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STATISTICAL ANALYSIS PLAN

A Randomized, Single-Dose, Open-Label, Parallel-Group Study in Healthy Volunteers to Assess the Relative Bioavailability of a Subcutaneous Dose of Nemolizumab When Administered with Auto-Injector Compared to Dual-Chamber Syringe

Protocol Number: RD.06.SPR.201590
Final Protocol Date: 17 May 2022
Protocol Version: 1.0
Protocol Clarification Letter (PCL) 1: 15 July 2022
Protocol Clarification Letter (PCL) 2: 23 August 2022
Compound Name: Nemolizumab (CD14152)

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Final Version 1.0
Date: 09 December 2022

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CCI [redacted]

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Compound Name: Nemolizumab

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Study Title: A Randomized, Single-Dose, Open-Label, Parallel-Group Study in Healthy Volunteers to Assess the Relative Bioavailability of a Subcutaneous Dose of Nemolizumab When Administered with Auto-Injector Compared to Dual-Chamber Syringe

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TABLE OF CONTENTS

1. INTRODUCTION

The following statistical analysis plan (SAP) provides the framework for the analysis and presentation of the data from this study. Any changes made from the planned analysis described in the protocol or after finalization of this SAP will be documented in the Clinical Study Report (CSR). The section referred to as "Table, Figure, and Listing Shells" within this SAP describes the Clinical Data Interchange Standards Consortium (CDISC) input in order to provide traceability to the corresponding tables, figures, and listings (TFLs). Analysis data model (ADaM) is the source for tables and figures (as well as listings that may contain derived data) and study data tabulation model (SDTM) is the source for the data listings.

Any additional exploratory analyses not addressed within this SAP and/or driven by the data, or requested by the Galderma Research & Development, LLC, will be considered out of scope and must be described in the CSR.

2. OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
To compare the rate and extent of absorption of a single dose of nemolizumab administered with auto injector (AI) (test) versus dual-chamber syringe (DCS) (reference) under controlled conditions in healthy adult subjects.	Change of primary pharmacokinetic (PK) parameters: C_{max} (rate of absorption) and $AUC_{0\text{-}inf}$ (extent of absorption) of nemolizumab administered with AI or DCS
Secondary	
To assess the safety and immunogenicity of nemolizumab following administration with AI or DCS in healthy adult subjects.	Change of secondary PK parameters ($AUC_{0\text{-}4\ weeks}$, $AUC_{0\text{-}last}$, T_{max}, and $t_{1/2}$) of nemolizumab administered with AI or DCS Assessment of the immunogenicity (anti-drug antibodies, ADA) of nemolizumab administered with AI or DCS CCI [redacted]

3. STUDY DESIGN

This study is designed to meet the objective(s) outlined in Section 2.

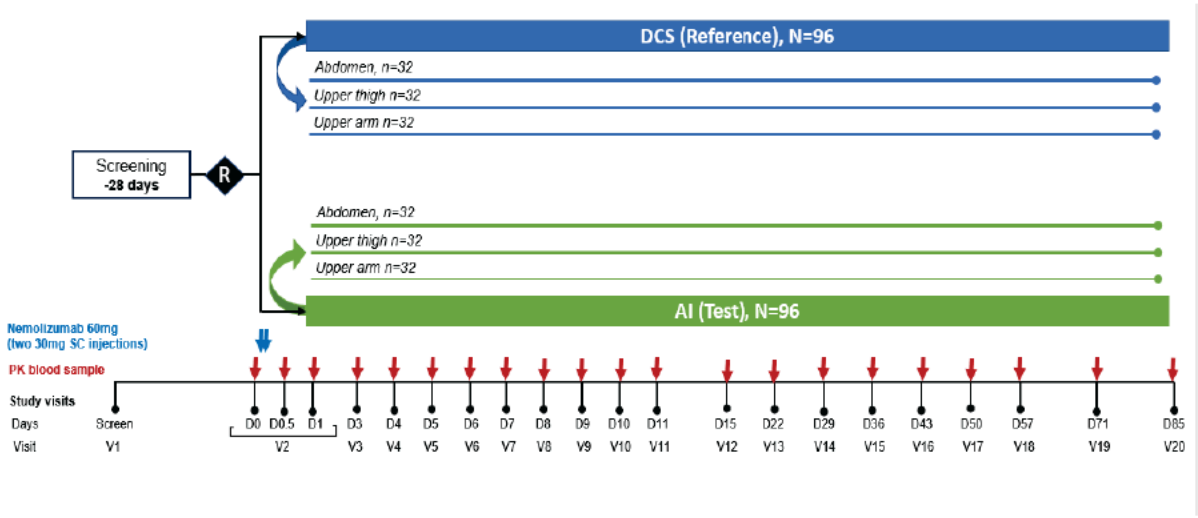
This is a randomized, multicenter, open-label, single-dose, parallel-group study in healthy adult subjects aged 18 to 65 years to assess the relative bioavailability of a 60-mg subcutaneous (SC) dose of nemolizumab administered with AI compared to DCS, stratified by injection site. The 60-mg dose will be administered as 2 successive SC injections of 30 mg (AI or DCS).

The study duration will be up to 16 weeks and consists of an up to 28-day screening period and a 12-week PK evaluation period.

The screening period will evaluate subject eligibility. At baseline, approximately 192 subjects will be randomized 1:1 to receive 60 mg nemolizumab delivered with either AI or DCS. Subjects will be further randomized 1:1:1 to receive injection in 1 of 3 injection sites, i.e., abdomen, front upper thigh, or outer upper arm. Approximately 32 subjects in each delivery group will be assigned to each injection site.

Subjects will receive a 60-mg dose of nemolizumab via 2 SC injections of 30 mg nemolizumab. Injections should be administered at the same location (i.e., abdomen, front upper thigh, or outer upper arm) and the same side with injection sites at least 1 inch (2.5 cm) apart. Blood samples will be collected before and after nemolizumab administration for up to 12 weeks postdose for determining the complete serum PK profile of nemolizumab.

Study design is presented in Figure 3.1:



Clinical assessments will occur according to the Schedule of Assessments defined in the protocol.

4. ANALYSIS POPULATIONS

Safety Population: The safety population (SAF) will consist of all randomized subjects who received the single dose of study drug and will be the primary population for all safety data.

PK Population: The PK population will include all randomized subjects who received the dose of study drug and provided evaluable data will be used for the PK analyses. Subjects with non-evaluable data are described in Section 7.2 (Protocol Deviations).

The PK population will be the primary population for PK analyses.

5. TREATMENT DESCRIPTIONS

Table 5.1 Treatments are described as follows:

Treatment		Short Descriptions (to be Used in the Text, Table headings, and Figure Legends)	Long Descriptions (to be Used in Table Footnotes)
Method	**Site**		
AI	Abdomen	AI, Abdomen	A single SC dose of nemolizumab 60 mg (2 x 30 mg injections) via AI in the abdomen
	Arm	AI, Arm	A single SC dose of nemolizumab 60 mg (2 x 30 mg injections) via AI in the upper arm
	Thigh	AI, Thigh	A single SC dose of nemolizumab 60 mg (2 x 30 mg injections) via AI in the upper thigh
DCS	Abdomen	DCS, Abdomen	A single SC dose of nemolizumab 60 mg (2 x 30 mg injections) via DCS in the abdomen
	Arm	DCS, Arm	A single SC dose of nemolizumab 60 mg (2 x 30 mg injections) via DCS in the upper arm
	Thigh	DCS, Thigh	A single SC dose of nemolizumab 60 mg (2 x 30 mg injections) via DCS in the upper thigh

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7. SAFETY

All relevant case report form (CRF) data will be listed by subject and chronologically by assessment time point. This will include rechecks, unscheduled, and early termination assessments.

Applicable continuous variables will be summarized using n, mean, SD, minimum, median, and maximum.

The level of precision will be presented as follows: minimum/maximum in the same precision as in the database, mean/median in one more precision level than minimum/maximum, SD in one more precision level than mean/median, and n will be presented as an integer. Percentages will be presented as an integer.

Where individual data points are missing because of dropouts or other reasons, the data will be summarized based on reduced denominators.

Baseline will be the result closest and prior to the dose unless otherwise stated in this section. Summaries for post-baseline time points will not include rechecks, unscheduled, or early termination measurements.

Tables summarizing safety data by assessment time point will only include summaries for baseline and post-baseline time points.

Treatment is a combination of method (AI, DCS) and site (Abdomen, Arm, and Thigh) in the summary analysis and listings.

7.1 Subject Disposition

Subjects will be summarized by the number and percent of subjects dosed, completed the study and discontinued the study (with discontinuation reasons), by treatment and overall.

7.2 Protocol Deviations

Once the deviations have been finalized, a Comma Separated Variable file with all protocol deviations will be downloaded from Veeva, and then imported into SDTM and a SAS generated listing of the deviations will be provided. Any deviations that are classified as an important protocol deviations (IPD) will be flagged in a separate column in the listing.

IPD are protocol deviations that might significantly affect the completeness, accuracy and/or reliability of the study data or that might significantly affect a subject's rights, safety, or well-being. An assessment of IPDs will be performed prior to database lock. The study team will review a listing of all protocol deviations reported in the study database and determine which deviations are IPDs.

IPDs will be tabulated by deviation category. A summary table will be generated to include the number and percentage of subjects reporting the IPD by randomized treatment and overall.

Deviations from the protocol assessed as "Important"/"Not important" are equivalent to "Major"/"Minor".

7.3 Demographics

Descriptive statistics will be calculated for continuous variables (age, body mass index, height, and weight) by treatment and overall. Age will be approximated by subtracting the year of birth from the year of informed consent. If year of informed consent – year of birth is one more than the protocol maximum age then the age approximation will be year of informed consent – year of birth – 1.

Frequency counts will be provided for categorical variables (sex, race, and ethnicity) for each randomized treatment and overall.

7.4 Adverse Events

All AEs occurring during this clinical trial will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®), Version 25.0.

All AEs captured in the database will be listed in a by-subject data listing including verbatim term, coded term, treatment, onset date/time, resolution date/time, frequency, severity, seriousness, AESI, relationship to study product, and action; however, only treatment-emergent AEs (TEAEs) will be summarized.

A TEAE is defined as an AE that is starting at the time of or after study product administration. Each TEAE will be attributed to the treatment based on the onset date and time of the AE compared to that of the respective treatment administration date and time.

If the onset time of an AE is missing and the onset date is the same as or occurs after the treatment dosing date, then the AE will be considered treatment emergent. If the onset date of an AE is missing, then the AE will be considered treatment emergent.

If an AE increases in severity, that AE will be given a resolution date and time and a new record will be initiated with the new severity. If the severity of an AE remains the same or decreases, the AE will be kept open through to resolution.

TEAEs, serious TEAEs, severe TEAE, drug-related TEAEs, TEAEs leading to study discontinuation, and treatment-emergent AESIs will be tabulated by System Organ Class (SOC) and Preferred Term. Summary tables will include the number of subjects reporting the event and as a percent of the number of subjects dosed by treatment and overall.

