only.

14. HANDLING OF MISSING DATA

Missing, unused, or spurious data will be handling in the following manner:

- There will be no imputations or substitution made for missing PD or safety data points;
- For the PK analyses, imputations will be made for missing data points. Please see section 9 for more detail.

15. CHANGES TO THE PLANNED ANALYSIS

No planned changes.

15.1 Final Analysis (End of Study)

The final analysis will be conducted after all subjects have completed the study, the clinical database has been locked and the analysis populations have been approved.

The final analysis will be based on the final version of the SAP. Any deviations from the planned analysis will be documented in the CSR.

16. SOFTWARE

The following software will be used to perform the statistical analyses:

- SAS® Version 9.4 or higher (SAS Institute, Cary, North Carolina, USA).
- The following software will be used to perform the PK analysis: Phoenix WinNonlin® version 6.3 or higher.

17. TABLES

No.	Title	Analysis Population
14.1.1.1	SD: Summary of Subject Enrolment and Disposition	Intent-to-Treat
14.1.1.2	MAD: Summary of Subject Enrolment and Disposition	Intent-to-Treat
14.1.2.1	SD: Summary of Demographics and Baseline Characteristics	Intent-to-Treat
14.1.2.2	MAD: Summary of Demographics and Baseline Characteristics	Intent-to-Treat
14.2.1.1	Day 1: Summary of Plasma pGSN Concentrations (unit) by Timepoint	PK
14.2.1.2	Day 2: Summary of Plasma pGSN Concentrations (unit) by Timepoint	PK
14.2.1.3	Day 3: Summary of Plasma pGSN Concentrations (unit) by Timepoint	PK
14.2.1.4	Day 1: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint	PK
14.2.1.5	Day 2: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint	PK
14.2.1.6	Day 3: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint	PK
14.2.2.1	Day 1: Summary of Plasma pGSN PK Parameters	PK
14.2.2.2	Day 2: Summary of Plasma pGSN PK Parameters	PK
14.2.2.3	Day 3: Summary of Plasma pGSN PK Parameters	PK
14.2.3.1	Day 1: Summary of Estimated Plasma rhu-pGSN PK Parameters	PK
14.2.3.2	Day 2: Summary of Estimated Plasma rhu-pGSN PK Parameters	PK
14.2.3.3	Day 3: Summary of Estimated Plasma rhu-pGSN PK Parameters	PK
14.2.4.1	SD: Summary of PD Parameters	Intent-to-Treat
14.2.4.2	MAD: Summary of PD Parameters	Intent-to-Treat
14.2.5.1	SD: Summary of PD Parameters	Per Protocol
14.2.5.2	MAD: Summary of PD Parameters	Per Protocol
14.3.1.1	SD: Summary of Concomitant Medication	Safety
14.3.1.2	MAD: Summary of Prior and Concomitant Medication	Safety
14.3.3.1.1	SD: Overall Summary of Treatment-Emergent Adverse Events	Safety
14.3.3.1.2	MAD: Overall Summary of Treatment-Emergent Adverse Events	Safety
14.3.3.2.1	SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT)	Safety
14.3.3.2.2	MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT)	Safety
14.3.3.3.1	SD: Summary of Treatment-Emergent Deaths (Summary by SOC, PT)	Safety
14.3.3.3.2	MAD: Summary of Treatment-Emergent Deaths (Summary by SOC, PT)	Safety

No.	Title	Analysis Population
14.3.3.4.1	SD: Summary of Serious Treatment-Emergent Adverse Events (Summary by SOC, PT)	Safety
14.3.3.4.2	MAD: Summary of Serious Treatment-Emergent Adverse Events (Summary by SOC, PT)	Safety
14.3.3.5.1	SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and NCI-CTCAE Grade)	Safety
14.3.3.5.2	MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and NCI-CTCAE Grade)	Safety
14.3.1.6.1	SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Drug)	Safety
14.3.3.6.2	MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Drug)	Safety
14.3.3.7.1	SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Procedure)	Safety
14.3.3.7.2	MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Procedure)	Safety
14.3.3.8.1	SD: Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation (Summary by SOC, PT)	Safety
14.3.3.8.2	MAD: Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation (Summary by SOC, PT)	Safety
14.3.3.9.1	SD: Summary of Overall Survival	Safety
14.3.3.9.2	MAD: Summary of Overall Survival	Safety
14.3.4.1.1.1	SD: Summary of CBC (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.1.1.2	MAD: Summary of CBC (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.1.2.1	SD: Summary of CBC Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.1.2.2	MAD: Summary of CBC Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.2.1.1	SD: Summary of Coagulation (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.2.1.2	MAD: Summary of Coagulation (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.2.2.1	SD: Summary of Coagulation Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.2.2.2	MAD: Summary of Coagulation Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.3.1.1	SD: Summary of Comprehesive Metabolic Profile (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.3.1.2	MAD: Summary of Comprehesive Metabolic Profile (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.3.2.1	SD: Summary of Comprehesive Metabolic Profile Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.3.2.2	MAD: Summary of Comprehesive Metabolic Profile Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.4.1	SD: Summary of Vital Signs (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.4.2	MAD: Summary of Vital Signs (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.5.1	SD: Summary of Vital Signs Interpretation by Timepoint	Safety
14.3.4.5.2	MAD: Summary of Vital Signs Interpretation by Timepoint	Safety
14.3.4.6.1	SD: Summary of Mean EKG (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.6.2	MAD: Summary of Mean EKG (Summary of Actual and Change from Baseline Values) by Timepoint	Safety

No.	Title	Analysis Population
14.3.4.7.1	SD: Summary of EKG Interpretation (Worst) by Timepoint	Safety
14.3.4.7.2	MAD: Summary of EKG Interpretation (Worst) by Timepoint	Safety
14.3.4.8.1	SD: Summary of CURB-65 Score(Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.8.2	MAD: Summary of CURB-65 Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.9.1	SD: Summary of PSI Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.9.2	MAD: Summary of PSI Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.10.1	SD: Summary of PSI Risk Class by Timepoint	Safety
14.3.4.10.2	MAD: Summary of PSI Risk Class by Timepoint	Safety
14.3.4.11.1	SD: Summary of SOFA Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.11.2	MAD: Summary of SOFA Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.12.1	SD: Summary of MMSE Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.12.2	MAD: Summary of MMSE Score (Summary of Actual and Change from Baseline Values) by Timepoint	Safety
14.3.4.13.1	SD: Summary of Hospitalization	Safety
14.3.4.13.2	MAD: Summary of Hospitalization	Safety

18. LISTINGS

No.	Title	Analysis Population
16.2.1.2.1	SD: Subject Disposition	Intent-to-Treat
16.2.1.2.2	MAD: Subject Disposition	Intent-to-Treat
16.2.2.1	SD: Protocol Deviations	Intent-to-Treat
16.2.2.2	MAD: Protocol Deviations	Intent-to-Treat
16.2.3.1	SD: Analysis Populations	Intent-to-Treat
16.2.3.2	MAD: Analysis Populations	Intent-to-Treat
16.2.4.1.1	SD: Demographics and Baseline Characteristics	Intent-to-Treat
16.2.4.1.2	MAD: Demographics and Baseline Characteristics	Intent-to-Treat
16.2.4.2.1	SD: Viral Serology	Intent-to-Treat
16.2.4.2.2	MAD: Viral Serology	Intent-to-Treat
16.2.4.3.1	SD: Medical History	Intent-to-Treat
16.2.4.3.2	MAD: Medical History	Intent-to-Treat
16.2.4.4.1	SD: Pregnancy Test Results	Intent-to-Treat
16.2.4.4.2	MAD: Pregnancy Test Results	Intent-to-Treat
16.2.4.5.1	SD: Confirmation of CAP	Intent-to-Treat
16.2.4.5.2	MAD: Confirmation of CAP	Intent-to-Treat
16.2.4.6.1	SD: Eligibility Assessment	Intent-to-Treat
16.2.4.6.2	MAD: Eligibility Criteria	Intent-to-Treat
16.2.4.7.1	SD: Prior Medications	Intent-to-Treat
16.2.4.7.2	MAD: Prior Medications	Intent-to-Treat
16.2.5.1.1	SD: Randomization	Intent-to-Treat
16.2.5.1.2	MAD: Randomization	Intent-to-Treat
16.2.5.2.1	SD: Study Drug Administration	Intent-to-Treat
16.2.5.2.2	MAD: Study Drug Administration	Intent-to-Treat
16.2.5.3.1	SD: Study Drug Interruption	Intent-to-Treat
16.2.5.3.2	MAD: Study Drug Interruption	Intent-to-Treat
16.2.6.1.1	SD: Individual pGSN Plasma Concentrations (unit)	Intent-to-Treat

No.	Title	Analysis Population
16.2.6.1.2	MAD: Individual pGSN Plasma Concentrations (unit)	Intent-to-Treat
16.2.6.2.1	SD: Individual Estimated Plasma rhu-pGSN Concentrations (unit)	Intent-to-Treat
16.2.6.2.2	MAD: Individual Estimated Plasma rhu-pGSN Plasma Concentrations (unit)	Intent-to-Treat
16.2.6.3.1	SD: Individual pGSN Plasma PK Parameters	Intent-to-Treat
16.2.6.3.2	MAD: Individual pGSN Plasma PK Parameters by Day	Intent-to-Treat
16.2.6.4.1	SD: Individual Estimated Plasma rhu-pGSN Plasma PK Parameters	Intent-to-Treat
16.2.6.4.2	MAD: Individual Estimated Plasma rhu-pGSN Plasma PK Parameters by Day	Intent-to-Treat
16.2.6.5.1	SD: Anti-rhu-pGSN Antibodies	Intent-to-Treat
16.2.6.5.2	MAD: Anti-rhu-pGSN Antibodies	Intent-to-Treat
16.2.6.6.1	SD: Biomarkers	Intent-to-Treat
16.2.6.6.2	MAD: Biomarkers	Intent-to-Treat
16.2.6.7.1	SD: Sputum and Blood Culture	Intent-to-Treat
16.2.6.7.2	MAD: Sputum and Blood Culture	Intent-to-Treat
16.2.7.1.1	SD: Adverse Events	Intent-to-Treat
16.2.7.1.2	MAD: Adverse Events	Intent-to-Treat
16.2.7.2.1	SD: Serious Adverse Events	Intent-to-Treat
16.2.7.2.2	MAD: Serious Adverse Events	Intent-to-Treat
16.2.7.3.1	SD: Adverse Events Leading to Study Medication Discontinuation	Intent-to-Treat
16.2.7.3.2	MAD: Adverse Events Leading to Study Medication Discontinuation	Intent-to-Treat
16.2.7.4.1	SD: Overall Survival	Intent-to-Treat
16.2.7.4.2	MAD: Overall Survival	Intent-to-Treat
16.2.8.1.1.1	SD: CBC	Intent-to-Treat
16.2.8.1.1.2	MAD: CBC	Intent-to-Treat
16.2.8.1.2.1	SD: Abnormal CBC	Intent-to-Treat
16.2.8.1.2.2	MAD: Abnormal CBC	Intent-to-Treat
16.2.8.2.1.1	SD: Coagulation	Intent-to-Treat
16.2.8.2.1.2	MAD: Coagulation	Intent-to-Treat
16.2.8.2.2.1	SD: Abnormal Coagulation	Intent-to-Treat
16.2.8.2.2.2	MAD: Abnormal Coagulation	Intent-to-Treat
16.2.8.3.1.1	SD: Comprehensive Metabolic Profile	Intent-to-Treat
16.2.8.3.1.2	MAD: Comprehensive Metabolic Profile	Intent-to-Treat

