INTEGRIUM, LLC
BIOMETRICS DEPARTMENT

Clinical Study Protocol: ORT-2020-01

A Multi-Center, Randomized, Double-Blind, Placebo-controlled Proof-of-Activity Study with Orticumab in Subjects with Moderate-to-Severe Psoriasis and Cardiometabolic Risk Factors

Statistical Analysis Plan (SAP) Documentation

Author(s): Kenneth E. Homer

Sponsor: Abcentra LLC

Document status: Version 1.0

Dates: 11AUG2022

Number of pages: 20

Signature Page

Statistical Analysis Plan for Clinical Study Protocol: ORT-2020-01

A Multi-Center, Randomized, Double-Blind, Placebo-controlled Proof-of-Activity Study with Orticumab in Subjects with Moderate-to-Severe Psoriasis and Cardiometabolic risk factors

Approved by:

08/11/22

Kevin Bacon, PhD
Chief Executive Officer,
Abcentra LLC

Date

Author(s):

Kenneth E Homer

12 Aug 2022

Kenneth E. Homer, M.S.
Sr. Director of Biostatistics and Clinical Systems
Integrium, LLC

Date

Document History

Version Number	Author	Date	Change
1.0	K. Homer	11AUG2022	Initial Version

Glossary of Abbreviations

AE	Adverse Event
BSA	Body Surface Area
CCTA	Coronary Computed Tomographic Angiography
CSR	Clinical Study Report
DBP	Diastolic Blood Pressure
DLQI	Dermatology Life Quality Index
I-NRS	Itch Numeric Rating Scale
IP	Investigational Product
ISRC	Internal Safety Review Committee
ITT	Intent-to-Treat
MedDRA	Medical Dictionary for Regulatory Activities
mL	milliliter
PASI	Psoriasis Area and Severity Index
PD	Pharmacodynamic
PI	Primary Investigator
PK	Pharmacokinetic
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SBP	Systolic Blood Pressure
sIGA	static Investigator Global Assessment
TEAE	Treatment-Emergent Adverse Events
WHO	World Health Organization

Table of Contents

1. Introduction

1.1. Scope

This document contains detailed information to aid the production of the Clinical Study Report (CSR) including summary tables and listings for trial ORT-2020-01. The contents of this document were reviewed by the sponsor, Abcentra LLC, and the trial biostatistician at Integrium.

1.2. Study Overview

This randomized, double-blind study is designed to compare the responses of orticumab [redacted] or placebo in subjects with moderate to severe psoriasis. A total of 75 subjects (enrolled in at least 17 study sites) with psoriasis will be randomized in a double-blind fashion to receive either an IV infusion of orticumab or placebo for up to 78 days. Before any study-related procedures are conducted, the subjects will sign a written informed consent. Subjects will be screened (Day -28 to -1) for the study, which will include clinical laboratory evaluations and CCTA. Prior to dosing on study Day 1, Baseline assessments will be performed. During treatment periods, dosing will be performed under supervision at the research center. Subjects will visit the research center on the morning of Days 1, 8, 15, 22, 50 and 78 for a pre-dose blood sample for PK purposes, Day 106 for End of Study assessments, and Day 120 for Follow-up assessments.

Following the Screening Period, participants will be enrolled into one of the two groups: [redacted] orticumab or placebo. Subjects will be randomized in a 2:1 ratio, orticumab to placebo and receive up to 11 weeks of treatment.

Planned treatments are weekly for 4 weeks, then monthly IV infusions of [redacted] orticumab or placebo. The Internal Safety Review Committee (ISRC) will review the blinded safety data after the first subject completes the first dose (Day 1), the ISRC will review all adverse reactions to all administered doses at these times. At the Investigator's discretion, subjects may be eligible for psoriasis rescue medications as discussed in Section 5.9.4 of the protocol.

Stopping criteria (as discussed in Section 12.2 of the protocol) will be utilized in this study based on treatment-emergent AEs (defined as AEs that begin or worsen after the first dose of IP) in determining if infusions in existing and future subjects may continue.