If data permit, incidence of positive ADA on treatment emergent adverse effects will be summarized by treatment.

At each level of SOC or preferred term, a subject with multiple events will only be counted once per SOC or preferred term. In addition, if a subject experiences more than 1 occurrence of the same AE, the occurrence with the greatest severity and the closest association with the study drug will be used in summary tables.

An overview of the number and percentage of subjects with TEAEs, drug-related TEAEs, TEAEs leading to study discontinuation, treatment-emergent AESIs, and serious adverse events (SAEs) will be tabulated by treatment. Number and percentage of subjects with TEAEs with maximum severity of mild, moderate, and severe will be included in the overview table.

SAEs, if present, will also be listed. Applicable narratives will be included in the CSR.

7.5 Clinical Laboratory Tests (Serum Chemistry, Hematology, Urinalysis)

Clinical laboratory tests will be measured at the following time points:

Clinical Laboratory Panels	Time Point		
	Period	CRF/Listing Day and Hour	Table
Serum Chemistry, Hematology, Urinalysis	Screening		Baseline
	1	Day 86 Hours 2039.50, 2040.00	Day 86

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listings will reflect the data found in the final subject CRFs.
If applicable, an early termination assessment will be performed.

Clinical laboratory results will be presented as extracted from the clinical laboratory database, which is in conventional units.

Out-of-normal range flags will be recorded as follows: high (H) and low (L) for numerical results and did-not-match (*) for categorical results. If a value fails the reference range, it will automatically be compared to a computer clinically significant (CS) range. If the value falls within the computer CS range, it will be noted as "N" for not clinically significant. If the value fails (i.e., fall outside of the CS range) the computer CS range, it will be flagged with a "Y" which prompts the PI to determine how the out-of-range value should be followed using 4 Investigator flags: "N", not clinically significant, "R", requesting a recheck, "^", checking at the next scheduled visit, or "Y", clinically significant. To distinguish the PI flag from the computer CS range flags, the PI flags of "N" and "Y" will be presented as "-" and "+", respectively, in the data listing.

Out-of-reference range values and corresponding recheck results will be listed. Results that are indicated as CS by the PI will be listed in a table.

For all numeric laboratory values, descriptive statistics will be presented for each laboratory test by assessment time point and treatment. Change from baseline will be summarized in a similar manner. For all numeric laboratory tests, the mean value calculated for each assessment time point and treatment will be compared to the reference range and flagged if outside of the reference range (* if above the reference range and ^ if below the reference range). In the event there is more than one reference range for a laboratory test, the comparison will be made against the lowest of the lower ranges and the highest of the higher ranges.

For each laboratory test, a shift table will be developed to compare the frequency of the results at baseline (above reference range, within reference range, or below reference range) with the respective postdose results. For urinalysis tests, the categories are within reference range and outside reference range.

7.6 Vital Signs

Vital signs will be measured at the following time points:

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
Blood Pressure, Heart Rate, Temperature	Screening		NA
	1	Day 1 Hour -1.00 Day 9 Hour 191.83 Day 44 Hour 1031.83 Day 86 Hour 2039.92	Baseline Day 9 Day 44 Day 86

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
Respiration	Screening		NA
Weight	Screening		NA
	1	Day 1 Hour -1.17 Day 86 Hour 2040.25	Baseline Day 86

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listing will reflect the data found in the final subject CRFs.
If applicable, an early termination assessment will be performed.
NA = Not applicable

Descriptive statistics will be presented for vital signs measurements (including weight) by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Height will be measured at screening and Day 86 Hour 2040.25, and listed.

7.7 Electrocardiogram

ECGs will be measured at the following time points:

Parameter	Time Point		
	Period	CRF/Listing Day and Hour	Table
QT, QTcF, RR, PR, HR, QRS	Screening		Baseline
	1	Day 86 Hour 2039.75	Day 86

Time points in the CRF/Listing column are approximated/based on the blank CRF and it should be noted that the data listing will reflect the data found in the final subject CRFs.
If applicable, an early termination assessment will be performed.
NA = Not applicable

Descriptive statistics will be presented for ECG measurements by assessment time point and treatment. Change from baseline will be summarized in a similar manner.

All ECG data will be listed by subject and QTcF values > 450 msec will be flagged.

7.8 Prior and Concomitant Medications

Prior and concomitant medications recorded during the study will be coded with the World Health Organization (WHO) Drug Dictionary Version 01-Mar-2022 b3 and listed.

7.9 Physical Examination

Abnormal physical examination findings will be reported as medical history or AEs. All data found in the CRF will be listed.

7.10 Medical History

All medical history will be coded using MedDRA®, Version 25.0 and listed.

8. SUMMARY OF CHANGES FROM PROTOCOL-PLANNED ANALYSIS

The analyses described in this SAP are aligned with those analyses described in the protocol except for the following:

Statistical Analysis of Pharmacokinetic Parameters: Protocol Section 17.3 indicates a linear mixed-effect model will be used with treatment and injection site as fixed effects and subject as a random effect. However, since each subject will have only one set of PK parameters, the random effect model is not applicable and the fixed effect two-way ANOVA (with interaction) model will be used instead (as described in the SAP Section 6.6).

These changes will also be documented in Section 9.8 of the CSR.

9. SUMMARY TABLES, FIGURES, AND LISTINGS

Summary tables and figures are numbered following the International Council on Harmonization (ICH) structure but may be renumbered as appropriate during the compilation of the tables and figures for the CSR.

Note that summary tables and figures will be generated using SAS® Version 9.4 or higher.

In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word for inclusion in the CSR. In compliance CCI SOP/PG, SAS® outputs will not be manually edited.

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9.2 Section 14 Summary Tables and Figures

The following is a list of table and figure titles that will be included in Section 14 of the report. Table and figure titles may be renumbered as appropriate during the compilation of the report.

14.1 Demographic Data and Protocol Deviation Summary Tables

Number	Title	Shell
Table 14.1.1	Disposition Summary (SAF)	CDS
Table 14.1.2	Demographic Summary (SAF)	CDEM
Table 14.1.3	Important Protocol Deviation Summary – Number of Subjects Reporting the Protocol Deviation (% of Subjects Dosed) (SAF)	CDPD

14.2 Pharmacokinetic/Immunogenicity Data Summary Tables and Figures

14.2.1 Serum Nemolizumab Tables

Number	Title	Shell
Table 14.2.1.1	Serum Nemolizumab Concentrations (ng/mL) Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI (PK Population)	CPCONC1
Table 14.2.1.2	Serum Nemolizumab Concentrations (ng/mL) Following the Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via DCS (PK Population)	CPCONC1

Number	Title	Shell
Table 14.2.1.3	Serum Nemolizumab Pharmacokinetic Parameters Following the Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI (PK Population)	CPPAR1
Table 14.2.1.4	Serum Nemolizumab Pharmacokinetic Parameters Following the Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via DCS (PK Population)	CPPAR1
Table 14.2.1.5	Statistical Comparisons of Serum Nemolizumab Pharmacokinetic Parameters: AI (Test) Versus DCS (Reference) (PK Population)	CPStat1
Table 14.2.1.6	Nonparametric Statistical Comparisons of Serum Nemolizumab PK Parameter Tmax: AI (Test) Versus DCS (Reference) (PK Population)	CPStat2

ADA:

Table 14.2.2.1	Assessment of Immunogenicity (Absolute Occurrence, Percent of Subjects, and Treatment-Emergent ADA) (SAF)	CAESO

14.2.3 Serum Nemolizumab Figures

Abdomen, Arm, and Thigh

Number	Title	Shell
Figure 14.2.3.1	Arithmetic Mean (SD) of Overall – Abdomen, Arm, and Thigh Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS (Linear Scale) (PK Population)	PFPConc1
Figure 14.2.3.2	Arithmetic Mean of Overall – Abdomen, Arm, and Thigh Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS (Linear Scale) (PK Population)	PFPConc2

Number	Title	Shell
Figure 14.2.3.3	Arithmetic Mean S of Overall – Abdomen, Arm, and Thigh Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS (Semi-Log Scale) (PK Population)	PFPConc3

Note: each figure will have 2 lines, one for each overall AI (Abdomen, Arm, and Thigh) and DCS (Abdomen, Arm, and Thigh).

Abdomen

Number	Title	Shell
Figure 14.2.3.4	Arithmetic Mean (SD) Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Abdomen and DCS, Abdomen (Linear Scale) (PK Population)	PFPConc1
Figure 14.2.3.5	Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Abdomen and DCS, Abdomen (Linear Scale) (PK Population)	PFPConc2
Figure 14.2.3.6	Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Abdomen and DCS, Abdomen (Semi-Log Scale) (PK Population)	PFPConc3

Note: each figure will have 2 line, one for each AI, Abdomen and DCS, Abdomen.

Arm

Number	**Title**	**Shell**
Figure 14.2.3.7	Arithmetic Mean (SD) Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Arm and DCS, Arm (Linear Scale) (PK Population)	PFPConc1

Number	Title	Shell
Figure 14.2.3.8	Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Arm and DCS, Arm (Linear Scale) (PK Population)	PFPConc2
Figure 14.2.3.9	Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Arm and DCS, Arm (Semi-Log Scale) (PK Population)	PFPConc3

Note: each figure will have 2 line, one for each AI, Arm and DCS, Arm.

Thigh

Number	Title	Shell
Figure 14.2.3.10	Arithmetic Mean (SD) Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Thigh and DCS, Thigh (Linear Scale) (PK Population)	PFPConc1
Figure 14.2.3.11	Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Thigh and DCS, Thigh (Linear Scale) (PK Population)	PFPConc2
Figure 14.2.3.12	Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI, Thigh and DCS, Thigh (Semi-Log Scale) (PK Population)	PFPConc3

Note: each figure will have 2 line, one for each AI, Thigh and DCS, Thigh.

ADA Figures

Figure 14.2.3.13	Serum Nemolizumab Concentrations (ng/mL) in ADA Positive and ADA Negative Subjects Over Time (Linear Scale) (PK Population)	PFPConc2

This figure will have 4 lines one for each AI, ADA Positive, AI, ADA Negative, DOCS, ADA Positive, and DOC, ADA Negative.