No.	Title	Analysis Population
16.2.8.3.2.1	SD: Abnormal Comprehensive Metabolic Profile	Intent-to-Treat
16.2.8.3.2.2	MAD: Abnormal Comprehensive Metabolic Profile	Intent-to-Treat
16.2.9.1	SD: Vital Signs	Intent-to-Treat
16.2.9.2	MAD: Vital Signs	Intent-to-Treat
16.2.10.1	SD: EKG	Intent-to-Treat
16.2.10.2	MAD: EKG	Intent-to-Treat
16.2.11.1	SD: Physical Examination	Intent-to-Treat
16.2.11.2	MAD: Physical Examination	Intent-to-Treat
16.2.12.1.1	SD: Outcome Prediction Models CURB-65	Intent-to-Treat
16.2.12.1.2	MAD: Outcome Prediction Models CURB-65	Intent-to-Treat
16.2.12.2.1	SD: Outcome Prediction Models PSI (Port Score)	Intent-to-Treat
16.2.12.2.2	MAD: Outcome Prediction Models PSI (Port Score)	Intent-to-Treat
16.2.12.3.1	SD: Outcome Prediction Models SOFA Score	Intent-to-Treat
16.2.12.3.2	MAD: Outcome Prediction Models SOFA Score	Intent-to-Treat
16.2.12.4.1	SD: Outcome Prediction Models MMSE Score	Intent-to-Treat
16.2.12.4.2	MAD: Outcome Prediction Models MMSE Score	Intent-to-Treat
16.2.13.1	SD: Concomitant Medications	Intent-to-Treat
16.2.13.2	MAD: Concomitant Medication	Intent-to-Treat
16.2.14.1	SD: Hospitalization Follow-Up	Intent-to-Treat
16.2.14.2	MAD: Hospitalization Follow-Up	Intent-to-Treat

19. FIGURES

No.	Title	Analysis Population
14.2.1.1	Individual pGSN Plasma Concentrations (ng/mL) (Linear scale) by Day	PK
14.2.1.2	Individual pGSN Plasma Concentrations (ng/mL) (Semi-logarithmic) by Day	PK
14.2.2.1	Individual Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on the Double Delta Analysis (Linear scale) by Day	PK
14.2.2.2	Individual Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on the Double Delta Analysis (Linear scale) by Day	PK
14.2.3.1	Mean (+/-SD) pGSN Plasma Concentrations (ng/mL) (Linear scale) by Day	PK
14.2.3.2	Mean (+/-SD) pGSN Plasma Concentrations (ng/mL) based on Changes from Pre-Injection (Linear scale) by Day (Semi-logarithmic) by Day	PK
14.2.4.1	Mean (+/-SD) Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on Changes from Pre-Injection (Linear scale) by Day	PK
14.2.4.2	Mean (+/-SD) Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on the Double Delta Analysis (Linear scale) by Day	PK
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14.3.2.2	MAD: Kaplan-Meier Plot of Length of Stay in Hospital (hours)	Safety
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20. APPENDICES

No.	Title	Analysis Population
14.3.3.9.1	SD: Summary of Overall Survival	Safety
14.3.3.9.2	MAD: Summary of Overall Survival	Safety
14.3.4.13.1	SD: Summary of Hospitalization	Safety
14.3.4.13.2	MAD: Summary of Hospitalization	Safety

21. REFERENCES

1) Clinical Study Protocol Amendment 1.0, 30 April 2018.

BTI-201: Mock Tables: Table of Contents

Tables

GENERAL COMMENTS

- Where a count is 0, the percentage will not be shown (e.g. 0 (0.0%) will be displayed as 0)
- Unless otherwise states, parameters will be listed in alphabetical order
- Percentages and their 95% CI, where appropriate, will be presented to one decimal place
- The minimum and maximum values will be presented to the same number of decimal places as recorded in the electronic Case Report Form (eCRF)
- Mean, median, and SD will be presented to one more decimal place than the raw data
- Percentages will be rounded to one decimal place, with the denominator being the number of subjects in the relevant population with non-missing data, unless otherwise specified
- Change from Baseline:
  Change from Baseline will be calculated as:

$$Change\ from\ baseline = new\ value - baseline\ value$$

- Unscheduled visits will be excluded from summary tables
- Names and order of Treatment Groups
  SD:
  - rhu-pGSN 6 mg/kg;
  - Placebo;
  - Overall.

  MAD:
  - rhu-pGSN 6 mg/kg;
  - rhu-pGSN 12 mg/kg;
  - rhu-pGSN 24 mg/kg;
  - Combined Placebo;
  - Overall.

- Names of visits
  SD:
    - Screening
    - Day 1
    - Day 2
    - Day 3/4
    - Day 7
    - Day 14
    - Day 28 / Early Termination (Combined visit for safety and PD)

  MAD:
    - Screening
    - Day 1
    - Day 2
    - Day 3
    - Day 4
    - Day 7
    - Day 14
    - Day 28 / Early Termination (Combined visit for safety and PD)
- Column widths and text-wrapping may be altered in final output in order to best present the data
- Footnotes may be added/amended if required

Table 14.1.1.1 SD: Summary of Subject Enrolment and Disposition
Protocol: BTI-201
Intent-to-Treat Population

	rhu-pGSN 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Number of Subjects Screened	xx	xx	xx
Number of Screening Failures[1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Randomized	xx	xx	xx
Number of Subjects who Completed the Study	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Discontinued	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Primary Reason for Discontinuation of Study			
Due to Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject withdrew consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-Compliance with the study procedures/protocol	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any clinically significant change in subject's medical condition	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Sponsor ended study	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects included in the ITT Population	x (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects included in the Safety Population	x (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects included in the PK Population	x (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects included in the PP Population	x (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1]Percentages are based on number of subjects screened.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.1.1.2 MAD: Summary of Subject Enrolment and Disposition
Protocol: BTI-201
Intent-to-Treat Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.1.1.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.1.2.1 SD: Summary of Demographics and Baseline Characteristics
Protocol: BTI-201
Intent-to-Treat Population

		rhu-pGSN 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Age (years) at Screening	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	SD	x.x	x.x	xx.x
	Minimum	xx	xx	xx
	Maximum	xx	xx	xx
Sex n(%)	Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race n(%)	Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Black or African	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Aborigine/Torres Strait Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Childbearing Potential n(%)*	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

*Percentages are based on the number of female participants.
SD: Standard Deviation

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.1.2.1 SD: Summary of Demographics and Baseline Characteristics
Protocol: BTI-201
Intent-to-Treat Population

		rhu-pGSN 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Height (cm)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	SD	x.x	x.x	xx.x
	Minimum	xx	xx	xx
	Maximum	xx	xx	xx
Weight (kg)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	SD	x.x	x.x	xx.x
	Minimum	xx	xx	xx
	Maximum	xx	xx	xx

*Percentages are based on the number of female participants.
SD: Standard Deviation

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.1.2.2 MAD: Summary of Demographics and Baseline Characteristics
Protocol: BTI-201
Intent-to-Treat Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name (version x.x), Output: filepath_name Created: DDMMMYYYY

Programming Note:
Repeat Table 14.1.2.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.2.1.1 Day 1: Summary of Plasma pGSN Concentrations (unit) by Timepoint
Protocol: BTI-201
PK Population

Time Point		SD/MAD rhu-pGSN 6 mg/kg (N=xx)			MAD rhu-pGSN 12 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Ratio from Pre-Injection	Ratio from Pre-Injection/ Placebo Ratio from Pre-Injection	Actual Value	Ratio from Pre-Injection	Ratio from Pre-Injection/ Placebo Ratio from Pre-Injection	Actual Value	Ratio from Pre-Injection
Pre-Injection	n	x			x			x	
	Mean	x.x			x.x			x.x	
	Median	x.x			x.x			x.x	
	SD	x.x			x.x			x.x	
	Minimum	x			x			x	
	Maximum	x			x			x	
	CV%	x.x			x.x			x.x	
	GeoMean	x.x			x.x			x.x	
	GeoCV%	x.x			x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	ln SD		x.x	x.x		x.x	x.x		x.x
	GeoMean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

….

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.1 Day 1: Summary of Plasma pGSN Concentrations (unit) by Timepoint (continued)
Protocol: BTI-201
PK Population

Time Point		MAD rhu-pGSN 24 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Ratio from Pre-Injection	Ratio from Pre-Injection/ Placebo Ratio from Pre-Injection	Actual Value	Ratio from Pre-Injection
Pre-Injection	n	x			x	
	Mean	x.x			x.x	
	Median	x.x			x.x	
	SD	x.x			x.x	
	Minimum	x			x	
	Maximum	x			x	
	CV%	x.x			x.x	
	GeoMean	x.x			x.x	
	GeoCV%	x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x
	Maximum	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x
	ln SD		x.x	x.x		x.x
	GeoMean	x.x	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

….

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.2 Day 2: Summary of Plasma pGSN Concentrations (unit) by Timepoint
Protocol: BTI-201
PK Population

Time Point		MAD rhu-pGSN 6 mg/kg (N=xx)			MAD rhu-pGSN 12 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Ratio from Pre-Injection	Ratio from Pre-Injection/ Placebo Ratio from Pre-Injection	Actual Value	Ratio from Pre-Injection	Ratio from Pre-Injection/ Placebo Ratio from Pre-Injection	Actual Value	Ratio from Pre-Injection
Pre-Injection	n	x			x			x	
	Mean	x.x			x.x			x.x	
	Median	x.x			x.x			x.x	
	SD	x.x			x.x			x.x	
	Minimum	x			x			x	
	Maximum	x			x			x	
	CV%	x.x			x.x			x.x	
	GeoMean	x.x			x.x			x.x	
	GeoCV%	x.x			x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	ln SD		x.x	x.x		x.x	x.x		x.x
	GeoMean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….									