1.3. Study Objectives and Endpoints

1.3.1 Primary Objectives

The primary safety objective of this study is to assess the safety and tolerability of orticumab [redacted] in subjects with moderate-to-severe psoriasis and cardiometabolic risk factors, as assessed by vital signs, clinical laboratory variables, and adverse events (AEs) monitoring, compared to placebo.

The primary efficacy objective is to demonstrate the efficacy of orticumab [redacted] in subjects with moderate-to-severe psoriasis and cardiometabolic risk factors with respect to both percent change in PASI and sIGA mod 2011 response at Week 15, compared to placebo.

1.3.2 Secondary Objectives

The secondary efficacy objectives are:

1. To demonstrate the efficacy of orticumab [redacted] in subjects with moderate-to-severe psoriasis and cardiometabolic risk factors with respect to percent change in PASI and PASI response by looking at PASI 75 and 50 response rates and sIGA mod 2011 response at Weeks 1, 3, 7,11, and 15 compared to placebo.
2. Assess the effect of orticumab [redacted] on BSA, Dermatology Life Quality Index (DLQI), and Itch Numerical Rating Scale Score in subjects with moderate-to-severe psoriasis and cardiometabolic risk factors.

1.3.3 Exploratory Objectives

The exploratory objectives are to assess the effect of orticumab [redacted] on cardiometabolic and inflammatory biomarkers in subjects with moderate-to-severe psoriasis and cardiometabolic risk factors.

1.3.4 Primary Endpoints

The primary safety endpoints for the study are:

1. Number and percent of participants with one or more Treatment Emergent Adverse Events (TEAEs) or any serious adverse events (SAEs).
2. Change in hemodynamic parameters from Baseline to Weeks 3, 7, 11 and 15.
3. Change in blood chemistry and hematology from Baseline to Weeks 3 and 15.
4. Change in physical examination from Baseline to Weeks 3, 7, 11 and 15.

The primary efficacy endpoints for the study are:

1. Mean percent change from Baseline in PASI at Week 15, compared to placebo.
2. Percentage of participants achieving treatment success (clear =0 or almost clear =1) and greater than or equal to (>=) 2 Point Improvement at Week 15 on the 5-point static Investigator's Global Assessment modified 2011 version (sIGA).

1.3.5 Secondary Endpoints

The secondary efficacy endpoints for the study are:

1. Mean percent change from Baseline in PASI at Weeks 1, 3, 7 and 11.
2. Percentage of Participants achieving PASI75 and PASI50 from Baseline at Weeks 1, 3, 7, 11 and 15 compared to placebo.
3. Percentage of participants achieving treatment success (clear =0 or almost clear =1) and greater than or equal to (>=) 2 Point Improvement at Weeks 1, 3, 7, and 11 on the 5-point static Investigator's Global Assessment modified 2011 version (sIGA).
4. Mean percent change from Baseline in BSA at Weeks 1, 3, 7, 11, and 15 compared to placebo.
5. Mean change from Baseline in Dermatology Life Quality Index (DLQI) at Weeks 3, 7, 11, and 15 compared to placebo.

6. Mean change from Baseline in Itch Numerical Rating Scale Score at Weeks 3 and 15 compared to placebo.

1.3.6 Exploratory Endpoints

The exploratory efficacy endpoints for the study are:

1. Mean change from Baseline in cardiometabolic and inflammatory biomarkers at Weeks 3 and 15 in:
    - Blood serum lipid parameters
        - ApoB, Apo A1, VLDL-c, oxLDL, oxHDL, Lp(a), oxLp(a), NMR-LP4
    - Blood serum inflammation biomarkers
        - Interleukin-6 (IL-6), IL-1β, IL-17, tumor necrosis factor-alpha (TNF-α), osteoprotegerin, high-sensitivity C-reactive protein (hs-CRP), serum amyloid A (SAA), and monocyte chemoattractant protein-1 (MCP-1)
    - Blood serum HDL efflux efficiency
        - ABCA-1
2. Change in coronary artery perivascular fat attenuation index (FAI) measured by coronary computed tomographic angiography (CCTA) at Week 15 as compared to Baseline in active and placebo treated subjects.
3. Change in Noncalcified and low attenuation coronary artery plaque volume, assessed by CCTA at week 15 as compared to Baseline, in active and placebo subjects.
4. Change in total plaque volume, assessed by CCTA at week 15 as compared to Baseline, in active and placebo subjects.