14.3 Safety Data Summary Tables

14.3.1 Displays of Adverse Events

Number	Title	Shell
Table 14.3.1.1	Overview of Treatment Emergent Adverse Events Frequency by Treatment - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	CAEOW
Table 14.3.1.2	Treatment-Emergent Adverse Event Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	CAES
Table 14.3.1.3	Serious Treatment-Emergent Adverse Event Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	
Table 14.3.1.4	Severe Treatment-Emergent Adverse Event Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	
Table 14.3.1.5	Drug-Related Treatment-Emergent Adverse Event Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	
Table 14.3.1.6	Treatment-Emergent Adverse Event Leading to Study Discontinuation Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	
Table 14.3.1.7	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	
Table 14.3.1.8	Treatment-Emergent Adverse Event Frequency by Treatment and ADA Status (I of II) - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	CAES2
Table 14.3.1.9	Treatment-Emergent Adverse Event Frequency by Treatment and ADA Status (II of II) - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)	

14.3.2 Listings of Deaths, other Serious and Significant Adverse Events

Number	Title	Shell
Table 14.3.2.1	Serious Adverse Events (SAF)	16.2.7

14.3.3 Narratives of Deaths, other Serious and Certain other Significant Adverse Events

14.3.4 Abnormal Laboratory Value Listing (each subject)

Number	Title	Shell
Table 14.3.4.1	Out-of-Range Values and Recheck Results – Serum Chemistry (SAF)	CLBO
Table 14.3.4.2	Out-of-Range Values and Recheck Results – Hematology (SAF)	
Table 14.3.4.3	Out-of-Range Values and Recheck Results – Urinalysis (SAF)	
Table 14.3.4.4	Clinically Significant Laboratory Values and Recheck Results (SAF)	CLBR

14.3.5 Displays of Other Laboratory, Vital Signs, Electrocardiogram, Physical Examination, and Other Safety Data

Number	Title	Shell
Table 14.3.5.1	Clinical Laboratory Summary and Change From Baseline – Serum Chemistry (SAF)	CLBD
Table 14.3.5.2	Clinical Laboratory Shift From Baseline – Serum Chemistry (SAF)	CLBS
Table 14.3.5.3	Clinical Laboratory Summary and Change From Baseline – Hematology (SAF)	CLBD
Table 14.3.5.4	Clinical Laboratory Shift From Baseline – Hematology (SAF)	CLBS
Table 14.3.5.5	Clinical Laboratory Summary and Change From Baseline – Urinalysis (SAF)	CLBD
Table 14.3.5.6	Clinical Laboratory Shift From Baseline – Urinalysis (SAF)	CLBS
Table 14.3.5.7	Vital Sign Summary and Change From Baseline (SAF)	CVS
Table 14.3.5.8	12-Lead Electrocardiogram Summary and Change From Baseline (SAF)	CEG

9.3 Section 16 Data Listings

Note: Hepatitis and HIV results that are provided by the clinical laboratory will not be presented in subject data listings and will not be included in any database transfer. All data

will be presented as outline in the CRF (i.e., time point information will be consistent with the CRF data).

Data listings are numbered following the ICH structure but may be renumbered as appropriate during the compilation of the TFLs for the CSR. The following is a list of appendix numbers and titles that will be included as data listings:

16.1 Study Information

16.1.9 Statistical Methods

Number	Title
Appendix 16.1.9.1	Statistical Analysis Plan
Appendix 16.1.9.2	Statistical Methods – Pharmacokinetics

16.1.10 Clinical Laboratory Reference Ranges

Number	Title
Appendix 16.1.10.1	Clinical Laboratory Reference Ranges

16.2 Subject Data Listings

16.2.1 Subject Discontinuation

Number	Title
Appendix 16.2.1.1	Subject Disposition (SAF)

16.2.2 Protocol Deviations

Number	Title
Appendix 16.2.2.1	Protocol Deviations

16.2.3 Subjects Excluded From the Pharmacokinetic/immunogenicity Analysis

Number	Title
Appendix 16.2.3.1	Subjects Excluded From the Pharmacokinetics / Immunogenicity Analysis

Note: Appendix 16.2.3.1 is generated in MS Word for inclusion in the study report.

16.2.4 Demographic Data

Number	Title
Appendix 16.2.4.1	Demographics (SAF)
Appendix 16.2.4.2	Physical Examination (SAF)
Appendix 16.2.4.3	Medical History (SAF)
Appendix 16.2.4.4	Substance Use (SAF)

16.2.5 Compliance and/or Drug Concentration Data

Number	Title	Shell
Appendix 16.2.5.1	Subject Eligibility (SAF)	
Appendix 16.2.5.2	Test Compound Description	
Appendix 16.2.5.3	Test Compound Administration Times (SAF)	
Appendix 16.2.5.4	Prior and Concomitant Medications (SAF)	
Appendix 16.2.5.5	Serum Nemolizumab Pharmacokinetic Blood Draw Times and Concentration Data (SAF)	LBLDPK
Appendix 16.2.5.6	Immunogenicity (ADA) and NAb of Nemolizumab Administered With AI or DCS (SAF)	LBLDPK

16.2.6 Individual Pharmacokinetic Response Data

Number	Title	Shell
Appendix 16.2.6.1	Serum Nemolizumab Concentration Versus Time Profiles for <Subject #>(Linear and Semi-Log Scale)	PFPConc5
Appendix 16.2.6.2	Intervals (Hours) Used for Determination of Serum Nemolizumab Kel Values (PK Population)	CPKel2

16.2.7 Adverse Events Listings

Number	Title
Appendix 16.2.7.1	Adverse Events (I of II) (SAF)
Appendix 16.2.7.2	Adverse Events (II of II) (SAF)
Appendix 16.2.7.3	Details for Serious Adverse Events (SAF) *This listing will be removed if no serious adverse events are reported.*

16.2.8 Clinical Laboratory Reports

Number	Title
Appendix 16.2.8.1	Clinical Laboratory Report - Serum Chemistry (SAF)
Appendix 16.2.8.2	Clinical Laboratory Report - Hematology (SAF)
Appendix 16.2.8.3	Clinical Laboratory Report - Urinalysis (SAF)
Appendix 16.2.8.4	Clinical Laboratory Report - Urine Drug Screening (SAF)
Appendix 16.2.8.5	Clinical Laboratory Report - Virology (SAF)
Appendix 16.2.8.6	Vital Signs (SAF)
Appendix 16.2.8.7	12-Lead Electrocardiogram (SAF)

10. TABLE, FIGURE, AND LISTING SHELLS

The following table shells provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this study, but are intended to show the general layout of the tables that will be presented and included in the final report. Unless otherwise noted, all in-text tables will be presented in Times New Roman font size 9 and post-text tables will be presented in Courier New font size 9. In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word for inclusion in the CSR. In compliance CCI SOP/PG, SAS® outputs will not be manually edited. Tables will be generated from ADaM datasets created in accordance with CDISC guidance (ADaM Model 2.1 and ADaM implementation Guide 1.1).

10.1 In-text Summary Tables Shells

In-text Shell IDS will be in the following RFT format:

Table IDS Disposition Summary (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Category	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Completed Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

Source: Table 14.1.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_disp.sas DDMMMYYYY HH:MM

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Table IDEM Demographic Summary (SAF)

		Treatment								
		AI (N = X)				DCS (N = X)				
Trait	Category/Statistic	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Sex	Female	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Male	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Race	Asian	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Black or African American	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	White	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Ethnicity	Hispanic or Latino	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
	Not Hispanic or Latino	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Age (yr)	n	X	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	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Weight (kg)	n	X	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	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Height (cm)	n	X	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	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

		Treatment								
		AI (N = X)				DCS (N = X)				
Trait	Category/Statistic	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Body Mass Index (kg/m²)	n	X	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	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

Source: Table 14.1.2
Program: /CAXXXXX/sas_prg/stsas/intext/t_dem.sas DDMMMYYYY HH:MM

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In-text Shell ITPPar1 will be in the following RTF format:

Table ITPPar1 Summary of Serum Nemolizumab Pharmacokinetic Parameters Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS in Abdomen, Arm, and Thigh (PK Population)

	AI			DCS		
Pharmacokinetic Parameters	**Abdomen**	**Arm**	**Thigh**	**Abdomen**	**Arm**	**Thigh**
Param1 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param2 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param3 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]
Param4 (units)	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]	XXX.X (XX.X) [n=xx]

AI = Auto-Injector (test)
DCS = Dual-Chamber Syringe (reference)
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

AUCs and C_{max} values are presented as geometric mean and geometric CV%.
T_{max} values are presented as median (min, max).
Other parameters are presented as arithmetic mean (± SD).
Source: Tables 14.2.1.3 and 14.2.1.4

Program: /CAXXXXX/sas_prg/pksas/intext-pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_intext_pkparam.sas DDMMMYYYY HH:MM

Presentation of Data:
The following PK parameters will be presented in the following order and with following units: $AUC_{0\text{-}4\ weeks}$ (ng*hr/mL), $AUC_{0\text{-}last}$ (ng*hr/mL), $AUC_{0\text{-}inf}$ (ng*hr/mL), $AUC_{\%extrap}$ (%), C_{max} (ng/mL), T_{max} (hr), K_{el} (1/hr), $t_{½}$ (hr), CL/F (L/hr), and V_d/F (L)
n will be presented as an integer (with no decimal);
Summary statistics will be presented with same precision as defined in the post-text shells.

In-text Shell ITPStat1 will be in the following RTF format:

Table ITPStat1 Summary of Statistical Comparisons of Serum Nemolizumab Pharmacokinetic Parameters: AI (Test) Versus DCS (Reference) (PK Population)

		Method ------- Geometric LSMs -------								
PK Parameter (unit)	Site	AI (Test)	(n)	DCS (Reference)	(n)	Geometric Mean Ratio (%)	90% Confidence Interval	Inter-subject CV%	Method by Site Interaction P-value	AI Versus DCS P-value
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XXX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XXX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	high	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XXX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XXX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XXX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX

Interaction p-value is associated with testing the hypothesis of no interaction between Method and Site. If the p-value is very small (e.g. < 0.05), then the overall comparison between methods is not valid. In such cases, the comparison between methods should be done at each site.
AI Versus DCS p-value is associated with testing the hypothesis of no difference between the two methods.

AI = Auto-Injector (test)
DCS = Dual-Chamber Syringe (reference)

All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

Parameters were ln-transformed prior to analysis.
Geometric least-squares means (LSMs) are calculated by exponentiating the LSMs from ANOVA.
Geometric Mean Ratio = 100 x (test/reference)
Inter-subject CV% = 100 x (square root (exp[MSE]-1), where MSE = Residual variance from ANOVA.

Notes for Generating the Actual Tables:

Presentation of Data:
The following PK parameters will be presented in the following order and with following units: AUC_{0-inf} (ng*hr/mL), C_{max} (ng/mL), AUC_{0-last} (ng*hr/mL), $AUC_{0-4\ weeks}$ (ng*hr/mL), and $t_{½}$ (hr)
n will be presented as an integer (with no decimal)
Geometric Mean Ratio, 90% CI, and inter-subject CV% will be presented to 2 decimal places,
p-values will be presented to 4 decimals.

Program: /CAXXXX/sas_prg/pksas/stats-tables-mixed.sas DDMMMYYYY HH:MM
Program: /CAXXXX/sas_prg/pksas/adam_statsmixed.sas DDMMMYYYY HH:MM

In-text Shell ITPStat2 will be in the following RTF format:

Table ITPStat2 Nonparametric Statistical Comparisons of Serum Nemolizumab PK Parameter Tmax: AI (Test) Versus DCS (Reference) (PK Population)

PK Parameter (unit)	Site	Median Difference: AI (Test) – DCS (Reference)		90% Confidence Interval	p-value
Tmax (hr)	Overall	X.XX	(n)	XX.XX – XXX.XX	X.XXX
	Abdomen	X.XX	(n)	XX.XX – XXX.XX	X.XXX
	Arm	X.XX	(n)	XX.XX – XXX.XX	X.XXX
	Thigh	X.XX	(n)	XX.XX – XXX.XX	X.XXX

AI = Auto-Injector (test)
DCS = Dual-Chamber Syringe (reference)
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

The p-value is based on the Wilcoxon Rank Sums statistics of two independent samples. The median difference (considered to be the treatment effect) is estimated using the Hodges-Lehmann method.