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.2 Day 2: Summary of Plasma pGSN Concentrations (unit) by Timepoint (continued)
Protocol: BTI-201
PK Population

Time Point		MAD rhu-pGSN 24 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Ratio from Pre-Injection	Ratio from Pre-Injection/ Placebo Ratio from Pre-Injection	Actual Value	Ratio from Pre-Injection
Pre-Injection	n	x			x	
	Mean	x.x			x.x	
	Median	x.x			x.x	
	SD	x.x			x.x	
	Minimum	x			x	
	Maximum	x			x	
	CV%	x.x			x.x	
	GeoMean	x.x			x.x	
	GeoCV%	x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x
	Maximum	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x
	ln SD		x.x	x.x		x.x
	GeoMean	x.x	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

….

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.3 Day 3: Summary of Plasma pGSN Concentrations (unit) by Timepoint
Protocol: BTI-201
PK Population

Programming Note: Repeat Table 14.2.1.2 for Day 3.

Table 14.2.1.4 Day 1: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint
Protocol: BTI-201
PK Population

Time Point		SD/MAD rhu-pGSN 6 mg/kg (N=xx)			MAD rhu-pGSN 12 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Change from Pre-Injection	(Change from Pre-Injection)-(Mean Placebo Change from Pre-Injection)	Actual Value	Change from Pre-Injection	(Change from Pre-Injection)-(Mean Placebo Change from Pre-Injection)	Actual Value	Change from Pre-Injection
Pre-Injection	n	x			x			x	
	Mean	x.x			x.x			x.x	
	Median	x.x			x.x			x.x	
	SD	x.x			x.x			x.x	
	Minimum	x			x			x	
	Maximum	x			x			x	
	CV%	x.x			x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)			x (xx.x%)			x (xx.x%)	
….									

SD: Standard Deviation; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.4 Day 1: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint (continued)
Protocol: BTI-201
PK Population

Time Point		MAD rhu-pGSN 24 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Change from Pre-Injection	(Change from Pre-Injection)-(Mean Placebo Change from Pre-Injection)	Actual Value	Change from Pre-Injection
Pre-Injection	n	x			x	
	Mean	x.x			x.x	
	Median	x.x			x.x	
	SD	x.x			x.x	
	Minimum	x			x	
	Maximum	x			x	
	CV%	x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x
	Maximum	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)			x (xx.x%)	
….						

SD: Standard Deviation; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.5 Day 2: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint
Protocol: BTI-201
PK Population

Time Point		MAD rhu-pGSN 6 mg/kg (N=xx)			MAD rhu-pGSN 12 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Change from Pre-Injection	(Change from Pre-Injection)-(Mean Placebo Change from Pre-Injection)	Actual Value	Change from Pre-Injection	(Change from Pre-Injection)-(Mean Placebo Change from Pre-Injection)	Actual Value	Change from Pre-Injection
Pre-Injection	n	x			x			x	
	Mean	x.x			x.x			x.x	
	Median	x.x			x.x			x.x	
	SD	x.x			x.x			x.x	
	Minimum	x			x			x	
	Maximum	x			x			x	
	CV%	x.x			x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)			x (xx.x%)			x (xx.x%)	
….									

SD: Standard Deviation; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.5 Day 2: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint (continued)
Protocol: BTI-201
PK Population

Time Point		MAD rhu-pGSN 24 mg/kg (N=xx)			Placebo (N=xx)	
		Actual Value	Change from Pre-Injection	(Change from Pre-Injection)-(Mean Placebo Change from Pre-Injection)	Actual Value	Change from Pre-Injection
Pre-Injection	n	x			x	
	Mean	x.x			x.x	
	Median	x.x			x.x	
	SD	x.x			x.x	
	Minimum	x			x	
	Maximum	x			x	
	CV%	x.x			x.x	
	BLQ	x (xx.x%)			x (xx.x%)	
5 to 10 mins post	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x
	Maximum	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x
	BLQ	x (xx.x%)			x (xx.x%)	
….						

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%; BLQ: Below Limit of Quantification

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all timepoints.

Table 14.2.1.6 Day 3: Summary of Estimated Plasma rhu-pGSN Concentrations (unit) by Timepoint
Protocol: BTI-201
PK Population

Programming Note: Repeat Table 14.2.1.5 for Day 3.

Table 14.2.2.1 Day 1: Summary of Plasma pGSN PK Parameters
Protocol: BTI-201
PK Population

Parameter (unit)		SD/MAD rhu-pGSN 6 mg/kg (N=xx)	MAD rhu-pGSN 12 mg/kg (N=xx)	MAD rhu-pGSN 24 mg/kg (N=xx)	Placebo (N=xx)
AUC_{0-t} (unit)	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x
	Median	x	x	x	x
	Maximum	x	x	x	x
	CV%	x.x	x.x	x.x	x.x
	GeoMean	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x
C_{max} (unit)	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x
	Median	x	x	x	x
	Maximum	x	x	x	x
	CV%	x.x	x.x	x.x	x.x
	GeoMean	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all PK parameters.

Table 14.2.2.2 Day 2: Summary of Plasma pGSN PK Parameters
Protocol: BTI-201
PK Population

Parameter (unit)		MAD rhu-pGSN 6 mg/kg (N=xx)	MAD rhu-pGSN 12 mg/kg (N=xx)	MAD rhu-pGSN 24 mg/kg (N=xx)	Placebo (N=xx)
AUC_{0-t} (unit)	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x
	Median	x	x	x	x
	Maximum	x	x	x	x
	CV%	x.x	x.x	x.x	x.x
	GeoMean	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x
C_{max} (unit)	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x
	Median	x	x	x	x
	Maximum	x	x	x	x
	CV%	x.x	x.x	x.x	x.x
	GeoMean	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all PK parameters.

Table 14.2.2.3 Day 3: Summary of Plasma pGSN PK Parameters
Protocol: BTI-201
PK Population

Parameter (unit)		MAD rhu-pGSN 6 mg/kg (N=xx)	MAD rhu-pGSN 12 mg/kg (N=xx)	MAD rhu-pGSN 24 mg/kg (N=xx)	Placebo (N=xx)
AUC_{0-t} (unit)	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x
	Median	x	x	x	x
	Maximum	x	x	x	x
	CV%	x.x	x.x	x.x	x.x
	GeoMean	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x
C_{max} (unit)	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x
	Median	x	x	x	x
	Maximum	x	x	x	x
	CV%	x.x	x.x	x.x	x.x
	GeoMean	x.x	x.x	x.x	x.x
	GeoCV%	x.x	x.x	x.x	x.x

SD: Standard Deviation; GeoMean: Geometric Mean; GeoCV%: Geometric CV%

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all PK parameters.

Table 14.2.3.1 Day 1: Summary of Estimated Plasma rhu-pGSN PK Parameters
Protocol: BTI-201
PK Population

		SD/MAD rhu-pGSN 6 mg/kg (N=xx)		MAD rhu-pGSN 12 mg/kg (N=xx)		MAD rhu-pGSN 24 mg/kg (N=xx)	
Parameter (unit)		Change from Pre-Injection	Double Delta Analysis	Change from Pre-Injection	Double Delta Analysis	Change from Pre-Injection	Double Delta Analysis
AUC_{0-t} (unit)	n	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x
C_{max} (unit)	n	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x

SD: Standard Deviation;

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Include the following: PK parameters (including dose normalized parameters):

- AUC_{0-t}
- AUC_{0-8h}
- C_{max}

Table 14.2.3.2 Day 2: Summary of Estimated Plasma rhu-pGSN PK Parameters
Protocol: BTI-201
PK Population

		MAD rhu-pGSN 6 mg/kg (N=xx)		MAD rhu-pGSN 12 mg/kg (N=xx)		MAD rhu-pGSN 24 mg/kg (N=xx)	
Parameter (unit)		Change from Pre-Injection	Double Delta Analysis	Change from Pre-Injection	Double Delta Analysis	Change from Pre-Injection	Double Delta Analysis
AUC_{0-t} (unit)	n	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x
C_{max} (unit)	n	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x

SD: Standard Deviation;

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Include the following: PK parameters (including dose normalized parameters):

- AUC_{0-t}
- AUC_{0-8h}
- C_{max}

Table 14.2.3.3 Day 3: Summary of Estimated Plasma rhu-pGSN PK Parameters
Protocol: BTI-201
PK Population

		MAD rhu-pGSN 6 mg/kg (N=xx)		MAD rhu-pGSN 12 mg/kg (N=xx)		MAD rhu-pGSN 24 mg/kg (N=xx)	
Parameter (unit)		Change from Pre-Injection	Double Delta Analysis	Change from Pre-Injection	Double Delta Analysis	Change from Pre-Injection	Double Delta Analysis
AUC_{0-t} (unit)	n	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x
C_{max} (unit)	n	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x
	SD	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x
	CV%	x.x	x.x	x.x	x.x	x.x	x.x

SD: Standard Deviation;

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Include the following: PK parameters (including dose normalized parameters):

- AUC_{0-t}
- AUC_{0-8h}
- C_{max}

Table 14.2.4.1 SD: Summary of PD Parameters
Protocol: BTI-201
Intent-to-Treat Population

			rhu-pGSN 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Parameter	Visit		Actual Value	Ratio from Baseline[1]	Actual Value	Ratio from Baseline[1]	Actual Value	Ratio from Baseline[1]
Procalcitonin (unit)	Baseline[1]	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
		GeoMean	x.xxx		x.xxx		x.xxx	
	Day 2	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		ln SD		x.xxx		x.xxx		x.xxx
		GeoMean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Day 3 or 4	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		ln SD		x.xxx		x.xxx		x.xxx
		GeoMean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration. Unscheduled visits not included in post baseline assessments.

Programming Note: Repeat for all PD parameters and all scheduled post baseline timepoints.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.2.4.2 MAD: Summary of PD Parameters
Protocol: BTI-201
Intent-to-Treat Population

Programming Note:
Repeat Table 14.2.4.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.2.5.1 SD: Summary of PD Parameters
Protocol: BTI-201
Per Protocol Population

			rhu-pGSN 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Parameter	Visit		Actual Value	Ratio from Baseline[1]	Actual Value	Ratio from Baseline[1]	Actual Value	Ratio from Baseline[1]
Procalcitonin (unit)	Baseline[1]	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
		GeoMean	x.xxx		x.xxx		x.xxx	
	Day 2	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		ln SD		x.xxx		x.xxx		x.xxx
		GeoMean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Day 3 or 4	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		ln SD		x.xxx		x.xxx		x.xxx
		GeoMean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration. Unscheduled visits not included in post baseline assessments.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note: Repeat for all PD parameters and all scheduled post baseline timepoints.