2. Detailed Statistical Methods

2.1. General Statistical Methods

All measured variables and derived parameters will be listed individually and, if appropriate, tabulated by descriptive statistics. For descriptive statistics summary tables will include by treatment group summaries of sample size, arithmetic mean, standard deviation, median, minimum and maximum values, and 95% Confidence Intervals (if appropriate). For categorical variables summary tables will include by study group summaries of frequency counts.

2.2. Study Populations

Safety population: All subjects who receive at least one dose of the study drug will be included in the safety population

Intent-to-Treat (ITT) population: all subjects in whom at least one treatment was given and in whom at least one efficacy measurement was collected both at baseline and during treatment will be included in the Intent-to-Treat population.

PK/PD population: All subjects who receive the study drug and for whom at least 1 trough PK concentration is collected will be included in the PK/PD population.

2.3. Patient Disposition and Characteristics

An account of the patients by disposition will be tabulated overall. The number of patients included in each analysis population will be summarized. Patients not completing the study will be summarized and listed with the reason for their premature discontinuation.

2.4. Demographic/Baseline Information

Demographic and Baseline characteristics will be summarized by treatment sequence, sex, and overall. Summary statistics (number of subjects, mean, median, standard deviation, minimum and maximum) will be generated for continuous variables (e.g., age and weight) and the number and percentage of subjects within each category will be presented for categorical variables (e.g., sex, ethnicity and race).

2.5. Study Drug Duration and Compliance

The number of times the subject received an IV infusion of investigational product will be summarized using frequency counts. The average percent infused per infusion and overall percent compliance will be summarized using summary statistics (number of subjects, mean, median, standard deviation, minimum and maximum).

2.6. Prior and Concomitant Medications

Prior and concomitant medications will be coded using World Health Organization (WHO) Drug dictionary March 2021 version.

Prior medications will be defined as any medication that stops prior to the day of first randomized treatment.

Concomitant medications will be defined as any medication that stops on or after the day of first randomized treatment.

Section 2.13 describes the imputation rules for partial dates. All medications will be presented in a data listing.

2.7. Safety Evaluations

2.7.1. Adverse Events

Adverse events will be coded using the Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 24.0 and tabulated, including categorical information of interest such as onset and resolution times, time of onset relative to dose, severity at onset, maximum severity, causal relationship to study medication, and action taken.

Treatment-emergent adverse events (TEAEs) are defined as any AE that starts or increases in severity after the first randomized dose of study treatment. The incidence of TEAEs will be tabulated by MedDRA preferred term, system organ class, treatment group, severity, and assigned relationship to study treatment. Adverse events will also be summarized by severity and relationship to the investigational product (IP).

The incidence of serious AEs, drug-related AEs, serious and drug-related AEs, and any AEs resulting in discontinuation from the study will be listed.

2.7.2. Laboratory Evaluations

Individual clinical lab (hematology, serum chemistry, and coagulation parameters) values will be listed by visit and summarized using descriptive statistics as appropriate (sample size, mean, standard deviation, median, minimum and maximum) for continuous data and frequency counts for categorical data. Individual changes from baseline (Visit 1) in laboratory values will be calculated and summarized descriptively for continuous variables. Shift tables from baseline (Visit 1) to post dose (Visit 4 and Visit 7) will also be produced for the laboratory assessments based on the categories of Low, Normal, and High.

A clinically significant abnormal value or clinically significant change from baseline (Visit 1), may be recorded as an AE, if deemed appropriate by the PI or sponsor.