Notes for Generating the Actual Table:

Programmer's note:
All statistics will be presented with same precision as defined in post-text shell.

Table 11-5 Assessment of Immunogenicity (Absolute Occurrence, Percent of Subjects, and Treatment-Emergent ADA) (SAF)

Time Point	Statistic	AI (N=X)				DCS (N=X)			
		Abdomen	Arm	Thigh	Overall	Abdomen	Arm	Thigh	Overall
Predose	Screening (ECLIA), n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Confirmation (ECLIA), n (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	ADA titer (ng/mL)	XX	XX	XX	XX	XX	XX	XX	XX
	n	XX	XX	XX	XX	XX	XX	XX	XX
	Mean	XX	XX	XX	XX	XX	XX	XX	XX
	SD	XX	XX	XX	XX	XX	XX	XX	XX
	Medina	XX	XX	XX	XX	XX	XX	XX	XX
	Min	XX	XX	XX	XX	XX	XX	XX	XX
	Max	XX	XX	XX	XX	XX	XX	XX	XX
	Neutralizing antibodies, n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Treatment Related ADA, n (%)	XX	XX	XX	XX	XX	XX	XX	XX
Day 30	Screening (ECLIA), n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Confirmation (ECLIA), n (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	ADA titer (ng/mL)	XX	XX	XX	XX	XX	XX	XX	XX
	n	XX	XX	XX	XX	XX	XX	XX	XX
	Mean	XX	XX	XX	XX	XX	XX	XX	XX
	SD	XX	XX	XX	XX	XX	XX	XX	XX
	Medina	XX	XX	XX	XX	XX	XX	XX	XX
	Min	XX	XX	XX	XX	XX	XX	XX	XX
	Max	XX	XX	XX	XX	XX	XX	XX	XX
	Neutralizing antibodies, n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX

	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Treatment Related ADA, n (%)	XX	XX	XX	XX	XX	XX	XX	XX
Day 85	Screening (ECLIA), n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Confirmation (ECLIA), n (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	ADA titer (ng/mL)	XX	XX	XX	XX	XX	XX	XX	XX
	n	XX	XX	XX	XX	XX	XX	XX	XX
	Mean	XX	XX	XX	XX	XX	XX	XX	XX
	SD	XX	XX	XX	XX	XX	XX	XX	XX
	Medina	XX	XX	XX	XX	XX	XX	XX	XX
	Min	XX	XX	XX	XX	XX	XX	XX	XX
	Max	XX	XX	XX	XX	XX	XX	XX	XX
	Neutralizing antibodies, n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Treatment Related ADA, n (%)	XX	XX	XX	XX	XX	XX	XX	XX

Treatment related ADA will be displayed only at post-baseline visits. The other stats (Screening, Confirmation, ADA titer, Neutralizing antibodies (Nab)) will be displayed at all visits.

Screening and Confirmation (note: screening is not the visit name. At each visit, there is a screening test, and a confirmation test only on positive screening):

The % for confirmation will be computed based on positive screening ADA.
ADA titer, Nab and treatment related ADA stats will be computed on the Positive subjects at Confirmation.

As mentioned in the SAP, Treatment-related ADA is defined when baseline screening or confirmatory ADA result is Negative and post-baseline confirmatory ADA result is Positive. Percentage is calculated based on the number of subjects with positive ADA results at confirmation test.

Program: /CA20737/sas_prg/pksas/adam_t1.sas DDMMMYYYY HH:MM

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Table IAEOW Overview of Treatment Emergent Adverse Events Frequency by Treatment - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Number of Subjects With	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Drug-Related TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
TEAEs leading to Study Discontinuation	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
TEAEs of Special Interest	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
SAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
TEAEs With Maximum Severity of Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
TEAEs With Maximum Severity of Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
TEAEs With Maximum Severity of Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
AE = Adverse event; SAE = Serious adverse event; TEAEs = Treatment-emergent adverse events

Source: Table 14.3.1.1
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

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Table IAES Treatment-Emergent Adverse Event Frequency by Treatment- Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Adverse Event	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Number of Subjects With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nervous system disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Headache	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Reproductive system and breast disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Vaginal discharge	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Respiratory, thoracic and mediastinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Epistaxis	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Skin and subcutaneous tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Sweating increased	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories.
Adverse events are classified according to MedDRA Version 25.0.
TEAEs = Treatment-emergent adverse events

Source: Table 14.3.1.2
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

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Table IAES2 Treatment-Emergent Adverse Event Frequency by Treatment and ADA Status (I of II) - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)

	AI (N = X)							
	Abdomen (N = X)		Arm (N = X)		Thigh (N = X)		Overall (N = X)	
Adverse Event	ADA +	ADA -	ADA +	ADA -	ADA +	ADA -	ADA +	ADA -
Number of Subjects Dosed	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)
Number of Subjects With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nervous system disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Headache	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Reproductive system and breast disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Vaginal discharge	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Respiratory, thoracic and mediastinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Epistaxis	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Skin and subcutaneous tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Sweating increased	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories.
Adverse events are classified according to MedDRA Version 25.0.
TEAEs = Treatment-emergent adverse events
ADA = anti-drug antibody
Source: Table 14.3.1.8
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Galderma Research & Development, LLC
Nemolizumab, Protocol Number RD.06.SPR.201590
CCI

Table IAES3 Treatment-Emergent Adverse Event Frequency by Treatment and ADA Status (II of II) - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)

	DCS (N = X)							
	Abdomen (N = X)		Arm (N = X)		Thigh (N = X)		Overall (N = X)	
Adverse Event	ADA +	ADA -	ADA +	ADA -	ADA +	ADA -	ADA +	ADA -
Number of Subjects Dosed	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)	XX (100%)
Number of Subjects With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nervous system disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Headache	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Reproductive system and breast disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Vaginal discharge	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Respiratory, thoracic and mediastinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Epistaxis	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Skin and subcutaneous tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Sweating increased	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

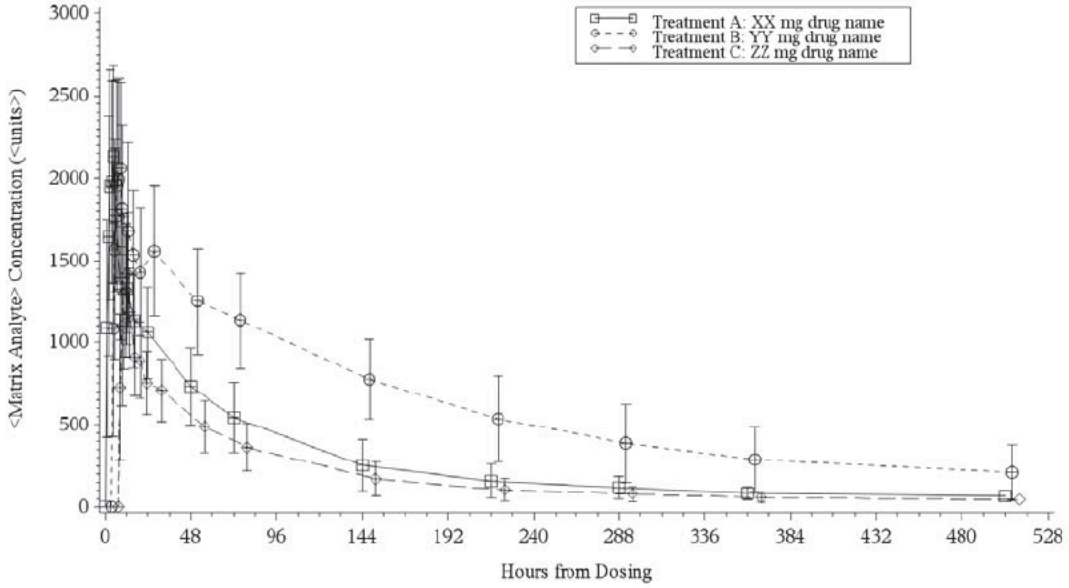
	DCS (N = X)							
	Abdomen (N = X)		Arm (N = X)		Thigh (N = X)		Overall (N = X)	
Adverse Event	**ADA +**	**ADA -**	**ADA +**	**ADA -**	**ADA +**	**ADA -**	**ADA +**	**ADA -**
AI = Auto-Injector, DCS = Dual-Chamber Syringe All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections) Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories. Adverse events are classified according to MedDRA Version 25.0. TEAEs = Treatment-emergent adverse events ADA = anti-drug antibody Source: Table 14.3.1.9 Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM								

10.2 Figures Shells

Post-text Shell PFPConc1 will be in the following RTF format:

Figure PFPConc1

Arithmetic Mean (SD) Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS in Abdomen, Arm, and Thigh (Linear Scale) (PK Population)

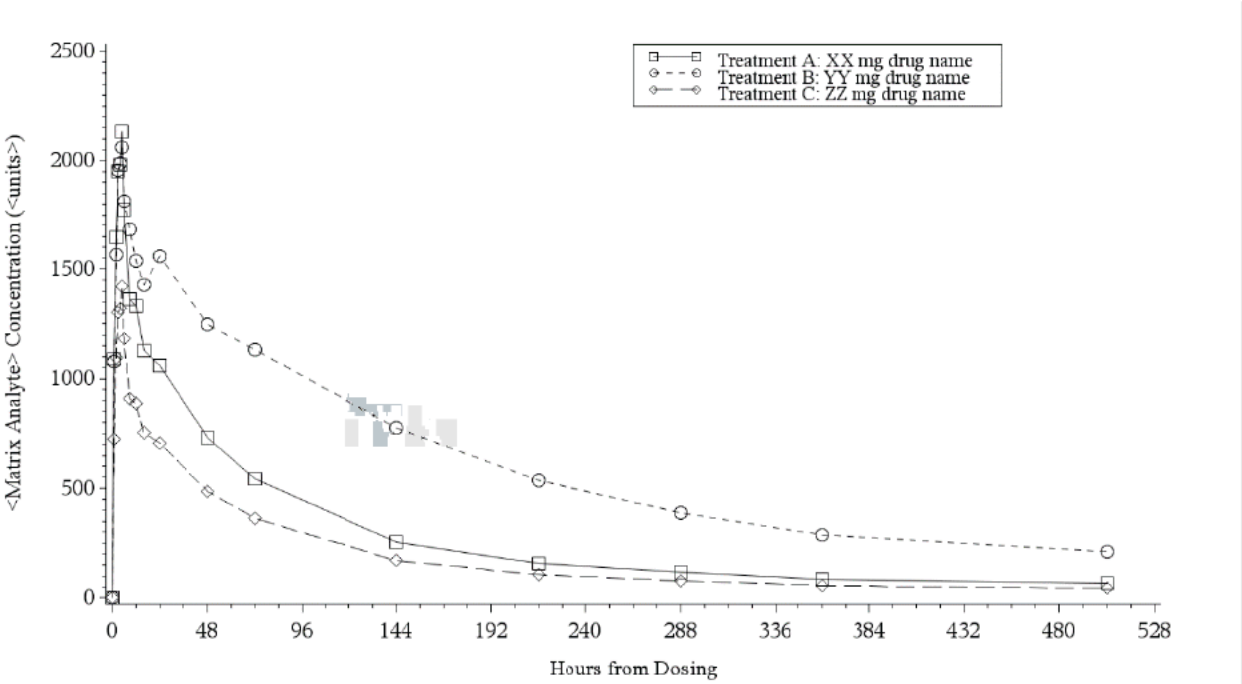


Treatments B and C are shifted to the right for ease of reading
Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYY HH:MM