Table 14.2.5.2 MAD: Summary of PD Parameters
Protocol: BTI-201
Per Protocol Population

Programming Note:
Repeat Table 14.2.5.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.1.1 SD: Summary of Concomitant Medication
Protocol: BTI-201
Safety Population

Anatomic Therapeutic Classification (ATC3) Preferred Term (PT)	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one Concomitant Medication	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC3/1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC3/2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC3/3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: If a subject has multiple occurrences of a medication, the subject is presented only once in the subject count (N).
Occurrences are counted each time in the mentions/Occurrence (M) column.
WHO-DD, XXXX

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.1.2 MAD: Summary of Prior and Concomitant Medication
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.1.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.1.1 SD: Overall Summary of Treatment-Emergent Adverse Events
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Number of subjects reporting at least:			
One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One NCI-CTEAE Grade 3 TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One Drug Related TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
TEAE Leading to Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One Procedure Related TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One TEAE leading to study treatment discontinuation	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Number of subjects reporting TEAEs by NCI-CTEAE Grade			
Grade 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Number of subjects reporting TEAEs by relationship to study medication			
Definitely not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely Related			
Number of subjects reporting TEAEs by relationship to study procedure			
Definitely not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely Related			

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term. Occurrences are counted each time in the mentions/occurrence (M) column. Related TEAE = A Possibly , Probably related TEAE or Definitely Related.MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.1.2 MAD: Overall Summary of Treatment-Emergent Adverse Events
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.1.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.2.1 SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.2.2 MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.2.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.3.1 SD: Summary of Treatment-Emergent Deaths (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one TEAE leading to Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.3.2 MAD: Summary of Treatment-Emergent Deaths (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.3.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.4.1 SD: Summary of Serious Treatment-Emergent Adverse Events (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.4.2 MAD: Summary of Serious Treatment-Emergent Adverse Events (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.4.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.5.1 SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and NCI-CTCAE Grade)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Grade 5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.5.2 MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and NCI-CTCAE Grade)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.5.1
Include: rhu-pGSN 6 mg/kg
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.1.6.1 SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Drug)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.6.2 MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Drug)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.6.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.7.1 SD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Procedure)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably not Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Definitely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.7.2 MAD: Summary of Treatment-Emergent Adverse Events (Summary by SOC, PT and Relationship to Study Procedure)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.7.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.8.1 SD: Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

	rhu-pGSN 6 mg/kg (N=xx) n (%) M	Placebo (N=xx) n (%) M	Overall (N=xx) n (%) M
Subjects with at least one TEAE Leading to Treatment Discontinuation	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT6	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Patient count (n) column for a given System Organ Class and Preferred Term.
Occurrences are counted each time in the mentions/Occurrence (M) column.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.8.2 MAD: Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation (Summary by SOC, PT)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.8.1
Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.3.9.1 SD: Summary of Overall Survival
Protocol: BTI-201
Safety Population

	rhu-pGSN: 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Deaths			
Number of Subjects that Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects that did not Die	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Survival Time (days) (95% CI[1])			
25th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Median	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
75th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)

Note: CI = Confidence Interval; [1]Brookmeyer and Crowley method (1982. Log-log transformation);
Overall Survival is defined as the difference (in days) between the
time of first study drug administration to the date of death + 1 (Include the day of the study drug administration.)
Subjects who did not die will be censored at the study exit visit.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.3.9.2 MAD: Summary of Overall Survival
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.3.9.1

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.1.1.1 SD: Summary of CBC (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Parameter	Visit		rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
			Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Hemoglobin (g/L)	Baseline[1]	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
	Day 2	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
	Day 3 or 4	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all CBC Parameters and all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.1.1.2 MAD: Summary of CBC (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.1.1.1
Include all CBC Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.1.2.1 SD: Summary of CBC Shifts from Baseline (Low, Normal, High)
Protocol: BTI-201
Safety Population

			Baseline[1]				
			rhu-pGSN: 6 mg/kg (N=xx)				
Parameter		Result Classification	Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
Hemoglobin (g/L)	Day 2	Low					
		Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day 3 or 4	Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.	etc.						

Note [1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Also Include: Placebo,
Overall

Include all CBC Parameters and all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.1.2.2 MAD: Summary of CBC Shifts from Baseline (Low, Normal, High)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.1.2.1
Include all CBC Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.2.1.1 SD: Summary of Coagulation (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

			rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Parameter	Visit		Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
PT/INR (unit)	Baseline[1]	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
	Day 2	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
	Day 3 or 4	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all Coagulation Parameters and all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.2.1.2 MAD: Summary of Coagulation (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.2.1.1
Include all Coagulation Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.2.2.1 SD: Summary of Coagulation Shifts from Baseline (Low, Normal, High)
Protocol: BTI-201
Safety Population

			Baseline[1]				
			rhu-pGSN: 6 mg/kg (N=xx)				
Parameter		Result Classification	Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
PT/INR (unit)	Day 2	Low					
		Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day 3 or 4	Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.	etc.						

Note [1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Also Include: Placebo,
Overall

Include all Coagulation Parameters and all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.2.2.2 MAD: Summary of Coagulation Shifts from Baseline (Low, Normal, High)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.2.2.1
Include all Coagulation Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.3.1.1 SD: Summary of Comprehensive Metabolic Profile (Summary of Actual and Change from Baseline Values) by Timepoint

Protocol: BTI-201
Safety Population

Parameter	Visit		rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
			Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Sodium (unit)	Baseline[1]	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
	Day 2	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
	Day 3 or 4	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all Comprehensive Metabolic Profile Parameters and all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.3.1.2 MAD: Summary of Comprehensive Metabolic Profile (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.3.1.1
Include all Comprehensive Metabolic Profile Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.3.2.1 SD: Summary of Comprehensive Metabolic Profile Shifts from Baseline (Low, Normal, High)
Protocol: BTI-201
Safety Population

			Baseline[1]				
			rhu-pGSN: 6 mg/kg (N=xx)				
Parameter		Result Classification	Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
Sodium (unit)	Day 2	Low					
		Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day 3 or 4	Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.	etc.						

Note [1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Also Include: Placebo,
Overall

Include all Comprehensive Metabolic Profile Parameters and all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.3.2.2 MAD: Summary of Comprehensive Metabolic Profile Shifts from Baseline (Low, Normal, High)
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.3.2.1
Include all Comprehensive Metabolic Profile Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.4.1 SD: Summary of Vital Signs (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

			rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Parameter	Visit		Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Systolic blood pressure (mmHg)	Baseline[1]	n	x		x			
		Mean	x.xxx		x.xxx			
		Median	x.xxx		x.xxx			
		SD	x.xxx		x.xxx			
		Minimum	x.xx		x.xx			
		Maximum	x.xx		x.xx			
	Day 1: End of Infusion	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Day 1: 30 mins	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration. Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all Vital Signs Parameters and all time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.4.2 MAD: Summary of Vital Signs (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.4.1
Include all Vital Sign Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.5.1 SD: Summary of Vital Signs Interpretation by Timepoint
Protocol: BTI-201
Safety Population

Visit		rhu-pGSN: 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline[1]	n	xx	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1: 30 mins	n	xx	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	n	xx	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.	etc.			

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
NCS = Not Clinically Significant; CS = Clinically Significant.
Unscheduled visits not included in post baseline assessments.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.5.2 MAD: Summary of Vital Signs Interpretation by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.5.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.6.1 SD: Summary of Mean EKG (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

			rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Parameter	Visit		Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Heart Rate (unit)	Baseline[1]	n	x		x			
		Mean	x.xxx		x.xxx			
		Median	x.xxx		x.xxx			
		SD	x.xxx		x.xxx			
		Minimum	x.xx		x.xx			
		Maximum	x.xx		x.xx			
	Day 28 / Early Termination	n	x	x	x	x	x	x
		Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
PR Interval (unit)	Baseline[1]	n	x		x		x	
		Mean	x.xxx		x.xxx		x.xxx	
		Median	x.xxx		x.xxx		x.xxx	
		SD	x.xxx		x.xxx		x.xxx	
		Minimum	x.xx		x.xx		x.xx	
		Maximum	x.xx		x.xx		x.xx	
etc.	etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration. Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all EKG Parameters and all time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.6.2 MAD: Summary of Mean EKG (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.6.1
Include all EKG Parameters and all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.7.1 SD: Summary of EKG Interpretation (Worst) by Timepoint
Protocol: BTI-201
Safety Population

Visit		rhu-pGSN: 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline[1]	n	xx	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 28 / Early Termination	n	xx	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
NCS = Not Clinically Significant; CS = Clinically Significant.
Unscheduled visits not included in post baseline assessments.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.7.2 MAD: Summary of EKG Interpretation (Worst) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.7.1

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.8.1 SD: Summary of CURB-65 Score(Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

		rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Visit		Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Baseline[1]	n	x		x			
	Mean	x.xxx		x.xxx			
	Median	x.xxx		x.xxx			
	SD	x.xxx		x.xxx			
	Minimum	x.xx		x.xx			
	Maximum	x.xx		x.xx			
Day 3 or 4	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Day 7	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.8.2 MAD: Summary of CURB-65 Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.8.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.9.1 SD: Summary of PSI Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

		rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Visit		Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Baseline[1]	n	x		x			
	Mean	x.xxx		x.xxx			
	Median	x.xxx		x.xxx			
	SD	x.xxx		x.xxx			
	Minimum	x.xx		x.xx			
	Maximum	x.xx		x.xx			
Day 3 or 4	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Day 7	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.9.2 MAD: Summary of PSI Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.9.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.10.1 SD: Summary of PSI Risk Class by Timepoint
Protocol: BTI-201
Safety Population

Visit	Risk Class	rhu-pGSN: 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline[1]	n	xx	xx	xx
	Class I	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class II	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class III	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class IV	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class V	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 28 / Early Termination	n	xx	xx	xx
	Class I	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class II	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class III	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class IV	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Class V	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
NCS = Not Clinically Significant; CS = Clinically Significant.
Unscheduled visits not included in post baseline assessments.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.10.2 MAD: Summary of PSI Risk Class by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.10.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.11.1 SD: Summary of SOFA Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Visit		rhu-pGSN: 6 mg/kg (N=xx) Actual Value	rhu-pGSN: 6 mg/kg (N=xx) Change from Baseline[1]	Placebo (N=xx) Actual Value	Placebo (N=xx) Change from Baseline[1]	Overall (N=xx) Actual Value	Overall (N=xx) Change from Baseline[1]
Baseline[1]	n	x		x			
	Mean	x.xxx		x.xxx			
	Median	x.xxx		x.xxx			
	SD	x.xxx		x.xxx			
	Minimum	x.xx		x.xx			
	Maximum	x.xx		x.xx			
Day 3 or 4	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Day 7	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.11.2 MAD: Summary of SOFA Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.11.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.12.1 SD: Summary of MMSE Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Visit		rhu-pGSN: 6 mg/kg (N=xx)		Placebo (N=xx)		Overall (N=xx)	
		Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]	Actual Value	Change from Baseline[1]
Baseline[1]	n	x		x			
	Mean	x.xxx		x.xxx			
	Median	x.xxx		x.xxx			
	SD	x.xxx		x.xxx			
	Minimum	x.xx		x.xx			
	Maximum	x.xx		x.xx			
Day 3 or 4	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Day 7	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Minimum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Maximum	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
etc.							

Note: SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
Unscheduled visits not included in post baseline assessments.