2.7.3. Vital Signs

Individual vital sign measurements (height, weight, seated SBP/DBP and heart rate) will be listed by measurement time and summarized using descriptive statistics as appropriate (sample size, mean, standard deviation, median, minimum and maximum). Individual changes from baseline (pre-dose Visit 1) in vital sign measurements will be calculated and summarized descriptively.

A clinically significant change from baseline may be recorded as an AE, if deemed appropriate by the PI or sponsor.

2.7.4. Physical Examination

Individual physical examination findings will be listed by visit.

A clinically significant change from start of randomized treatment will be recorded as an AE if deemed appropriate by the Investigator.

2.8. PK/PD Evaluations

Trough PK concentrations will be summarized using descriptive statistics (sample size, mean, standard deviation, median, minimum and maximum) at each visit in which PK is collected.

2.9. Efficacy Evaluations

2.9.1. Primary Efficacy Evaluation

There are two primary endpoints for this study: Percent change in PASI and sIGA response rate.

Percent change in PASI will be analyzed using a linear mixed model analysis. The model will be implemented using PROC MIXED in SAS, and will include fixed effects for treatment, site and Baseline PASI as a covariate.

The sIGA response rate will be analyzed using Fisher's Exact Test with treatment and response as the factors.

2.9.2. Secondary and Exploratory Efficacy Evaluations

Continuous variables will be analyzed using a linear mixed model similar to the primary efficacy evaluation.

Response rates and other dichotomous variables will be analyzed using Fisher's Exact Test.

Categorical data that has more than two possible responses will be analyzed using the Cochran-Mantel-Haenszel Row Mean Score.

2.9.3. Psoriasis Area and Severity Index (PASI)

PASI total score, change from baseline and percent change from baseline will be calculated for each post-baseline visit. The difference between active and placebo will be tested using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with Baseline PASI total sore as a covariate at each post-baseline visit.

PASI75 (75% improvement from baseline in PASI total score) and PASI50 (50% improvement from baseline in PASI total score) responder rates will be derived and analyzed using a Fisher's exact test to test for differences between placebo and active at Weeks 1, 3, 7, 11 and 15.

2.9.4. static Investigator Global Assessment (sIGA)

The sIGA will be summarized at each visit using frequency counts. The difference between active and placebo will be tested using a Cochran-Mantel-Haenszel (CMH) test at each visit that sIGA is collected.

Treatment success in sIGA is defined as having a value of clear=0 or almost clear=1 and greater than or equal to a 2 point improvement on the 5-point static Investigator's Global Assessment test. Responder rates based on treatment success will be summarized and analyzed using a Fisher's Exact test at each post-baseline visit that sIGA is collected.

2.9.5. Psoriasis Body Surface Area (BSA) Involvement

Observed, change from baseline and percent change from baseline in BSA will be derived and analyzed using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with Baseline BSA as a covariate at each post-baseline visit.

2.9.6. Dermatology Life Quality Index (DLQI)

The DLQI total score will be derived at each visit in which DLQI is collected. The observed, change from baseline and percent change from baseline in DLQI total score will be derived and analyzed using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with Baseline DLQI total score as a covariate at each post-baseline visit.

Each question on the DLQI is scored on a four-point Likert scale:

- Very much = 3
- A lot = 2
- A little = 1
- Not at all = 0
- Not relevant = 0
- Question unanswered = 0

The DLQI total score is calculated by adding the score of each question, resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired. A score higher than 10 indicates that the patient's life is being severely affected by their skin disease.

2.9.7. Coronary Computed Tomographic Angiography (CCTA)

The observed and change in coronary artery perivascular fat attenuation index (FAI) measured by coronary computed tomographic angiography (CCTA) will be summarized and analyzed using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with Baseline FAI as a covariate at each post-baseline visit in which CCTA is performed.

The observed and change in noncalcified an low attenuation coronary artery plaque volume, assessed by CCTA will be summarized and analyzed using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with baseline value as a covariate at each post-baseline visit in which CCTA is performed.

The observed and change in total plaque volume, assessed by CCTA will be summarized and analyzed using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with Baseline Total Plaque Volume as a covariate at each post-baseline visit in which CCTA is performed.