In-text/Post-text Shell PFPConc2 will be in the following RTF format:

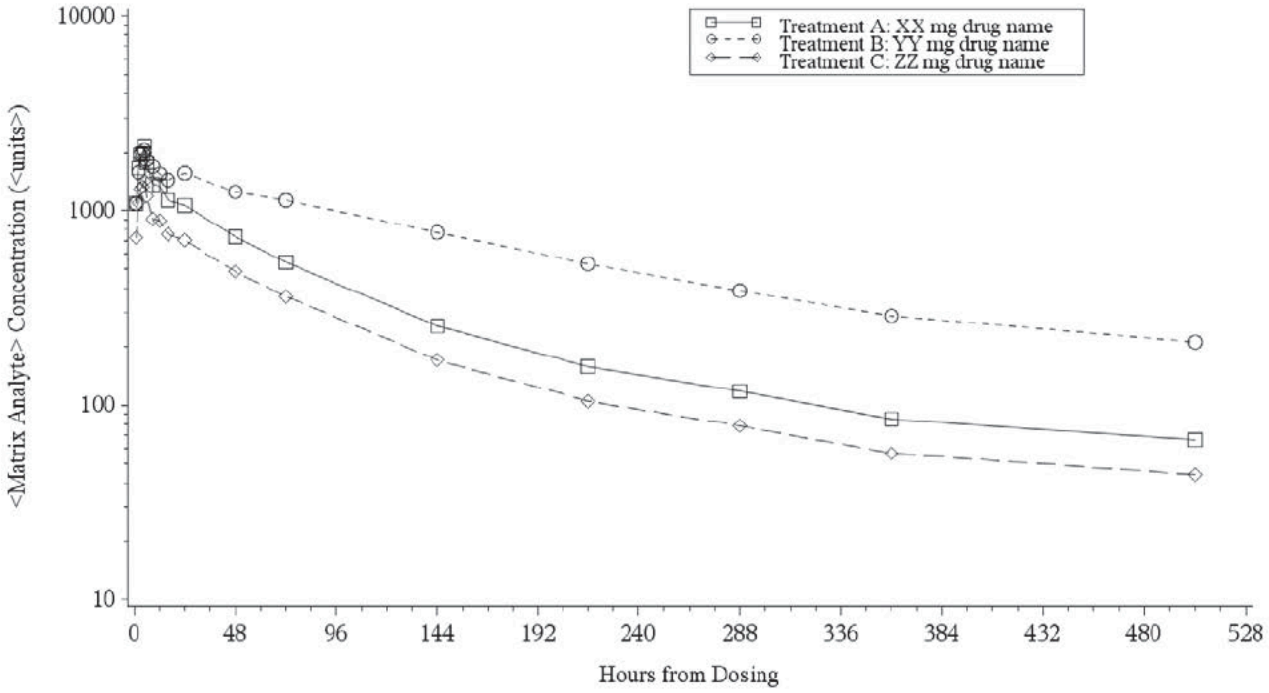
Figure PFPConc2

Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS in Abdomen, Arm, and Thigh (Linear Scale) (PK Population)



Post-text Shell PFPConc3 will be in the following RTF format:

Figure PFPConc3
Arithmetic Mean Serum Nemolizumab Concentration Versus Time Profiles Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI and DCS in Abdomen, Arm, and Thigh (Semi-Log Scale) (PK Population)



Program: /CAXXXXX/sas_prg/pksas/adam_meangraph.sas DDMMMYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/meangraph.sas DDMMMYYY HH:MM

Notes for Generating the Actual Mean Figures:

Legend will be as described below:
Figures 14.2.3.1-3;

AI: Overall (Abdomen, Arm, Thigh)
DCS: Overall (Abdomen, Arm, Thigh)

Figures 14.2.3.4-6;

AI, Abdomen
DCS, Abdomen

Figures 14.2.3.7-9;

AI, Arm
DCS, Arm

Figures 14.2.3.10-12

AI, Thigh
DCS, Thigh

Y-axis label will be "Serum Nemolizumab Concentration (ng/mL)"
X-axis label will be "Nominal Hours From Dosing"

For figures with SD (Figure 14.2.3.1), add the following footnote: "DCS is shifted to the right for the ease of reading."

For figure with SD (Figure 14.2.3.4), add the following footnote: "DCS, Abdomen is shifted to the right for the ease of reading."

For Figure with SD (Figure 14.2.3.7): add the following footnote: "DCS, Arm is shifted to the right for the ease of reading."

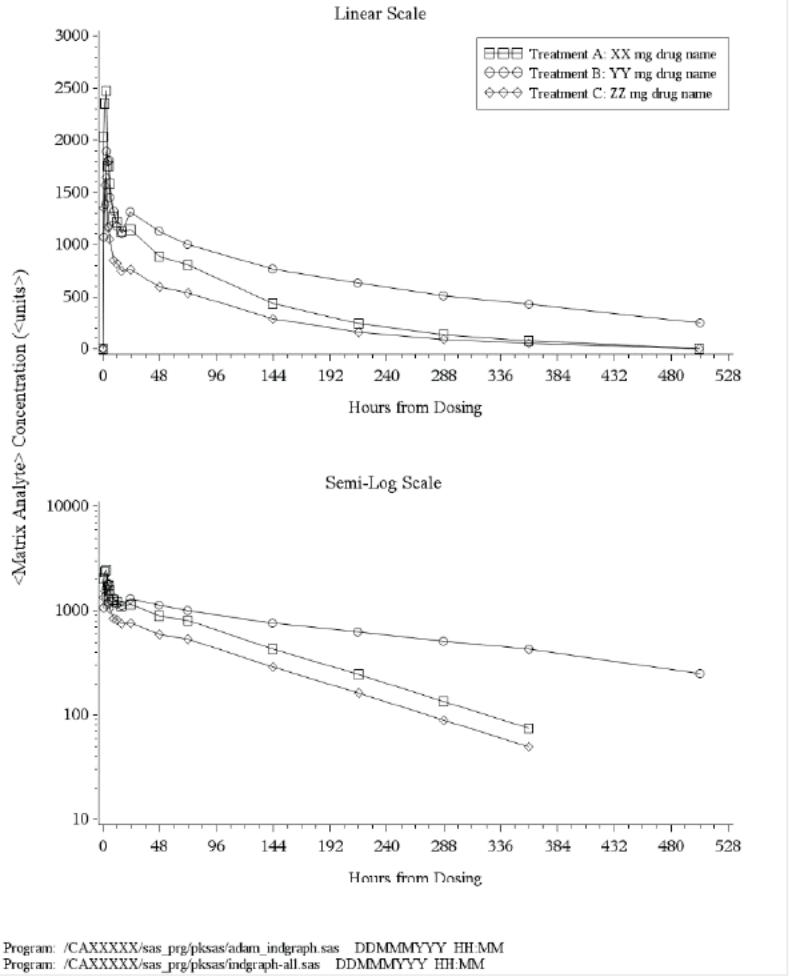
For Figure with SD (Figure 14.2.3.10): add the following footnote: "DCS, Thigh is shifted to the right for the ease of reading."

ADA figure 14.2.3.13
Legends:
AI, ADA Positive, AI, ADA Negative, DOCS, ADA Positive, and DOC, ADA Negative.
Y-axis label will be "Serum Nemolizumab Concentration (ng/mL)"
X-axis label will be "Predose, Day 30, Day 85"

Appendix Shell PFPConc5 will be in the following RTF format:

PFPConc5

Serum Nemolizumab Concentration Versus Time Profiles for <Subject #> (Linear and Semi-



Y=axis label will be Nemolizumab (ng/mL)
X-axis label will be "Hours From Dosing".

10.3 Section 14 Summary Tables Shells

Shell CDS will be in the following LST format:

Table CDS Disposition Summary (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Category	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Completed Study	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Study	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<Reason>	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMMYYYY HH:MM

Table CDEM Demographic Summary (SAF)

		Treatment								
		AI (N = X)				DCS (N = X)				
Trait	Category/Statistic	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	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	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Body Mass Index (kg/m^2)	n	X	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	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

<Also include Height (cm) and Weight (kg)>
AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Descriptive statistics for body mass index, height, and weight are calculated using screening measurements.
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CDPD Important Protocol Deviation Summary – Number of Subjects Reporting the Protocol Deviation (% of Subjects Dosed) (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Deviation Category	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< Category 1 >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< Category 2 >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< Category 3 >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Overall = number of subjects with at least one important protocol deviation
Deviations from the protocol assessed as "Important"/"Not important" are equivalent to "Major"/"Minor".
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Shell CPConc1 will be in the following LST format:

Table CPConc1 Serum Nemolizumab Concentrations (ng/mL) Following Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI (PK Population))

Subject		Sample Times (hr)								
Number	Site	Predose	XX	XX	XX	XX	XX	XX	XX	XX
X	X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
X	X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
X	X	BLQ	XX	XX	XX	XX	XX	XX	XX	XX
Overall										
n		XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		.	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum		XX	XX	XX	XX	XX	XX	XX	XX	XX
Median		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum		XX	XX	XX	XX	XX	XX	XX	XX	XX
Abdomen										
n		XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		.	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum		XX	XX	XX	XX	XX	XX	XX	XX	XX
Median		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum		XX	XX	XX	XX	XX	XX	XX	XX	XX
Arm										
n		XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		.	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

SEM	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Thigh									
n	XX	XX	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%	.	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

For the calculation of summary statistics, values that are below the limit of quantitation (BLQ) of <XX> are treated as <0> before the first quantifiable concentration and as missing elsewhere.

. = Value missing or not reportable.
Program: /CAXXXXX/sas_prg/pksas/adam_conc.sas DDMMMYYYY HH:MM

Notes for Generating the Actual Table:

Presentation of Data:
Concentrations will be presented to same precision as in bio data.
Summary statistics presentation with respect to the precision of the bio data: n = integer; Mean and Median +1; SD and SEM +2; Min and Max +0; CV% to 1 decimal

Per study design needs, the following changes are made to this table relative to CCI standard: columns <Treatment Sequence> and <Study Period> will be removed".