Programming Note:
Include all scheduled time points.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.12.2 MAD: Summary of MMSE Score (Summary of Actual and Change from Baseline Values) by Timepoint
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.12.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

Table 14.3.4.13.1 SD: Summary of Hospitalization
Protocol: BTI-201
Safety Population

Parameter (Kaplan-Meier Estimates)	rhu-pGSN: 6 mg/kg (N=xx)	Placebo (N=xx)	Overall (N=xx)
Hospital Stay			
Number of Subjects Discharged	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects not Discharged	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Length of Stay in Hospital (hours) (95% CI[1])			
25th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Median	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
75th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
ICU Stay			
Number of Subjects in ICU	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects not in ICU	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Length of Stay in ICU (days) (95% CI[1])			
25th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Median	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
75th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Intubation			
Number of Subjects Intubated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects not Intubated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Length of Intubation (days) (95% CI[1])			
25th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Median	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
75th Percentile	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)

Note: CI = Confidence Interval; [1]Brookmeyer and Crowley method (1982. Log-log transformation);
Length of stay in hospital is defined as the date and time of discharge/date of study exit (23:59 PM) - date and time of hospitalization admission due to CAP in hours

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Table 14.3.4.13.2 MAD: Summary of Hospitalization
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Repeat Table 14.3.4.13.1
Include all scheduled time points.

Include: rhu-pGSN 6 mg/kg;
rhu-pGSN 12 mg/kg;
rhu-pGSN 24 mg/kg;
Combined Active;
Combined Placebo;
Overall

BTI-201: Mock Listings: Table of Contents

Listings

GENERAL COMMENTS

- Unless otherwise states, parameters will be listed in alphabetical order
- Change from Baseline:
  Change from Baseline will be calculated as:

$$Change\ from\ baseline = new\ value - baseline\ value$$

- Names and order of Treatment Groups
  SD:
  - Cohort 1: rhu-pGSN 6 mg/kg;
  - Cohort 1: Placebo

  MAD:
  - Cohort 2: rhu-pGSN 6 mg/kg;
  - Cohort 2: Placebo
  - Cohort 3: rhu-pGSN 12 mg/kg;
  - Cohort 3: Placebo
  - Cohort 4: rhu-pGSN 24 mg/kg;
  - Cohort 4: Placebo
- Names of visits
  SD:
  - Screening
  - Day 1
  - Day 2
  - Day 3/4
  - Day 7
  - Day 14
  - Day 28 / Early Termination (Combined visit for safety and efficacy)
  - Unscheduled

  MAD:
  - Screening
  - Day 1
  - Day 2
  - Day 3
  - Day 4
  - Day 7
  - Day 14

    - Day 28 / Early Termination (Combined visit for safety and efficacy)
    - Unscheduled
- Column widths and text-wrapping may be altered in final output in order to best present the data
- Footnotes may be added/amended if required

Listing 16.2.1.2.1 SD: Subject Disposition
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Final Disposition	Reason for Discontinuation	Date of Study Exit (DDMMMYYYY)	Date of Last Contact (DDMMMYYYY)
XXX	Withdrawn	Due to Adverse Event: AE#: XXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
XXX	Completed		DDMMMYYYY	
XXX	Completed		DDMMMYYYY	
XXX	Withdrawn	Other: XXXXXXXXXXXXX	DDMMMYYYY	
etc.				

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.1.2.2 MAD: Subject Disposition
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.1.2.1 for MAD.

Listing 16.2.2.1 SD: Protocol Deviations
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Type of Deviation	Date of Deviation (DDMMMYYYY)	Description of Deviation
XXX	ABCD	DDMMMYYYY	ABCD
	ABCD	DDMMMYYYY	ABCD
…			
XXX	ABCD	DDMMMYYYY	ABCD
	ABCD	DDMMMYYYY	ABCD
…			
XXX	ABCD	DDMMMYYYY	ABCD
	ABCD	DDMMMYYYY	ABCD
…			
XXX	ABCD	DDMMMYYYY	ABCD
XXX	ABCD	DDMMMYYYY	ABCD

Clinical cut-off date: DDMMMYYYY Page x of x

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

```
Listing 16.2.2.2 MAD: Protocol Deviations
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg
```

Programming Note:
Repeat Listing 16.2.2.1 for MAD.

Listing 16.2.3.1 SD: Analysis Populations
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Intent-to-Treat Population	Safety Population	PK Population	Per Protocol Population
XXX	Yes	Yes	Yes	Yes
XXX	Yes	Yes	Yes	Yes
XXX	Yes	Yes	Yes	Yes
XXX	Yes	Yes	Yes	Yes
XXX	Yes	Yes	Yes	Yes
XXX	Yes	Yes	Yes	Yes
XXX	Yes	Yes	Yes	Yes
Etc.				

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

```
Listing 16.2.3.2 MAD: Analysis Populations
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg
```

Programming Note:
Repeat Listing 16.2.3.1 for MAD.

Listing 16.2.4.1.1 SD: Demographics and Baseline Characteristics
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Date of Informed Consent (DDMMMYYYY)	Protocol Version	Date of Birth (DDMMMYYYY)	Age at Informed Consent	Sex	Child Bearing Potential	Contraceptive Methods	Race	Height (cm)	Weight (kg)
XXX	DDMMMYYYY	Amendment 1	DDMMMYYYY	xx	Male			White	xxx	xx.x
XXX	DDMMMYYYY	Amendment 1	DDMMMYYYY	xx	Female	No		White	xxx	xx.x
XXX	DDMMMYYYY	Amendment 1	DDMMMYYYY	xx	Male			White	xxx	xx.x
XXX	DDMMMYYYY	Amendment 1	DDMMMYYYY	xx	Female	Yes	Hormonal methods	Other: XXXXXXXXX	xxx	xx.x
etc.										

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.4.1.2 MAD: Demographics and Baseline Characteristics
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.4.1.1 for MAD.

Listing 16.2.4.2.1 SD: Viral Serology
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Visit	Visit Date (DDMMMYYYY	Test	Result	Most Recent Viral Load (unit)	Most Recent CD4 Count (unit)
XXX	Screening	DDMMMYYYY	HIV	Negative	xxxxxx	xxx.x
			Hepatitis B Surface Antigen	Negative		
			Hepatitis C	Negative		
XXX	Screening	DDMMMYYYY	HIV	Negative	xxxxxx	xxx.x
			Hepatitis B Surface Antigen	Negative		
			Hepatitis C	Negative		
etc.						

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.4.2.2 MAD: Viral Serology
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.4.2.1 for MAD.

Listing 16.2.4.3.1 SD: Medical History
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Condition/ Body System	System Organ Class / Preferred Term	Date of Diagnosis (DDMMMYYYY)	Resolution Date (DDMMMYYYY)	Concomitant Medication Taken	Ongoing
XXX	XXXXXXXXXXX/ YYYYYYYYYYY	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	DDMMMYYYY	DDMMMYYYY	No	No
	XXXXXXXXXXX/ YYYYYYYYYYY	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	DDMMMYYYY	DDMMMYYYY	Yes	Yes
…						
XXX	XXXXXXXXXXX/ YYYYYYYYYYY	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	DDMMMYYYY	DDMMMYYYY	No	No
XXX	XXXXXXXXXXX/ YYYYYYYYYYY	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	DDMMMYYYY	DDMMMYYYY		
…						
XXX	XXXXXXXXXXX/ YYYYYYYYYYY	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	DDMMMYYYY	DDMMMYYYY	No	No
XXX	XXXXXXXXXXX/ YYYYYYYYYYY	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	DDMMMYYYY	DDMMMYYYY	No	No

Note: MedDRA Version XX.X

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.4.3.2 MAD: Medical History
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.4.3.1 for MAD.

Listing 16.2.4.4.1 SD: Pregnancy Test Results
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Assessment Performed – Reason Not Performed	Visit	Sample Date/ Time (DDMMMYYY/ HH:MM)	Sample Type	Result
XXX	Yes	Screening	DDMMMYYY/ HH:MM	Serum	Negative
		Day 1	DDMMMYYY/ HH:MM	Urine	Negative
		Day 28 / Early Termination	DDMMMYYY/ HH:MM	Urine	Negative
XXX	Yes	Screening	DDMMMYYY/ HH:MM	Serum	Negative
		Day 1	DDMMMYYY/ HH:MM	Urine	Negative
		Day 28 / Early Termination	DDMMMYYY/ HH:MM	Urine	Negative
XXX	Yes	Screening	DDMMMYYY/ HH:MM	Serum	Negative
		Day 1	DDMMMYYY/ HH:MM	Urine	Negative
		Day 28 / Early Termination	DDMMMYYY/ HH:MM	Urine	Negative
etc.					

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.4.4.2 MAD: Pregnancy Test Results
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.4.4.1 for MAD.

Listing 16.2.4.5.1 SD: Confirmation of CAP
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Visit	Visit Date (DDMMMYYY)	Was there clinical confirmation of CAP	Was there radiological confirmation of CAP (CXR or CT)	Was CXR or CT Scan Performed: Date Performed (DDMMMYYY)	CXR or CT Scan Findings	Date and Time of presentation to the hospital (DDMMMYYY/ HH:MM)	Date and Time of Hospitalization Admission due to CAP (DDMMMYYY/ HH:MM)	Subject Randomized
XXX	Screening	DDMMMYYYY	Yes	Yes	Yes: DDMMMYYYY	XXXXXXXXX	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes
XXX	Screening	DDMMMYYYY	Yes	Yes	Yes: DDMMMYYYY	XXXXXXXXX	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes
XXX	Screening	DDMMMYYYY	Yes	Yes	Yes: DDMMMYYYY	XXXXXXXXX	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes
etc.									

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

```
Listing 16.2.4.5.2 MAD: Confirmation of CAP
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg
```

Programming Note:
Repeat Listing 16.2.4.5.2 for MAD.

Listing 16.2.4.6.1 SD: Eligibility Assessment
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Eligibility Assessment Date (DDMMMYYYY)	Did the patient meet all inclusion criteria?	Inclusion criterion not met	Did the patient meet all exclusion criteria?	Exclusion Criterion not met
XXX	DDMMMYYYY	Yes		Yes	
XXX	DDMMMYYYY	Yes		Yes	
XXX	DDMMMYYYY	Yes		Yes	
XXX	DDMMMYYYY	Yes		Yes	
XXX	DDMMMYYYY	Yes		Yes	
XXX	DDMMMYYYY	Yes		Yes	

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.4.6.2 MAD: Eligibility Criteria
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.4.6.1 for MAD.

Listing 16.2.4.7.1 SD: Prior Medications
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	CM#	Drug Name/ATC3/PT	Indication	Start Date/ Stop Date (DDMMMYYYY)	Ongoing	Dose	Unit	Frequency	Route
XXX	1	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Pre-existing condition: MH#	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
	2	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Other: YYYYYY	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
XXX	1	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Other: YYYYYY	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
	2	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Other: YYYYYY	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
XXX	1	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Pre-existing condition: MH#	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
Etc.									