2.9.8. Itch Numeric Rating Scale (I-NRS)

The I-NRS will be summarized at each visit using frequency counts. The difference between active and placebo will be tested using a Cochran-Mantel-Haenszel (CMH) test at each visit that I-NRS is collected.

2.9.9. Cardiometabolic and Inflammatory Biomarkers

The biomarkers will be analyzed according to standard ELISA multiplexes which provide quantitative values. There may be LLOQ for some subjects for some biomarkers, but the ones chosen are the more common and suspected to be elevated in these subjects.

The observed value and change from baseline in the biomarkers will be summarized (number of observations with BLQ values, n, mean, std. dev., median, minimum and maximum) and analyzed using a mixed effects linear model (PROC MIXED in SAS) that will include fixed effects for treatment and site with baseline value as a covariate at each post-baseline visit in which biomarkers are collected.

2.10. Interim Analyses

This study will utilize a modified adaptive design model. There will be 2 planned stages for the analysis. Stage 1 will consist of the first 30 randomized subjects. After enrollment is completed for Stage 1, enrollment will begin for Stage 2 (there will be no pause in enrollment).

In order to ensure an overall alpha of approximately 0.05, Stage 1 will be analyzed at an alpha level of 0.01 and the final analysis (Stage 1 and Stage 2 combined) will be analyzed at an alpha level of 0.04. A hierarchical testing strategy will be utilized in which the percentage change in PASI will be tested initially. If the p-value for this initial test is less than the indicated alpha level, the result will be concluded as real. If the percentage change in PASI is concluded as real, the change in sIGA will be tested at the indicated alpha level.

In order to preserve type I error, the method presented by Cui, et al will be used to combine the data from Stage 1 and Stage 2.

The planned number of subjects for the study is 75. Stage 1 will consist of the first 30 subjects, so the weight given to Stage 1 in the analyses will be 30/75 (0.40). The weight given to Stage 2 in the analyses will be 45/75 (0.60).

The combining of the Stage 1 and Stage 2 analyses will be performed as follows:

- The Stage 1 p-value will be converted to a Z score (standard normal score).
- The Stage 2 p-value will be converted to a Z score (standard normal score).
- The Z scores will be combined using the weights previously indicated to create the combined Z score.
- The combined Z score will be converted to a p-value.

2.11. Sample Size and Power Considerations

No formal statistical assessment, in terms of sample size, was conducted for the endpoints analyzed in this study. Given the typical placebo response rates of 0-10% in psoriasis clinical trials, it is assumed that a 2:1 randomization involving at least 40 subjects on orticumab or placebo will allow for the exploration of meaningful measure of efficacy.

The primary endpoints are mean percent change from baseline PASI and sIGA success at Week 15.

Given that this is a Phase 2 study, no correction for multiplicity will be applied.

For percent change from baseline in PASI, assuming a standard deviation of 10% (a bit high, but good for power calculations:

> The study has 80% power to detect a difference of 7% improvement between active and placebo.

The study has 90% power to detect a difference of 8% improvement between active and placebo.

For sIGA success rate, assuming a placebo success rate of 10%:

If the true active success rate is 40%, the study has 80% power to detect a difference.

If the true active success rate is 45%, the study has 90% power to detect a difference.

Subjects will be stratified by five geographic regions: Northeast, Southeast, Upper Midwest (including Alaska); Lower Midwest; and West Coast (Including Hawaii).

2.12. Randomization Scheme and Codes

The randomization details for this study are presented in a separate randomization plan.

2.13. Handling Missing Data

Descriptive statistics and listings will be provided for all data. No substitution of missing data will be used in any calculations. Data points that appear to be spurious will be investigated and will not be excluded from the listings. Influential cases will be handled in an appropriate statistical manner.

Dates related to the adverse events and medications will be imputed using the rules below in an effort to categorize them properly into the summary tables.