Programmer Note:

PK Time points are: pre-dose, 12 hours, 24 hours, 3, 4, 5, 6, 7, 8, 9, 10, 11, 15, 22, 29, 36,43, 50, 57, 71, and 85 days postdose

Program: /CAXXXXX/sas_prg/pksas/pk-conc-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/pk-conc-tables-sig.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_conc.sas DDMMMYYYY HH:MM

Shell CPPar1 will be in the following LST format

Table CPPar1 Serum Nemolizumab Pharmacokinetic Parameters Following the Administration of a Single 60 mg (2 x 30 mg Injections) SC Dose of Nemolizumab via AI (PK Population)

		Parameters					
Subject Number	Site	param1 (units)	param2 (units)	param3 (units)	param4 (units)	param5 (units)	param6 (units)
X	X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
X	X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
X	X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	X	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
X	X	X.XX	X.XX	XXX	XXX	XX.X	X.XXX
X	X	XXX	X.XX	XXX	XXX	XX.X	X.XXX
Overall							
n		XX	XX	XX	XX	XX	XX
Mean		XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum		XX.X	X.XX	XXX	XXX	XX.X	X.XXX
Median		XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Maximum		XXX	X.XX	XXX	XXX	XX.X	X.XXX
Geom Mean		XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Abdomen							
n		XX	XX	XX	XX	XX	XX
Mean		XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
SD		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM		XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum		XX.X	X.XX	XXX	XXX	XX.X	X.XXX
Median		XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Maximum		XXX	X.XX	XXX	XXX	XX.X	X.XXX
Geom Mean		XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Geom CV%		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Geom CV%		XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

Arm						
n	XX	XX	XX	XX	XX	XX
Mean	XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
Median	XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Maximum	XXX	X.XX	XXX	XXX	XX.X	X.XXX
Geom Mean	XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Geom CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Geom CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Thigh						
n	XX	XX	XX	XX	XX	XX
Mean	XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SEM	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX.X	X.XX	XXX	XXX	XX.X	X.XXX
Median	XX.XX	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Maximum	XXX	X.XX	XXX	XXX	XX.X	X.XXX
Geom Mean	XXX.X	X.XXX	XXX.X	XXX.X	XX.XX	X.XXXX
Geom CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Geom CV%	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

. = Value missing or not reportable.

Program: /CAXXXXX/sas_prg/pksas/adam_pkparam.sas DDMMMYYYY HH:MM

The following PK parameters will be presented in the following order and with following units: AUC0-4 weeks (ng*hr/mL), AUC0-last (ng*hr/mL), AUC0-inf (ng*hr/mL), AUC%extrap (%), Cmax (ng/mL), Tmax (hr), Kel (1/hr), t½ (hr), CL/F (L/hr), and Vd/F (L)
n will be presented as an integer (with no decimal);
Parameter values for exposure based parameters (i.e. AUCs, Cmax, Vd/F, CL/F) will be presented with, at maximum, the precision of the bioanalytical data, and, at minimum, 3 significant figures. Summary statistics for exposure parameters will be presented as: Mean, Median, and Geom Mean+1; SD and SEM +2; Min and Max +0.

Values for time-based parameters (i.e. Tmax, t1/2) will be presented with 2 decimals. Summary statistics for time-based parameters will be presented as: Mean, Median, and Geom Mean +1; SD and SEM +2; Min and Max +0.
Values for rate constants (i.e. Kel) will be presented with 3 significant figures. Summary statistics for K_{el} will be presented as: Mean, Median, and Geom Mean +1; SD and SEM +2; Min and Max +0.
CV% and Geom CV% for all parameters will be presented with 1 decimal

Program: /CAXXXXX/sas_prg/pksas/pk-tables.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_pkparam.sas DDMMMYYYY HH:MM

Shell CPStat1 will be in the following LST format:

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Table CPStat1 Statistical Comparisons of Serum Nemolizumab Pharmacokinetic Parameters: AI (Test) Versus DCS (Reference) (PK Population)

PK Parameter (unit)	Site	Method Geometric LSMs AI (Test)	(n)	Method Geometric LSMs DCS (Reference)	(n)	Geometric Mean Ratio (%)	90% Confidence Interval	Inter-subject CV%	Method by Site Interaction P-value	AI Vesus DCS P-value
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
XXXX ( )	Overall	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX	X.XX	X.XXX
	Abdomen	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Arm	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX
	Thigh	X.XX	(n)	X.XX	(n)	X.XX	XX.XX - XXX.XX	X.XX		X.XXX

Interaction p-value is associated with testing the hypothesis of no interaction between Method and Site. If the p-value is very small (e.g. < 0.05), then the overall comparison between methods is not valid. In such cases, the comparison between methods should be done at each site.
AI Versus DCS p-value is associated with testing the hypothesis of no difference between the two methods.

AI = Auto-Injector (test)
DCS = Dual-Chamber Syringe (reference)
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

Parameters were ln-transformed prior to analysis.
Geometric least-squares means (LSMs) are calculated by exponentiating the LSMs from ANOVA.
Geometric Mean Ratio = 100 x (test/reference)
Inter-subject CV% = 100 x (square root (exp[MSE]-1), where MSE = Residual variance from ANOVA.

Notes for Generating the Actual Table:

Presentation of Data:
Geometric LSMs be presented to same precision as Mean in the PK parameter table CPPar1,
Geometric Mean Ratio, 90% CI, and inter-subject CV% will be presented to 2 decimal places,
p-values will be presented to 4 decimals.

PK Parameters are:
The following PK parameters will be presented in the following order and with following units: AUC_{0-inf} (ng*hr/mL), C_{max} (ng/mL), AUC_{0-last} (ng*hr/mL), $AUC_{0-4\ weeks}$ (ng*hr/mL), and $t_{½}$ (hr)

Program: /CAXXXXX/sas_prg/pksas/stats-tables-mixed.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_statsmixed.sas DDMMMYYYY HH:MM

All CPStat2 tables are in the following format:

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Table CPStat2 Nonparametric Statistical Comparisons of Serum Nemolizumab PK Parameter Tmax: AI (Test) Versus DCS (Reference) (PK Population)

PK Parameter (unit)	Site	Median Difference: AI (Test) – DCS (Reference)		90% Confidence Interval	p-value
Tmax (hr)	Overall	X.XX	(n)	XX.XX – XXX.XX	X.XXX
	Abdomen	X.XX	(n)	XX.XX – XXX.XX	X.XXX
	Arm	X.XX	(n)	XX.XX – XXX.XX	X.XXX
	Thigh	X.XX	(n)	XX.XX – XXX.XX	X.XXX

AI = Auto-Injector (test)
DCS = Dual-Chamber Syringe (reference)
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

The p-value is based on the Wilcoxon Rank Sums statistics of two independent samples. The median difference (considered to be the treatment effect) is estimated using the Hodges-Lehmann method.

Notes for Generating the Actual Table:

Presentation of Data:

- Median difference will be presented to 2 decimals or 3 significant figures
- 90% CI will be presented to 4 decimals
- p-value will be presented to 4 decimals

Program: DM_PX:[HLXXXXX.PKSAS]XXXX.SAS DDMMMYYYY HH:MM

Galderma Research & Development, LLC
Nemolizumab, Protocol Number RD.06.SPR.201590
CCI

Table 14.2.2.1 Assessment of Immunogenicity (Absolute Occurrence, Percent of Subjects, and Treatment-Emergent ADA) (SAF)

Time Point	Statistic	AI (N=X)				DCS (N=X)			
		Abdomen	Arm	Thigh	Overall	Abdomen	Arm	Thigh	Overall
Predose	Screening (ECLIA), n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Confirmation (ECLIA), n (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	ADA titer (ng/mL)	XX	XX	XX	XX	XX	XX	XX	XX
	n	XX	XX	XX	XX	XX	XX	XX	XX
	Mean	XX	XX	XX	XX	XX	XX	XX	XX
	SD	XX	XX	XX	XX	XX	XX	XX	XX
	Medina	XX	XX	XX	XX	XX	XX	XX	XX
	Min	XX	XX	XX	XX	XX	XX	XX	XX
	Max	XX	XX	XX	XX	XX	XX	XX	XX
	Neutralizing antibodies, n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Treatment Related ADA, n (%)	XX	XX	XX	XX	XX	XX	XX	XX
Day 30	Screening (ECLIA), n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Confirmation (ECLIA), n (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	ADA titer (ng/mL)	XX	XX	XX	XX	XX	XX	XX	XX
	n	XX	XX	XX	XX	XX	XX	XX	XX
	Mean	XX	XX	XX	XX	XX	XX	XX	XX
	SD	XX	XX	XX	XX	XX	XX	XX	XX
	Medina	XX	XX	XX	XX	XX	XX	XX	XX
	Min	XX	XX	XX	XX	XX	XX	XX	XX
	Max	XX	XX	XX	XX	XX	XX	XX	XX
	Neutralizing antibodies, n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX

	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Treatment Related ADA, n (%)	XX	XX	XX	XX	XX	XX	XX	XX
Day 85	Screening (ECLIA), n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Confirmation (ECLIA), n (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	ADA titer (ng/mL)	XX	XX	XX	XX	XX	XX	XX	XX
	n	XX	XX	XX	XX	XX	XX	XX	XX
	Mean	XX	XX	XX	XX	XX	XX	XX	XX
	SD	XX	XX	XX	XX	XX	XX	XX	XX
	Medina	XX	XX	XX	XX	XX	XX	XX	XX
	Min	XX	XX	XX	XX	XX	XX	XX	XX
	Max	XX	XX	XX	XX	XX	XX	XX	XX
	Neutralizing antibodies, n, (%)	XX	XX	XX	XX	XX	XX	XX	XX
	Negative	XX	XX	XX	XX	XX	XX	XX	XX
	Positive	XX	XX	XX	XX	XX	XX	XX	XX
	Treatment Related ADA, n (%)	XX	XX	XX	XX	XX	XX	XX	XX

Treatment related ADA will be displayed only at post-baseline visits. The other stats (Screening, Confirmation, ADA titer, Neutralizing antibodies (Nab)) will be displayed at all visits.

Screening and Confirmation (note: screening is not the visit name. At each visit, there is a screening test, and a confirmation test only on positive screening):

The % for confirmation will be computed based on positive screening ADA.
ADA titer, Nab and treatment related ADA stats will be computed on the Positive subjects at Confirmation.

As mentioned in the SAP, Treatment-related ADA is defined when baseline screening or confirmatory ADA result is Negative and post-baseline confirmatory ADA result is Positive. Percentage is calculated based on the number of subjects with positive ADA results at confirmation test.