Note: Prior medications are defined as any medication where the use was stopped prior to the first administration of the study medication.
WHO-DD, xxxxxxxxxx

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.4.7.2 MAD: Prior Medications
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.4.7.1 for MAD.

Listing 16.2.5.1.1 SD: Randomization
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Date /Time of Randomization (DDMMMYYYY/ HH:MM)	Randomization Number	Date /Time of Emergency Unblinding (DDMMMYYYY/ HH:MM)	Reason for Emergency Unblinding
XXX	DDMMMYYYY/ HH:MM	XXXXX		
XXX	DDMMMYYYY/ HH:MM	XXXXX		
XXX	DDMMMYYYY/ HH:MM	XXXXX		
XXX	DDMMMYYYY/ HH:MM	XXXXX	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	DDMMMYYYY/ HH:MM	XXXXX		
XXX	DDMMMYYYY/ HH:MM	XXXXX		

etc.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

```
Listing 16.2.5.1.2 MAD: Randomization
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg
```

Programming Note:
Repeat Listing 16.2.5.1.1 for MAD.

Listing 16.2.5.2.1 SD: Study Drug Administration
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Visit	Was Study Drug Administered? (If no, provide reason)	Start Date/ Time of Injection (DDMMMYYYY/ HH:MM)	Stop Date/ Time of Injection (DDMMMYYYY/ HH:MM)	Study Drug Administered per Dose Prescribed	Reason not Successfully Administered	Volume Administered (mL)	Total Duration of Injection (Including Interruptions - minutes)
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	No	XXXXXXXXXXXX	xx	
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
XXX	Day 1	No - XXXXXXXXX						

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.5.2.2 MAD: Study Drug Administration
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Subject	Visit	Was Study Drug Administered? (If no, provide reason)	Start Date/ Time of Injection (DDMMMYYYY/ HH:MM)	Stop Date/ Time of Injection (DDMMMYYYY/ HH:MM)	Study Drug Administered per Dose Prescribed	Reason not Successfully Administered	Volume Administered (mL)	Total Duration of Injection (Including Interruptions - minutes)
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
	Day 2	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
	Day 3	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	No	XXXXXXXXXXX	xx	xx
XXX	Day 1	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
	Day 2	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	Yes		xx	xx
	Day 3	No - XXXXXXXXX						

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.5.3.1 SD: Study Drug Interruption
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Visit	Interruption	Date and Time of Interruption (DDMMMYYYY/ HH:MM)	Date and Time of Injection Re-start (DDMMMYYYY/ HH:MM)	Reason for Interruption
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
		2			
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.5.3.2 MAD: Study Drug Interruption
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Visit	Interruption	Date and Time of Interruption (DDMMMYYYY/ HH:MM)	Date and Time of Injection Re-start (DDMMMYYYY/ HH:MM)	Reason for Interruption
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 2	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 3	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXX	Day 1	1	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.1.1 SD: Individual pGSN Plasma Concentrations (unit)
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	Day	Date/Time of Dose on Dosing Day (DDMMMYYYY/ HH:MM)	Sampling Time	Was PK Sample Collected?	Date of PK Sample Collection (DDMMMYYYY)	Time of PK Sample Collection (HH:MM)	Time Deviation	Concen-tration (ng/mL)	Ratio from Pre-Injection Day 1	Ratio from Pre-Injection / Placebo Ratio from Pre-Injection	Comments
XXX	1	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			YYYYYYYY
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
XXX	1	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	YYYYYYYY
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
….			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.1.2 MAD: Individual pGSN Plasma Concentrations (unit)
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	Day	Date/Time of Dose on Dosing Day (DDMMMYYYY/ HH:MM)	Sampling Time	Was PK Sample Collected?	Date of PK Sample Collection (DDMMMYYYY)	Time of PK Sample Collection (HH:MM)	Time Deviation	Concen-tration (ng/mL)	Ratio from Pre-Injection Day 1	Ratio from Pre-Injection / Placebo Ratio from Pre-Injection	Comments
XXX	1	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			YYYYYYYY
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
	2	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	YYYYYYYY
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
….			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.2.1 SD: Individual Estimated Plasma rhu-pGSN Concentrations (unit)
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	Day	Date/Time of Dose on Dosing Day (DDMMMYYYY/ HH:MM)	Sampling Time	Was PK Sample Collected?	Date of PK Sample Collection (DDMMMYYYY)	Time of PK Sample Collection (HH:MM)	Time Deviation	Concen-tration (ng/mL)	Change from Pre-Injection Day 1	(Change from Pre-Injection) – (Mean Placebo Change from Pre-Injection)	Comments
XXX	1	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			YYYYYYYY
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
XXX	1	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	YYYYYYYY
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
….			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.2.2 MAD: Individual Estimated Plasma rhu-pGSN Concentrations (unit)
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	Day	Date/Time of Dose on Dosing Day (DDMMMYYYY/ HH:MM)	Sampling Time	Was PK Sample Collected?	Date of PK Sample Collection (DDMMMYYYY)	Time of PK Sample Collection (HH:MM)	Time Deviation	Concen-tration (ng/mL)	Change from Pre-Injection Day 1	(Change from Pre-Injection) – (Mean Placebo Change from Pre-Injection)	Comments
XXX	1	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			YYYYYYYY
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
	2	DDMMMYYYY/ HH:MM	Pre-Injection	Yes	DDMMMYYYY	HH:MM	xx mins	XXX			
			5 to 10 mins post	Yes	DDMMMYYYY	HH:MM	xx mins	XXX	X.XX	X.XX	YYYYYYYY
			2 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			8 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			12 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
….			16 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	
			24 hours post	Yes	DDMMMYYYY	HH:MM	xx hours	XXX	X.XX	X.XX	

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.3.1 SD: Individual pGSN Plasma PK Parameters
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Day 1

Subject Number	AUC_{0-t} (unit)	AUC_{0-8h} (unit)	AUC_{0-inf} (unit)	C_{max} (unit)	T_{max} (unit)	k_{el} (unit)	$t_{½}$ (unit)	CL/F (unit)	V_z/F (unit)	%AUC_{ext}	DN_AUC_{0-t}	DN_AUC_{0-8}	DN_AUC_{0-inf}	DN_C_{max}
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
….														

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.3.2 MAD: Individual pGSN Plasma PK Parameters by Day
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Day 1

Subject Number	AUC_{0-t} (unit)	AUC_{0-8h} (unit)	AUC_{0-inf} (unit)	C_{max} (unit)	T_{max} (unit)	k_{el} (unit)	$t_{½}$ (unit)	CL/F (unit)	V_z/F (unit)	$\%AUC_{ext}$	DN_AUC_{0-t}	DN_AUC_{0-8}	DN_AUC_{0-inf}	DN_C_{max}
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

….

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.4.1 SD: Individual Estimated Plasma rhu-pGSN PK Parameters
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Day 1

	Change from Pre-Injection						Double Delta Analysis					
Subject Number	AUC_{0-t} (unit)	AUC_{0-8h} (unit)	C_{max} (unit)	DN_AUC_{0-t}	DN_AUC_{0-8}	DN_C_{max}	AUC_{0-t} (unit)	AUC_{0-8h} (unit)	C_{max} (unit)	DN_AUC_{0-t}	DN_AUC_{0-8}	DN_C_{max}
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
….												

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.4.2 MAD: Individual Estimated Plasma rhu-pGSN PK Parameters by Day
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Day 1

	Change from Pre-Injection						Double Delta Analysis					
Subject Number	AUC_{0-t} (unit)	AUC_{0-8h} (unit)	C_{max} (unit)	DN_AUC_{0-t}	DN_AUC_{0-8}	DN_C_{max}	AUC_{0-t} (unit)	AUC_{0-8h} (unit)	C_{max} (unit)	DN_AUC_{0-t}	DN_AUC_{0-8}	DN_C_{max}
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
XXX	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
….												

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.6.5.1 SD: Anti-rhu-pGSN Antibodies
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Programming Note:
Listing shell will be updated once data transfer agreement is available.

Listing 16.2.6.5.2 MAD: Anti-rhu-pGSN Antibodies
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.6.5.1 for MAD.
Include all time points and all parameters.

Listing 16.2.6.6.1 SD: Biomarkers
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline	Reference Ranges	High/ Low Flag	Comments
XXX	Procalcitonin (unit)	Day 1*	DDMMMYYYY/ HH:MM	xx		xx, xx		
		Day 2	DDMMMYYYY/ HH:MM	xx		xx, xx		
		Day 3	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	
		Day 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	
Etc.	Etc.							

Note: *Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.6.6.2 MAD: Biomarkers
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.6.6.1 for MAD.
Include all time points and all parameters.

Listing 16.2.6.7.1 SD: Sputum and Blood Culture
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Study Visit	Sputum Culture Collected – Reason Not Performed	Date/Time of Collection	Gram-Stains	Results			
					Antigen Detection	Immunoassay	Genomic Diagnostic Test	Result
XXXXX	Screening	Yes	DDMMMYYYY/ HH:MM					
XXXXX	Screening	Yes	DDMMMYYYY/					

etc.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.6.7.2 MAD: Sputum and Blood Culture
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.6.7.1 for SD.

Listing 16.2.7.1.1 SD: Adverse Events
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	AE#	Adverse Event Verbatim/ System Organ Class/ Preferred Term	Start Date/ Stop Date/ (DDMMMYYYY/ DDMMMYYYY)	SAE	Severity (NCI-CTCAE)	Relationship to Study Drug	Relationship to Study Procedure	Action Taken with Study Drug	Other Action	Outcome	TEAE
XXX	1	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Yes	Grade 1	Possibly Related	Possibly Related	None	None	Recovered / Resolved	Yes
	2	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Yes	Grade 1	Definitely not Related	Definitely not Related	None	None	Recovered / Resolved	Yes
XXX	1	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	No	Grade 1	Definitely not Related	Definitely not Related	None	None	Recovered / Resolved	No
	2	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY / Ongoing	No	Grade 1	Definitely not Related	Definitely not Related	Drug withdrawn	None	Recovered / Resolved	Yes

etc.

Note: TEAE = A treatment-emergent adverse event.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.7.1.2 MAD: Adverse Events
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.7.1.1 for MAD.