Imputing partial or missing start dates:

- If the year is unknown, then the start date will not be imputed. The date will remain missing.
- If the month is unknown and the year is the same as the first dose date of the study, then impute the month and day of the date to be equal to the first dose month and day. Otherwise, impute the month as January.
- If the day is unknown and the month and year are the same as the first dose date of the study, then impute the day to be equal to the day of the first dose. Otherwise, impute the day as '01'.

Impute partial or missing stop dates:

- If the year is unknown, then the stop date will not be imputed. The date will remain missing.
- If the month is unknown, impute the month as December.
- If the day is unknown, impute the day to be the last day of the month.

If an imputed stop date is greater than the date of study completion/discontinuation date of the study, then the imputed stop date will be set equal to the date of completion/discontinuation date.

The imputed dates will be stored in the analysis datasets along with the original dates as recorded by the sites.

2.14. Protocol Deviations

Protocol deviations will be displayed in a data listing as provided by the clinical team.

2.15. Computer Systems and Packages Used for Statistical Analyses

Server SAS® version 9.4 on the Microsoft Windows Server 2008R2 64-bit platform will be used for all analyses. All computations will be performed using SAS®. The exact form of the various algorithms will be the SAS® defaults. The output from any SAS® procedure will be used in the tables using SAS® macros.

3. References

Cui, L, HM Hung, and SJ Wang, 1999, Modification of Sample Size in Group Sequential Clinical Trials, Biometrics, 55(3):853–857.

4. Data Listing Shells

4.1. Data Listings Table of Contents

The following post-text listings will be generated.

Listing Number	Listing Title
16.1.7	Randomization Schedule
16.2.1	Subject Completion/Discontinuation
16.2.2	Protocol Deviations
16.2.3	Population Status
16.2.4.1	Demographics and Baseline Characteristics
16.2.4.2	Childbearing Potential
16.2.4.3	Substance Use
16.2.4.4	Inclusion / Exclusion Criteria and Informed Consent
16.2.4.5	Medical History
16.2.4.6	Prior and Concomitant Medications
16.2.5	IV Administration
16.2.6.1.1	Psoriasis Area and Severity Index (PASI) - Observed Values
16.2.6.1.2	Psoriasis Area and Severity Index (PASI) - Derived Parameters
16.2.6.2	static Investigator Global Assessment (sIGA)
16.2.6.3	Psoriasis Body Surface Area (BSA) Involvement
16.2.6.4	Dermatology Life Quality Index (DLQI)

Listing Number	Listing Title
16.2.6.5	Itch Numeric Rating Scale (I-NRS)
16.2.6.6	Cardiometabolic and Inflammatory Biomarkers
16.2.6.7	Coronary Computed Tomographic Angiography (CCTA)
16.2.6.8	Trough Pharmacokinetic Concentrations
16.2.7.1	Adverse Events
16.2.7.2	Serious Adverse Events
16.2.7.3	Adverse Events Leading to Study Treatment Discontinuation
16.2.8.1	Laboratory Test Results - Hematology
16.2.8.2	Laboratory Test Results – Chemistry
16.2.8.3	Laboratory Test Results – Coagulation Parameters
16.2.8.4	Laboratory Test Results - Other
16.2.9.1	Vital Signs
16.2.9.2	Physical Examination Results

4.2. Data Listings

All subjects and all data will be presented in the listings. The listings will be sorted by treatment and subject number.

There are currently 29 listings that are planned to be generated. The 29 listings are broken down as follows: 14 Standard Unique, 6 Standard Repeat, 9 Non-Standard Unique and 0 Non-Standard Repeat.

5. Summary Table and Figure Shells

5.1. Post-text Table of Contents

The following post-text tables will be generated.