Program: /CA20737/sas_prg/pksas/adam_t1.sas DDMMMYYYY HH:MM

Table CAEOW Overview of Treatment Emergent Adverse Events Frequency by Treatment - Number of Subjects Reporting the Event
(% of Subjects Dosed) (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Number of Subjects With	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
TEAEs	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
Drug-Related TEAEs	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
TEAEs leading to Study Discontinuation	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
TEAEs of Special Interest	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
SAEs	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
TEAEs With Maximum Severity of Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
TEAEs With Maximum Severity of Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)
TEAEs With Maximum Severity of Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	XX (XX%)

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
AE = Adverse event; SAE = Serious adverse event; TEAEs = Treatment-emergent adverse events
Source: <ADaM and/or SDTM dataset reference>

Program: /CA33026/sas_prg/stsas/tab_Part2/adam_tblae1a_overall.sas 26AUG2022 5:32

Table CAES Treatment-Emergent Adverse Event Frequency by Treatment – Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)

	Treatment								
	AI (N = X)				DCS (N = X)				
Adverse Event	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Overall (N = X)
Number of Subjects With TEAEs	X (XX%)	X (XX%)	X (X%)	X (XX%)	X (XX%)	X (X%)	X (XX%)	X (XX%)	X (XX%)
Eye disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vision blurred	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Gastrointestinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Dyspepsia	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nausea	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal and connective tissue disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Back pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Muscle cramps	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nervous system disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Headache	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reproductive system and breast disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vaginal discharge	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Respiratory, thoracic and mediastinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Epistaxis	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Skin and subcutaneous tissue disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Sweating increased	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)

Programmer Note: For Tables 14.3.1.3, 14.3.1.4, 14.3.1.5, 14.3.1.6, and 14.3.1.7 change the first row to: "Number of Subjects With Serious TEAEs", "Number of Subjects With Severe TEAEs" "Number of Subjects With Drug-Related TEAEs", "Number of Subjects With TEAEs Leading to Study Discontinuation", and "Number of Subjects With TEAEs of Special Interest", respectively. If there is no subject in a table, contain statement: "There were no events that met this criteria."

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories.
Adverse events are classified according to MedDRA Version 25.0.
TEAEs = Treatment-emergent adverse event
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CAES2 Treatment-Emergent Adverse Event Frequency by Treatment and ADA Status (I of II) - Number of Subjects Reporting the Event (% of Subjects Dosed) (SAF)

	AI (N = X)							
	Abdomen (N = X)		Arm (N = X)		Thigh (N = X)		Overall (N = X)	
Adverse Event	ADA+	ADA-	ADA+	ADA-	ADA+	ADA-	ADA+	ADA-
Number of Subjects Dosed	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)
Number of Subjects With TEAEs	X (XX%)	X (XX%)	X (X%)	X (XX%)	X (XX%)	X (X%)	X (XX%)	X (XX%)
Eye disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vision blurred	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Gastrointestinal disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Dyspepsia	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nausea	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal and connective tissue disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Back pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Muscle cramps	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Musculoskeletal pain	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Nervous system disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Headache	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reproductive system and breast disorders	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Vaginal discharge	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)

Programmer Note: For Table 14.3.1.9, update (I of II) in title to (II of II) and "AI (N = X)" to "DCS (N = X)"

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Although a subject may have had 2 or more adverse events, the subject is counted only once within a category. The same subject may appear in different categories.
Adverse events are classified according to MedDRA Version 25.0.
TEAEs = Treatment-emergent adverse event; ADA = anti-drug antibody
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table 14.3.2.1 Serious Adverse Events (SAF)

Will match format of Appendix 16.2.7

Or contain statement as follows:

"There were no events that met this criteria."

Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBO Out-of-Range Values and Recheck Results - <Clinical Laboratory Panel> (SAF)

Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Parameter1 <Range> (Unit)	Parameter2 <Range> (Unit)	Parameter3 <Range> (Unit)	Parameter4 <Range> (Unit)
X	XX/X	Screen				DDMMMYYYY	HH:MM:SS	XX HN		XX L	XX HRN
		1	AI, Abdomen -X	-X.XX		DDMMMYYYY	HH:MM:SS	XX L	XX LY^N		XX HN

Programmer Note: Replace Parameter1, 2 etc. with actual lab tests in the study. Sort unscheduled assessment and early termination chronologically with other scheduled assessments and rechecks. Recheck should be sorted with the scheduled time point the recheck is for. Unscheduled and Early Termination records should only be included if they are out of range or recheck results.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
F = Female; M = Male
Range Flag: H = Above reference range, L = Below reference range, * = Did not match reference range
CS Flag: Y = Yes, N = Not clinically significant
PI Interpretation: - = Not clinically significant, + = Clinically significant, R = Request recheck, ^ = Will be retested later
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBR Clinically Significant Laboratory Values and Recheck Results (SAF)

Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Department	Test	Result		Reference Range	Unit
X	XX/X	1	AI, Abdomen	X	-X.XX	DDMMMYYYY	HH:MM:SS	Clinical Chemistry	Cholesterol	XXX		X - X	mg/dL
				X	XX.XX	DDMMMYYYY	HH:MM:SS	Clinical Chemistry	Cholesterol	XXX	HYR+	X - X	mg/dL
				X	XX.XX	DDMMMYYYY	HH:MM:SS	Clinical Chemistry	Cholesterol	XXX	HY+	X - X	mg/dL
				X	XX.XX	DDMMMYYYY	HH:MM:SS	Clinical Chemistry	Cholesterol	XXX	HN	X - X	mg/dL

Programmer Note: All timepoints for a subject/test with at least one value deemed as CS by the PI will be presented in this table. If no event meets this criteria then include a statement as follows: 'There were no clinical laboratory results documented as clinically significant by the Principal Investigator.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
F = Female, M = Male
Range Flag: H = Above reference range, L = Below reference range, * = Did not match reference range
CS Flag: Y = Yes, N = Not clinically significant
PI Interpretation: - = Not clinically significant, + = Clinically significant, R = Request recheck, ^ = Will be retested later Clinically Significant Values are based on the PI interpretation.
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMMYYYY HH:MM

Table CLBD Clinical Laboratory Summary and Change From Baseline – <Clin Lab Panel> (SAF)

				Treatment							
				AI (N = X)				DCS (N = X)			
Laboratory Test (units)	Reference Range	Time Point	Statistic	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)
Testname (Unit)	< - >#	Baseline	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Day 86 Absolute	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

Programmer Note: Treatment means at specific time points will be flagged (with a *) if they are above or below the reference range. This only applies to the clinical laboratory treatment results (i.e., not the change from baseline or any other endpoints). Time Point column will match those found in Section 7.5 of the SAP.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Baseline is the last measurement collected prior to dose which is typically the measurements at screening.
= Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.
* = Above reference range; ^ = Below reference range
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CLBS Clinical Laboratory Shift From Baseline - Serum Chemistry (SAF)

			Baseline L			Baseline N			Baseline H		
			Postdose			Postdose			Postdose		
Laboratory Test (units)	Treatment	Time Point	L	N	H	L	N	H	L	N	H
Testname (unit)	AI, Abdomen	Day 86	X	XX	X	X	XX	X	X	XX	X
	AI, Arm	Day 86	X	XX	X	X	XX	X	X	XX	X
	AI, Thigh	Day 86	X	XX	X	X	XX	X	X	XX	X
	AI, Overall	Day 86	X	XX	X	X	XX	X	X	XX	X
	DCS, Abdomen	Day 86	X	XX	X	X	XX	X	X	XX	X
	DCS, Arm	Day 86	X	XX	X	X	XX	X	X	XX	X
	DCS, Thigh	Day 86	X	XX	X	X	XX	X	X	XX	X
	DCS, Overall	Day 86	X	XX	X	X	XX	X	X	XX	X

Programmer Note: Time Point column will match those found in Section 7.5 of the SAP. For urinalysis, the following footnote is used since the categories of N and O will be used instead of L, N, H:
N = Within reference range; O = Outside reference range

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Baseline is the last measurement collected prior to dose which is typically the measurements at screening.
N = Within reference range; L = Below reference range; H = Above reference range
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CVS Vital Sign Summary and Change From Baseline (SAF)

				Treatment							
				AI (N = X)				DCS (N = X)			
Vital Sign (units)	Time Point		Statistic	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)
Testname (Unit)	Baseline		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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
	Day 9	Absolute	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

< Similarly for Day 44 and Day 86 >
Programmer Note: Time Point column will match those found in Section 7.6 of the SAP.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Baseline is the last measurement collected prior to dose which is typically the measurements at Day 1.
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Table CEG 12-Lead Electrocardiogram Summary and Change From Baseline (SAF)

				Treatment							
				AI (N = X)				DCS (N = X)			
Measurement (units)	Time Point		Statistic	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)	Abdomen (N = X)	Arm (N = X)	Thigh (N = X)	Overall (N = X)
Testname (Unit)	Baseline		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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
	Day 86	Absolute	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	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.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

Programmer Note: Time Point column will match those found in Section 7.7 of the SAP.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Baseline is the last measurement collected prior to dose which is typically the measurements at screening.
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

11. LISTING SHELLS

The following listing shells provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this study, but are intended to show the general layout of the listings that will be presented and included in the final report. Listings will be generated from data created in accordance with SDTM Model 1.4 with Implementation Guide 3.2. All listings will be presented in Courier New size font 9. Time point information (period, day, hour) will match that found in the CRF.

Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

Laboratory Group	Site	Test Name	Sex	Age Category	Reference Range	Unit
Serum Chemistry	XXXX	Testname1	MALE		XX - XXX	mEq/L
	XXXX	Testname2	MALE	0-25	XX - XXX	U/L
				26-99	XX - XXX	U/L
<similar for all other tests, note that age will only be presented when different reference range exists>						
Hematology	<similar to serum chemistry>					
Urinalysis	XXXX	Testname	MALE		NEGATIVE	
Urine Drug Screening	XXXX	Amphetamines	MALE		NOT DETECTED	

Programmer Note: Please don't include Reference Ranges if they are identical acroos the sites.

Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.1.1 Subject Disposition (SAF)

Subject Number	Treatment	Did Subject Complete the Study?	Date of Completion or Discontinuation	Primary Study Discontinuation Reason	Specify
1	AI, Abdomen	Yes	DDMMMYYYY		
2	DCS, Arm	No	DDMMMYYYY	Personal Reason	XXXXXXXXXXX
3	AI, Thigh	No	DDMMMYYYY	Other	XXXXXXXXXXX

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.2.1 Protocol Deviations

Subject Number	Study Period	Treatment	Day	Hour	Date	Deviation Category	Deviation Details	Severity	Important Protocol Deviation?
1	X	AI, Abdomen	X	X	DDMONYYYY	OTHER	XXXXXXXXXXXXX		
2	X	DCS, Abdomen	X	X	DDMONYYYY	OTHER	XXXXXXXXXXXXX		
3	<similar to above.								

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Deviations from the protocol assessed as "Important"/"Not important" are equivalent to "Major"/"Minor".
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Nemolizumab, Protocol Number RD.06.SPR.201590
CCI

Appendix 16.2.4.1 Demographics (SAF)

Subject Number	Year Of Birth	Age (yr)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	Body Mass Index (kg/m²)	Informed Consent Date	Protocol Version	Protocol Date
1	YYYY	47	Male	< >	Not Hispanic or Latino	XXX	XX.X	XX.XX	DDMMMYYYY	XXXXXXX	DDMMMYYYY
2	<similar to above.										