Listing 16.2.7.2.1 SD: Serious Adverse Events
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	AE#	Adverse Event Verbatim/ System Organ Class/ Preferred Term	Start Date/ Stop Date/ (DDMMMYYYY/ DDMMMYYYY)	SAE Criteria	Severity (NCI-CTCAE)	Relationship to Study Drug	Relationship to Study Procedure	Action Taken with Study Drug	Other Action	Outcome	TEAE
XXX	1	XXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Is Life Threatening	Grade 1	Possibly Related	Possibly Related	None	None	Recovered / Resolved	Yes
	2	XXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Is Life Threatening	Grade 1	Definitely not Related	Definitely not Related	None	None	Recovered / Resolved	Yes
XXX	1	XXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Is Life Threatening	Grade 1	Definitely not Related	Definitely not Related	None	None	Recovered / Resolved	No
	2	XXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYY	DDMMMYYYY / Ongoing	Is Life Threatening	Grade 1	Definitely not Related	Definitely not Related	Drug withdrawn	None	Recovered / Resolved	Yes

etc.

Note: TEAE = A treatment-emergent adverse event.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.7.2.2 MAD: Serious Adverse Events
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.7.2.1 for MAD.

Listing 16.2.7.3.1 SD: Adverse Events Leading to Study Medication Discontinuation
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	AE#	Adverse Event Verbatim/ System Organ Class/ Preferred Term	Start Date/ Stop Date/ (DDMMMYYYY/ DDMMMYYYY)	SAE	Severity (NCI-CTCAE)	Relationship to Study Drug	Relationship to Study Procedure	Action Taken with Study Drug	Other Action	Outcome	TEAE
XXX	1	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Yes	Grade 1	Possibly Related	Possibly Related	Drug withdrawn	None	Recovered / Resolved	Yes
	2	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	Yes	Grade 1	Definitely not Related	Definitely not Related	Drug withdrawn	None	Recovered / Resolved	Yes
XXX	1	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY/ HH:MM DDMMMYYYY/ HH:MM	No	Grade 1	Definitely not Related	Definitely not Related	Drug withdrawn	None	Recovered / Resolved	No
	2	XXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	DDMMMYYYY / Ongoing	No	Grade 1	Definitely not Related	Definitely not Related	Drug withdrawn	None	Recovered / Resolved	Yes

etc.

Note: TEAE = A treatment-emergent adverse event.
MedDRA Version xx.x

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.7.3.2 MAD: Adverse Events Leading to Study Medication Discontinuation
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.7.3.1 for MAD.

Listing 16.2.7.4.1 SD: Overall Survival
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Date of First Study Drug Administration (DDMMMYYYY)	Event/Censoring Date DDMMMYYYY)	Event or Censoring Description	Days to Event
XXX	DDMMMYYYY	DDMMMYYYY	Death	xxx
XXX	DDMMMYYYY	DDMMMYYYY	Last assessment date	xxx
XXX	DDMMMYYYY	DDMMMYYYY	Last assessment date	xxx
XXX	DDMMMYYYY	DDMMMYYYY	Death	xxx
etc.				

Note: Overall Survival is defined as the difference (in days) between the time of first study drug administration to the date of death + 1 (Include the day of the study drug administration.) Subjects who did not die will be censored at the study exit visit.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.7.4.2 MAD: Overall Survival
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.7.4.1 for MAD.

Listing 16.2.8.1.1.1 SD: CBC
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline[1]	Reference Ranges	High/ Low Flag	Clinical Significance	Abnormality Description
XXX	Haemoglobin (unit)	Screening	DDMMMYYYY/ HH:MM	xx		xx, xx			
		Day 1[1]	DDMMMYYYY/ HH:MM	xx		xx, xx			
		Day 2	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	NCS	
		Day 3 or 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	CS	XXXXXXXXXXXXXXX
Etc.	Etc.								

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.8.1.1.2 MAD: CBC
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.8.1.1.1 for MAD.
Include all time points and all parameters.

Listing 16.2.8.1.2.1 SD: Abnormal CBC
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline[1]	Reference Ranges	High/ Low Flag	Clinical Significance	Abnormality Description
XXX	Haemoglobin (unit)	Day 2	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	NCS	
		Day 3 or 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	CS	XXXXXXXXXXXXXXX
Etc.	Etc.								

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.8.1.2.2 MAD: Abnormal CBC
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.8.1.2.1 for MAD.
Include all time points and all parameters.

Listing 16.2.8.2.1.1 SD: Coagulation
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline[1]	Reference Ranges	High/ Low Flag	Clinical Significance	Abnormality Description
XXX	PT/INR (unit)	Screening	DDMMMYYYY/ HH:MM	xx		xx, xx			
		Day 1[1]	DDMMMYYYY/ HH:MM	xx		xx, xx			
		Day 2	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	NCS	
		Day 3 or 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	CS	XXXXXXXXXXXXXXX
Etc.	Etc.								

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.8.2.1.2 MAD: Coagulation
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.8.2.1.1 for MAD.
Include all time points and all parameters.

Listing 16.2.8.2.2.1 SD: Abnormal Coagulation
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline[1]	Reference Ranges	High/ Low Flag	Clinical Significance	Abnormality Description
XXX	PT/INR (unit)	Day 2	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	NCS	
		Day 3 or 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	CS	XXXXXXXXXXXXXXX
Etc.	Etc.								

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.8.2.2.2 MAD: Abnormal Coagulation
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.8.2.2.1 for MAD.
Include all time points and all parameters.

Listing 16.2.8.3.1.1 SD: Comprehensive Metabolic Profile
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline[1]	Reference Ranges	High/ Low Flag	Clinical Significance	Abnormality Description
XXX	Sodium (unit)	Screening	DDMMMYYYY/ HH:MM	xx		xx, xx			
		Day 1[1]	DDMMMYYYY/ HH:MM	xx		xx, xx			
		Day 2	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	NCS	
		Day 3 or 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	CS	XXXXXXXXXXXXXXX
Etc.	Etc.								

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range, NCS = Not Clinically Significant; CS = Clinically Significant.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.8.3.1.2 MAD: Comprehensive Metabolic Profile
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.8.3.1.1 for MAD.
Include all time points and all parameters.

Listing 16.2.8.3.2.1 SD: Abnormal Comprehensive Metabolic Profile
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Study Visit	Sample Date/ Time (DDMMMYYYY/ HH:MM)	Actual Value	Change from Baseline[1]	Reference Ranges	High/ Low Flag	Clinical Significance	Abnormality Description
XXX	Sodium (unit)	Day 2	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	H	NCS	
		Day 3 or 4	DDMMMYYYY/ HH:MM	xx	xx	xx, xx	L	CS	XXXXXXXXXXXXXXX
Etc.	Etc.								

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
L = Below Normal Range, H = Above Normal Range, NCS = Not Clinically Significant; CS = Clinically Significant.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

Listing 16.2.8.3.2.2 MAD: Abnormal Comprehensive Metabolic Profile
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.8.3.2.1 for MAD.
Include all time points and all parameters.

Listing 16.2.9.1 SD: Vital Signs
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Assessment Performed – Reason Not Performed	Study Visit	Assessment Date (DDMMMYYYY)	Timepoint	Time (HH:MM)	Actual Value	Change from Baseline[1]	Investigator's Overall Interpretation	If Abnormal, specify
XXX	Systolic Blood Pressure (mmHg)	Yes	Screening	DDMMMYYYY		HH:MM	xx		Normal	
		Yes	Day 1	DDMMMYYYY	Pre-dose[1]	HH:MM	xx		Abnormal NCS	XXXXXXXXX
					End of Infusion	HH:MM	xx	xx	Abnormal NCS	XXXXXXXXX
Etc.	Etc.									

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
NCS = Not Clinically Significant, CS = Clinically Significant

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all time points and all parameters.

```
Listing 16.2.9.2 MAD: Vital Signs
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note: Repeat Listing 16.2.9.1.1 for the MAD.
```

Programming Note:
Repeat Listing 16.2.9.1 for MAD.
Include all time points and all parameters.

Listing 16.2.10.1 SD: EKG
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Parameter (Unit)	Assessment Performed – Reason Not Performed	Study Visit	Assessment Date (DDMMMYYYY)	Timepoint	Time (HH:MM)	Actual Value	Mean Actual Value	Mean Change from Baseline[1]	Investigator's Overall Interpretation	Worst Investigator's Overall Interpretation	If Abnormal, specify
XXX	Heart Rate (unit)	Yes	Screening	DDMMMYYYY	EKG 1	HH:MM	xx			Normal		
					EKG 2	HH:MM	xx	xx.x		Abnormal NCS	Abnormal NCS	XXXXXXXXX
		Yes	Day 1[1]	DDMMMYYYY	EKG 1	HH:MM	xx			Abnormal NCS		
					EKG 2	HH:MM	xx	xx.x		Abnormal NCS	Abnormal NCS	XXXXXXXXX
		Yes	Day 28 / Early Termination	DDMMMYYYY	EKG 1	HH:MM	xx			Abnormal NCS		
					EKG 2	HH:MM	xx	xx.x	xx.x	Abnormal CS	Abnormal NCS	XXXXXXXXX
etc.	etc.											

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.
NCS = Not Clinically Significant, CS = Clinically Significant

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
Include all parameters.

```
Listing 16.2.10.2 MAD: EKG
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg
```

Programming Note:
Repeat Listing 16.2.10.1 for MAD.
Include all parameters.

Listing 16.2.11.1 SD: Physical Examination
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Assessment Performed – Reason Not Performed	Visit	Date/Time Physical Examination performed (DDMMMYYYY)	Body System	Result	If Abnormal, specify
XXX	Yes	Screening	DDMMMYYYY/ HH:MM	Skin	Normal	
				HEENT	Normal	
				….	Abnormal NCS	ZZZZZZZZZZZ
				Musculoskeletal	Abnormal NCS	ZZZZZZZZZZZ
	Yes	Day 1	DDMMMYYYY/ HH:MM	Skin	Normal	
				HEENT	Normal	
				….	Abnormal NCS	ZZZZZZZZZZZ
				Musculoskeletal	Abnormal NCS	ZZZZZZZZZZZ
	Yes	Day 2	DDMMMYYYY/ HH:MM	Skin	Normal	
			…	HEENT	Normal	
XXX	No – ZZZZZZZZ			….		
…				Musculoskeletal	Normal	

Note: NCS = Not Clinically Significant, CS = Clinically Significant

Programming Note:
Include all time points and all parameters.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.11.2 MAD: Physical Examination
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.9.11.1 for MAD.
Include all time points and all parameters.

Listing 16.2.12.1.1 SD: Outcome Prediction Models CURB-65
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Study Visit	Test Performed – Reason Not Performed	Visit Date	Confusion of New Onset	Blood Urea Nitrogen	Respiratory Rate (breaths/min)	Systolic/ Diastolic BP (mmHg)	Age (years)	CURB-65 Score	
									Actual Value	Change from Baseline[1]
XXXXX	Screening[1]	Yes	DDMMMYYYY	xx	xx (unit)	xx	xxx/ xx	xx	xx	
	Day 3/4	Yes	DDMMMYYYY	xx	xx (unit)	xx	xxx/ xx	xx	xx	xx
	Day 7	Yes	DDMMMYYYY	xx	xx (unit)	xx	xxx/ xx	xx	xx	xx
	Day 14	Yes	DDMMMYYYY	xx	xx (unit)	xx	xxx/ xx	xx	xx	xx
	Day 28 / Early Termination	Yes	DDMMMYYYY	xx	xx (unit)	xx	xxx/ xx	xx	xx	xx

Etc.

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.12.1.2 MAD: Outcome Prediction Models CURB-65
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.12.1.1 for MAD.

Listing 16.2.12.2.1 SD: Outcome Prediction Models PSI (Port Score)
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Study Visit	Test Performed – Reason Not Performed	Visit Date	PSI Score		
				Actual Value	Change from Baseline[1]	PSI Class
XXXXX	Screening[1]	Yes	DDMMMYYYY	xx		I
	Day 3/4	Yes	DDMMMYYYY	xx	xx	II
	Day 7	Yes	DDMMMYYYY	xx	xx	III
	Day 14	Yes	DDMMMYYYY	xx	xx	IV
	Day 28 / Early Termination	Yes	DDMMMYYYY	xx	xx	V

Etc.

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.12.2.2 MAD: Outcome Prediction Models PSI (Port Score)
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.12.2.1 for MAD.

Listing 16.2.12.3.1 SD: Outcome Prediction Models SOFA Score
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Study Visit	Test Performed – Reason Not Performed	Visit Date	SOFA Score Actual Value	SOFA Score Change from Baseline[1]
XXXXX	Screening[1]	Yes	DDMMMYYYY	xx	
	Day 3/4	Yes	DDMMMYYYY	xx	xx
	Day 7	Yes	DDMMMYYYY	xx	xx
	Day 14	Yes	DDMMMYYYY	xx	xx
	Day 28 / Early Termination	Yes	DDMMMYYYY	xx	xx

Etc.

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.12.3.2 MAD: Outcome Prediction Models SOFA Score
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.12.3.1 for MAD.

Listing 16.2.12.4.1 SD: Outcome Prediction Models MMSE Score
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject	Study Visit	Test Performed – Reason Not Performed	Visit Date	MMSE Score Actual Value	MMSE Score Change from Baseline[1]
XXXXX	Screening[1]	Yes	DDMMMYYYY	xx	
	Day 3/4	Yes	DDMMMYYYY	xx	xx
	Day 7	Yes	DDMMMYYYY	xx	xx
	Day 14	Yes	DDMMMYYYY	xx	xx
	Day 28 / Early Termination	Yes	DDMMMYYYY	xx	xx

etc.

Note: [1]Baseline. Baseline is defined as the last valid, non-missing assessment prior to first study drug administration.

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.12.4.2 MAD: Outcome Prediction Models MMSE Score
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.12.4.1 for MAD.

Listing 16.2.13.1 SD: Concomitant Medications
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

Subject Number	CM#	Drug Name/ATC3/PT	Indication	Start Date/ Stop Date (DDMMMYYYY)	Ongoing	Dose	Unit	Frequency	Route
XXX	1	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE#	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
	2	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Other: YYYYYY	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
XXX	1	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Other: YYYYYY	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
	2	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	Other: YYYYYY	DDMMMYYYY / Ongoing	Yes	XX	Unit	YYYYYY	ZZZZZ
XXX	1	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE#	DDMMMYYYY / DDMMMYYYY	No	XX	Unit	YYYYYY	ZZZZZ
Etc.									

Note: Concomitant medications are medications taken at least once after first study-drug administration.
WHO-DD, xxxxxxxxxx

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.13.2 MAD: Concomitant Medication
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.9.13.1 for MAD.

Listing 16.2.14.1 SD: Hospitalization Follow-Up
Protocol: BTI-201
Intent-to-Treat Population

Cohort 1: rhu-pGSN 6 mg/kg

		Length of Hospital Stay			ICU Stay		Intubation			
Subject	Discharged from Hospital	Date and Time of Hospitalization Admission due to CAP (DDMMMYYYY/ HH:MM)	Date/ Time of Discharge/ Study Exit (DDMMMYYYY/ HH:MM)	Number of Hours	Yes/No	Number of Days	Yes/No	Number of Days	Administered Antibiotics	Require Vasopressors
XXX	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	xx	Yes	xx	Yes	xx	Yes	No
XXX	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	xx	Yes	xx	No		No	No
XXX	Yes	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	xx	No		No		No	No
XXX	No	DDMMMYYYY/ HH:MM	DDMMMYYYY/ HH:MM	xx	No		No		No	No
etc.										

Note: Length of stay in hospital is defined as the date and time of discharge/date of study exit (23:59 PM) - date and time of hospitalization admission due to CAP in hours

Clinical cut-off date: DDMMMYYYY

Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Listing 16.2.14.2 MAD: Hospitalization Follow-Up
Protocol: BTI-201
Intent-to-Treat Population

Cohort 2: rhu-pGSN 6 mg/kg

Programming Note:
Repeat Listing 16.2.14.1 for MAD.

BTI-201: Mock Figures: Table of Contents

Figures

GENERAL COMMENTS

- Names of Treatment Groups:
  SD:
  - rhu-pGSN 6 mg/kg.

  MAD:
  - rhu-pGSN 6 mg/kg;
  - rhu-pGSN 12 mg/kg;
  - rhu-pGSN 24 mg/kg.

- Names of PK sampling times:
  Day 1 (SD and MAD) & Day 3 (MAD)
  - Pre-injection
  - 5 to 10 mins
  - 2h
  - 8h
  - 12h
  - 16h
  - 24h

Figure 14.2.1.1 Individual pGSN Plasma Concentrations (ng/mL) (Linear scale) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the actual study time in hours (0 – 24 hours).
The y-axis will represent the pGSN Plasma Concentrations (ng/mL). The y-axis will be on the linear scale.
All subjects will be represented on a single page. Each dose level will be presented as a distinct line type. A separate figure will be created for each Day. SD and MAD subjects will be presented on the same page by Day.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.1.2 Individual pGSN Plasma Concentrations (ng/mL) (Semi-logarithmic) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the actual study time in hours (0 – 24 hours).
The y-axis will represent the pGSN Plasma Concentrations (ng/mL). The y-axis will be on the log scale.
All subjects will be represented on a single page. Each dose level will be presented as a distinct line type. A separate figure will be created for each Day. SD and MAD subjects will be presented on the same page by Day.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.2.1 Individual Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on Changes from Pre-Injection (Linear scale) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the actual study time in hours (0 – 24 hours).
The y-axis will represent the Estimated Plasma rhu-pGSN Concentrations (ng/mL). The y-axis will be on the linear scale.
All subjects will be represented on a single page. Each dose level will be presented as a distinct line type. A separate figure will be created for each Day. SD and MAD subjects will be presented on the same page by Day.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.2.2 Individual Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on the Double Delta Analysis (Linear scale) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the nominal study time in hours (0 – 24 hours).
The y-axis will represent the Estimated Plasma rhu-pGSN Concentrations (ng/mL). The y-axis will be on the linear scale.
All subjects will be represented on a single page. Each dose level will be presented as a distinct line type. A separate figure will be created for each Day. SD and MAD subjects will be presented on the same page by Day.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.3.1 Mean (+/-SD) pGSN Plasma Concentrations (ng/mL) (Linear scale) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the nominal study time in hours (0 – 24 hours).
The y-axis will represent the mean pGSN Plasma Concentrations (ng/mL) per Dose level. Whiskers will be included to reflect the SDs. The y-axis will be on the linear scale. All treatments will be represented on a single page. Each dose level will be presented as a distinct line type.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.3.2 Mean (+/-SD) pGSN Plasma Concentrations (ng/mL) based on Changes from Pre-Injection (Linear scale) by Day (Semi-logarithmic) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the nominal study time in hours (0 – 24 hours).
The y-axis will represent the mean rhu-pGSN Plasma Concentrations (ng/mL) per Dose level. Whiskers will be included to reflect the SDs. The y-axis will be on the log scale. All treatments will be represented on a single page. Each dose level will be presented as a distinct line type.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.4.1 Mean (+/-SD) Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on Changes from Pre-Injection (Linear scale) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the nominal study time in hours (0 – 24 hours).
The y-axis will represent the mean Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) per Dose level. Whiskers will be included to reflect the SDs. The y-axis will be on the linear scale. All treatments will be represented on a single page. Each dose level will be presented as a distinct line type.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.2.4.2 Mean (+/-SD) Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) based on the Double Delta Analysis (Linear scale) by Day
Protocol: BTI-201
PK Populations

Day 1

Programming Note:
The x-axis will represent the nominal study time in hours (0 – 24 hours).
The y-axis will represent the mean Estimated Plasma rhu-pGSN Plasma Concentrations (ng/mL) per Dose level. Whiskers will be included to reflect the SDs. The y-axis will be on the linear scale. All treatments will be represented on a single page. Each dose level will be presented as a distinct line type.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Figure 14.3.1.1 SD: Kaplan-Meier Plot of Overall Survival Time
Protocol: BTI-201
Safety Population

Note: Overall Survival is defined as the difference (in days) between the time of first study drug administration to the date of death + 1 (Include the day of the study drug administration.) Subjects who did not die will be censored at the study exit visit.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph.

Figure 14.3.1.2 MAD: Kaplan-Meier Plot of Overall Survival Time
Protocol: BTI-201
Safety Population

Note: Overall Survival is defined as the difference (in days) between the
time of first study drug administration to the date of death + 1 (Include the day of the study drug administration.)
Subjects who did not die will be censored at the study exit visit.

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph.

Figure 14.3.2.1 SD: Kaplan-Meier Plot of Length of Stay in Hospital (hours)
Protocol: BTI-201
Safety Population

Note: Length of stay in hospital is defined as the date and time of discharge/date of study exit (23:59 PM) - date and time of hospitalization admission due to CAP in hours

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph.

Figure 14.3.2.2 MAD: Kaplan-Meier Plot of Length of Stay in Hospital (hours)
Protocol: BTI-201
Safety Population

Note: Length of stay in hospital is defined as the date and time of discharge/date of study exit (23:59 PM) - date and time of hospitalization admission due to CAP in hours

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph.

Figure 14.3.3.1 SD: Kaplan-Meier Plot of Duration of ICU Stay
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph. Only include subjects that stayed in the ICU.

Figure 14.3.3.2 MAD: Kaplan-Meier Plot of Duration of ICU Stay
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph. Only include subjects that stayed in the ICU.

Figure 14.3.4.1 SD: Kaplan-Meier Plot of Duration of Intubation
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph. Only include subjects that were intubated.

Figure 14.3.4.2 MAD: Kaplan-Meier Plot of Duration of Intubation
Protocol: BTI-201
Safety Population

Clinical cut-off date: DDMMMYYYY
Program: filepath_name, Output: filepath_name (version x.x) Created: DDMMMYYYY HH:MM

Programming Note:
rhu-pGSN and combined Placebo treatments will be presented on one graph. Only include subjects that were intubated.