Table Number	Table Title
14.1.1.1	Summary of Subject Disposition (Safety Population)
14.1.1.2	Summary of Subject Disposition (Intent-to-Treat Population)
14.1.1.3	Summary of Subject Disposition (PK/PD Population)
14.1.2.1	Summary of Demographics and Baseline Characteristics (Safety Population)

Table Number	Table Title
14.1.2.2	Summary of Demographics and Baseline Characteristics (Intent-to-Treat Population)
14.1.2.3	Summary of Demographics and Baseline Characteristics (PK/PD Population)
14.1.3	Summary of Medical History (Safety Population)
14.1.4.1	Summary of Prior Medications (Safety Population)
14.1.4.2	Summary of Concomitant Medications (Safety Population)
14.1.5.1	Summary of Study Drug Infusion (Safety Population)
14.1.5.2	Summary of Study Drug Infusion (Intent-to-Treat Population)
14.1.5.3	Summary of Study Drug Infusion (PK/PD Population)
14.2.1	Psoriasis Area and Severity Index (PASI) Parameters (Intent-to-Treat Population)
14.2.2	static Investigator Global Assessment (sIGA) (Intent-to-Treat Population)
14.2.3	Psoriasis Body Surface Area (BSA) Involvement (Intent-to-Treat Population)
14.2.4	Dermatology Life Quality Index (DLQI) (Intent-to-Treat Population)
14.2.5	Itch Numeric Rating Scale (I-NRS) (Intent-to-Treat Population)
14.2.6	Cardiometabolic and Inflammatory Biomarkers (Intent-to-Treat Population)
14.2.7	Coronary Computed Tomographic Angiography (CCTA) (Intent-to-Treat Population)
14.2.8	Trough Pharmacokinetic Concentrations (PK/PD Population)
14.3.1.1	Adverse Events Overall Summary (Safety Population)
14.3.1.2	Summary of Treatment Emergent Adverse Events by System Organ Class, and Preferred Term (Safety Population)
14.3.1.3	Summary of Treatment Emergent Adverse Events Leading to Discontinuation of Study (Safety Population)
14.3.1.4	Summary of Serious Treatment Emergent Adverse Events (Safety Population)
14.3.1.5	Summary of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Severity (Safety Population)
14.3.1.6	Summary of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Relationship to Study Treatment (Safety Population)
14.3.2.1	Summary of Laboratory Values - Hematology (Safety Population)
14.3.2.2	Summary of Laboratory Values – Chemistry (Safety Population)

Table Number	Table Title
14.3.2.3	Summary of Laboratory Values – Coagulation Parameters (Safety Population)
14.3.2.4	Summary of Laboratory Values – Other (Safety Population)
14.3.3.1	Summary of Vital Signs (Safety Population)
14.3.3.2	Summary of Physical Examination (Safety Population)

5.2. Summary Tables

There are currently 32 tables that are planned to be generated. The 32 tables are broken down as follows: 12 Standard Unique, 6 Standard Repeat, 12 Non-Standard Unique and 2 Non-Standard Repeat.

6. Post-text Figures Tables of Contents

The following post-text figures will be generated.

Figure Number	Figure Title
14.2.1.1	Psoriasis Area and Severity Index (PASI) Total Score
14.2.1.2	Psoriasis Area and Severity Index (PASI) Percent Change from Baseline
14.2.2	static Investigator Global Assessment (sIGA)
14.2.3	Psoriasis Body Surface Area (BSA) Involvement
14.2.4	Dermatology Life Quality Index (DLQI) Total Score
14.2.5	Itch Numeric Rating Scale (I-NRS)
14.2.6	Cardiometabolic and Inflammatory Biomarkers
14.2.7	Coronary Computed Tomographic Angiography (CCTA)
14.2.8.1	Trough Pharmacokinetic Concentrations - Mean
14.2.8.2	Trough Pharmacokinetic Concentrations - Individual

6.1. Post-Text Figures

There are currently 10 figures that are planned to be generated. The 10 figures are broken down as follows: 0 Standard Unique, 0 Standard Repeat, 10 Non-Standard Unique and 0 Non-Standard Repeat.

7. Table Shells

The table shells can be found in a separate file. The following number of decimal places will be used when presenting summary statistics:

- N to 0 decimal places
- Minimum and maximum to the same number of decimal places as recorded in the raw data.
- Means and medians to 1 more decimal place than is recorded in the raw data. Standard deviations to 2 more decimal places than is recorded in the raw data.
- Percentages to 1 decimal place.

The precision may be changed for individual endpoints as needed.