Age is approximated as year of informed consent – year of birth. There will be a subtraction of 1 if the difference in years is 1 more than the age specified in the inclusion criteria.
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.2 Physical Examination (SAF)

Subject Number	Study Period	Treatment	Day	Hour	Date	Question	Answer
1	Screen				DDMONYYYY	Was PE performed? (Yes/No)	YES
	1	AI, Abdomen	-1	-2.00	DDMONYYYY	Was PE performed? (Yes/No)	YES
			9	191.67	DDMONYYYY	Was PE performed? (Yes/No)	NO
			44	1031.67	DDMONYYYY	Was PE performed? (Yes/No)	YES
			86	2040.25	DDMONYYYY	Was PE performed? (Yes/No)	YES
2		<similar to above>					

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
PE = Physical examination
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.3 Medical History (SAF)

Subject Number	Any History?	Condition or Event	Date: Start	Date: End	Ongoing?	Preferred Term	System Organ Class
1	No						
2	Yes	< >	YYYY	YES	XXXXXXXXXXX	XXXXXXXXXXX	
		<note date can be YYYY, MONYYYY, or DDMONYYYY based on individual subject data>					

Medical histories are classified according to MedDRA Version 25.0.
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.4.4 Substance Use (SAF)

Subject Number	Substance	Description of Use	Start Date	End Date
1	Tobacco Use	0-4 CIGARETTES WEEK	DDMONYYYY	DDMONYYYY
		NON-SMOKER	DDMONYYYY	
2	Tobacco Use	NON-SMOKER	DDMONYYYY	

Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.1 Subject Eligibility (SAF)

Subject Number	Study Period	Did subject meet all eligibility criteria?	Criterion Not Met	Specify
1	Screen	YES		
2	Screen	NO	Exclusion 5	<specify and criterion not met will only be presented if populated>

Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.2 Test Compound Description

CRF Treatment Description	Form	Route
< >	SOLUTION	INJECTION SUBCUTANEOUS

Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.3 Test Compound Administration Times (SAF)

Subject Number	Study Period	Treatment	Day	Hour	Dose Date	First Injection Time	Second Injection Time	Injection Location	Compound	Planned Dosage	Comments
1	1	AI, Abdomen	1	0.00	DDMONYYYY	HH:MM:SS	HH:MM:SS	Abdomen	< >	60 mg	<This column prints only if data is

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.5.4 Prior and Concomitant Medications (SAF)

Subject Number	Treatment	Prior?	Medication (WHO DD)	Dosage	Route	Start Date	Start Time	End Date	End Time	Frequency	Indication	Ongoing?	AE Number
1			None										
2			None										
3		Yes	CETIRIZINE (CETIRIZINE)	X MG	BY MOUTH	DDMONYYYY		DDMONYYYY	HH:MM	XXXXXXX	XXXXXXX	NO	
	AI, Abdomen	No	PARACETAMOL (PARACETAMOL)	X MG	XXXXXXXXX	DDMONYYYY	HH:MM	XXXXXXXXX	HH:MM	XXXXXXXX	XXXXXXXX	XX	XXXXXXX

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Concomitant medications are coded with WHO Drug Dictionary Version 01-Mar-2022 b3.
WHO DD = World Health Organization Drug Dictionary
Prior is defined as a medication administered prior to the first study drug administration.
AE = Adverse Event
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix LBLDPK Pharmacokinetic Blood Draw Times and Concentration Data Shells

Appendix LBLDPK Serum Nemolizumab Pharmacokinetic Blood Draw Times and Concentration Data (SAF)

Subject Number	Treatment	CRF Day	CRF Hour	Blood Draw Date	Blood Draw Time	Elapsed Time From Last Dose (Hour)	<Analyte> Concentration (units)	Comments
1	AI, Abdomen	1	-0.05	DDMONYYYY	HH:MM:SS	0.0	X.XX	
			0.25	DDMONYYYY	HH:MM:SS	0.265	X.XX	
			0.50	DDMONYYYY	HH:MM:SS	0.590	X.XX	Late Draw
		< >						
		5	-95.95	DDMONYYYY	HH:MM:SS	0.0	X.XX	
			96.25	DDMONYYYY	HH:MM:SS	0.248	X.XX	
			96.50	DDMONYYYY	HH:MM:SS	0.495	X.XX	Hemolyzed
<similar for all other time points and subjects>								

AI = Auto-Injector
DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

Program: /CAXXXXX/sas_prg/pksas/standardlis/pk_bld.sas DDMMMYYYY HH:MM

Programmer Notes:
If more than 1 blood draw tube was collected, use this shell and create a separate but identical listing for each tube.
Population: Safety population (SAF) will be used in this listing. If applicable, concentration data will be left blank for subjects who received placebo treatment.
If SS are not present in Time in the EDC/offsite studies, then Time may be presented as HH:MM.

Table CPKel2. Intervals (Hours) Used for Determination of <Marix Analyte> Kel Values

Subject Number	Treatment	Interval	R^2	n
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X
X	X	XX.X - XX.X	X.XXX	X

AI, Abdomen = <> (test)
DCS, Abdomen = <> (reference)
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

R^2 = Coefficient of determination
n = Number of points used in Kel calculation
. = Kel value not reportable.

Notes for Generating the Actual Table:

Presentation of Data:

- Interval start and stop times will be presented to 1 decimal or 3 sig figures min;
- R^2 will be presented to 3 decimals;
- n will be presented as an integer (with no decimal)

Per study design needs, the following changes are made to this table relative to CCI standard: <>, <>
Per client preference, the following changes are made to this table relative to CCI standard: <>, <>

Program: /CAXXXXX/sas_prg/pksas/kel-tables-parallel.sas DDMMMYYYY HH:MM
Program: /CAXXXXX/sas_prg/pksas/adam_kel.sas DDMMMYYYY HH:MM

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Nemolizumab, Protocol Number RD.06.SPR.201590
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Appendix LBLDPK Immunogenicity (ADA) and NAb of Nemolizumab Administered With AI or DCS (SAF)

Subject Number	Treatment	Was the Sample Collected?	CRF Day	Date	Result	Titer value
X	AI, Abdomen	Yes	X	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX
		X	X	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX
		X	X	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX
		X	X	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX
		X	X	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX
		X	X	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX

AI = Auto-Injector (test)
DCS = Dual-Chamber Syringe (reference)
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)

Program: /CA29639/sas_prg/pksas/ada/adam_istable.sas 07APR2022 4:34

Appendix 16.2.7.2 Adverse Events (II of II) (SAF)

Subject Number	Age/ Sex	Treatment	TE?	System Organ Class/ Preferred Term (Verbatim)	Time From Last Dose (DD:HH:MM)	Date:Time Start/ End Duration (DD:HH:MM)	AESI?/ Type	Discontinued Study due to this Event?	Is the Event Related to Covid-19?
1	30/F			None					
2	24/M			None					
3	52/M	AI, Abdomen	Yes	XXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX XXXXXXXXXXX)	XX:XX:XX	DDMONYYYY:HH:MM/ DDMONYYYY:HH:MM 00:23:15	Yes/ 4	No	No
				<similar to above>					

Programmer Note: AEs should be presented start date/time order for each subject.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Adverse events are classified according to MedDRA Version 25.0.
TE = Abbreviation for treatment-emergent; AESI = Abbreviation for adverse event of special interest
Type of AESI: 3=N/A, 4=Injection related reaction, 5=Infection, 6=Peripheral edema: limbs, bilateral, 7=Facial edema, 8=Elevated ALT or AST (>3x ULN) combined with elevated bilirubin (>2x ULN)
F = Female; M = Male
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.7.3 Details for Serious Adverse Events (SAF)

Subject Number	Age/ Sex	Treat-ment	TE?	System Organ Class/ Preferred Term (Verbatim)	Date:Time Start/ End Duration (DD:HH:MM)	Serious Event?	Congenital Anomaly/ Birth Defect?	Persistent or Significant Disability or Incapacity?	Hospital-ization?	Life-Threat?	Important Medical Event?	Death?
3	52/M	AI, Abdomen	Yes	XXXXXXXXXXX/ XXXXXXXXXXXXXXXXX (XXXXXXXXXXX)	DDMONYYYY:HH:MM/ DDMONYYYY:HH:MM 00:23:15	Yes	No	No	Yes	No	Yes: < >	No

Programmer Note: If Serious = Yes then present AEs in this listing otherwise please do not include this listing.

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
Adverse events are classified according to MedDRA Version 25.0.
TE = Abbreviation for treatment-emergent
F = Female; M = Male
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Nemolizumab, Protocol Number RD.06.SPR.201590
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Appendices 16.2.8.2 – 16.2.8.5 will resemble 16.2.8.1.

Appendix 16.2.8.1 Clinical Laboratory Report - Serum Chemistry (SAF)

Subject Number	Age/ Sex	Study Period	Treat-ment	Day	Hour	Date	Time	Chloride M: 97-105 (mEq/L)	Potassium M: 3.7-5.2 (mEq/L)	Phosphorus M: 2.4-4.4 (mg/dL)	Sodium M: 135-143 (mEq/L)
1	XX/M	Screen				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX HY-
		1	AI, Abdomen	86	2039.50	DDMONYYYY	HH:MM:SS	XXX HY^	X.X	X.X	XXX HN-
		Recheck				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X LN	XXX

<similar to above for all subjects/time points>

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
F = Female; M = Male
Range Flag: H = Above reference range, L = Below reference range, * = Did not match reference range
CS Flag: Y = Yes, N = Not clinically significant
PI Interpretation: - = Not clinically significant, + = Clinically significant, R = Request recheck, ^ = Will be retested later Clinically
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Appendix 16.2.8.6 Vital Signs (SAF)

Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respiration (brpm)	Temperature (°C)	Weight (kg)
1	30/F	Screen				DDMONYYYY	HH:MM:SS					XX.X
								XXX/ XX	XX	XX	XX.X	
						R	HH:MM:SS	XXX/ XX				
						R	HH:MM:SS	XXX/ XX				
		1	AI, Abdomen	1	-1.00	DDMONYYYY	HH:MM:SS	XXX/ XX				

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
F = Female; M = Male
R = Recheck value; brpm = breaths/min
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Galderma Research & Development, LLC
Nemolizumab, Protocol Number RD.06.SPR.201590
CCI

Appendix 16.2.8.7 12-Lead Electrocardiogram (SAF)

Subject Number	Age/ Sex	Study Period	Treatment	Day	Hour	Date	Time	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Specify/Comments
1	30/F	Screen				DDMONYYYY	X:XX:XX	WNL	XX	XXX	XX	XX	XXX	XXX	EARLY REPOLARIZATION; LEFT AXIS DEVIATION
		1	AI, Abdomen	86	X.XX	DDMONYYYY	XX:XX:XX	ANCS	XX	XXX	XX	XX	XXX	410	LEFT AXIS DEVIATION
				86	X.XX R	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XX	XXX	451#	

AI = Auto-Injector, DCS = Dual-Chamber Syringe
All subjects received a single dose of nemolizumab 60 mg (2 x 30 mg injections)
F = Female; M = Male
R = Recheck value; WNL = Within normal limits; ANCS = Abnormal, not clinically significant
QTcF = QT corrected for heart rate using Fridericia's correction
# = QTc value greater than 450 msec
Source: <ADaM and/or SDTM dataset reference>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM