CELLTRION Inc.
CT-P43 3.1

A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients with Moderate to Severe Plaque Psoriasis

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Statistical Analysis Plan

Final Version 1.0 (B)

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Upon review of this document, including table, listing and figure shells, the undersigned approves the final statistical analysis plan. The analysis methods and data presentation are acceptable, and the table, listing and figure production can begin.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
ADA	anti-drug antibody
AE	adverse event
AESI	adverse event of special interest
ANCOVA	analysis of covariance
BP	blood pressure
BSA	body surface area
BMI	body mass index
CFR	Code of Federal Regulations
CI	confidence interval
CRO	contract research organization
CSR	clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
CV	curriculum vitae
DLQI	Dermatology Life Quality Index
DRM	data review meeting
DSMB	data safety monitoring board
ECG	electrocardiogram
eCRF	electronic case report form
EOS	End-of-study
EU	European Union
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
HBcAb	hepatitis B core antibody
HBsAb	hepatitis B surface antibody
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCAb	hepatitis C antibody
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
ICF	informed consent form
ICH	International Council for Harmonisation
IgG	immunoglobulin G
IGRA	interferon-γ release assay
IEC	independent ethics committee
IL	interleukin
IRB	institutional review board
ITT	intent to treat
IWRS	interactive web response system

Abbreviation	Definition
IQR	interquartile range
MedDRA	Medical Dictionary for Regulatory Activities
MFDS	Ministry of Food and Drug Safety
mITT	modified intent to treat
PASI	Psoriasis Area and Severity Index
PFS	pre-filled syringe
PK	pharmacokinetic(s)
PPS	Per-protocol Set
PsA	psoriatic arthritis
PT	preferred term
PVG	pharmacovigilance
QoL	quality of life
SAE	serious adverse event
SAP	statistical analysis plan
SC	subcutaneous
SD	standard deviation
SI	Système International d'Unités
SOC	system organ class
sPGA	static Physician Global Assessment
TB	tuberculosis
TLF	table, listing and figure
TEAE	treatment-emergent adverse event
ULN	upper limit of normal
US	United States
USA	United States of America
VAS	visual analog scale
WHO	World Health Organization

1. ADMINISTRATIVE STRUCTURE

This study is being conducted under the sponsorship of CELLTRION, Inc. (hereinafter referred to as "CELLTRION"). The clinical monitoring and medical writing are being performed under contract with PPD, in collaboration with CELLTRION. The randomization is being performed under contract with LSK. The data management and statistical analyses are being performed by CELLTRION.

2. INTRODUCTION

This Statistical Analysis Plan (SAP) defines the statistical methods to be used by CELLTRION Clinical Statistics team in the analysis and presentation of data from CELLTRION study number CT-P43 3.1, entitled as "A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients with Moderate to Severe Plaque Psoriasis".

There are two clinical study reports (CSRs) planned for the following time points:

- 1st CSR: After all eligible patients have completed the Week 28 assessment
- Final CSR: After all patients have completed or terminated from the study

If additional CSRs are required for regulatory or academic purposes after the 1st CSR, additional CSRs will be generated after the database lock and unblinding process.

This SAP covers all specified analyses and is based on the following documents:

- Study Protocol Version 2.0 B.0 – 14th July 2021
- Unique Case Report Form Version 2.0 – 13th July 2021

Table, Listing and Figure (TLF) mock shells will be provided as an addendum to this document.

2.1. Data Cut-off for Analysis

The 1st CSR will include all analysis results, using data up to Week 28 of the Treatment Period of each patient. For the data that are monitored continuously (e.g. data collected on 'Adverse Events', 'Prior & Concomitant Medications' and 'Phototherapy' Electronic case report form (eCRF) pages), the data of which start date is on or before Week 28 will be included.

For patients who have terminated the study participation up to Week 28 (actual or planned), all collected data will be included. For patients who skipped visit of Week 28, all collected data

up to planned Week 28 will be included. In addition, if patients have discontinued study treatment before Week 28 (planned), the discontinuation data collected on 'Study Drug Discontinuation' (eCRF) page will be included.

The final CSR will include all analysis results collected up to the completion or termination of all patients from the study.

3. Study Objective

Primary, secondary and exploratory objectives are described as below.

3.1. Primary Objective

- To demonstrate that CT-P43 is equivalent to EU-approved Stelara (hereafter in this document referred to as Stelara), in terms of efficacy as determined by the mean percent improvement from baseline in Psoriasis Area and Severity Index (PASI) score at Week 12.

3.2. Secondary Objectives

- To evaluate efficacy, pharmacokinetics (PK), quality of life (QoL) and overall safety including immunogenicity up to Week 52.

3.3. Exploratory Objectives

- To evaluate additional efficacy up to Week 52 and to characterize biomarker.

4. INVESTIGATIONAL PLAN

4.1. Study Design and Procedures

This study is a randomized, active-controlled, double-blind, multicenter, Phase 3 study designed to evaluate efficacy, PK, QoL, and overall safety including immunogenicity and biomarker of CT-P43 compared with Stelara in patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Patients will be randomly assigned to receive either 45 mg or 90 mg of CT-P43 or Stelara by subcutaneous (SC) injection via pre-filled syringe (PFS) based on patient's baseline body weight. Second randomization will be performed prior to dosing at Week 16. In case significant body weight change occurs and results in over 10% outside from threshold weight (i.e., 100 kg) at Week 16 predose (e.g., ≤100 kg at baseline but increased to >110 kg at Week 16 OR >100 kg at baseline but decreased

to ≤90 kg at Week 16), adjusted dose will be administered to all treatment groups in Treatment Period II.

The overall schedule of study procedure and assessments is provided in Appendix 1.

5. GENERAL STATISTICAL CONSIDERATIONS

Continuous data will be summarized using descriptive statistics: number of patients (n), mean, standard deviation (SD), minimum, median, and maximum, unless otherwise specified. The descriptive statistics will be calculated using raw data before rounding although rounded values are listed. The following rules will be followed with regards to the number of decimal places:

- Minimum and maximum will be presented to the same number of decimal places as reported.
- Mean, median, geometric mean and percent coefficient of variation (CV%) will be rounded to one more decimal place than the maximum decimal place of values in the source listing.
- SD will be rounded to one more decimal place than mean.
- Point estimate and confidence intervals (CI) obtained from statistical procedures will be displayed to two decimal places.

Geometric mean will not be reported if the dataset includes zero values and CV% will not be reported if the mean is zero.

Categorical data will be summarized using frequency tables showing numbers and percentages of patients. Percentages will be rounded to one decimal place and will be suppressed when the count is zero. A row denoted “Missing” will be included in count tabulations where necessary to account for missing values. The denominator for all percentages will be the number of patients within each treatment group for the population of interest, unless otherwise specified.

If there are repeated measurements at a time point, the initial scheduled measurement at that time point will be used in the summary tables.

Unscheduled visit will not be summarized in visit-based tables, unless otherwise specified. However, all data will be displayed in listings. Unless otherwise specified, listings will be sorted by the treatment group, patient number and visit, if applicable. In cases where more ordering is required, other variables will be included in the sort order as applicable.

When combining data from eCRF and analytical facilities such as Central Laboratory, discrepancy will be handled as following:

1) Recorded as sample collected in eCRF but no corresponding results from analytical facility – listing will display only sample collection visit/date from eCRF;

2) No corresponding records in eCRF for results from analytical facility – listing will display only specimen collection visit/date and results from analytical facility;

3) Discrepancy in sample collection date from eCRF and analytical facility – listing will display results from analytical facility and visit/date from eCRF if not missing; if sample collection date is missing in eCRF then use specimen collection visit/date from analytical facility.

All available results from analytical facilities will be included in the summary table.

This statistical analysis plan (SAP) could be updated after the data review meeting (DRM) but prior to database hard lock to document any deviations.

5.1. Software

All statistical analyses will be conducted using Statistical Analysis System (SAS®) software (SAS Institute Inc., Cary, North Carolina, United States of America [USA]) Version 9.4 or higher.

5.2. Sample Size

A total sample size will be planned to be a minimum of 446 patients (a minimum of 223 patients in each treatment group of CT-P43 and Stelara). Considering that the drop-out rate has been hypothesized at 10%, a minimum sample size of 400 patients (a minimum of 200 patients in each treatment group of CT-P43 and Stelara) is estimated to provide at least 90% statistical power for the demonstration of similarity of the mean percent improvement from change baseline in the PASI score at Week 12 with an equivalence margin of –10% to 10% using 90% CI approach corresponding to two one-sided tests with 5% significance level. The sample size assumes that the SD of the percent improvement in PASI score at Week 12 is 29.0 and the expected difference to be 0.

5.3. Randomization, Stratification, and Blinding

An interactive web response system (IWRS) will be used for the randomization. The randomization schedule for IWRS, which will link sequential patient randomization numbers to treatment codes, will be generated.

Patients will be randomly assigned to receive CT-P43 (45 mg or 90 mg) or Stelara (45mg or 90 mg) on Day 1 (Week 0) prior to the study drug administration. Second randomization will be performed prior to dosing at Week 16. Patients in the Stelara treatment group will be randomly assigned in a ratio of 1:1 to either continue Stelara or undergo transition to CT-P43 based on the body weight at Week 16 predose. All patients who were initially randomly assigned to CT-P43 at Day 1 (Week 0) will continue their treatment with CT-P43 until Week 40. The second randomization process will also be conducted in the CT-P43 group prior to dosing at Week 16 to maintain the study blind.

The first randomization to treatment assignment will be stratified by the followings:

- Country
- Body weight (≤100 kg vs. >100 kg)
- Prior biologic use approved for psoriasis treatment (Yes or No)

The second randomization for Stelara group will be stratified by the following:

- Dose at Week 16 (45mg vs. 90 mg)

This study will be double-blind. Under normal circumstances, the blind should not be broken. The blind should be broken only if specific emergency treatment would be dictated as knowing the study drug assignment is required for medical management. In such cases, the investigator may determine the identity of the study drug by using the applicable procedure in the IWRS. The date, time, and reason for the unblinding must be documented in the appropriate field of the eCRF and will be listed along with information of patient disposition.

The overall randomization code will be broken only for reporting purposes. This will occur after database lock for data up to Week 28 of each patient and data up to study completion for all patients. The unblinded team will be pre-defined and documented prior to performing the analyses. The study will remain blinded to the investigators, patients, and pre-defined CELLTRION, Inc. and PPD blinded teams until all patients have completed the study and the database has been finalized for study termination.

5.4. Analysis sets

The following analysis sets are defined: Intent-to-Treat (ITT) Set, Modified Intent-to-Treat (mITT) Set, Per-Protocol Set (PPS), Pharmacokinetic (PK) Set and Safety Set. The following analysis subsets are also defined: ITT - Treatment Period II subset, mITT - Treatment Period II subset, PK - Treatment Period II subset, and Safety - Treatment Period II subset. Analysis sets will be used for the summary of the Baseline and Treatment Period I (Week 0 to Week 12 and

before study drug administration of Week 16). Analysis subsets will be used only for the summary of the Baseline, Treatment Period II (Week 16 to Week 40), and EOS visit (Week 52). Patients who have any major protocol deviations (as defined in Section 5.6) may be excluded from the related analysis sets. The relevant decision will be taken at the blinded DRM prior to database lock. Each analysis set will be specified in the related sections.

For ITT Set, mITT Set and PPS, patients will be assigned to either CT-P43 or Stelara treatment group according to the treatment they were randomized to. The other sets in Treatment Period I will be analyzed according to actual treatment. The actual treatment group will be assigned according to their actual treatment, not according to the randomized treatment, even if there is a discrepancy between the actual treatment and the randomized treatment. If there is a patient with such a discrepancy, patients receiving at least one CT-P43 will be treated as "CT-P43" treatment group. All other patients will be treated as "Stelara" treatment group.

For ITT - Treatment Period II subset and mITT - Treatment Period II subset, patients will be assigned to "CT-P43 Maintenance", "Stelara Maintenance" or "Switched to CT-P43" according to the treatment they were randomized. The other subsets in Treatment Period II will be analyzed according to actual treatment they received during Treatment Period I and Treatment Period II. The actual treatment group for Treatment Period II subset will be assigned according to their actual treatment received in Treatment Period I and Treatment period II, not according to the randomized treatment, even if there is a discrepancy between the actual treatment and the randomized treatment. Patients receiving at least one CT-P43 for Treatment Period I will be treated as "CT-P43 Maintenance" treatment group. Patients who receive Stelara only for Treatment Period I and receive at least one CT-P43 for Treatment Period II will be treated as "Switched to CT-P43" treatment group. All other patients will be treated as "Stelara Maintenance" treatment group.

For the summary of Overall Period, analysis sets defined above will be used, and patients will be assigned to "CT-P43", "Stelara", "CT-P43 Maintenance", "Stelara Maintenance" and "Switched to CT-P43", as defined above. In case of Overall Period summary, it will be presented only in some analyses and is mentioned in each section.

The number of patients in all sets and subsets will be tabulated by the treatment group. The number of patients in mITT Set, PK Set, and Safety Set by ADA status of which definition are respectively described in Section 10.1, Section 11.1, and Section 12.1 will be summarized in the same table. A listing will also be produced displaying data on ITT Set.

5.4.1. Intent-to-Treat (ITT) Set

The ITT Set is defined as all patients randomly assigned to receive study drug (CT-P43 or Stelara).

5.4.1.1. Intent-to-Treat (ITT) - Treatment Period II subset

The ITT - Treatment Period II subset is defined as all patients in ITT Set who are randomly assigned to receive study drug (CT-P43 or Stelara) prior to dosing at Week 16.

5.4.2. Modified Intent-to-Treat (mITT) Set

The mITT Set is defined as all patients who are randomly assigned and received at least 1 (full or partial) dose of study drug (CT-P43 or Stelara).

5.4.2.1. Modified Intent-to-Treat (mITT) - Treatment Period II subset

The mITT - Treatment Period II subset is defined as all patients in mITT Set who are randomly assigned at Week 16 prior to dosing and received at least 1 dose (full or partial) of study drug (CT-P43 or Stelara) at or after Week 16.

5.4.3. Per-Protocol Set (PPS)

The PPS is defined as all randomly assigned patients who receive the full dose of study drug (CT-P43 or Stelara) at Weeks 0 and 4 and have a PASI assessment at baseline and Week 12. The patients who have any major protocol deviation that may affect the interpretation of study results of primary efficacy endpoint will be excluded from PPS. Final determinations of the PPS will be made at the blinded DRM held in accordance with International Council for Harmonisation (ICH) harmonised guideline E9.

5.4.4. Pharmacokinetic (PK) Set

The PK Set is defined as all randomly assigned patients who receive at least 1 full dose of study drug (CT-P43 or Stelara) and who have at least 1 post-treatment PK result with an above the lower limit of quantification. If any patient is found to be non-compliant with respect to dosing, a determination of the PK Set will be made on a case-by-case basis at the blinded DRM.

5.4.4.1. Pharmacokinetic (PK) - Treatment Period II subset

The PK - Treatment Period II subset will consist of all patients in PK Set who receive at least 1 full dose of either of study drug (CT-P43 or Stelara) and have at least 1 post-treatment PK result with an above the lower limit of quantification at or after Week 16.

5.4.5. Safety Set

The Safety Set is defined as all randomly assigned patients who receive at least 1 dose (full or partial) of study drug (CT-P43 or Stelara).

5.4.5.1. Safety - Treatment Period II subset

The Safety - Treatment Period II subset will consist of all patients in Safety Set who receive at least 1 dose (full or partial) of study drug (CT-P43 or Stelara) at or after Week 16.

5.5. Definition of Baseline

The baseline value will be considered to be the last non-missing value before the first study drug administration. Post-baseline values will be considered to be all values collected after the first study drug administration.

5.6. Protocol Deviations

Protocol deviation will be categorized as “major” or “minor”. A major protocol deviation is one that may affect the interpretation of study results or the patient’s rights, safety or welfare, and will be identified prior to study unblinding. Major protocol deviations and population to be excluded are defined as follows:

- Mis-randomization (defined as patients who received the opposite treatment to which they were assigned at any point during the study)
- Non-adherence to inclusion or exclusion criteria which affect efficacy result
- Significant Good Clinical Practice (GCP) non-compliance
- Receipt of prohibited medication or treatment which affect Week 12 efficacy assessment

Patients with mis-randomizations up to Week 16 will be excluded from PPS and PK Set. Patients with mis-randomizations after Week 16 will be excluded only from PK - Treatment Period II subset. Patients with non-adherence to inclusion or exclusion criteria, which affect efficacy result, will be excluded from PPS. Patients with significant GCP non-compliance will be excluded from all analysis sets. Patients with protocol prohibited medication or treatment which affect Week 12 efficacy assessment will be excluded from PPS.

The major protocol deviations and other categories used for exclusion will be summarized for all randomly assigned patients. A listing of major protocol deviations and other categories for each patient will also be provided by treatment group for all randomly assigned patients.

5.7. Missing values and Outliers

In general, missing data will not be imputed unless the methods for handling missing data are specified. The handling method of missing values for sensitivity analysis is presented in Section 10.1.1. For missing or incomplete dates of psoriasis history, prior and concomitant treatments, and adverse events are presented in Section 7.5, Section 9.1 and Section 12.1.

Any outliers that are detected during the review of the data will be investigated and discussed during the DRM. In general, outliers will not be excluded. Details of outliers detected will be presented in the footnotes of the relevant outputs.

6. PATIENTS DISPOSITION

The disposition of patients will be summarized in a table for the ITT Set and the ITT - Treatment Period II subset by treatment group. The number of patients who were randomized, treated, discontinued from the study treatment, and terminated from the study will be displayed along with percentage by each treatment period and treatment group, if applicable.

Patient disposition will be defined as follows:

- Screened: Patient recorded to agree in 'Informed Consent' eCRF page and have records in 'Inclusion/Exclusion Criteria' eCRF page.
- Screening Failure: Patient recorded as not eligible to enroll in the study on 'Inclusion/Exclusion Criteria' eCRF page.
- Randomized: The randomized ID is recorded on 'Randomization' eCRF page at Day 1 (Week 0) and at Week 16 for each treatment period.
- Treatment Administered: Patient answered to have study drug administered and the administered date of study drug is recorded on 'Study Drug Administration' eCRF page at Day 1 (Week 0) for Treatment Period I. Patient who has 2nd randomized ID and answered to have study drug administered, and the administered date of study drug is recorded at Week 16 for Treatment Period II.
- Discontinued Treatment Period: Patient who treated study drug answered 'No' to question on completion of study drug administration on 'Study Drug Discontinuation' eCRF page. The patient who has been assigned with study drug at 2nd randomization and discontinued the study drug after 2nd randomization will be considered to have discontinued in the Treatment Period II, whereas the patient will be considered to have

discontinued the study drug in Treatment Period I if discontinuation of study drug occurred before 2nd randomization.

- Terminated from the study: Patient who treated study drug answered 'No' to question on completion of EOS visit on 'Study Termination' eCRF page. The patient who has been assigned with study drug at 2nd randomization and terminated the study after 2nd randomization will be considered to have terminated in the Treatment Period II, whereas the patient will be considered to have terminated study in Treatment Period I if termination of study occurred before 2nd randomization.

- Completed the study: Patient who treated study drug answered 'Yes' to both question on completion of the study drug administration on 'Study Drug Discontinuation' and question on completion of EOS visit on 'Study Termination' eCRF page.

The number of patients who were screened and failed at Screening will be displayed along with the primary reason for screening failure.

The number and percentage of patients who discontinued the study treatment will be displayed by primary reason for study treatment discontinuation and treatment group. The number and percentage of patients who were terminated from the study will also be displayed by reasons for study termination and treatment group. Primary reasons for study treatment discontinuation and study termination will be presented respectively, based on the 'Study Discontinuation' and 'Study Termination' page of eCRF.

In addition, time on study treatment prior to discontinuation will also be summarized, for those patients who initiate the study treatment and prematurely discontinue for the ITT Set and for the ITT - Treatment Period II subset by treatment group. The treatment duration in days will be calculated as (date of last administration – date of first administration+1). The date of first administration of study drug will be taken as the earliest date recorded on the 'Study Drug Administration' page of eCRF. The date of last dose of study drug will be taken as the last date recorded on the 'Study Drug Administration' page of eCRF.

Patient disposition data will be listed for the ITT Set by treatment group. A separate listing of patients reported as screening failures will be provided.

7. DEMOGRAPHICS, BASELINE, AND BACKGROUND CHARACTERISTICS

7.1. Demographics and Stratification Details

The following demographic measures and stratification details will be summarized for the ITT Set and for the ITT - Treatment Period II subset by treatment group:

- Demographics: Age (years); Gender (male, female); Fertility Status (pre-menarche, surgically sterilized, post-menopausal, potentially able to bear children); Race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, not allowed by investigator country regulations, other); Ethnicity (Hispanic or Latino, non-Hispanic or non-Latino, unknown); Screening values of Height (cm), Baseline values of Weight (kg) and BMI (kg/m^2)

- Stratifications Details: Country; Baseline Body Weight (≤100 kg vs. >100 kg); Prior biologic use approved for psoriasis treatment (Yes vs. No); Dose at Week 16 (45 mg vs. 90 mg)

Age will be automatically calculated in eCRF system based on the date of the informed consent visit and the year of birth considering whether birth date has passed the informed consent date or not. Dose at Week 16 will be automatically populated in eCRF system based on the body weight which will be recorded on 'Vital Sign' eCRF page prior to 2nd randomization. The number and percentage of dose at Week 16 will only be presented in the summary of Treatment Period II.

The stratification factors will be summarized using the final data collected on eCRF. Demographics and stratification details will be presented in separate listings for the ITT Set by treatment group.

7.2. Body Surface Area with Psoriasis Involvement

Descriptive statistics of involved BSA (%) with psoriasis at baseline will be summarized by treatment group for the ITT Set and ITT – Treatment Period II subset. A listing for involved BSA (%) with psoriasis data will be displayed for the ITT Set by treatment group.

7.3. Viral Serology Test

The following assessments for serologic markers will be performed:

- Hepatitis B Surface Antibody (HBsAb)

- Hepatitis B Surface Antigen (HBsAg)

- Hepatitis B Core Antibody (HBcAb)
- Hepatitis B virus DNA (HBV DNA)
- Hepatitis C Antibody (HCAb)
- Hepatitis C Virus Ribonucleic Acid (HCV RNA)
- Human Immunodeficiency Virus (HIV-1 Antibody and/or HIV-2 Antibody)

Viral serology results at baseline will be tabulated by treatment group for the ITT Set, and results of HBsAg, HBsAb, and HBV DNA at Week 16 and EOS visit will be summarized for patients who are enrolled with a negative HBV DNA test in the ITT - Treatment Period II subset. All viral serology results will be listed for the ITT Set by treatment group.

7.4. Medical History

Medical history will be coded using Medical Dictionary for Regulatory Activities (MedDRA Version 23.0 or the higher version). Medical history will be summarized by treatment group, system organ class (SOC) and preferred term (PT) for the ITT Set and for the ITT - Treatment Period II subset. Total number of medical history and the number and percentage of patients with at least one medical history will be also summarized. Medical history will be listed for the ITT Set by treatment group.

7.5. Psoriasis History

The initial plaque-type psoriasis diagnosis date and presence of psoriatic arthritis (PsA) at Screening are recorded. Presence of PsA and time since plaque-type psoriasis diagnosis will be tabulated for ITT Set and ITT - Treatment Period II subset by treatment group. Time (years) since plaque-type psoriasis diagnosis will be calculated as [(the first administration date of study drug – date of psoriasis diagnosis)/365.25]. Age at plaque-type psoriasis diagnosis (years) will be calculated as [year of psoriasis diagnosis - year of birth]. If an incomplete date of psoriasis diagnosis is recorded for a patient, the date will be imputed using the latest possible date as below.

- Missing day (e.g. XXMAR2020): Assume the last day of the month.
- Missing day and month (e.g. XXXXX2020): Assume December 31st.
- Missing day, month and year (e.g. XXXXXXXXX): Leave it as missing.

If the imputed date is later than the first administration date of study drug, it will be imputed using the first administration date of study drug. If the whole date is missing, time since plaque-

type psoriasis diagnosis and age at plaque-type psoriasis diagnosis will not be calculated. Psoriasis history will also be listed for the ITT Set by treatment group.

7.6. Inclusion and Exclusion Criteria

Details of inclusion and exclusion criteria can be found in Sections 4.1.1 and 4.1.2 of the protocol. Non-adherence of inclusion/exclusion criteria patients will be presented in a listing for ITT Set.

8. BIOMARKER ASSESSMENTS (Optional)

Results of each genotype will be summarized for the ITT Set and for the ITT - Treatment period II subset by treatment group. Percentages will be calculated by using the number of patients who sign an informed consent form (ICF) for biomarker assessments as the denominator. All results of biomarker assessments will be listed for the ITT Set.

9. TREATMENTS AND MEDICATIONS

9.1. Prior and Concomitant Medications

All medications will be coded according to the World Health Organization drug (WHO Drug Dictionary September 2021 or the later version). If the medications for multiple adverse events or medical histories, primary adverse event or medical history is specified.

Medications will be classified as either prior or concomitant.

For the purpose of inclusion in prior or concomitant medication tables, incomplete medication start and stop dates will be imputed as follows:

If the stop date is incomplete, the following rules will be applied:

- Missing day: Assume the last day of the month.
- Missing day and month: Assume December 31st.
- Missing day, month, and year: Leave it as Missing.

In the case of the death of a patient, and the imputed stop date is after the date of death, the stop date will be imputed as the date of death.

If the start date is incomplete, the following rules will be applied. If the stop date is incomplete, imputed stop date will be used instead of reported stop date:

- Missing day: Assume the first day of the month.

However, if the partial start date and the date of first study drug administration (defined as the earliest date recorded on the 'Study Drug Administration' page of eCRF) lie within the same month and year, and the date of first study drug administration is not after the stop date of the medication, set to the date of first study drug administration. If the date of first study drug administration is after the stop date of the medication, then set to stop date of the medication.

- Missing day and month: Assume January 1st.

However, if the partial start date and the date of first study drug administration lie within the same year, and the date of first study drug administration is not after the stop date of the medication, set to the date of first study drug administration. If the date of first study drug administration is after the stop date of the medication, then set to stop date of the medication.

- Missing day, month, and year: Assume date of first study drug administration, if not after the stop date for the medication. Otherwise, set to stop date for the medication.

A prior medication is defined as any medication where the start and stop dates or imputed start and stop dates are before the date of first study drug administration and will be classified as following.

- A medication checked as 'Yes' to 'If stop date is unknown, was this drug stopped before the first study drug administration of study drug?' on eCRF, or

- A medication having actual/imputed stop date of medication before the first study drug administration date.

A concomitant medication is defined as any medication that has an actual or imputed stop date on or after the date of first study drug administration or missing. If it is recorded that still taking the medication ('Ongoing' box checked) on the 'Prior & Concomitant Medications' eCRF page. Concomitant medications will be classified for Treatment Period I and Treatment Period II, defined as follows: a concomitant medication with a start date prior to the first study drug administration of study drug in Treatment Period II, or concomitant medication for those patients who did not administer study drug during Treatment Period II, or concomitant medication for those who has unknown start date and is still taking the medication or concomitant medication recorded as 'Medical History' for the reason on the 'Prior & Concomitant Medications' eCRF page will be included in Treatment Period I. Concomitant medication with a start date on or after the date of first study drug administration in Treatment Period II will be included in Treatment Period II.

The prior medications will be summarized by treatment group, drug class (using Anatomical Therapeutic Chemical [ATC] level 2), and PT along with the total number of prior medications and the number and percentage of patients with at least one prior medication for the Safety Set. The prior medications will be summarized using the same analysis set and treatment groups used for the summary of Overall Period. Regarding prior medication for treatment of psoriasis and the systemic agents that could affect psoriasis, the summary will be separately generated by treatment group, drug class, and PT along with the total number and the number and percentage of patients with at least one prior medication for psoriasis will be also summarized for Overall Period.

The separate tables will be also generated for the concomitant medications by treatment group, drug class (using ATC level 2), and PT along with the total number of concomitant medications and the number and percentage of patients with at least one concomitant medication for the Safety Set and the Safety –Treatment Period II subset. The concomitant medications will also be summarized for Overall Period. When ATC Level 2 for drug class is not available, Level 1 will be used instead.

All prior and concomitant medications will be listed separately by treatment group for the Safety Set.

9.2. Exposure to Study Drug

The number and percentage of patients with dose administered and of patients by the dose will be summarized on the Safety Set by treatment group at each scheduled dose week, along with the number and percentage of patients who did and did not have whole volume of study drug administered successfully. For patients who are not administered study drug, the number and percentage of patients with each reason why the dose was not administered (Adverse Event, Other) will be displayed by visit. In addition, the frequency of doses received will be summarized by treatment group. Summaries will be based on the Safety Set and the Safety–Treatment Period II subset. For the frequency of doses received, summary will also be conducted for Overall Period on the Safety Set.

A listing will be provided by treatment group for the Safety Set showing the details of study drug administration.

10. EFFICACY ANALYSIS

The primary endpoint is the mean percent improvement from baseline in PASI score at Week 12. The primary efficacy analysis and sensitivity analysis on primary efficacy endpoint will be

conducted on the mITT Set unless otherwise specified. All analysis for the secondary efficacy endpoints and exploratory efficacy analysis will be conducted on for the mITT Set, PPS, and mITT -Treatment Period II subset at specified visits (Appendix 1) unless otherwise specified.

All efficacy listings will be based on the ITT Set.

10.1. Primary Efficacy Analysis

The percent improvement from baseline in PASI score at Week 12 is defined as:

$$\frac{PASI\ score_{Baseline} - PASI\ score_{Week\ 12}}{PASI\ score_{Baseline}} \times 100$$

The primary efficacy analysis will be conducted on the mITT Set using an analysis of covariance (ANCOVA) model coupled with Multiple imputation (MI) with the Missing at random (MAR) assumption for missing data handling. The ANCOVA model will include the treatment as a fixed effect and country, baseline body weight, prior biologic use approved for psoriasis treatment and baseline PASI score as covariates. A supportive analysis for the primary efficacy endpoint will be conducted on the PPS.

Multiple imputation (MI) with the Missing at random (MAR) assumption will be applied using MI procedure in SAS®. The multiple imputed datasets will be generated based on regression models with country, baseline body weight, prior biologic use approved for psoriasis treatment, baseline PASI score and treatment group as covariates. All patients with baseline PASI score in mITT Set will be included in the analysis. Ten imputed datasets will be created and, in the case that the imputed value of percent improvement from baseline in PASI score at Week 12 is over 100, it will be replaced with 100. ANCOVA for the mean percent improvement in PASI at Week 12 will be applied to each of the imputed datasets. The results from each set of imputed datasets will then be combined using MIANALYZE procedure in SAS® based on Rubins' rules for final statistical inference. For the demonstration of efficacy, point estimate and 90% CI for the difference in the mean percent improvement from baseline in PASI score at Week 12 between CT-P43 and Stelara will be computed. Therapeutic equivalence of clinical response will be concluded if the 90% CI for treatment difference is entirely within -10% to 10%.

In addition, descriptive statistics for the percent PASI improvement at Week 12 will be summarized by ADA status at Week 12 and treatment group for the mITT Set. However, if the number of either subset is very small (≤5% of the mITT Set) then the subset will not be summarized since it is not statistically meaningful. In the mITT Set, patients who show "Positive" result in immunogenicity test obtained at Week 12 will be considered as "ADA positive subgroup". All patients who only have "Negative" results in post-treatment immunogenicity test at Week 12 will be considered as "ADA negative subgroup".

10.1.1. Sensitivity Analysis for Primary Efficacy Endpoint

In order to evaluate the impact of missing data on the primary efficacy endpoint results, additional analyses with missing data imputation will be conducted for the primary efficacy endpoint in mITT Set.

To assess the robustness, a tipping point analysis will be conducted under Missing Not at Random (MNAR) scenarios. Imputed values will be shifted gradually from the imputed values by MI under MAR, by treatment groups (CT-P43 vs. Stelara) to make MNAR scenarios. A point estimate and 90% CI for treatment difference will also be provided using an ANCOVA considering the treatment as a fixed effect and country, baseline body weight, prior biologic use approved for psoriasis treatment and baseline PASI score as covariates under the scenarios. The scenario where confidence interval no longer rules out differences in the percent PASI improvement from baseline at Week 12 for the therapeutic equivalence margin ±10% will be displayed. All the MNAR scenarios and corresponding CIs will be provided.

In the case where imputed values are out of the range of PASI score, a tipping point analysis is not a valid method as sensitivity analysis. No matter what values within the boundary are imputed, it is hard to assess the robustness on such an occasion. In place of a tipping point analysis, ‘best-worst case’ and ‘worst-best case’ sensitivity analyses will be conducted. First, a ‘best-worst case’ scenario dataset will be generated on the assumption that the missing values in CT-P43 are imputed with ‘100’ percent meaning that PASI scores at Week 12 go down to all zeros, and the missing values in Stelara are imputed with ‘0’ percent meaning that PASI scores at Week 12 remain unchanged from baseline. Then a ‘worst-best case’ scenario dataset is generated on the premise that the missing values in CT-P43 are imputed with ‘0’ percent and the missing values in Stelara are imputed with ‘100’ percent. Point estimate and 90% CI for treatment difference will also be provided using an ANCOVA considering the treatment as a fixed effect and country, baseline body weight, prior biologic use approved for psoriasis treatment and baseline PASI score as covariates under the scenarios.

10.2. Secondary Efficacy Analysis

The following parameters will be analyzed as secondary efficacy endpoints:

- The PASI scores at Weeks 0, 2, 4, 8, 12, 16, 28, 40, and 52
- The mean percent improvement from baseline in PASI score at Weeks 2, 4, 8, 16, 28, 40, and 52
- The proportion of patients who achieve at least 50/75/90/100 % improvement from baseline in PASI (PASI 50/75/90/100) at Weeks 2, 4, 8, 12, 16, 28, 40, and 52

- The proportion of patients with static Physician Global Assessment (sPGA) score on a 5-point scale of clear (0) or almost clear (1) at Weeks 0, 2, 4, 8, 12, 16, 28, 40, and 52

- The change in Dermatology Life Quality Index (DLQI) score from baseline at Weeks 2, 4, 8, 12, 16, 28, 40, and 52

10.2.1. Psoriasis Area Severity Index

The PASI score can range from 0 to 72, with the higher score indicating more severe disease. If any individual component is missing, the PASI score will not be calculated.

PASI score will be summarized using descriptive statistics of actual value by treatment group at each scheduled visit. The mean percent improvement from baseline in PASI score will be summarized by treatment group at specified visits. The difference on means between CT-P43 and Stelara and its 95% CIs in PASI score and the mean percent improvement from baseline in PASI score will be estimated using t-test at specified visits. The descriptive statistics, the difference on mean between two treatment groups and its 95% CIs will be presented within a summary table. In addition, individual components, PASI score and the percent improvement from baseline for PASI score will be listed.

10.2.2. Proportions of PASI 50/75/90/100 responders

The number and proportion of patients who achieve at least 50/75/90/100% improvement from baseline in PASI (PASI 50/75/90/100) will be summarized by treatment group at each scheduled visit. The difference between CT-P43 and Stelara and its 95% CIs of the proportion of PASI 50/75/90/100 responders will be estimated using Wald method at specified visits. The proportion of PASI 50/75/90/100 responders, estimated difference and its 95% CIs will be presented within a summary table. The listing including PASI score information will also present PASI 50/75/90/100 responders.

10.2.3. Static Physician's Global Assessment

The number and proportion of patients with sPGA score of clear (0) or almost clear (1) will be summarized by treatment group at each scheduled visit. The difference between CT-P43 and Stelara and its 95% CIs of the proportion of patients with sPGA of clear (0) or almost clear (1) will be estimated using Wald method at specified visits. The proportion of sPGA score, estimated difference and its 95% CIs will be presented within a summary table. The number and proportion of each sPGA score of clear (0), almost clear (1), mild (2), and severe (4) will be summarized by treatment group and visit. A listing will be provided by treatment group and visit, showing the individual score of components for sPGA score and final sPGA score.

10.2.4. Dermatology Life Quality Index

The DLQI produces a numeric score that can range from 0 to 30. A higher score indicates more severe disease. If the answer to one question in a domain is missing, that domain is treated as missing. If two or more questions are left unanswered (missing), DLQI total score is treated as missing.

Summary for the DLQI score will be provided using descriptive statistics of actual value and change from baseline by treatment group at each scheduled visit. The difference on means between CT-P43 and Stelara and its 95% CIs of change of baseline of DLQI score will be estimated using t-test at specified visits. A listing for the DLQI score will be provided by treatment group and visit.

10.3. Exploratory Efficacy Analysis

The following parameters will be analyzed as exploratory efficacy endpoints:

- The change in patient pain VAS from baseline in patients with Psoriatic Arthritis (PsA) at Weeks 12, 16, 28, and 52
- The change in Patient Global Assessment VAS from baseline in patients with PsA at Weeks 12, 16, 28, and 52

10.3.1. Patient Pain Visual Analog Scale for Psoriatic Arthritis

Patient pain VAS for PsA will be summarized using descriptive statistic of actual value and change from baseline by treatment group at each scheduled visit. A listing of the patient pain VAS for PsA will be provided by treatment group and visit.

10.3.2. Patient Global Assessment for Psoriatic Arthritis

Patient global assessment for PsA will be summarized using descriptive statistics of actual value and change from baseline by treatment group at each scheduled visit. A listing will be displayed by treatment group and visit, showing the patient global assessment for PsA.

11. PHARMACOKINETIC ANALYSIS

All PK analyses will be conducted on the PK Set and the PK – Treatment Period II subset according to Treatment Period by treatment group. Blood samples for PK analyses will be collected at time points specified in the schedule of events (Appendix 1).

11.1. Serum Concentrations

Descriptive statistics (n, mean, SD, geometric mean, CV%, minimum, median, and maximum) for serum concentrations will be summarized by treatment group and dose of study drug. The dose of study drug prior to Week 16 will be classified depending on the dose at Week 0, and the dose on or after Week 16 will be classified depending on the dose at Week 16.

An additional summary of descriptive statistics for the serum concentration will be produced by ADA status, treatment group and visit for Treatment Period I. In PK Set, patients who show at least one "Positive" result in immunogenicity test obtained after study drug exposure prior to Week 16 will be considered as "at least one ADA positive subgroup". All patients who only have "Negative" results in post treatment immunogenicity test before Week 16 will be considered as "all ADA negative subgroup". However, if the number of either subgroup is very small (≤5% of the PK Set) then the subset will not be summarized since it is not statistically meaningful.

For the descriptive summary, below lower limit of quantification (BLQ) prior to the first study drug administration (Week 0, Dose 1) will be treated as zero (0), and all other BLQ values will also be set to zero (0).

Serum concentration of ustekinumab and collection times will be listed for the Safety Set by treatment group.

12. SAFETY ANALYSIS

All safety analyses will be conducted on the Safety Set and Safety – Treatment Period II subset, unless otherwise specified. All safety data will be listed for the Safety Set.

12.1. Adverse Events

An adverse event (AE) is defined as any untoward medical occurrence in a patient enrolled (i.e., when the ICF is signed) into this study regardless of its causal relationship to study drug.

A treatment-emergent adverse event (TEAE) is defined as any untoward medical occurrence in a patient after administration of a drug, whether or not considered drug related. This includes any occurrence that is new in onset or aggravated in intensity or frequency from the baseline condition.

MedDRA version 24.1 will be used to code all AEs. AEs will be graded for intensity according to the Common Terminology Criteria for Adverse Events (CTCAE) v5.0.

If the stop date of an AE is partial or missing the following rules will be applied.

- Missing day: Assume the last day of the month.
- Missing day and month: Assume December 31st.
- Missing day, month, and year: Leave it as Missing.

In case a patient dies during the study, the stop date will be imputed as the date of death if the imputed stop date is after the date of death.

If the start date of an AE is partial or missing, the following rules will be applied. If the stop date of the AE is partial, the imputed stop date will be used instead of reported stop date.

- If the day of an AE is missing, the month and year of the partial date will be compared to the date of the first exposure to study drug.
    - If the month and year are equal for both dates, the AE start date will be imputed as the earlier date of: (i) the date of the first exposure to study drug, and (ii) the stop date of the AE. If the AE stop date is missing, the AE start date will be imputed as the date of the first exposure to study drug.
    - If the month or year are not equal, the AE start date will be imputed as the first day of the month.
- If the day and month is missing, the year of the partial date will be compared to the date of the first exposure to study drug.
    - If the years of both dates are equal, start date will be imputed as the earlier date of: (i) the date of the first exposure to study drug, and (ii) the stop date of the AE. If the AE stop date is missing, the AE start date will be imputed as the date of the first exposure to study drug.
    - If the year is not equal, start date will be imputed as the 1st of January of the partial date year.
- If the AE start date is missing, start date will be imputed as the earlier date of: (i) the date of the first exposure to study drug, and (ii) the stop date of the AE. If the AE stop date is missing, the AE start date will be imputed as the date of the first exposure to study drug.

The recorded/imputed dates of AEs will be used for decision whether the event is TEAE and classification of treatment periods.

TEAEs will be classified by period, defined as follows:

- Treatment Period I: TEAEs with a start date (recorded or imputed) prior to the date of first administration of study drug in Treatment Period II, or TEAEs for those patients who did not administer study drug during Treatment Period II will be included.

- Treatment Period II: TEAEs with a start date (recorded or imputed) on or after the date of first administration of study drug in Treatment Period II will be included.

All AEs are summarized during the study by period, treatment group, severity, and relationship to study drug. In summaries, AEs will be considered to be related if the relationship is possible, probable, or definite. If relationship or intensity is missing, it will be summarized separately under a missing category. An additional summary will be produced by ADA status and treatment group for Treatment Period I. In Safety Set, patients who show at least one "Positive" result in immunogenicity test obtained after study drug exposure prior to Week 16 will be considered as "at least one ADA positive subgroup". All patients who only have "Negative" results in post treatment immunogenicity test before Week 16 will be considered as "all ADA negative subgroup". However, if the number of either subgroups is very small (≤5% of the Safety Set) then the subset will not be summarized since it is not statistically meaningful.

A listing will be provided by treatment group showing the details of AEs: SOC, PT and Verbatim term; start and stop date/time; TEAE flag; treatment period (Treatment Period I, Treatment Period II); outcome (recovered/resolved, recovering/resolving, recovered/resolved with sequelae, not recovered/not resolved, fatal, unknown); any treatment received (no, medication, non-medication treatment, both medication and non-medication treatment); intensity (CTCAE Grade 1 to 5); action taken with study drug (dose not changed, drug interrupted, drug withdrawn, not applicable); relationship with study drug (unrelated, possible, probable, definite); whether the event was serious (yes, no); whether the AE is hypersensitivity reaction or injection site reaction (ISR); and infection/malignancy flag. All AEs will be listed.

12.1.1. Incidence of Treatment-Emergent Adverse Events

The TEAEs during the study will be summarized by treatment group, SOC, PT, relationship, and intensity, displaying the number and percentage of patients with at least one TEAE using only the worst intensity recorded at each level of summarization. The total number of events and number of patients with at least one TEAE over all SOCs will also be displayed. TEAEs with PT reported for at least 3% of patients in either treatment group will be summarized separately. The TEAE summaries including relationship information will be generated for Treatment Period I, Treatment Period II and Overall period, separately.

Additionally, TEAEs will be summarized by treatment group, SOC, PT and intensity, regardless of relationship, displaying the number and percentage of patients experiencing at least one TEAE using only the worst intensity.

12.1.2. Serious Adverse Events

A Serious Adverse Events (SAEs) is defined as any event that is immediately life threatening, requires inpatient hospitalization or prolong of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or results in death. Important medical events that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Treatment-emergent serious adverse events (TESAEs) will be summarized by treatment group, SOC, PT, relationship and intensity/serious criteria, displaying the number and percentage of patients with at least one TESAE using only the most severe SAE recorded at each level of summarization. The total number of events and number of patients with at least one TESAE over all SOCs will also be displayed. The TESAE summaries including relationship information will be generated for Treatment Period I, Treatment Period II and Overall Period, separately.

Additionally, TESAEs will be summarized by treatment group and SOC, PT and intensity regardless of relationship, displaying the number and percentage of patients experiencing at least one TESAE using only the worst intensity.

All SAEs will be listed by treatment group including the details of the information in Section 12.1. Also, an additional listing for serious criteria and SAE description will be presented by treatment group.

12.1.3. Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation

All patients who have a TEAE with an action taken with study drug of “Drug Withdrawn” will be summarized by treatment group and by SOC, PT, relationship and intensity, displaying the number and percentage of patients with at least one TEAE leading to study drug discontinuation, using only the most severe TEAE recorded at each level of summarization. The total number of events and number of patients with at least one TEAE that led to study drug discontinuation will also be displayed. The TEAE leading to study drug discontinuation summaries including relationship information will be generated for Treatment Period I, Treatment Period II and Overall Period, separately.

Additionally, TEAEs leading to study drug discontinuation will be summarized by treatment group, SOC, PT and intensity regardless of relationship. The number and percentage of patients who experience at least on TEAE leading to study drug discontinuation will be tabulated using only the worst intensity.

A listing will be provided by treatment group showing the details referred in Section 12.1 of TEAEs leading to study drug discontinuation.

12.1.4. Treatment-Emergent Adverse Events of Special Interest

The TEAEs of special interest are as following:

- **Infections/serious infections**: TEAEs coded with a SOC of 'Infections and Infestations' will be included.
- **Injection site reactions (ISR)**: TEAEs classified as ISR in the eCRF will be included.
- **Hypersensitivity reactions**: TEAEs recorded as Hypersensitivity reactions in the eCRF will be included.
- **Malignancies**: TEAEs coded with PTs from the Malignant or unspecified tumors Standardised MedDRA Queries (SMQ) as defined in MedDRA Version 23.0 or the higher version (SMQ: 20000091, which includes the sub-SMQs: 20000195 [Tumours of unspecified malignancy] and 20000194 [Malignant tumours]). It will be determined to include by medical review.

TEAEs of special interest will be summarized in separate tables. These will be displayed by treatment group, SOC, PT, relationship, and intensity, displaying the number and percentage of patients with at least one TEAE using only the most severe TEAE recorded at each levels of summarization. The total number of events and number of patients with at least one TEAE of special interest will also be displayed. The TEAE of special interest summaries including relationship information will be generated for Treatment Period I, Treatment Period II and Overall Period, separately.

In addition, tables for signs and symptoms regarding Hypersensitivity reactions and ISR will be provided separately by SOC, PT (as coded by MedDRA version 24.1) and intensity.

TEAEs classified as Hypersensitivity reactions and ISR will be listed separately including a subset of the variables detailed in Section 12.1. Experienced signs and symptoms will also be listed for Hypersensitivity reactions and ISR, separately.

The TEAEs of special interest will be flagged in listings for AEs.

12.1.5. Deaths

All patients who have a SAE with serious criteria of "Death" will be presented in a listing, and the following information will be included: date of first/last dose, date of last visit, date of death, time to death from first/last dose, days on study, TEAE flag, SOC/PT, cause of death, autopsy after death (yes, no), completion of death certificate (yes, no) and relationship to study drug.

Time (days) to death from first/last dose will be calculated as (date of death – date of first/last dose + 1). In case of death during the study, days on study will be calculated as (date of death – date of first dose + 1). Otherwise, days on study will be calculated as (date of last visit – date of first dose + 1).

12.2. Clinical Laboratory Evaluations

Clinical laboratory (clinical chemistry, hematology, and urinalysis) test samples will be analyzed at the central laboratory at each scheduled visit. Only the parameters specified in the protocol will be analyzed (Table 1).

Actual value and change from baseline of all numeric laboratory parameters including clinical chemistry, hematology and urinalysis will be summarized using descriptive statistics by treatment group, laboratory category, test parameter and visit. All numeric values recorded BLQ or above the upper limit of quantification are set to the respective limit for all summaries.

The central laboratory test results for parameters including urinalysis, clinical chemistry and hematology (if applicable) are categorized as "Normal" or "Abnormal" and will be summarized in a shift table from baseline to each scheduled visit. The number and percentage of patients will be displayed for post-baseline visits by treatment group, laboratory category, test parameter and visit. Some numeric parameters will be labeled with a CTCAE term and grading will be applied to post-baseline values for numeric parameters where possible according to CTCAE v 5.0. Grades that require clinical input only will not be assigned to these parameters. Grades which are part numeric and part clinical input will be assigned based on the numeric portion only. If different grades share the same criteria due to exclusion of clinical input, lower grade will be used. The CTCAE terms and ranges for applicable parameters are listed in Appendix 2. The CTCAE grades for this analysis will be Grade 1 (Mild), Grade 2 (Moderate), Grade 3 (Severe) and Grade 4 (Life-threatening). The CTCAE Grade 5 (Death) will not be applied in this analysis since death cannot be determined from a numeric laboratory result. If the post-baseline result for a patient does not satisfy any CTCAE grade, it will be classified as "No Grade".

The number and percentage of patients by laboratory category, treatment group and CTCAE term will be summarized using the most severe grade after the first study drug administration for each treatment period. The most severe grade will be selected including all post-baseline scheduled and unscheduled visits. The summary of most severe CTCAE grading will be generated for Treatment Period I, Treatment Period II and Overall Period, separately.

All clinical laboratory results of clinical chemistry, hematology and urinalysis will be presented by treatment group at each visit in separate listings along with high and low flags, if applicable, to show if a value was outside the normal range and CTCAE results for applicable parameters. Creatinine clearance will only be listed at Screening.

Table 1. Clinical Laboratory Test

Clinical chemistry	• Total protein • Total and direct serum bilirubin • Alanine aminotransferase • Aspartate aminotransferase • Alkaline phosphatase • γ-glutamyltransferase • Blood urea nitrogen • Creatinine • Albumin • Sodium • Potassium	• Calcium • Chloride • Inorganic phosphorus • Glucose • Lactate dehydrogenase • Total cholesterol • Triglyceride • High-density lipoprotein cholesterol • C-reactive protein (CRP) • Uric acid
Hematology	• Red blood cells count • Total and differential white blood cell count • Absolute neutrophil count	• Platelet count • Hemoglobin • Hematocrit
Urinalysis	• Bilirubin[1] • Blood • Glucose • Ketones • Leukocytes	• Nitrite • pH • Protein • Specific gravity • Urobilinogen

[1] In case of that there is Urinary Bilirubin Icotest result, there is no urinary bilirubin result. Since its laboratory normal range and unit are the same with urinary bilirubin's, its result will be considered as urinary bilirubin result.

12.3. Vital Signs and Body Weight

Vital signs (including systolic and diastolic blood pressure [BP], pulse and respiratory rate, and body temperature) and weight will be assessed at each scheduled visit prior to beginning of the study drug administration. For hypersensitivity monitoring, vital signs will also be assessed at the following time points of scheduled visit:

- Prior to the study drug administration
- 1 hour (±10 minutes) after the end of the study drug administration

All vital signs and weight will be summarized using descriptive statistics of actual value and change from baseline by treatment group and parameter at each scheduled visit. The number and percentage of patients who have clinically notable hypersensitivity result will be summarized in a table by treatment group, visit, time points and parameter. The criteria for clinical notable results are defined in Table 2.

Table 2. Hypersensitivity Classification for Vital Signs

Parameter	Low	High
Systolic blood pressure (mmHg)	≤ 90	≥ 160
Diastolic blood pressure (mmHg)	≤ 50	≥ 90
Pulse rate (beats per minute)	≤ 50	≥ 100
Respiratory rate (breaths per minute)	≤ 12	≥ 20
Body temperature (°C)	≤ 35.0	≥ 38.0

In addition, all results of vital signs including hypersensitivity monitoring results and weight will be listed by treatment group, visit, time points and parameter. High and low flags will also be presented in the listing to show whether a value is outside of the normal range.

12.4. Electrocardiograms

12-lead ECGs will be performed locally at the time points specified in the schedule of events (Appendix 1). Findings of 12-lead ECG will be collected as "Normal", "Abnormal, Not Clinically Significant", or "Abnormal, Clinically Significant".

The number and percentage of patients will be summarized by treatment group and visit, in the form of a shift table to detect changes from baseline. All 12-lead ECGs data will be listed by treatment group and visit. In addition, all ECG data for hypersensitivity reactions monitoring will be listed within ECG listing.

12.5. Physical Examination

Physical examinations with particular attention to AESIs (i.e., infections/serious infections, injection site reactions, hypersensitivity reactions, and malignancies) will be performed at the time points specified in the schedule of events (Appendix 1). The following body systems will be examined:

- General Appearance

- Head and neck
- Skin
- Cardiovascular system
- Respiratory system
- Abdominal system
- Neurological system
- Musculoskeletal system
- Lymphatic system

The investigator (or a qualified observer at the study center) will assess physical examinations, and if it is recorded that the physical examination was performed on the 'Physical Examination' page of eCRF, body system that is interpreted as "Abnormal, Not Clinically Significant", "Abnormal, Clinically Significant", or "Not Done" will be considered as "Normal".

The number and percentage of patients will be tabulated for normal and abnormal findings by treatment group, visit and body system, in the form of a shift table to detect changes from baseline. All physical examination data will be listed for each patient by treatment group, visit and body system.

12.6. Tuberculosis Assessment

Tuberculosis (TB) will be assessed using Interferon - γ Release Assay (IGRA) and Chest X-ray, and clinically monitored throughout the study.

Results for IGRA will be classified as either "Positive", "Indeterminate" or "Negative". All IGRA results will be listed. The number and percentage of patients with IGRA results will be summarized for baseline and scheduled visit in Treatment Period.

Results for Chest X-ray will be classified as either "Normal", "Abnormal, Not Clinically Significant" or "Abnormal, Clinically Significant". The patients will be monitored throughout the study to confirm the presence of any signs or symptoms indicative of TB.

Each patient's IGRA, Chest X-ray and TB clinical monitoring results will be separately listed by treatment group and visit.

12.7. Local Site Pain

Local site pain measurements using 100 mm VAS will be performed immediately (within 15 minutes) after the end of the study drug administration at the time points specified in the schedule of events (Appendix 1). Local site pain data will be summarized using descriptive statistics by treatment group and visit. All local site pain data will be listed by treatment group and visit.

12.8. Pregnancy Test

Pregnancy tests will be conducted and summarized only for female patients of childbearing potential who have not been surgically sterilized. Pregnancy tests consist of serum and urine pregnancy tests. Serum pregnancy tests will be performed by central laboratory at Screening and at the EOS visit. Urine pregnancy tests will be performed locally prior to dosing at each scheduled visit or more frequently if required by country-specific legislation. If a urine pregnancy test result is positive, a confirmatory serum pregnancy test will be performed at the central laboratory.

The number and percentage of the results of serum and urine pregnancy test will be summarized by treatment group and visit. All pregnancy test results will be listed for each patient tested by treatment group and visit.

12.9. Immunogenicity

Serum sample for immunogenicity testing will be collected prior to dosing of study drug at the time points specified in the schedule of events (Appendix 1). Additional immunogenicity will be assessed when immune-related AEs occur. Immunogenicity assessment consists of anti-drug antibody (ADA) and neutralizing antibody (NAb) test, and the analysis will be performed at the bioanalytical laboratory.

The results of immunogenicity will be summarized for Overall Period on the Safety Set. The number and percentage of patients will be presented by treatment group and test at each scheduled visit.

The positive conversion in ADA and NAb will also be summarized including all scheduled and unscheduled visits for Treatment Period I, Treatment Period II, and Overall Period. The proportion of patients who reported at least one ADA positive result between each first study drug administration of Treatment Period I and Treatment Period II in patients who had at least one ADA result between each first study drug administration of Treatment Period I and Treatment Period II and had not any ADA positive result before the first study drug administration will be presented for the Safety Set. The proportion of patients who reported at

least one NAb positive result between each first study drug administration of Treatment Period I and Treatment Period II in patients who had at least one ADA result between each first study drug administration of Treatment Period I and Treatment Period II and had not any NAb positive result before the first study drug administration will also be presented for the Safety Set.

For the Safety - Treatment Period II subset, proportion of patients who reported at least one ADA positive result after the first study drug administration in Treatment Period II in patients who had at least one ADA result after the first study drug administration in Treatment Period II and had not any ADA positive result before the first study drug administration in Treatment Period II will be presented. The proportion of patients who reported at least one NAb positive result after the first study drug administration in Treatment Period II in patients who had at least one ADA result after the first study drug administration in Treatment Period II and had not any NAb positive result before the first study drug administration in Treatment Period II will also be presented.

When it comes to summarizing for the positive conversion in ADA and NAb, patient whose ADA or NAb result at Week 0 is missing will be excluded from its denominator respectively regardless of Treatment Period.

In addition, the results of ADA titration will be summarized by treatment group and visit using descriptive statistics including interquartile range (IQR) for Overall Period on the Safety Set. The proportion of patients who report ADA positive result after first administration will be summarized by treatment group and original scale at each scheduled visit for Overall Period on the Safety Set.

A listing showing immunogenicity test results will be provided by treatment group and visit.

13. Changes in the Planned Analysis

For secondary efficacy analysis, difference on mean (or proportion) between the 2 treatment groups and its 95% CIs have been added from those described in the protocol v2.0 A.0 as per the recommendation from the Ministry of Food and Drug Safety (MFDS).

14. Reference List

Protocol: A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients with Moderate to Severe Plaque Psoriasis. Version 2.0 B. 0, 14July 2021.

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15. APPENDIX

Appendix 1: Schedule of Events

	Screening	Treatment Period I					Treatment Period II			EOS[1]
Visit Number		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	
Study Week	**–6**	**0**	**2**	**4**	**8**	**12[2]**	**16**	**28[3]**	**40**	**52**
Study Day	**–42 to –1**	**1**	**15**	**29**	**57**	**85**	**113**	**197**	**281**	**365**
Visit Window (days)[4]			**± 3**	**± 3**	**± 3**	**± 3**	**± 7**	**± 7**	**± 7**	**± 7**
Screening/Baseline assessments										
Informed consent	X									
Demographics, height	X									
Medical history	X									
Inclusion/exclusion criteria	X	X[11]								
% BSA involvement	X	X[11]								
Randomization[5]		X[11]					X[11]			
Hepatitis B[6]	X						(X[11])			(X)
Hepatitis C and HIV-1 & -2 test[7]	X									
Serum pregnancy test[8]	X									X
Chest X-ray[9]	X									
Interferon-γ release assay[10]	X						X[11]			
Study drug/Related assessments										
Study drug (CT-P43 or Stelara) administration[11]		X		X			X	X	X	
Hypersensitivity/injection site reactions monitoring[12]		X		X			X	X	X	
Local injection site pain by VAS[13]		X		X			X	X	X	
Efficacy assessments										

	Screening	Treatment Period I					Treatment Period II			EOS[1]
Visit Number		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	
Study Week	**–6**	**0**	**2**	**4**	**8**	**12[2]**	**16**	**28[3]**	**40**	**52**
Study Day	**–42 to –1**	**1**	**15**	**29**	**57**	**85**	**113**	**197**	**281**	**365**
Visit Window (days)[4]			**± 3**	**± 3**	**± 3**	**± 3**	**± 7**	**± 7**	**± 7**	**± 7**
Psoriasis Area Severity Index[14]	X	X[11]	X	X[11]	X	X	X[11]	X[11]	X[11]	X
Static Physician's Global Assessment[14]	X	X[11]	X	X[11]	X	X	X[11]	X[11]	X[11]	X
Dermatology Life Quality Index[15]		X[11]	X	X[11]	X	X	X[11]	X[11]	X[11]	X
Patient pain VAS for PsA[15]		X[11]				X	X[11]	X[11]		X
Patient Global Assessment VAS for PsA[15]		X[11]				X	X[11]	X[11]		X
PK/Immunogenicity/ Biomarker assessments										
Pharmacokinetic sampling[16]		X[11]		X[11]		X	X[11]	X[11]	X[11]	X
Immunogenicity sampling[17]		X[11]		X[11]		X	X[11]	X[11]	X[11]	X
Biomarker sampling[18]		X[11]								
Safety assessments										
Vital signs, body weight[19]	X	X[11]		X[11]	X	X	X[11]	X[11]	X[11]	X
Physical examination	X	X[11]		X[11]	X	X	X[11]	X[11]	X[11]	X
Urine pregnancy test[20]		X[11]		X[11]			X[11]	X[11]	X[11]	
Clinical laboratory tests[21]	X	X[11]		X[11]	X	X	X[11]	X[11]	X[11]	X
12-Lead ECG[22]	X					X		X		X
Prior, concomitant medications[23]	X									
Tuberculosis clinical monitoring[24]	X									
Adverse event monitoring[25]	X									

Abbreviations: BSA, body surface area; ECG, electrocardiogram; EOS, end-of-study; HIV, human immunodeficiency virus; ICF, informed consent form; IGRA, interferon- γ release assay; sPGA, static Physician's Global Assessment; PK, pharmacokinetic; PsA, psoriatic arthritis; TB, tuberculosis; VAS, visual analog scale.

Note: For all patients who discontinue study drug early, every effort should be made to have the patient continue in the study and complete regularly scheduled study visits. If a patient cannot or is unwilling to attend any visit(s), a safety follow-up (i.e., adverse events, concomitant medications) will be conducted by telephone according to the study visit schedule. If a patient discontinues study drug prior to Week 12 for the primary efficacy endpoint assessment, when the primary endpoint is assessed, they should return to the site at Week 12, even if they initiated psoriasis medication changes (including those prohibited by the protocol).

1. The End-of-Study (EOS) visit will be performed at the Week 52 visit for the patients who completed or discontinued study drug.
2. At Week 12, it is recommended that patients who achieve at least PASI 50 continue study drug administration in the Treatment period II in all groups.
3. At Week 28, it is recommended that patients who achieve at least PASI 75 continue further study drug administration in all groups.
4. A dose visit window of ±3 days is recommended up to and including Week 12 and a visit window of ±7 days is recommended thereafter, based on the baseline visit, including the EOS visit. If any study visit has to be rescheduled, subsequent visits should follow the original visit date scheduled.
5. Patients will be randomly assigned to receive CT-P43 (45 or 90 mg) or Stelara (45 or 90 mg) on Day 1 (Week 0) prior to the study drug administration. A second randomization will be performed at the Week 16 visit prior to the study drug administration. Patients in the Stelara group will be randomly assigned again to either continue Stelara or undergo transition to CT-P43 from Week 16. All patients who were initially randomly assigned to the CT-P43 group on Day 1 (Week 0) will continue their treatment with CT-P43.
6. At Screening, HBsAg, HBsAb, and HBcAb must be assessed in all patients (mandatory). If the HBsAg test result is positive, the patient must be excluded from the study. If a patient has HBsAg (negative), HBsAb (negative or positive), and HBcAb (positive), a HBV DNA test will be performed at Screening. If the HBV DNA test result is positive, the patient will be excluded from the study; if the HBV DNA test result is negative, the patient can be included in the study. For patients who are enrolled based on the HBV DNA test, testing of HBsAg, HBsAb, HBV DNA, aspartate aminotransferase, alanine aminotransferase, and total bilirubin will be performed at the Week 16 and EOS visits. If the patient develops hepatitis B reactivation, a study drug should be discontinued. Hepatitis B analysis will be performed at the central laboratory.
7. At Screening, hepatitis C antibody will be assessed in all patients. If the HCV test results is positive, HCV RNA will be performed at Screening. If the HCV RNA test result is negative, the patient can be included in the study at the investigator's discretion. Further evaluation for the patients who are enrolled based on HCV RNA test can be done depending on the investigator's discretion during the study. If the HIV test result is positive, the patient must be excluded from the study. Hepatitis C and HIV analysis will be performed at the central laboratory.
8. A serum pregnancy test for women of childbearing potential should be conducted at Screening and at the EOS visit. Patients who are of childbearing potential with only negative results from a serum pregnancy test can be enrolled. A serum pregnancy test will be performed at the central laboratory.
9. A chest X-ray (both posterior–anterior and lateral views) is not required at Screening if a chest X-ray from within 12 weeks prior to the first administration of the study drug (Day 1) is available.
10. The IGRA analysis will be performed at the central laboratory. No further IGRA testing is required during the treatment period for patients who have at least 1 positive IGRA result and have completed the country-specific TB prophylaxis. For patient who early discontinued study drug, IGRA test is unnecessary after the discontinuation.
11. For study drug administration visits, procedures will be performed prior to the study drug administration. Study drug will be administered by a predefined unblinded staff at the site during the study.
12. Additional vital signs including BP, pulse and respiratory rates, and body temperature (prior to the beginning of the study drug administration and 1 hour [±10 minutes] after the end of the study drug administration) will be monitored for possible hypersensitivity reactions. In addition, hypersensitivity will be monitored by routine continuous clinical monitoring, including patient-reported signs and symptoms. In case of hypersensitivity, emergency equipment, such as adrenaline, antihistamines, corticosteroids, and respiratory support including inhalational therapy, oxygen, and artificial ventilation must be available; in addition, any types of ECG can be performed. Hypersensitivity that may occur after the administration of the study drug will be monitored. If the patient experiences any of hypersensitivity signs and symptoms outside study center, the patient can visit the study center for further assessment. Injection site reactions will be assessed 30 minutes (± 10 minutes) after the end of the study drug administration. For the patients who early discontinued study drug, monitoring of hypersensitivity/injection site reactions are unnecessary after the study drug discontinuation.
13. Local site pain by patient using 100 mm VAS will be assessed immediately (within 15 minutes) after the study drug administration. For patient who early discontinued study drug, this assessment is unnecessary after the discontinuation.

14. The investigator-reported outcomes assessments (i.e., PASI, sPGA) will be performed by a qualified efficacy assessor at the site. If possible, it is recommended that the same assessor perform the investigator-reported outcomes assessments throughout the entire study period.
15. The patient-reported outcomes/quality of life questionnaires should be completed by the patient prior to any of the other study-related assessments being performed, that is, physical examinations, blood sampling, and other efficacy evaluations, and study drug administration.
16. Blood samples for PK analysis will be collected at predose (prior to the beginning of study drug administration) except Week 12 and EOS at which the blood sample will be taken at any time. For patients who early discontinued the study drug, PK sampling will only be collected until the next scheduled dosing visit and further PK sampling is unnecessary. However, if a patient is discontinued the study drug at Week 40, PK sampling will be required at the EOS visit. .
17. Serum samples for immunogenicity testing will be drawn at the same time as the clinical laboratory tests before dosing except Week 12 and EOS at which the sample will be taken at any time, where applicable. Additional serum samples for immunogenicity testing may be collected if a patient experiences immune-related AEs. Analysis will be performed at the central laboratory. For patient who early discontinued study drug, immunogenicity sampling will only be collected until the next scheduled dosing visit and further immunogenicity sampling is unnecessary. However, if a patient is discontinued the study drug at Week 40, immunogenicity sampling will be required at the EOS visit.
18. Only for patients who sign a separate ICF for the biomarker assessment, a blood sample for evaluation of any necessary genotypes will be collected prior to dosing on Day 1 (Week 0).
19. Vital signs (including systolic and diastolic BP, pulse and respiratory rates, and body temperature) will be measured after 5 minutes of rest (sitting). In addition, weight will be measured prior to study drug administration.
20. A urine pregnancy test for women of childbearing potential will be used to confirm that patients are not pregnant before the study drug administration on each visit date or more frequently if required by country-specific legislation. A urine pregnancy test will be performed locally. If a urine pregnancy test result is positive, a confirmatory serum pregnancy test will be performed at the central laboratory. For patient who early discontinued study drug, urine pregnancy test is unnecessary after the discontinuation.
21. Clinical laboratory (clinical chemistry, hematology, and urinalysis) test samples will be analyzed at the central laboratory.

Clinical chemistry	Total protein, serum bilirubin (total and direct), alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, γ-glutamyltransferase, blood urea nitrogen, creatinine, albumin, sodium, potassium, calcium, chloride, inorganic phosphorus, glucose, lactate dehydrogenase, total cholesterol, triglyceride, high-density lipoprotein cholesterol, C reactive protein, and uric acid
Hematology	Red blood cells, total and differential white blood cell count, absolute neutrophil count, platelet count, hemoglobin, and hematocrit
Urinalysis	Bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen

22. All scheduled 12-lead ECGs must be performed locally after the patient has rested quietly for at least 5 minutes in the supine position. Regardless of the 12-lead ECG result, further cardiological evaluation can be conducted at the investigator's discretion.
23. Use of all prior and concomitant medications and/or therapies for the treatment of psoriasis and the systemic agents that could affect psoriasis, from the diagnosis of disease until the EOS visit, will be recorded in both the source documents and the eCRF. Use of all medications for other purposes, taken from 42 days prior to the first administration of study drug will be recorded until the EOS visit in both the source documents and the eCRF.
24. Throughout the study, patients will be monitored for the clinical signs and symptoms of TB. An additional IGRA or chest X-ray can be performed at the investigator's discretion based on the judgment per the signs and symptoms of TB monitoring. The investigator will confirm the absence of active TB prior to the subsequent dose administration.
25. Adverse events will be assessed from the date the informed consent form is signed until up to EOS visit, regardless of the relationship to the study drug. After the EOS visit, serious adverse drug reaction will be reported to CELLTRION, Inc. or its designee.

*If a study center is not equipped to perform the specified tests, this will be discussed and arranged with the sponsor or the sponsor's designee.

Appendix 2: Table of CTCAE Terms and Grades

CTCAE Term	Laboratory Parameter	Level	Grade 1	Grade 2	Grade 3	Grade 4
Alanine aminotransferase increased	Alanine Aminotransferase (ALT)	High	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Hypoalbuminemia	Albumin	Low	<LLN - 3 g/dL; <LLN - 30 g/L	<3 - 2 g/dL; <30 - 20 g/L	<2 g/dL; <20 g/L	-
Alkaline phosphatase increased	Alkaline phosphatase (ALP)	High	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnormal	>2.5 - 5.0 x ULN if baseline was normal; >2.5 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Aspartate aminotransferase increased	Aspartate Aminotransferase (AST)	High	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Leukocytosis	White Blood Cells	High	-	-	>100,000/mm^3	-
White blood cell decreased	White Blood Cells	Low	<LLN - 3000/mm^3; <LLN - 3.0 x $10e^9$ /L	<3000 - 2000/mm^3; <3.0 - 2.0 x $10e^9$ /L	<2000 - 1000/mm^3; <2.0 - 1.0 x $10e^9$ /L	<1000/mm^3; <1.0 x $10e^9$ /L
Creatinine increased [1)]	Creatinine	High	>ULN - 1.5 x ULN	>1.5 - 3.0 x baseline; >1.5 - 3.0 x ULN	>3.0 x baseline; >3.0 - 6.0 x ULN	>6.0 x ULN
GGT increased	Gamma Glutamyl Transferase (GGT)	High	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnormal	>2.5 - 5.0 x ULN if baseline was normal; >2.5 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Hypoglycemia	Glucose	Low	<LLN - 55mg/dL; <LLN - 3.0 mmol / L	< 55 - 40mg/dL; < 3.0 – 2.2 mmol / L	< 40 -30mg/dL; < 2.2 – 1.7 mmol / L	<30mg/dL; <1.7 mmol/L
Anemia	Hemoglobin	Low	<LLN - 10.0 g/dL; <LLN - 100 g/L; <LLN – 6.2 mmol/L	<10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 – 80 g/L	<8.0 g/dL; <4.9 mmol/L; <80 g/L	-

Hemoglobin increased	Hemoglobin	High	Increase in >0 - 2 g/dL from ULN	Increase in >2 - 4 g/dL from ULN	Increase in >4 g/dL from ULN	-
Blood lactate dehydrogenase increased	Lactate Dehydrogenase (LDH)	High	>ULN	-	-	-
Lymphocyte count decreased	WBC Differential, Lymphocytes	Low	<LLN - 800/mm^3; <LLN - 0.8 x $10e^9$ /L	<800 - 500/mm^3; <0.8 - 0.5 x $10e^9$ /L	<500 - 200/mm^3; <0.5 - 0.2 x $10e^9$ /L	<200/mm^3; <0.2 x $10e^9$ /L
Lymphocyte count increased	WBC Differential, Lymphocytes	High	-	>4000/mm^3 - 20,000/mm^3	>20,000/mm^3	-
Platelet count decreased	Platelet count	Low	<LLN - 75,000/mm^3; <LLN - 75.0 x $10e^9$ /L	<75,000-50,000/mm^3; <75.0 - 50.0 x $10e^9$ /L	<50,000-25,000/mm^3; <50.0 - 25.0 x $10e^9$ /L	<25,000/mm3; <25.0 x $10e^9$ /L
Hyperkalemia	Potassium	High	>ULN - 5.5 mmol/L	>5.5 - 6.0 mmol/L	>6.0 - 7.0 mmol/L	>7.0 mmol/L
Hypokalemia	Potassium	Low	<LLN - 3.0 mmol/L	-	<3.0 - 2.5 mmol/L	<2.5 mmol/L
Blood bilirubin increased	Total Bilirubin	High	>ULN - 1.5 x ULN if baseline was normal; > 1.0 - 1.5 x baseline if baseline was abnormal	>1.5 - 3.0 x ULN if baseline was normal; >1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 10.0 x ULN if baseline was normal; >3.0 - 10.0 x baseline if baseline was abnormal	>10.0 x ULN if baseline was normal; >10.0 x baseline if baseline was abnormal
Cholesterol high	Total Cholesterol	High	>ULN - 300 mg/dL; >ULN - 7.75 mmol/L	>300 - 400 mg/dL; >7.75 - 10.34 mmol/L	>400 - 500 mg/dL; >10.34 - 12.92 mmol/L	>500 mg/dL; >12.92 mmol/L
Neutrophil count decreased	WBC Differential, Neutrophils	Low	<LLN - 1500/mm^3; <LLN - 1.5 x $10e^9$ /L	<1500 - 1000/mm^3; <1.5 - 1.0 x $10e^9$ /L	<1000 - 500/mm^3; <1.0 - 0.5 x $10e^9$ /L	<500/mm^3; <0.5 x $10e^9$ /L
Hypertriglyceridemia	Triglyceride	High	150 mg/dL - 300 mg/dL; 1.71 mmol/L - 3.42 mmol/L	>300 mg/dL - 500 mg/dL; >3.42 mmol/L - 5.7 mmol/L	>500 mg/dL - 1000 mg/dL; >5.7 mmol/L - 11.4 mmol/L	>1000 mg/dL; >11.4 mmol/L
Eosinophilia	Eosinophils	High	>ULN and >baseline	-	-	-

Hypernatremia	Sodium	High	>ULN - 150 mmol/L	>150 - 155 mmol/L	>155 - 160 mmol/L	>160 mmol/L
Hyponatremia	Sodium	Low	<LLN - 130 mmol/L	125 - 129 mmol/L	120 - 124 mmol/L regardless of symptoms	<120 mmol/L

LLN = lower limit of normal, ULN = upper limit of normal.
1) The most severe grade is counted if the CTCAE grade is discrepant by multiple definitions.
Note: The LLN and ULN values will be the lower and upper limits of the normal ranges as provided by the central laboratory at each relevant transfer. In case numeric value for grading is identical such as Hypokalemia, CTCAE grade which includes numeric value will only be applied, because abnormal laboratory value with clinical input was reported as an adverse event and graded accordingly.

Table of Contents

Table 14.1.1
Summary of Patient Disposition
ITT Set

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Total Number of Patients			
Screened [1]			xxx
Screening Failure			xx
Primary Reason for Screening Failure [2]			
Inclusion/Exclusion Criteria Not Met			xx
Patient Withdrew Consent			xx
Lost to Follow-up			xx
Other			xx

Note: [1] This includes screening failures.
[2] This summary includes screening failures only.
[3] Only for patients who initiated the study treatment during each treatment period and are prematurely discontinued from study treatment calculated as (Date of last administration – Date of first administration +1).

Source Data: Listing 16.2.1.1 and Listing 16.2.2.3.

Table 14.1.1
Summary of Patient Disposition
ITT Set

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Randomized (1st)	xx	xx	xx
Administered the study drug in Treatment Period I	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued the study drug in Treatment Period I	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Terminated the study in Treatement Period I	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Primary Reason for Study Treatment Discontinuation in Treatment Period I			
Inadequate Efficacy at Week 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Patient	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnanacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: [1] This includes screening failures.
[2] This summary includes screening failures only.
[3] Only for patients who initiate the study drug during each treatment period and are prematurely discontinued from study drug calculated as (Date of last administration – Date of first administration +1).

Source Data: Listing 16.2.1.1 and Listing 16.2.2.3.

Programming note: Repeat for ITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43). The number and percentages of patients who completed the study will only be summarized after Treatment Period II.

Table 14.1.1
Summary of Patient Disposition
ITT Set

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Time on Study drug Prior to Discontinuation in Treatment Period I (days) [3]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Minimum	xx	xx	xx
Median	xx.x	xx.x	xx.x
Maximum	xx	xx	xx
Primary Reason for Study Termination in Treatment Period I			
Withdrawal by Patient	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: [1] This includes screening failures.
[2] This summary includes screening failures only.
[3] Only for patients who initiate the study drug during each treatment period and are prematurely discontinued from study drug calculated as (Date of last administration – Date of first administration+1).

Source Data: Listing 16.2.1.1 and Listing 16.2.2.3.

Programming note: Repeat for ITT–Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43). The number and percentages of patients who completed the study will only be summarized in Treatment Period II.

Table 14.1.2
Analysis Sets

	CT-P43	Stelara	Total
Intent-to-Treat (ITT) Set	xxx	xxx	xxx
Modified Intent-to-Treat (mITT) Set	xxx	xxx	xxx
ADA Positive at Week 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ADA Negative at Week 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Per-Protocol Set (PPS)	xxx	xxx	xxx
Pharmacokinetic (PK) Set	xxx	xxx	xxx
At least 1 ADA Positive subgroup	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
All ADA Negative subgroup	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Set	xxx	xxx	xxx
At least 1 ADA Positive subgroup	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
All ADA Negative subgroup	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: The numbers of patients in the ITT Set, mITT Set and PPS are presented by the treatment group assigned from 1st randomization. For the Safety Set and PK Set, patients are counted in treatment group based on the study drug they actually received. Percentage is calculated using the number of patients of parent set as the denominator.
Source Data: Listing 16.2.2.1

Programming note: Repeat for Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) with updated footnote. No need to repeat ADA status for Treatment Period II subset.

Table 14.1.3
Major Protocol Deviations and Other Reasons for Exclusion from Analysis Set
All randomly assigned patients

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)	Excluded Sets [1]
Major Protocol Deviation				
Mis-randomization	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	XXX
Non-adherence to I/E criteria which affect efficacy result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	XXX
Siginficant GCP non-compliance	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	ALL
…				
Other Reasons for Exclusion				
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	XXX

Note: [1] Protocol deviation excludes patients from the following sets.
GCP = Good Clinical Practice, I/E criteria = Inclusion or Exclusion criteria, PPS = Per-protocol Set, PK = Pharmacokinetic Set, PK2=PK-Treatment Period II subset, ALL = Intent-to-Treat Set, modified Intent-to-Treat Set, Per-protocol Set, Pharmacokinetic Set, and Safety Set (including each subset in Treatment Period II).

Source Data: Listing 16.2.2.2

Programming note: Mis-randomization after Week 16 will also be presented for ITT–Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.4
Demographics and Stratification Details
ITT Set

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Minimum	xx	xx	xx
Median	xx.x	xx.x	xx.x
Maximum	xx	xx	xx
Gender			
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Fertility Status [1]			
Pre-Menarche	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Surgically Sterilized	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Post-Menopausal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Potentially Able to Bear Children	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BMI = Body Mass Index, PsA = Psoriatic Arthritis.
[1] Percentages are calculated by using the number of female patients
Source Data: Listing 16.2.4.1 and Listing 16.2.4.2.

Programming note: Repeat for the parameters Race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, not allowed by investigator country regulations, Other); Ethnicity (Hispanic or Latino, Non-Hispanic or Non-Latino, Unknown); screening values of Height (cm), baseline values of Weight (kg) and BMI (kg/m^2); Country; Baseline Body Weight (<=100 kg vs. >100 kg); Prior Biologic use approved for Ps treatment (Yes vs. No); Dose at Week 16 (45 mg vs. 90 mg) in order displaying summary statistics (n, Mean, SD, Minimum, Median, Maximum) or counts and percentages as applicable. Repeat for ITT-Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43). Dose at Week 16 (45 mg vs. 90 mg) will be summarized only for Treatment Period II.

Table 14.1.5
Descriptive Statistics for Percentage of Psoriasis involved Body Surface Area (BSA)
ITT Set

Visit Statistic	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Baseline			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Minimum	xx	xx	xx
Median	xx.x	xx.x	xx.x
Maximum	xx	xx	xx
…			

Source Data: Listing 16.2.4.3

Programming note: Repeat for ITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.6
Summary of Viral Serology
ITT Set

Visit Parameter Result	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Baseline			
Hepatitis B Surface Antibody			
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indeterminate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hepatitis B Surface Antigen			
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indeterminate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Hepatitis B virus DNA [1]			
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indeterminate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hepatitis C virus RNA [2]			
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indeterminate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: For patients who are enrolled with a negative HBV DNA test, testing of HBsAg, HBsAb, HBV DNA will be performed at the Week 16 and EOS visits.
[1] Hepatitis B virus DNA is counted for subjects who have HBsAg negative, HBsAb negative or positive, and HBcAb positive at Screening.
[2] Hepatitis C virus RNA is counted for subjects who have HCV test positive at Screening.

Source Data: Listing 16.2.4.4

Programming note: Repeat for Hepatitis B Core Antibody, Hepatitis C Antibody, and Human Immunodeficiency Virus (HIV-1, HIV-2). Repeat HBsAg, HBsAb, HBV DNA at Week 16 and EOS for the patients who are enrolled with a negative HBV DNA in ITT–Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.7
Summary of Medical History
ITT Set

System Organ Class [1] Preferred Term [1]	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Total Number of Medical History	xxx	xxx	xxx
Number of Patients with at Least One Medical History	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
System Organ Class #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Note: At each level of summarization, patients are counted once if they reported one or more findings.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.4.5

Programming note: Sort alphabetical by SOC and PT. Repeat for ITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.8
Summary of Psoriasis History
ITT Set

Parameter Result	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Presence of Psoriasis Arthritis at Screening			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Time since Plaque-type Psoriasis Diagnosis (year) [1]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Minimum	Xx	xx	xx
Median	xx.x	xx.x	xx.x
Maximum	xx	xx	xx
Age at Plaque-type Psoriasis Diagnosis (year) [2]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Minimum	Xx	xx	xx
Median	xx.x	xx.x	xx.x
Maximum	xx	xx	xx

Note: [1] Time since Plaque-type Psoriasis diagnosis is calculated as [(the first administration date of study drug – date of plaque-type psoriasis diagnosis)/365.25].
[2] Age at Plaque-type Psoriasis diagnosis is calculated as [year of plaque-type psoriasis diagnosis - year of birth].

Source Data: Listing 16.2.4.6

Programming note: Repeat for ITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.9
Summary of Genotype
ITT Set

Parameter Result	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
HLA-C*06:02			
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
…			

Note: Percentages are calculated by using the number of patients who sign an Informed Consent Form for biomarker assessments as the denominator.

Source Data: Listing 16.2.4.8

Programming note: Repeat for collected parameters. Repeat for ITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.10
Summary of Prior Medications
Safety Set

Overall Period

Drug Class [1] **Preferred Term [1]**	**CT-P43 (N=XXX)**	**CT-P43 Maintenance (N=XXX)**	**Stelara (N=XXX)**	**Stelara Maintenance (N=XXX)**	**Switched to CT-P43 (N=XXX)**	**Total (N=XXX)**
Total Number of Prior Medications	xxx	xxx	xxx	xxx	xxx	xxx
Number of Patients with at least one Prior Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…						

Note: Patients may have more than one medication per drug class and preferred term. At each level of summarization, a patient is counted once if they reported one or more medications.
[1] From the WHO Drug Dictionary version XXXXXXXXX.

Source Data: Listing 16.2.4.9

Programming note: Sort in descending order by drug class and preferred term based on the total of all treatment groups.

Table 14.1.11
Summary of Prior Medications for Psoriasis
Safety Set

Overall Period

Medication **Drug Class [1]** **Preferred Term [1]**	**CT-P43 (N=XXX)**	**CT-P43 Maintenance (N=XXX)**	**Stelara (N=XXX)**	**Stelara Maintenance (N=XXX)**	**Switched to CT-P43 (N=XXX)**	**Total (N=XXX)**
Total Number of Prior Medications for Psoriasis	xxx	xxx	xxx	xxx	xxx	xxx
Number of Patients with at least one Prior Medication for Psoriasis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Prior use of Phototherapy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ultraviolet A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ultraviolet B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Prior use of Biologic Agents	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Prior use of Non-Biologic Systemic Agents	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Prior use of Systemic Steroids	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…						

Note: Patients may have more than one medication per drug class and preferred term. At each level of summarization, a patient is counted once if they reported one or more medications. Use of all prior medications and/or therapies for the treatment of psoriasis, and the systemic agents that could affect psoriasis is summarized.
[1] From the WHO Drug Dictionary version XXXXXXXXX.

Source Data: Listing 16.2.4.9

Programming note: Sort in descending order by drug class and preferred term based on the total of all treatment groups.

Table 14.1.12
Summary of Concomitant Medications
Safety Set

Treatment Period I

Drug Class [1] **Preferred Term [1]**	**CT-P43** **(N=XXX)**	**Stelara** **(N=XXX)**	**Total** **(N=XXX)**
Total Number of Concomitant Medications	xxx	xxx	xxx
Number of Patients with at least one Concomitant Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Drug Class #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Note: Patients may have more than one medication per drug class and preferred term. At each level of summarization, a patient is counted once if they reported one or more medications.
[1] From the WHO Drug Dictionary version XXXXXXXXX.

Source Data: Listing 16.2.4.10

Programming note: Sort in descending order by drug class and preferred term based on the total of all treatment groups. Repeat for Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II, and for the Safety Set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.1.13
Summary of Study Drug Administration
Safety Set

	CT-P43 (N=XXX)	Stelara (N=XXX)
Week 0		
Dose		
45 mg	xx (xx.x%)	xx (xx.x%)
90 mg	xx (xx.x%)	xx (xx.x%)
Dose Administered		
Yes	xx (xx.x%)	xx (xx.x%)
Was whole volume of the study drug administered successfully?		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
If No, Reason Dose Not Administered		
Adverse Event	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
…		

Source Data: Listing 16.2.5.1

Programming Note: Repeat for Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.1.14
Summary of the Total Number of Doses Received
Safety Set

Treatment Period I

Total Number of Doses Received	CT-P43 (N=XXX)	Stelara (N=XXX)
1	xxx (xx.x%)	xxx (xx.x%)
2	xxx (xx.x%)	xxx (xx.x%)

Source Data: Listing 16.2.5.1

Programming Note: Repeat for Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) in the Treatment Period II, and for the Safety Set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) in the Overall Period.

Table 14.2.1.1
Summary of Mean Percent Improvement from Baseline in PASI score at Week 12
mITT Set

Visit Statistic	CT-P43 (N=XXX)	Stelara (N=XXX)
Week 12		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Minimum	xx	xx
Median	xx.x	xx.x
Maximum	xx	xx

Note: If any individual component is missing, the PASI score will not be calculated.

Source Data: Listing 16.2.6.1

Programming Note: Repeat for the PPS.

Table 14.2.1.1a
Summary of Mean Percent Improvement from Baseline in PASI score at Week 12 by ADA status
mITT – ADA Negative subset

Use the same table layout as Table 14.2.1.1.

Note: If any individual component is missing, the PASI score will not be calculated.

Source Data: Listing 16.2.6.1

Programming Note: Repeat for the mITT - ADA Positive subset. Patients who show "Positive" result in immunogenicity test obtained at Week 12 will be considered as "ADA positive subgroup". All patients who only have "Negative" results in post-treatment immunogenicity test at Week 12 will be considered as "ADA negative subgroup.

Table 14.2.1.2
Statistical Analysis of Mean Percent Improvement from Baseline in PASI score at Week 12 (ANCOVA) – Multiple Imputation (MI)
mITT Set

Comparison	Treatment	n	LS Mean (SE)	Estimate of Treatment Difference	90% CI of Treatment Difference
CT-P43 vs. Stelara	Test	xxx	xx.x (xx.xx)	xx.xx	(xx.xx, xx.xx)
	Reference	xxx	xx.x (xx.xx)		

Note: SE= Standard Error, CI = Confidence Interval, LS = Least Squares, n = The number of subjects administered each treatment.
An analysis of covariate (ANCOVA) was performed with the treatment as a fixed effect and country, baseline body weight, prior biologic use approved for psoriasis treatment and baseline PASI score as covariates. Imputation with the missing at random (MAR) assumption was used for missing data imputation. For the case that the imputed value of percent improvement from baseline in PASI score at Week 12 is over 100, it will be replaced with 100. Final statistical inference based on Rubin's rule was displayed by combining the results from each set of imputed datasets. Adjusted least squares means and standard error, estimate of treatment difference [CT-P43 – Stelara] and 90% confidence interval calculated from the ANCOVA model.

Source Data: Listing 16.2.6.1

Programming Note: Repeat for PPS. If there is no missing value in dataset, footnote will cover that the statistical analysis is conducted without imputation.

Table 14.2.1.2a
Tipping Point Result for the Mean Percent Improvement from Baseline in PASI score
mITT Set

Shift for CT-P43 [2]	**Shift for Stelara [1]**									
	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
x.xx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)

Note: Cell contents are the difference point estimate and the estimated 90% confidence interval. Missing value of the mean percent improvement from baseline at Week 12 will be imputed by Multiple imputation (MI). Tipping point analyses will be conducted under MNAR (Missing Not at Random) scenarios, with imputed values shifted gradually from the imputed values by MI, by treatment groups (CT-P43 vs. Stelara).
[1] Assumed difference in Week 12 Mean percent improvement of PASI score between observed and missing group on Stelara.
[2] Assumed difference in Week 12 Mean percent improvement of PASI score between observed and missing group on CT-P43.

Source Data: Listing 16.2.6.1.

Table 14.2.1.2a
Statistical Analysis of Mean Percent Improvement from Baseline in PASI score at Week 12 (ANCOVA) – Worst and Best Case Assessment
mITT Set

Best-worst case scenario

Comparison	Treatment	n [1]	LS Mean (SE)	Estimate of Treatment Difference	90% CI of Treatment Difference
CT-P43 vs. Stelara	Test	xxx (x)	xx.x (xx.xx)	xx.xx	(xx.xx, xx.xx)
	Reference	xxx (x)	xx.x (xx.xx)		

Note: SE= Standard Error, CI = Confidence Interval, LS = Least Squares, n = The number of subjects administered each treatment.
An analysis of covariate (ANCOVA) was performed with the treatment as a fixed effect and country, baseline body weight, prior biologic use approved for psoriasis treatment and baseline PASI score as covariates on the assumption that the missing values in CT-P43 are imputed with '100' percent and the ones in Stelara are imputed with '0' percent. Adjusted least squares means and standard error, estimate of treatment difference [CT-P43 – Stelara] and 90% confidence interval calculated from the ANCOVA model.
[1] The number of missing values in mITT set is presented in the parenthesis.

Source Data: Listing 16.2.6.1

Programming Note: 'Best-worst case' and 'Worst-best case' sensitivity analyses will be conducted if a tipping point analysis is not a valid method. Repeat for 'Worst-best case scenario' and adjust footnote as per scenario.

Table 14.2.2.1
Statistical Analysis of PASI score
mITT Set

Visit Statistic	CT-P43 (N=XXX)	Stelara (N=XXX)	Estimate of Treatment Difference	95% CI of Treatment Difference
Baseline				
n	xxx	xxx		
Mean	xx.x	xx.x	xx.x	(xx.xx, xx.xx)
SD	xx.xx	xx.xx		
Minimum	xx	xx		
Median	xx.x	xx.x		
Maximum	xx	xx		
Week 2				
n	xxx	xxx		
Mean	xx.x	xx.x	xx.x	(xx.xx, xx.xx)
SD	xx.xx	xx.xx		
Minimum	xx	xx		
Median	xx.x	xx.x		
Maximum	xx	xx		
…				

Note: If any individual component is missing, the PASI score will not be calculated. The difference on mean and its 95% confidence interval (CI) of two treatment group is produced using t-test.
CI = Confidence Interval.

Source Data: Listing 16.2.6.1

Programming Note: Repeat for Weeks 4, 8, 12, 16, 28, 40, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.2.2
Statistical Analysis of Mean Percent Improvement from baseline in PASI score
mITT Set

Visit Statistic	CT-P43 (N=XXX)	Stelara (N=XXX)	Estimate of Treatment Difference (%)	95% CI of Treatment Difference (%)
Week 2				
n	xxx	xxx		
Mean	xx.x	xx.x	xx.x	(xx.xx, xx.xx)
SD	xx.xx	xx.xx		
Minimum	xx	xx		
Median	xx.x	xx.x		
Maximum	xx	xx		
…				

Note: If any individual component is missing, the PASI score will not be calculated. The difference on mean and its 95% confidence interval (CI) of two treatment group is produced using t-test.
CI = Confidence Interval.

Source Data: Listing 16.2.6.1

Programming Note: Repeat for Week 4, 8, 12, 16, 28 and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43)

Table 14.2.2.3
Proportion of PASI 50/75/90/100 Responders
mITT Set

Parameter Visit	CT-P43 (N=XXX)	Stelara (N=XXX)	Estimate of Treatment Difference (%)	95% CI of Treatment Difference (%)
PASI 50				
Week 2	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)
Week 4	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)
Week 8	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)
Week 12	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)
Week 16	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)

Note: Percentages are calculated by using the number of patients in the set as the denominator. The difference on proportion and its 95% confidence interval (CI) of two treatment group is produced using Wald method. CI = Confidence Interval. NC = Not Calculated.

Source Data: Listing 16.2.6.1

Programming Note: Repeat for PASI 75, 90, 100. Repeat for Weeks 4, 8, 12, 16, 28, 40, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.2.4
Proportion of sPGA score (0 or 1)
mITT Set

Visit	CT-P43 (N=XXX)	Stelara (N=XXX)	Estimate of Treatment Difference (%)	95% CI of Treatment Difference (%)
Week 2	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)
Week 4	xxx (xx.x%)	xxx (xx.x%)	xx.x	(xx.xx, xx.xx)
…				

Note: Percentages are calculated by using the number of patients in the set as the denominator. The difference on proportion and its 95% confidence interval (CI) of two treatment group is produced using Wald method. CI = Confidence Interval.

Source Data: Listing 16.2.6.2

Programming Note: Repeat for Weeks 4, 8, 12, 16, 28, 40, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.2.5
Proportion of sPGA score
mITT Set

Visit Category	CT-P43 (N=XXX)	Stelara (N=XXX)
Baseline		
Clear (0)	xxx (xx.x%)	xxx (xx.x%)
Almost Clear (1)	xxx (xx.x%)	xxx (xx.x%)
Mild (2)	xxx (xx.x%)	xxx (xx.x%)
Moderate (3)	xxx (xx.x%)	xxx (xx.x%)
Severe (4)	xxx (xx.x%)	xxx (xx.x%)
…		

Source Data: Listing 16.2.6.2

Programming Note: Repeat for Week 2, Weeks 4, 8, 12, 16, 28, 40, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.2.6
Statistical Analysis of DLQI score
mITT Set

Visit Statistic	CT-P43 (N=XXX) Actual Result	CT-P43 (N=XXX) Change From Baseline	Stelara (N=XXX) Actual Result	Stelara (N=XXX) Change From Baseline	Estimate of Treatment Difference	95% CI of Treatment Difference
Baseline						
n	xxx		xxx			
Mean	xx.x		xx.x			
SD	xx.xx		xx.xx			
Minimum	xx		xx			
Median	xx.x		xx.x			
Maximum	xx		xx			
Week 2						
n	xxx	xxx	xxx	xxx		
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.xx, xx.xx)
SD	xx.xx	xx.xx	xx.xx	xx.xx		
Minimum	xx	xx	xx	xx		
Median	xx.x	xx.x	xx.x	xx.x		
Maximum	xx	xx	xx	xx		
…						

Note: If the answer to one question in a domain is missing, that domain is treated as missing. If two or more questions are left unanswered (missing), DLQI total score is treated as missing and not calculated. The difference on mean change from baseline and its 95% confidence interval (CI) of two treatment group is produced using t-test. CI = Confidence Interval.

Source Data: Listing 16.2.6.3

Programming Note: Repeat for Weeks 4, 8, 12, 16, 28, 40, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.3.1
Descriptive Statistics for Actual Value and Change from Baseline of Patient Pain VAS for PsA
mITT Set

Visit Statistic	CT-P43 (N=XXX)		Stelara (N=XXX)	
	Actual Result	Change From Baseline	Actual Result	Change From Baseline
Baseline				
n	xxx		xxx	
Mean	xx.x		xx.x	
SD	xx.xx		xx.xx	
Minimum	xx		xx	
Median	xx.x		xx.x	
Maximum	xx		xx	
Week 12				
n	xxx	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Minimum	xx	xx	xx	xx
Median	xx.x	xx.x	xx.x	xx.x
Maximum	xx	xx	xx	xx
…				

Note: Patient assessment of psoriatic pain VAS is assessed only for the patients with concomitant PsA and is measured by the patient indicating the extent of their pain in the past week by marking one line through the 100-mm line, ranging from 0 (no pain) to 100 (severe pain).

Source Data: Listing 16.2.6.4

Programming Note: Repeat for Weeks 16, 28, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.3.2
Descriptive Statistics for Actual Value and Change from Baseline of Patient Global Assessment for PsA
mITT Set

Use the same table layout as Table 14.2.3.1

Note: Patient's global assessment of disease activity is assessed only for the patients with concomitant PsA and is measured over the past week by the patient indicating the extent of their condition by marking one line through the 100-mm line, ranging from 0 (very well) to 100 (very poor).

Source Data: Listing 16.2.6.5

Programming Note: Repeat for Weeks 16, 28, and 52. Repeat for the PPS and the mITT – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.2.4.1
Descriptive Statistics of Serum Concentrations of Ustekinumab (Unit)
PK Set

Visit **Dose** **Statistic**	**CT-P43** **(N=XXX)**	**Stelara** **(N=XXX)**
Week 0		
45 mg		
n	xx	xx
Mean	xx.xxx	xx.xxx
SD	xx.xxxx	xx.xxxx
Geometric Mean	xx.xxx	xx.xxx
CV%	xx.xxx	xx.xxx
Minimum	xx.xx	xx.xx
Median	xx.xxx	xx.xxx
Maximum	xx.xx	xx.xx
90 mg		
…		

Note: SD = Standard Deviation, %CV = Percent Coefficient of Variation, NC = Not Calculated; Below lower limit of quantification (BLQ) prior to the first study drug administration (Week 0, Dose 1) will be treated as zero (0), and all other BLQ values will also be set to zero (0). Samples are collected at predose (prior to the beginning of study durg administration) except Week 12 and EOS at which the blood sample will be taken at any time.

Source Data: Listing 16.2.6.6

Programming note: Sort by Visit and Dose. Repeat for all scheduled Time points. Repeat for the PK – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43). Please update the unit in the title when the actual data are available. Geometric mean will be set to 'NC' if minimum is zero.

Table 14.2.4.2
Descriptive Statistics of Serum Concentrations of Ustekinumab (Unit) by ADA Status
PK Set

All ADA Negative subgroup

Use the same table layout as Table 14.2.4.1

Note: SD = Standard Deviation, %CV = Percent Coefficient of Variation, NC = Not Calculated; Below lower limit of quantification (BLQ) prior to the first study drug administration (Week 0, Dose 1) will be treated as zero (0), and all other BLQ values will also be set to zero (0). Samples are collected at predose (prior to the beginning of study durg administration) except Week 12 and EOS at which the blood sample will be taken at any time.

Source Data: Listing 16.2.6.6

Programming note: Sort by Visit amd Dose. Repeat for "At least one ADA Positive subgroup" and all scheduled Time points. Please update the unit in the title when the actual data are available. Geometric mean will be set to 'NC' if minimum is zero. Patients who show at least one "Positive" result in immunogenicity test obtained after study drug exposure prior to Week 16 will be considered as "at least one ADA positive subgroup". All patients who only have "Negative" results in post treatment immunogenicity test before Week 16 will be considered as "all ADA negative subgroup". If the number of either subgroup is very small (≤ 5% of the PK set) then the subset will not be summarized.

Table 14.3.1.1
Treatment-Emergent Adverse Events by Relationship and Intensity
Safety Set

Treatment Period I

System Organ Class [1] Preferred Term [1]	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Total Number of Treatment-Emergent Adverse Events (TEAEs)	xxx	xxx	xxx
Number of Patients with at Least One Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
System Organ Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Note: The total number of TEAEs count includes events for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.1

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.1a
Treatment-Emergent Adverse Events with PT Reported for at Least 3% in Either Treatment Group by Relationship and Intensity
Safety Set

Treatment Period I

Use the same table layout as Table 14.3.1.1

Note: Only TEAEs reported for at least 3% of patients in either treatment group were included. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.1

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationship which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.1b
Treatment-Emergent Adverse Events by Intensity
Safety Set

Treatment Period I

System Organ Class [1] Preferred Term [1]	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Total Number of Treatment-Emergent Adverse Events (TEAEs)	xxx	xxx	xxx
Number of Patients with at Least One Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
System Organ Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
…			

Note: The total number of TEAEs count includes events for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.1

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity which occur in the data. If intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote.

Table 14.3.1.1c
Overall Summary of Treatment-Emergent Adverse Events by Relationship and Intensity by ADA Status
Safety Set

All ADA Negative subgroup

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Total Number of Treatment-Emergent Adverse Events (TEAEs)	xxx	xxx	xxx
Number of Patients with at Least One Treatment-Emergent Adverse Events (TEAEs)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Total Number of Treatment-Emergent Serious Adverse Events (TESAEs)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Patients with at Least One Treatment-Emergent Serious Adverse Events (TESAEs)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Note: The total number of TEAEs count includes events occurred in Treatment Period I for all patients in the Safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.

Source Data: Listing 16.2.7.1

Programming note: Repeat for TEAE leading to discontinuation of study drug and clasffied as infections/serious infections, injection site reactions, hypersensitivity reactions, maliganacies, and death. Include only those levels of intensity and relationships which occur in the data for Treatment Period I. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for "At least one ADA Positive subgroup" and only for Treatment Period I. Patients who show at least one "Positive" result in immunogenicity test obtained after study drug exposure prior to Week 16 will be considered as "at least one ADA positive subgroup". All patients who only have "Negative" results in post treatment immunogenicity test before Week 16 will be considered as "all ADA negative subgroup". If the number of either subgroup is very small (≤ 5% of the Safety set) then the subset will not be summarized.

Table 14.3.1.2
Treatment-Emergent Serious Adverse Events by Relationship and Intensity
Safety Set

Treatment Period I

Use the same table layout as Table 14.3.1.1

Note: The total number of TESAEs count includes events for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.3

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.2a
Treatment-Emergent Serious Adverse Events by Intensity
Safety Set

Treatment Period I

Use the same table layout as Table 14.3.1.1b

Note: The total number of TESAEs count includes events for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.3

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity which occur in the data. If intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote.

Table 14.3.1.3
Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Relationship and Intensity
Safety Set

Treatment Period I

Use the same table layout as Table 14.3.1.1

Note: The total number of TEAEs count includes events which lead to study discontinuation for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.4

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.3a
Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Intensity
Safety Set

Treatment Period I

Use the same table layout as Table 14.3.1.1b

Note: The total number of TEAEs count includes events which lead to study discontinuation for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.4

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity which occur in the data. If intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote.

Table 14.3.1.4
Treatment-Emergent Adverse Events classified as Infections/Serious Infections by Relationship and Intensity
Safety Set

Treatment Period I

Use the same Table layout as Table 14.3.1.1

Note: The total number of TEAEs count includes events classified as Infections/Serious Infections for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.5

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.5
Treatment-Emergent Adverse Events classified as Injection Site Reactions by Relationship and Intensity
Safety Set

Treatment Period I

Use the same Table layout as Table 14.3.1.1

Note: The total number of TEAEs count includes events classified as Injection Site Reactions for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.6

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.6
Signs and Symptoms of Injection Site Reactions
Safety Set

Treatment Period I

System Organ Class [1] Preferred Term [1]	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
System Organ Class #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term #1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Preferred Term #2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Note: At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.6a

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity which occur in the data. If intensity is missing, add a missing category at the appropriate level of summarization. Repeat the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.7
Treatment-Emergent Adverse Events classified as Hypersensitivity Reactions by Relationship and Intensity
Safety Set

Treatment Period I

Use the same Table layout as Table 14.3.1.1

Note: The total number of TEAEs count includes events classified as Hypersensitivity Reactions for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.7

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.8
Signs and Symptoms of Hypersensitivity Reactions
Safety Set

Treatment Period I

Use the same table layout as Table 14.3.1.6

Note: At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.7a

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity which occur in the data. If intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.1.9
Treatment-Emergent Adverse Events classified as Malignancy by Relationship and Intensity
Safety Set

Treatment Period I

Use the same Table layout as Table 14.3.1.1

Note: The total number of TEAEs count includes events classified as Malignancy for all patients in the safety set. At each level of summarization, patients are counted once if they reported one or more events. Only the most severe event is counted. The event is considered to be related if the relationship is defined as 'Possible', 'Probable' and 'Definite'. The intensity is defined as Grade 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Death.
[1] From the MedDRA dictionary, version xx.x.

Source Data: Listing 16.2.7.8

Programming note: Sort alphabetical by SOC and PT. Include only those levels of intensity and relationships which occur in the data. If relationship or intensity is missing, add a missing category at the appropriate level of summarization. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II with updated footnote, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.5.1
Descriptive Statistics for Actual Result and Change from Baseline in Numeric Laboratory Parameters
Safety Set

Laboratory Category: Clinical Chemistry

Parameter Visit Statistic	CT-P43 (N=XXX)		Stelara (N=XXX)		Total (N=XXX)	
	Actual Result	Change From Baseline	Actual Result	Change From Baseline	Actual Result	Change From Baseline
Lab test #1 (unit)						
Baseline						
n	xx		xx		xx	
Mean	xx.x		xx.x		xx.x	
SD	xx.xx		xx.xx		xx.xx	
Minimum	xx		xx		xx	
Median	xx.x		xx.x		xx.x	
Maximum	xx		xx		xx	
Week 4						
n	xx	xx	xx	xx	xx	xx
Mean	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
Minimum	xx	xx	xx	xx	xx	xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Maximum	xx	xx	xx	xx	xx	xx
…						

Note: All numeric values recorded below the lower limit or above the upper limit of quantification are set to the respective limit for all summaries.

Source Data: Listing 16.2.8.1, Listing 16.2.8.2 and Listing 16.2.8.3

Programming Note: Sort alphabetical by lab parameters and visit. Repeat for Hematology and Urinalysis, and each test parameters. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.3.5.2
Shift Table of Categorical Laboratory Parameters
Safety Set

Laboratory Category: Clinical Chemistry

Parameter Visit Result	CT-P43 (N=XXX) Baseline Normal	 Abnormal	Stelara (N=XXX) Baseline Normal	 Abnormal	Total (N=XXX) Baseline Normal	 Abnormal
Lab test #1						
Week 4						
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…						

Source Data: Listing 16.2.8.1, Listing 16.2.8.2 and Listing 16.2.8.3

Programming Note: Sort alphabetical by lab parameters and visit. Repeat for Hematology (if applicable) and Urinalysis and each test parameters. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.3.5.3
Summary of Most Severe CTCAE Grading by Period
Safety Set

Treatment Period I
Laboratory Category: Clinical Chemistry

CTCAE Term Grade	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
CTCAE Term #1			
No Grade	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (Mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (Moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (Severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4 (Life-threatening)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CTCAE Term #2			
No Grade	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (Mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (Moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (Severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4 (Life-threatening)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Note: All values collected after first study drug administration are considered as post-baseline values. If a patient's most extreme post-baseline value fails to satisfy any CTCAE criteria, the result is classified as 'No Grade'.
All results in the period including unscheduled visit are used for summary.

Source Data: Listing 16.2.8.1, Listing 16.2.8.2 and Listing 16.2.8.3

Programming Note: Sort alphabetical by lab parameters. Repeat for Hematology, Urinalysis (if applicable) and each CTCAE terms. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.6.1
Descriptive Statistics for Actual Result and Change from Baseline in Vital Signs and Weight
Safety Set

Parameter Visit Statistic	CT-P43 (N=XXX)		Stelara (N=XXX)		Total (N=XXX)	
	Actual Result	Change From Baseline	Actual Result	Change From Baseline	Actual Result	Change From Baseline
Systolic blood pressure (mmHg)						
Baseline						
n	xx		xx		xx	
Mean	xx.x		xx.x		xx.x	
SD	xx.xx		xx.xx		xx.xx	
Minimum	xx		xx		xx	
Median	xx.x		xx.x		xx.x	
Maximum	xx		xx		xx	
Week 4						
n	xx	xx	xx	xx	xx	xx
Mean	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
Minimum	xx	xx	xx	xx	xx	xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Maximum	xx	xx	xx	xx	xx	xx
…						

Source Data: Listing 16.2.9.1

Programming note: Repeat for diastolic blood pressure, pulse rate, respiratory rate, body temperature and weight. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.3.6.2
Summary of Hypersensitivity Monitoring
Safety Set

Visit Time points Parameter	CT-P43 (N=XXX)		Stelara (N=XXX)		Total (N=XXX)	
	Low	High	Low	High	Low	High
Week 0						
Prior to the study drug administration						
Systolic Blood Pressure (mmHg)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Diastolic Blood Pressure (mmHg)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pulse Rate (beats per minute)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Respiratory Rate (breaths per minute)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Body Temperature (°C)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 hour (±10 minutes) after the end of the study drug administration						
…	…	…	…	…		
…						
Week 4						
Prior to the study drug administration						
Systolic Blood Pressure (mmHg)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Diastolic Blood Pressure (mmHg)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pulse Rate (beats per minute)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Respiratory Rate (breaths per minute)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Body Temperature (°C)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 hour (±10 minutes) after the end of the study drug administration						
…	…	…	…	…		

Note: Systolic Blood Pressure (mmHg): low <= 90, high >= 160. Diastolic Blood Pressure (mmHg): low <= 50, high >= 90. Pulse Rate (beats per minute): low <= 50, high >= 100. Respiratory Rate (breaths per minute): low <= 12, high >= 20. Body Temperature (°C): low <= 35.0, high >= 38.0.

Source Data: Listing 16.2.9.1

Programming Note: Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43).

Table 14.3.6.3
Shift Table of 12-Lead Electrocardiograms
Safety set

Visit Result	CT-P43 (N=XXX) Baseline Normal	 Abnormal, NCS	 Abnormal, CS	Stelara (N=XXX) Baseline Normal	 Abnormal, NCS	 Abnormal, CS	Total (N=XXX) Baseline Normal	 Abnormal, NCS	 Abnormal, CS
Week 12									
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 28									
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
...	…	…	…	…	…	…	…	…	…

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

Source Data: Listing 16.2.9.2

Programming Note: Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) including EOS visit.

Table 14.3.6.4
Shift Table of Physical Examination Findings
Safety Set

Body system Visit Result	CT-P43 (N=XXX) Baseline Normal	 Abnormal, NCS	 Abnormal, CS	Stelara (N=XXX) Baseline Normal	 Abnormal, NCS	 Abnormal, CS	Total (N=XXX) Baseline Normal	 Abnormal, NCS	 Abnormal, CS
General Appearance									
Week 4									
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8									
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	…	…		…	…		…	…	

Note: CS = Clinically Significant, NCS = Not Clinically Significant, EOS = End of Study.

Source Data: Listing 16.2.9.3

Programming Note: Repeat for other Body systems. Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) including EOS visit.

Table 14.3.6.5
Summary of Interferon-Gamma Release Assay (IGRA)
Safety Set

Visit Result	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Baseline			
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indeterminate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16			
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indeterminate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	…	…	…

Source Data: Listing 16.2.9.4

Programming Note: Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) including EOS visit.

Table 14.3.6.6
Summary of Local Site Pain Assessment: Visual Analogue Scale (VAS)
Safety Set

Visit Statistic	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Week 0			
n	xx	xx	xx
Mean	xxx.xx	xxx.xx	xxx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Minimum	xxx.x	xxx.x	xxx.x
Median	xxx.xx	xxx.xx	xxx.xx
Maximum	xxx.x	xxx.x	xxx.x
…			

Note: The VAS value of 0 mm means no pain and 100 mm means most severe pain.

Source Data: Listing 16.2.9.7

Programming Note: Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) including EOS visit.

Table 14.3.6.7
Summary of Serum Pregnancy Test
Safety Set

Visit Result	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Baseline			
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Indeterminate	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)

Note: Percentages are calculated by using the number of female patients who is childbearing potential who have not been surgically sterilized in the Safety set as the denominator.

Source Data: Listing 16.2.9.8 and Listing 16.2.4.1

Programming note: Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) with updated footnote including EOS visit.

Table 14.3.6.8
Summary of Urine Pregnancy Test
Safety Set

Visit Result	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Week 0			
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Week 4			
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Week 16			
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
…			

Note: Percentages are calculated by using the number of female patients who is childbearing potential who have not been surgically sterilized in the Safety set as the denominator.

Source Data: Listing 16.2.9.9 and Listing 16.2.4.1

Programming note: Repeat for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) with updated footnote.

Table 14.3.6.9
Summary of Immunogenicity Results
Safety Set

Overall Period

Visit ADA Result NAb Result	CT-P43 (N=XXX)	CT-P43 Maintenance (N=XXX)	Stelara (N=XXX)	Stelara Maintenance (N=XXX)	Switched to CT-P43 (N=XXX)	Total (N=XXX)
Week 0						
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…						

Note: The Anti-drug Antibody (ADA) test involved both screening and confirmatory assays to confirm true positive results. Samples that were positive in the screening assay are spiked with excess study drug to determine if patients were a true positive, labeled ‘Positive’. The Neutralizing Antibody (NAb) screening assessments are only made on samples with an ADA confirmatory assay result of ‘Positive’.

Source Data: Listing 16.2.9.10

Programming note: Repeat for Week 12, Week 16, Week 28, Week 40 and EOS visit.

Table 14.3.6.10
Summary of Positive Conversion in ADA or NAb
Safety Set

Treatment Period I

	CT-P43 (N=XXX)	Stelara (N=XXX)	Total (N=XXX)
Positive Conversion in ADA	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Positive Conversion in NAb	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)

Note: ADA = Anti-drug Antibody, NAb = Neutralizing Antibody; The numerator is the number of patients with at least one ADA or NAb positive result after first study drug administration in Treatment Period I and before the first study drug administration in Treatment Period II. The denominator is the number of patients who had at least one ADA result after first study drug administration in Treatment Period I and before the first study drug administration in Treatment Period II and had not any ADA positive (in case of ADA summary) or NAb positive (in case of NAb summary) result before the first study drug administration. Patients whose ADA or NAb result at Week 0 is missing are excluded from its denominator respectively.

Source Data: Listing 16.2.9.10

Programming note: Repeat for all scheduled and unscheduled visits for the Safety – Treatment Period II subset (CT-P43 Maintenance, Stelara Maintenance and Switched to CT-P43) for the Treatment Period II, and for the Safety set (CT-P43, CT-P43 Maintenance, Stelara, Stelara Maintenance and Switched to CT-P43) for the Overall Period.

Table 14.3.6.11
Summary of ADA Titration Results
Safety Set

Overall Period

Visit Statistic	CT-P43 (N=XXX)	CT-P43 Maintenance (N=XXX)	Stelara (N=XXX)	Stelara Maintenance (N=XXX)	Switched to CT-P43 (N=XXX)	Total (N=XXX)
Week 0						
n	xx	xx	xx	xx	xx	xx
Mean	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
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
IQR	xx	xx	xx	xx	xx	xx
…						

Note: ADA = Anti-drug Antibody, SD = Standard Deviation, IQR = Interquartile Range, EOS = End of Study.

Source Data: Listing 16.2.9.10

Programming note: Repeat for Week 4, Week 12, Week 16, Week 28, Week 40 and EOS visit.

Table 14.3.6.12
Proportion of Patient by ADA Titer
Safety Set

Overall Period

Visit ADA Titer	CT-P43 (N=XXX)	CT-P43 Maintenance (N=XXX)	Stelara (N=XXX)	Stelara Maintenance (N=XXX)	Switched to CT-P43 (N=XXX)	Total (N=XXX)
Week 0						
XX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…						

Note: ADA = Anti-drug Antibody, EOS = End of Study.

Source Data: Listing 16.2.9.10

Programming note: Repeat for Week 4, Week 12, Week 16, Week 28, Week 40 and EOS visit.

Listing 16.2.1.1
Patient Disposition
ITT Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treament Period II subset [1]	Date of First Admin. / Last Admin.	Date of 1st Random/ 2nd Random	Date of Discontinuation /Last Visit	Complete the Study?	Detailed Reason of Discontinuation [2]	Time (days) [3]	Terminate the Study? [4]	Unblinded? [5]
XXXX-XXXX	XX/X/X	C	DDMMMYYYY/ Continuing	DDMMMYYYY/ DDMMMYYYY						
XXXX-XXXX	XX/X/X	C	DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY		Yes				
XXXX-XXXX	XX/X/X		DDMMMYYYY/ DDMMMYYY	DDMMMYYYY	DDMMMYYYY / DDMMMYYYY	No	XXXXXXXXXX	XX	Yes, DDMMMYYYY, XXXXXXXXX	Yes/ DDMMMYYYY HH:MM/ XXXXXXX

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for ITT set–Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] If a patient's discontinuation is due to progressive disease or patient lost to follow-up, the relevant date is specified. If it is due to adverse event, protocol deviation or investigator decision, the specified reason is presented. If it is due to death, both date and reason are specified.
[3] Time on study drug prior to discontinuation is calculated as (Date of last administration – Date of first administration +1).
[4] If a patient is terminated from the study, specify date and reason of termination.
[5] If a patient is unblinded during the study, specify date and time of unblinding and reason.

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.2.1
Analysis Sets
ITT Set

Footnotes:

Analysis Sets are defined as below.

ITT= Intent-to-Treat Set
ITT2= ITT - Treatment Period II subset
mITT= modified Intent-to-Treat Set
mITT2= mITT – Treatment Period II subset
PPS=Per-Protocol Set
PK= Pharmacokinetic Set
PK2=PK – Treatment Period II subset
SAF= Safety Set
SAF2= Safety -Treatment Period II subset

[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] ADA12 = ADA status at Week 12. Patients who show "Positive" result at Week 12 in immunogenicity test obtained after study drug exposure will be considered as "ADA positive subgroup". All patients who have "Negative" results at Week 12 will be considered as "ADA negative subgroup. P = ADA positive subgroup, N = ADA negative subgroup.
[3] ADA16 = ADA status prior to Week 16. Patients who show at least one "Positive" result in immunogenicity test obtained after study drug exposure prior to Week 16 will be considered as "at least one ADA positive subgroup". All patients who only have "Negative" results in post treatment immunogenicity test before Week 16 will be considered as "all ADA negative subgroup.

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.2.1
Analysis Sets
ITT Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	ITT	ITT2	mITT	mITT2	PPS	PK	PK2	SAF	SAF2	ADA12 [2]	ADA16 [3]
XXXX-XXXX	XX/X/X	C	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	P	P
XXXX-XXXX	XX/X/X	C	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	N	P
XXXX-XXXX	XX/X/X	C	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	X	X
XXXX-XXXX	XX/X/X	C	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	X	X
XXXX-XXXX	XX/X/X	C	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	X	X
XXXX-XXXX	XX/X/X	C	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	X	X

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No. Repeat for Stelara treatment group. For the 1st CSR, subsets will be excluded in the listing. The foot notes will be updated in Final CSR.

Listing 16.2.2.2
Major Protocol Deviations and Other Reasons for Exclusion from Analysis Set
All Randomly Assigned Patient

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II subset [1]	Category	Type of Deviation	Description	Excluded Sets [2]
XXXX-XXXX	XX/X/X	C	xxxx	XXX	XXXXXXXXXXXXXXXXXX	XXX
XXXX-XXXX	XX/X/X	C	Other	…	XXXXXXXXXXXXXXXXXX	

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. I/E criteria= Inclusion or Exclusion criteria, GCP = Good Clinical Practice.
[1] Displayed only for ITT–Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] Major protocol deviations exclude patients from one or more of the following Sets.
PPS = Per-protocol Set, PK = Pharmacokinetic Set, PK2=PK-Treatment Period II subset, ALL = Intent-to-Treat Set, modified Intent-to-Treat Set, Per-protocol Set, Pharmacokinetic Set, and Safety Set (including each subset in Treatment Period II).

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.2.3
Screening Failures

Patient No.	Age/Gender/Race	Date of Screening Failure	Primary Reason
XXXX-XXXX	XX/X/X	DDMMMYYYY	XXXXXXXXXX
XXXX-XXXX	XX/X/X	DDMMMYYYY	XXXXXXXXXX
XXXX-XXXX	XX/X/X	DDMMMYYYY	XXXXXXXXXX

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Programming Note: Sort by Patient No.

Listing 16.2.4.1
Demographics
ITT Set

Treatment Group: CT-P43

Patient No.	Treatment Period II subset [1]	Year of Birth	Age (years)	Gender	Country	Female Fertility Status (If other, specify)	Race (If other, specify)	Ethnicity	Screening Height (cm)	Baseline Weight (kg)	Baseline BMI (kg/m^2) [2]
XXXX-XXXX	C	YYYY	XX	Male	Korea		Asian	Non-Hispanic or Non-Latino	XX.X	XX.X	XX.X
XXXX-XXXX	C	YYYY	XX	Female	Poland	XXXXXXX	XXXX	XX	XX.X	XX.X	XX.X
XXXX-XXXX	C	YYYY	XX	Female	Czech	XXXXXXX	XXXX	XX	XX.X	XX.X	XX.X

Note: BMI = Body Mass Index
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] BMI = Baseline Weight / $\{(\text{Screening Height} \times 0.01)^2\}$

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.2
Stratification Details
ITT Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II subset [1]	Country	Baseline Body Weight [2]	Prior Biologic use approved for Ps	Dose at Week 16	Body weight Change [3]
XXXX-XXXX	XX/X/X	C	XXXXXX	≤ 100	Yes	90 mg	Yes
XXXX-XXXX	XX/X/X	C	XXXXXX	> 100	No	90 mg	No
XXXX-XXXX	XX/X/X		XXXXXX	XXX	XXX		

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. Ps = Psoriasis
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] If body weight on Day 1 is not available, the body weight based on the Screening is recorded.
[3] A significant body weight change occurs and results in over 10% outside from threshold weight (i.e., 100 kg) at Week 16 predose (e.g., <=100 kg at baseline but increased to >110 kg at Week 16 OR >100 kg at baseline but decreased to <=90 kg at Week 16)

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.3
Percentage of Psoriasis involved Body Surface Area (BSA)
ITT Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II subset [1]	Visit		Assessment Performed? (Yes / No, specify)	Assessment Date	Involved BSA (%) with Psoriasis
XXXX-XXXX	XX/X/X	C	Screening	#	Yes	DDMMMYYYY	XX
XXXX-XXXX	XX/X/X	C	Day 1	#	Yes	DDMMMYYYY	XX
XXXX-XXXX	XX/X/X				No, XXXXXXXX		

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. BSA = Body Surface Area, # = Baseline Visist.
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.4
Viral Serology
ITT Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II subset [1]	Visit		Was the sample collected? (Yes / No, specify)	Date of Sample collection	Serology Test	Result
XXXX-XXXX	XX/X/X	C	Screening	#	Yes	DDMMMYYYY	HBsAb	Negative
				#			HBsAg	Negative
				#			HBcAb	Positive
				#			HCAb	Positive
				#			HIV-1/2	Negative
				#			HBV DNA	Negative
				#			HCV RNA	Negative
			Week 16		Yes	DDMMMYYYY	HBsAg	Negative
							HBsAb	Negative
							HBV DNA	Negative
			…					
XXXX-XXXX	XX/X/X	C	Screening		No, XXXXXXX			

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. # = Baseline Visit.
HBsAb=Hepatitis B surface antibody, HBsAg=Hepatitis B surface antigen, HBcAb=Hepatitis B core antibody, HCAb=Hepatitis C Antibody, HIV=Human Immunodeficiency Virus, HBV DNA=Hepatitis B virus DNA, HCV RNA= Hepatitis C Virus Ribonucleic Acid.
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.5
Medical History
ITT Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II subset [1]	Disease/Surgery	System Organ Class [2]/ Preferred Term [2]	Date Started	Date Stopped	Ongoing
XXXX-XXXX	XX/X/X	C	XXXXXXXX	XXXXXXXXXXX/ XXXXXXXX	DDMMMYYYY	DDMMMYYYY	
			XXXXXXXX	XXXXXXXXXXX/ XXXXXXXX	DDMMMYYYY		Yes
XXXX-XXXX	XX/X/X	C	XXXXXXXX	XXXXXXXXXXX/ XXXXXXXX	DDMMMYYYY	DDMMMYYYY	

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] From the MedDRA dictionary, version xx.x.

Programming Note: Sort by Patient No., Date Started, SOC and PT. Repeat for Stelara treatment group.

Listing 16.2.4.6
Psoriasis History
ITT Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Date of Initial Plaque-type Psoriasis diagnosis	Age at plaque-type psoriasis diagnosis (years) [2]	Time since Plaque-type Psoriasis diagnosis (years) [3]	Presence of Psoriatic Arthritis at Screening
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	X	XX.X	Yes
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	XX	XX.X	No
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	X	XX.X	xxx

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] Age at plaque-type psoriasis diagnosis (years) will be calculated as [year of psoriasis diagnosis-year of birth]
[3] Time (years) since psoriasis diagnosis will be calculated as [(the first administration date of study drug – date of psoriasis diagnosis)/365.25]

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.7
Non-Adherence Inclusion/Exclusion Criteria
ITT Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Category of Criteria	Deviated Primary Criteria No.
XXXX-XXXX	XX/X/X	Inclusion Criteria	XX
XXXX-XXXX	XX/X/X	Exclusion Criteria	XX
…			

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.8
Genotype
ITT Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Visit	ICF agreed? (Date of ICF signed)	Use of clinical data agreed?	Sample collected? (Yes / No, specify)	Sampling Date	Parameter	Result
XXXX-XXXX	XX/X/X	C	Screening	Yes (DDMMMYYYY)	Yes	Yes	DDMMMYYYY	HLA-C*06:02	Positive
XXXX-XXXX	XX/X/X	C	Screening	Yes (DDMMMYYYY)	Yes	Yes	DDMMMYYYY	HLA-C*06:02	Negative
XXXX-XXXX	XX/X/X	SW	Screening	No	No	No			

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for ITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. Repeat for Stelara treatment group.

Listing 16.2.4.9
Prior Medications
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Date of First Administration	Treatment Period II Start Date	Drug Class [2]/ Preferred Term [2]/ Drug Name	Ps [3]	Start Date/ Stop Date	Reason for Medication/ Indication [4]	Single Dose	Unit	Frequency	Route
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	*	UNUNKUNUN/ DDMMMYYYY	Plaque Psoriasis	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX		DDMMMYYYY/ UNMMMYYYY	AE, XXXXXXX	XXX	XXX	XXXXXX	XXXX
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	*	DDMMMYYYY/ DDMMMYYYY	Psoriatic Arthritis	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX		DDMMMYYYY/ UNUNKUNUN	AE, XXXXXXX	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	*	UNUNKUNUN/ DDMMMYYYY	MH, XXXXXXX	XXX	XXX	XXXXXX	XXXX

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other, Ps = Psoriasis, AE = Adverse Event, MH = Medical History
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] From the WHO Drug Dictionary version XXXXXXXXX.
[3] * indicates a systemic agent which is not indicated for the treatment of psoriasis but could affect psoriasis or a treatment of psoriasis.
[4] If the reason is due to multiple AEs or medical histories, primary adverse event or medical history is specified. If it is due to other, reason is specified.

Programming Note: Sort by Patient No., Start Date, Stop Date, Drug Class and Preferred term. Repeat for Stelara treatment group.

Listing 16.2.4.10
Concomitant Medications
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Date of First Administration	Treatment Period II Start Date	Drug Class [2]/ Preferred Term [2]/ Drug Name	Start Date/ Stop Date	Reason for Medication/ Indication [3]	PER [4]	Single Dose	Unit	Frequency	Route
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXX/ XXXXXXXXXXXX/ XXXXXXXXXXXX	UNUNKUNUN/ DDMMMYYYY	XXXXXXXXXX	1	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXX/ XXXXXXXXXXXX/ XXXXXXXXXXXX	DDMMMYYYY/ UNMMMYYYY	AE, XXXXXXX	1	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXX/ XXXXXXXXXXXX/ XXXXXXXXXXXX	DDMMMYYYY/ DDMMMYYYY	MH, XXXXXXX	1	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXX/ XXXXXXXXXXXX/ XXXXXXXXXXXX	DDMMMYYYY/ Ongoing	AE, XXXXXXX	2	XXX	XXX	XXXXXX	XXXX
					XXXXXXXXXXXX/ XXXXXXXXXXXX/ XXXXXXXXXXXX	UNUNKUNUN/ DDMMMYYYY	AE, XXXXXXX	2	XXX	XXX	XXXXXX	XXXX

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other, AE = Adverse Event, MH = Medical History
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] From the WHO Drug Dictionary version XXXXXXXXX.
[3] If the reason is due to multiple AEs or medical histories, primary adverse event or medical history is specified. If it is due to other, reason is specified.
[4] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.

Programming Note: Sort by Patient No., Start Date, Stop Date, Drug Class and Preferred term. Repeat for Stelara treatment group.

Listing 16.2.5.1
Study Drug Administration
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Visit	Study drug Administered? (Yes / No, specify)	Date of Administration	Prescribed Dose (mg)	Whole[2]	Dispensed Kit Number	Administered Kit Number	Injection Time [3]
XXXX-XXXX	XX/X/X	C	XXXXX	Yes	DDMMMYYYY	XX	Yes	XXXXXX	XXXXXX	HH:MM
			XXXXX	Yes	DDMMMYYYY	XX	Yes	XXXXXX	XXXXXX	HH:MM
			XXXXX	No, XXXXX						
XXXX-XXXX	XX/X/X	C	XXXXX	Yes	DDMMMYYYY	XX	Yes	XXXXXX/ XXXXXX	XXXXXX/ XXXXXX	HH:MM
			XXXXX	Yes	DDMMMYYYY	XX	No, XXXXXXX	XXXXXX/ XXXXXX	XXXXXX/ XXXXXX	HH:MM/ HH:MM
…										

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] Whole = Was whole volume of the syringe injected successfully?
[3] If the subsequent injection is delayed because of dose interruption or other unexpected situations, provide the injection time of second kit.
[4] ISR = Was Injection site reaction assessed? (Yes / No, Specify)

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.5.1
Study Drug Administration
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Visit	Study drug Administered? (Yes / No, specify)	Injection Site of Body	Comment	ISR [4]
XXXX-XXXX	XX/X/X	C	XXXXX	Yes	Left upper arm		No, XXXXXX
			XXXXX	Yes	Left thigh		No, XXXXXX
			XXXXX	No, XXXXX			
XXXX-XXXX	XX/X/X	C	XXXXX	Yes	Left upper arm/ Right upper arm		Yes
			XXXXX	Yes	XXXXXXX/ XXXXXXX		Yes
…							

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43
[2] Whole = Was whole volume of the syringe injected successfully?
[3] If the subsequent injection is delayed because of dose interruption or other unexpected situations, provide the injection time of second kit.
[4] ISR = Was Injection site reaction assessed? (Yes / No, Specify)

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.6.1
Psoriasis Area Severity Index (PASI)
ITT Set

Footnotes:

[1] mITT = Include in mITT?, PPS = Included in PP Set?
[2] Displayed for mITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

The Psoriasis Area Severity Index (PASI) is a quantative rating score for measuring the severity of psoriatic lesion based on area coverage and plaque appearance. The sum of all lesion scores can range from 0 to 72, with the higher score indicating more severe disease.

Lesion Score: 0 = None, 1 = Slight, 2= Moderate, 3 = Severe, 4 = Very severe
Area Score: 0 = 0%, 1 = 1% - 9%, 2 = 10% - 29%, 3 = 30% - 49%, 4 = 50 % - 69%, 5 = 70 % - 89 % 6 = 90% - 100%
Plaque characteristic: Erythema, Induration/Thickness, Scaling
Percentage area affected: Area Score

[3] ADA: ADA status
P: ADA positive subgroup in which patients show positive result in immunogenicity test obtained at Week 12
N: ADA negative subgroup in which patients show negative result in immunogenicity test obtained at Week 12

[4] Total score is calculated by multiplying each of the subtotals, which is multiplication of lesion score sum by area score for each body resion, by amount of body surface area presented by that region. (i.e. x0.1 for head, x0.2 for upper limbs, x0.3 for trunk, x0.4 for lower limbs)
[5] Final PASI score is the sum of scores for each body region. ACT = actual PASI score at the visit, PCHG = % improvement from baseline for PASI score

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. # = Baseline Visit.

Listing 16.2.6.1
Psoriasis Area Severity Index (PASI)
ITT set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	mITT [1]	PPS [1]	Treatment Period II subset [2]	ADA [3]	Visit		Assessment Performed? (Yes / No, specify)	Assessment Date	Type [4]	Head	Upper Limbs	Trunk	Lower Limbs	Final PASI Score [5]	
															ACT	PCHG
XXXX -XXXX	XX/X/X	Yes	Yes	C	P	Screening		Yes	DDMMMYYYY	Erythema	x	x	x	x		
										Induration/ Thickness	x	x	x	x		
										Scaling	x	x	x	x		
										Area Score	xx	xx	x.x	xx		
										Total	xx.x	xx.x	xx.x	xx.x	xxx.x	
						Week 0	#	Yes	DDMMMYYYY	Erythema	x	x	x	x		
							#			Induration/ Thickness	x	x	x	x		
							#			Scaling	x	x	x	x		
							#			Area Score	xx	xx	x.x	xx		
							#			Total	xx.x	xx.x	xx.x	xx.x	xxx.x	
						Week 2		Yes	DDMMMYYYY	Erythema	x	x	x	x		
										Induration/ Thickness	x	x	x	x		
										Scaling	x	x	x	x		
										Area Score	xx	xx	x.x	xx		
										Total	xx.x	xx.x	xx.x	xx.x	xxx.x	xx.x
						…										

Note: Footnotes are presented in the first page.

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.6.2
Static Physician's Global Assessment (sPGA)
ITT Set

Footnotes:

[1] mITT = Include in mITT?, PPS = Included in PP Set?
[2] Displayed for mITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

[3] The sPGA is is a 5-point score ranging from 0 to 4, based on the physician's assessment of the erythema, average thickness, and scaling of all psoriatic lesions at a given time point. The sum of the 3 scales will be divided by 3 to obtain a final sPGA score. A lower score indicates less body coverage, with 0 being clear and 1 being almost clear.

Erythema (averaged over all lesions)
- 0 = Normal (post-inflammatory hyper/hypopigmentation may be present)
- 1 = Faint, diffuse pink or slight red coloration
- 2 = Mild (light red coloration)
- 3 = Definite red coloration (Dull to bright red)
- 4 = Bright to Deep red coloration of lesions

Induration (averaged over all lesions)
- 0 = None
- 1 = Just detectable (slight elevation above normal skin)
- 2 = Mild thickening (slight but definite elevation, typically edges are indistinct or sloped)
- 3 = Clearly distinguishable to moderate thickening (marked definite elevation with rough or sloped edges)
- 4 = Severe thickening with hard edges (marked elevation typically with hard or sharp edges)

Scaling (averaged over all lesions)
- 0 = No scaling
- 1 = Minimal focal scaling (surface dryness with some desquamation)
- 2 = Predominately fine scaling (fine scale partially or mostly covering lesions)
- 3 = Moderate scaling (coarser scale covering most or all of the lesions)
- 4 = Severe /coarse scaling covering almost all or all lesions (coarse, non-tenacious scale predominates)

Scoring
- 0 = 0 = for all three (Clear)
- 1 = mean >0, <1.5 (Almost clear)
- 2 = mean >= 1.5, <2.5 (Mild)
- 3 = mean >= 2.5, <3.5 (Moderate)
- 4 = mean >= 3.5 (Severe)

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. # = Baseline Visit.

Listing 16.2.6.2
Static Physician's Global Assessment (sPGA)
ITT set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	mITT [1]	PPS [1]	Treatment Period II subset [2]	Visit		Assessment Performed? (Yes / No, specify)	Assessment Date	Erythema	Induration	Scaling	Final sPGA Score [3]
XXXX -XXXX	XX/X/X	Yes	Yes	C	Screening		Yes	DDMMMYYYY	x	x	x	x
					Week 0	#	Yes	DDMMMYYYY	x	x	x	x
					Week 2		Yes	DDMMMYYYY	x	x	x	x
					Week 4		No, XXXXXXXXXX					
					…							

Note: Footnotes are presented in the first page.

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.6.3
Dermatology Life Quality Index (DLQI)
ITT Set

Footnotes:

[1] mITT = Include in mITT?, PPS = Included in PP Set?
[2] Displayed for mITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

Q1. Over the last week, how itchy, sore, painful or stinging has your skin been? Very Much; A Lot; A Little; Not at All.
Q2. Over the last week, how embarrassed or self-conscious have you been because of your skin? Very Much; A Lot; A Little; Not at All.
Q3. Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden? Very Much; A Lot; A Little; Not at All; Not Relevant
Q4. Over the last week, how much has your skin influenced the clothes you wear? Very Much; A Lot; A Little; Not at All; Not Relevant
Q5. Over the last week, how much has your skin affected any social or leisure activities? Very Much; A Lot; A Little; Not at All; Not Relevant
Q6. Over the last week, how much has your skin made it difficult for you to do any sport? Very Much; A Lot; A Little; Not at All; Not Relevant
Q7. Over the last week, has your skin prevented you from working or studying? Yes; No; Not Relevant
Q7a. Over the last week, how much has your skin been a problem at work or studying? A Lot; A Little; Not at All
Q8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives? Very Much; A Lot; A Little; Not at All; Not Relevant
Q9. Over the last week, how much has your skin caused any sexual difficulties? Very Much; A Lot; A Little; Not at All; Not Relevant
Q10. Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time? Very Much; A Lot; A Little; Not at All; Not Relevant

Scoring
The scoring of each question is as follows:

Very much	scored 3
A lot	scored 2
A little	scored 1
Not at all	scored 0
Not relevant	scored 0

If question 7 is answered 'Yes', it will be scored 3. If question 7 will be answered 'No' or ‘Not Relevant' but then either 'a lot' or 'a little' is ticked for Question 7a, it will then be respectively scored 2 or 1.

The DLQI is calculated by summing 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.
If the answer to one question in a domain is missing, that domain is treated as missing. If two or more questions are left unanswered (missing), DLQI total score is treated as missing.

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other, # = Baseline Visit.

Listing 16.2.6.3
Dermatology Life Quality Index (DLQI)
ITT set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	mITT [1]	PPS [1]	Treatment Period II Subset [2]	Visit		Assessment Date	Assessment Performed? (Yes / No, specify)	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q7a	Q8	Q9	Q10	DLQI Score
XXXX-XXXX	XX/X/X	Yes	Yes	C	Week 0	#	XXXXXXXXX	Yes	x	x	x	x	x	x	x	x	x	x	x	xx
					Week 2		XXXXXXXXX	Yes	x	x	x	x	x	x	x	x	x	x	x	xx
					Week 4		XXXXXXXXX	Yes	x	x	x	x	x	x	x	x	x	x	x	xx
					Week 8		XXXXXXXXX	Yes	x	x	x	x	x	x	x	x	x	x	x	xx
					…															

Note: Footnotes are presented in the first page.

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.6.4
Visual Analogue Scale (VAS) Measurements – Patient Pain Visual Analog Scale for Psoriatic Arthritis
ITT Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	mITT [1]	PPS [2]	Treatment Period II subset [3]	Visit		Assessment Performed? (Yes / No, specify)	Assessment Date	Result (mm)	Total Length (mm)	Standardized Result (mm)	Change from Baseline (mm)
XXXX-XXXX	XX/X/X	Yes	Yes	C	Week 0	#	Yes	DDMMMYYYY	xx.x	xxx.x	xx.x	
					Week 12		Yes	DDMMMYYYY	xx.x	xxx.x	xx.x	xx.x
					Week 16		Yes	DDMMMYYYY	xx.x	xxx.x	xx.x	xx.x
					…							

Note: A higher score indicates more severe pain or poorer disease status. Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. # = Baseline Visit.
[1] mITT = Included in mITT Set?
[2] PPS = Included in PP Set?
[3] Displayed for mITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.6.5
Visual Analogue Scale (VAS) Measurements – Patient Global Assessment for Psoriatic Arthritis
ITT Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	mITT [1]	PPS [2]	Treatment Period II subset [3]	Visit		Assessment Performed? (Yes / No, specify)	Assessment Date	Result (mm)	Total Length (mm)	Standardized Result (mm)	Change from Baseline (mm)
XXXX-XXXX	XX/X/X	Yes	Yes	C	Week 0	#	Yes	DDMMMYYYY	xx.x	xxx.x	xx.x	
					Week 12		Yes	DDMMMYYYY	xx.x	xxx.x	xx.x	xx.x
					Week 16		Yes	DDMMMYYYY	xx.x	xxx.x	xx.x	xx.x
					…							

Note: A higher score indicates more severe pain or poorer disease status. Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. # = Baseline Visit.
[1] mITT = Included in mITT Set?
[2] PPS = Included in PP Set?
[3] Displayed for mITT – Treatment Period II subset. C = CT-P43 Maintenance, S = Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment group.

Listing 16.2.6.6
Individual Serum Concentrations of Ustekinumab
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	PK [1]	ADA [2]	Treatment Period II subset [3]	Visit [4]	Sample collected? (Yes / No, specify)	Sampling Date	Sample collected prior to study drug administration? (Yes / No, specify)	Concentration (Unit)
XXXX-XXXX	XX/X/X	Yes	N	C	Week 0	Yes	DDMMMYYYY	Yes	x.xx
					Week 4	Yes	DDMMMYYYY	Yes	x.xx
					Week 12	Yes	DDMMMYYYY	No, XXXXXXX	x.xx

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] PK = Included in PK Set?
[2] ADA = ADA Status. P = At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16. N = All ADA negative subgroup where patients who only have “Negative” results in post treatment immunogenicity test before Week 16 [3] Displayed only for PK – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[4] Samples are collected at predose (prior to the beginning of study durg administration) except Week 12 and EOS at which the blood sample will be taken at any time.

Programming Note: Sort by Patient No. and visit. Repeat for Stelara treatment group.

Listing 16.2.7.1
Adverse Events
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have "Negative" results in post treatment immunogenicity test before Week 16
[3] From the MedDRA Dictionary, version xx.x.
[4] # indicates a Treatment-Emergent Adverse Event.
[5] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[6] Out = Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Recovered/Resolved With Sequelae: specify,
4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
[7] Trt = Any Treatment Received: 1=No, 2=Medication, 3=Non-Medication Treatment, 4=Both Medication and Non-Medication Treatment.
If either 3 or 4, specify.
[8] Int = Intensity: 1=Grade 1, 2=Grade 2, 3=Grade 3, 4=Grade 4, 5=Grade 5.
[9] Act = Action Taken: 1=Dose Not Changed, 2=Drug Interrupted, 3=Drug Withdrawn, 4=Not Applicable.
[10] Rel = Relation to Study Drug: 1=Unrelated, 2=Possible, 3=Probable, 4=Definite.
[11] Ser = Was Event Serious?: N=No, Y=Yes.
[12] HAR = Is Adverse Event classified as Hypersensitivity reaction?: Y=Yes
[13] ISR = Is Adverse event classified as an injection site reaction?: Y=Yes.
[14] Inf = Is Adverse event classified as Infection: Y=Yes.
[15] Mal = Is Adverse event classified as Malignancy: Y=Yes.

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.1
Adverse Events
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	Sequence Number	ADA [2]	System Organ Class [3]/ Preferred Term [3]/ Adverse Event	Start Date/Time/ Stop Date/Time	TEAE [4]	Per [5]	Out [6]	Trt [7]	Int [8]	Act [9]	Rel [10]	Ser [11]	HA R [12]	ISR [13]	Inf [14]	Mal [15]
XXXX - XXXX	XX/X/X	C	DDMMMYYYY	1	P	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM			1	2: XXX XXX	X	X	X	X				
				2		XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM	#	1	3: XXX XXX	1	X	X	X	X	Y		Y	
XXXX - XXXX	XX/X/X	C	DDMMMYYYY	1	N	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM			X	X	X	X	X	X		Y		
				2		XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM	#	2	X	X	X	X	X	X	Y	Y		

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.2
Deaths
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Date of First/ Last Administration	Date of Last Visit	Date of Death	TEAE [2]	Days from First Dose [3]	Days from Last Dose [4]	Days On Study [5]	System Organ Class [6]/ Preferred Term [6]/ Cause of Death	Aut [7]	Cer [8]	Rel [9]
XXXX-XXXX	XX/X/X		DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY	DDMMMYYYY		XXX	XXX	XXX	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	X	X	X

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] # indicates a Treatment-Emergent Adverse Event.
[3] Time to death from first dose is calculated by (Date of death – Date of first dose +1).
[4] Time to death from last dose is calculated by (Date of death – Date of last dose +1).
[5] In case of death during the study, days on study will be calculated as (Date of death – Date of first dose +1). Otherwise, days on study is calculated by (Date of Last Visit – Date of first dose +1).
[6] From the MedDRA Dictionary, Version xx.x.
[7] Aut = Was an Autopsy Performed? : N=No, Y=Yes.
[8] Cer = Was a Death Certificate Completed? : N=No, Y=Yes.
[9] Rel = Relation to Study Drug: 1=Unrelated, 2=Possible, 3=Probable, 4=Definite.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.3
Serious Adverse Events
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have "Negative" results in post treatment immunogenicity test before Week 16
[3] From the MedDRA Dictionary, version xx.x.
[4] # indicates a treatment-emergent adverse event.
[5] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[6] Out = Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Recovered/Resolved With Sequelae: specify,
4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
[7] Trt = Any Treatment Received: 1=No, 2=Medication, 3=Non-Medication Treatment, 4=Both Medication and Non-Medication Treatment. If either 3 or 4, specify.
[8] Int = Intensity: 1=Grade 1, 2=Grade 2, 3=Grade 3, 4=Grade 4, 5=Grade 5.
[9] Act = Action Taken: 1=Dose Not Changed, 2=Drug Interrupted, 3=Drug Withdrawn, 4=Not Applicable.
[10] Rel = Relation to Study Drug: 1=Unrelated, 2=Possible, 3=Probable, 4=Definite.

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.3
Serious Adverse Events
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	ADA [2]	System Organ Class [3]/ Preferred Term [3]/ Adverse Event	Start Date/Time/ Stop Date/Time	TEAE [4]	Per [5]	Out [6]	Trt [7]	Int [8]	Act [9]	Rel [10]
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	P	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM			1	2: XXXXXXX	X	X	X
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	#	1	3: XXXXXXX	1	X	X	X
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	N	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM			X	X	X	X	X
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	#	2	X	X	X	X	X

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.3a
Serious Adverse Events: Additional Information
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] From the MedDRA Dictionary, Version xx.x.
[3] CRI = Serious Criteria: 1=Hospitalization, Initial, 2=Hospitalization, Prolongation, 3=Life-threatening, 4=Congenital Anomaly/Birth Defect, 5=Important Medical Event, 6=Disability/Incapacity, 7=Death
[4] # indicates a treatment-emergent adverse event.
[5] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[6] If the SAE resulted in hospitalization, admission date and discharge date are presented.
[7] ABAT = SAE abating. Did the SAE abate after use of study drug stopped?: Y=Yes, N=No, NA=Not Applicable, UK=Unknown.
[8] REOC = SAE reoccurring. Did the SAE reoccur after reintroduction of study drug/treatment?: Y=Yes, N=No, NA=Not Applicable, UK=Unknown.
[9] Unrel = If relationship to study drug/treatment is 'Unrelated', select the cause of event: 1=Concomitant Medication, Specify, 2=Concomitant Disease, Specify, 3=Other, Specify.

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.3a
Serious Adverse Events: Additional Information
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	System Organ Class [2]/ Preferred Term [2]/ Adverse Event	Start Date/Time/ Stop Date/Time	CRI [3]	TEAE [4]	Per [5]	Admission/ Discharge Date [6]	ABAT [7]	REOC [8]	Unrel [9]	SAE Description
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	2				X	X		XXXXXXX
				XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	3	#	1		X	X	1: XXXX	XXXXXXX
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	1			DDMMMYYYY/ DDMMMYYYY	X	X	4: XXXX	XXXXXXX
				XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	X	#	2		X	X	X	XXXXXXX

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.4
Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have "Negative" results in post treatment immunogenicity test before Week 16
[3] From the MedDRA Dictionary, version xx.x.
[4] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[5] Out = Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Recovered/Resolved With Sequelae: specify,
4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
[6] Trt = Any Treatment Received: 1=No, 2=Medication, 3=Non-Medication Treatment, 4=Both Medication and Non-Medication Treatment. If either 3 or 4, specify.
[7] Int = Intensity: 1=Grade 1, 2=Grade 2, 3=Grade 3, 4=Grade 4, 5=Grade 5.
[8] Rel = Relation to Study Drug: 1=Unrelated, 2=Possible, 3=Probable, 4=Definite.
[9] Ser = Was Event Serious?: N=No, Y=Yes.

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.4
Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II subset [1]	Treatment Period II Start Date	ADA [2]	System Organ Class [3]/ Preferred Term [3]/ Adverse Event	Start Date/Time/ Stop Date/Time	Per [4]	Out [5]	Trt [6]	Int [7]	Rel [8]	Ser [9]
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	P	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM		X	2: XXXXXXX	X	X	X
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	1	X	1	X	X	X
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	P	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM		X	X	X	X	X
					XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/HH:MM/ DDMMMYYYY/ HH:MM	2	X	X	X	X	X

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.5
Treatment-Emergent Adverse Events classified as Infection/Serious Infection
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have "Negative" results in post treatment immunogenicity test before Week 16
[3] From the MedDRA Dictionary, version xx.x.
[4] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[5] Out = Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Recovered/Resolved With Sequelae: specify,
4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
[6] Trt = Any Treatment Received: 1=No, 2=Medication, 3=Non-Medication Treatment, 4=Both Medication and Non-Medication Treatment. If either 3 or 4, specify.
[7] Int = Intensity: 1=Grade 1, 2=Grade 2, 3=Grade 3, 4=Grade 4, 5=Grade 5.
[8] Act = Action Taken: 1=Dose Not Changed, 2=Drug Interrupted, 3=Drug Withdrawn, 4=Not Applicable.
[9] Rel = Relation to Study Drug: 1=Unrelated, 2=Possible, 3=Probable, 4=Definite.
[10] Ser = Was Event Serious?: N=No, Y=Yes.

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.5
Treatment-Emergent Adverse Events classified as Infection/Serious Infection
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	Sequence Number	ADA [2]	System Organ Class [3]/ Preferred Term [3]/ Adverse Event	Start Date/Time/ Stop Date/Time	Per [4]	Out [5]	Trt [6]	Int [7]	Act [8]	Rel [9]	Ser [10]
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM		1	2: XXXXXXX	X	X	X	
				2		XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM	1	3: XXXXXXX	1	X	X	X	
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM		X	X	X	X	X	
				2		XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/	2	X	X	X	X	X	

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.6
Treatment-Emergent Adverse Events classified as Injection Site Reactions
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have "Negative" results in post treatment immunogenicity test before Week 16
[3] From the MedDRA Dictionary, version xx.x.
[4] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[5] Out = Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Recovered/Resolved With Sequelae: specify,
4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
[6] Trt = Any Treatment Received: 1=No, 2=Medication, 3=Non-Medication Treatment, 4=Both Medication and Non-Medication Treatment. If either 3 or 4, specify.
[7] Int = Intensity: 1=Grade 1, 2=Grade 2, 3=Grade 3, 4=Grade 4, 5=Grade 5.
[8] Act = Action Taken: 1=Dose Not Changed, 2=Drug Interrupted, 3=Drug Withdrawn, 4=Not Applicable.
[9] Rel = Relation to Study Drug: 1=Unrelated, 2=Possible, 3=Probable, 4=Definite.
[10] Ser = Was Event Serious?: N=No, Y=Yes.

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.6
Treatment-Emergent Adverse Events classified as Injection Site Reactions
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	Sequence Number	ADA [2]	System Organ Class [3]/ Preferred Term [3]/ Adverse Event	Start Date/Time/ Stop Date/Time	Per [4]	Out [5]	Trt [6]	Int [7]	Act [8]	Rel [9]	Ser [10]
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM		1	2: XXXXXXX	X	X	X	N
				2		XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM	1	3: XXXXXXX	1	X	X	X	Y
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM		X	X	X	X	X	N
				2		XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY/ HH:MM/ DDMMMYYYY/ HH:MM	2	X	X	X	X	X	N

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.6a
Treatment-Emergent Adverse Events classified as Injection Site Reactions: Additional Information
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	Sequence Number	ADA [2]	Per [3]	System Organ Class [4]/ Preferred Term [4]/ Sign and Symptom/ Intensity [5]	Comments
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 3	XXXXXXXXXX
				2		X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 3	
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 2	XXXXXXXXXX
				2		X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 1	XXXXXXXXXX

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have “Negative” results in post treatment immunogenicity test before Week 16
[3] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[4] From the MedDRA Dictionary, Version xx.x.
[5] Intensity of sign and symptom

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.7
Treatment-Emergent Adverse Events classified as Hypersensitivity Reactions
Safety Set

Treatment Group: CT-P43

Use the same listing layout as Listing 16.2.7.6

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.7a
Treatment-Emergent Adverse Events classified as Hypersensitivity Reactions: Additional Information
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] ADA: ADA status
P: At least one ADA positive subgroup where patients who show at least one positive result in immunogenicity test obtained after study drug exposure prior to Week 16
N: All ADA negative subgroup where patients who only have "Negative" results in post treatment immunogenicity test before Week 16
[3] Per = Occurred Period: 1=Treatment Period I, 2=Treatment Period II.
[4] From the MedDRA Dictionary, Version xx.x.
[5] Intensity of sign and symptom
[6] If hypotension/hypertension was a sign of Hypersensitivity/allergic reaction, specify.
SBP=Systolic blood pressure (mmHg), DBP=Diastolic blood pressure (mmHg)
[7] In case of hypersensitivity/allergic reaction, any types of ECG can be performed.
If the result of overall interpretation of ECG is abnormal, specify the abnormality.
N=Normal (Clear, Finding), AB (NCS)=Abnormal, Not Clinically Significant, AB (CS)=Abnormal, Clinically Significant

Note: Gender: M = Male, F = Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.

Listing 16.2.7.7a
Treatment-Emergent Adverse Events classified as Hypersensitivity Reactions: Additional Information
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Treatment Period II Start Date	Sequence Number	ADA [2]	Per [3]	System Organ Class [4]/ Preferred Term [4]/ Sign and Symptom/ Intensity [5]	SBP [6]	DBP [6]	BP Assessment Date/ Time [6]
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	1	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 3			
				2		X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 3			
XXXX-XXXX	XX/X/X	C	DDMMMYYYY	1	N	X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 2	XXX	XXX	DDMMMYYYY/ HH:MM
				2		X	XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXX/ Grade 1			

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.7a
Treatment-Emergent Adverse Events classified as Hypersensitivity Reactions: Additional Information
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Sequence Number	ADA [2]	Per [3]	ECG Performed, Type [7]	ECG Assessment Date/Time [7]	Overall interpretation, specify [7]	Comments
XXXX-XXXX	XX/X/X	1	N	1	Yes, 12-lead ECG	DDMMMYYYY/ HH:MM	N	
		2		X	Yes, 12-lead ECG	DDMMMYYYY/ HH:MM	AB (NCS), XXXX	
XXXX-XXXX	XX/X/X	1	N	X	Yes, Other, xxxx	DDMMMYYYY/ HH:MM	AB (CS), XXXX	
		2		X	No			

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.7.8
Treatment-Emergent Adverse Events classified as Malignancy
Safety Set

Treatment Group: CT-P43

Use the same listing layout as Listing 16.2.7.5

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No, Start Date, SOC and PT. Repeat for Stelara treatment groups.

Listing 16.2.8.1
Serum Clinical Chemistry
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Visit	Sample collected? (Yes / No, specify)	Sampling Date	Parameter	Result			Normal Range		Interpretation	CTCAE Term	CTCAE Grade
										Low	High			
XXXX-XXXX	XX/X/X	C	XXX	Yes	DDMMMYYYY	XXXXX (unit)	XXX.XX	#	L	XX.X	XX.X	Abnormal	XXXXX XXX	1
				Yes	DDMMMYYYY	XXXXX (unit)	XXX.XX	#		XX.X	XX.X	Normal		
				Yes	DDMMMYYYY	XXXXX (unit)	XXX.XX			XX.X	XX.X	XXXXXX		
			XXX	No, XXXXXXXX										
			…											

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
= Baseline Value. L = Low, H = High.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Visit and test parameters. Repeat for Stelara treatment groups.

Listing 16.2.8.2
Hematology
Safety Set

Treatment Group: CT-P43

Use the same listing layout as Listing 16.2.8.1

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
# = Baseline Value.
L = Low, H = High.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Visit and test parameters. Repeat for Stelara treatment groups.

Listing 16.2.8.3
Urinalysis
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Visit	Sample collected? (Yes / No, specify)	Sampling Date	Parameter	Result		Normal Range		Interpretation
									Low	High	
XXXX-XXXX	XX/X/X	C	XXXX	Yes	DDMMMYYYY	XXXXX (unit)	XXX.XX #		XXXXX	XXXXX	Normal
				Yes	DDMMMYYYY	XXXXX (unit)	XXX.XX #	H	XXXXX	XXXXX	Abnormal
				Yes	DDMMMYYYY	XXXXX (unit)	XXX.XX		XXXXX	XXXXX	XXXXXX
			XXXX	No, XXXXXXXX							
			…								

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
= Baseline Value. L = Low, H = High.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Visit and test parameters. Repeat for Stelara treatment groups.

Listing 16.2.9.1
Vital Signs and Weight
Safety Set

Footnotes:

[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43
[2] TP = Time point
0 = After 5 minutes of rest for Vital signs
1 = Prior to the study treatment administration for Hypersensitivity Monitoring
2 = 1 hour (±10 minutes) after the end of the study treatment administration for Hypersensitivity Monitoring,

The followings represent the range of Hypersensitivity Classification for Vital Signs
Systolic Blood Pressure (mmHg). Low: ≤ 90, High: ≥ 160
Diastolic Blood Pressure (mmHg). Low: ≤ 50, High: ≥ 90
Pulse Rate (beats/min). Low: ≤ 50, High: ≥ 100
Respiratory Rate (breaths/min). Low: ≤ 12, High: ≥ 20
Body Temperature (◦C). Low: ≤ 35.0, High: ≥ 38.0

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other. Vital Sign: SBP= Systolic Blood Pressure, DBP= Diastolic Blood Pressure, PR= Pulse Rate, RR= Respiratory Rate, BT= Body Temperature
= Baseline value. L/H = Indicates a low or high clinically notable result respectively.
In the case of Weight values on scheduled visit, Assessment time and whether or not performed are not collected.

Listing 16.2.9.1
Vital Signs and Weight
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II subset [1]	Visit	TP [2]	Assessment Performed? (Yes / No, specify)	Assessment Date/Time	Parameter	Result		
XXXX-XXXX	XX/X/X	C	Screening	0	Yes	DDMMMYYYY	SBP (mmHg)	XXX	#	
							DBP (mmHg)	XXX	#	L
							PR (beats/min)	XX	#	
							RR (breaths/min)	XX	#	
							BT (◦C)	XX.X	#	H
							Weight (kg)	XX.X	#	
XXXX-XXXX	XX/X/X	C	Week 0	0	Yes	DDMMMYYYY/ HH:MM	SBP (mmHg)	XXX		
							…	…		
				2	Yes	DDMMMYYYY/ HH:MM	…	…		
							…	…		
			Week 4		No, xxxxxxxx	DDMMMYYYY				
			…							

Note: Footnotes are listed on the first page.

Programming Note: Sort by Patient No., Visit and Date/time points. Repeat for Stelara treatment groups.

Listing 16.2.9.2
12-Lead Electrocardiograms
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II subset [1]	Visit		ECG Performed? (Yes / No, specify)	Assessment Date	Overall Interpretation	If Abnormal, Specify
XXXX-XXXX	XX/X/X	C	Screening	#	Yes	DDMMMYYYY	Normal	
			Week 0		No, XXXXXXXXXX			
			Week 0 Unscheduled		Yes	DDMMMYYYY	Abnormal, NCS	XXXXXXXXXX
			…					

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
ECG = Electrocardiograms. CS = Clinically Significant, NCS = Not Clinically Significant. # = Baseline visit.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Visit and Date. Repeat for Stelara treatment groups.

Listing 16.2.9.3
Physical Examinations
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II Subset [1]	Visit		Assessment Date	Examination Performed? (Yes / No, specify)	Category	Interpretation	If Abnormal, Specify
XXXX-XXXX	XX/X/X	C	Screening		DDMMMYYYY	Yes	XXXXXXXXXXX	Abnormal, CS	XXXXXXXXXXXXX
							XXXXXXXXXXX	Normal	
							…		
			Week 0	#	DDMMMYYYY	Yes	XXXXXXXXXXX	Abnormal, NCS	XXXXXXXXXXXXX
							XXXXXXXXXXX	Normal	
							…		
			Week 4			No, XXXXXXXXXXX			
			…						

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
CS = Clinically Significant, NCS = Not Clinically Significant. # = Baseline visit.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Visit, Date and Category. Repeat for Stelara treatment groups.

Listing 16.2.9.4
Tuberculosis Assessment: Interferon-Gamma Release Assay (IGRA)
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II subset [1]	Visit	Sample collected? (Yes / No, specify)	Sampling Date	Result	
XXXX-XXXX	XX/X/X	C	Screening	Yes	DDMMMYYYY	XXXX	#
			Week 16	Yes	DDMMMYYYY	XXXX	
			XXXX	No, XXXXXXXXXX			
XXXX-XXXX	XX/X/X		Screening	Yes	DDMMMYYYY	XXXX	#
			Week 16	Yes	DDMMMYYYY	XXXX	
			Week 16 Unscheduled	Yes	DDMMMYYYY	XXXX	
			…				

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
= Baseline Value.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Date and Visit. Repeat for Stelara treatment groups.

Listing 16.2.9.5
Tuberculosis Assessment: Chest X-Ray
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II Subset [1]	Visit	Test Performed? (Yes / No, specify)	Assessment Date	Interpretation	If Abnormal, Specify
XXXX-XXXX	XX/X/X	C	Screening	Yes	DDMMMYYYY	Abnormal, CS	XXXXXXXXXXXXX
XXXX-XXXX	XX/X/X	C	Screening	No, XXXXXXXXXXX			
XXXX-XXXX	XX/X/X		Screening	Yes	DDMMMYYYY	Normal	
…							

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
CS = Clinically Significant, NCS = Not Clinically Significant.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Date and Visit. Repeat for Stelara treatment groups.

Listing 16.2.9.6
Tuberculosis Clinical Monitoring
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II Subset [1]	Visit	Clinical Signs and Symptoms Monitored? (Yes / No, specify)	Assessment Date	Were There Any Signs or Symptoms Present Indicative of Tuberculosis?
XXXX-XXXX	XX/X/X	C	Screening	Yes	DDMMMYYYY	No
			Week 0	No, XXXXXXXXXXXX		
			Week 2	Yes	DDMMMYYYY	Yes
			Week X Unscheduled	Yes	DDMMMYYYY	No
			…			

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment groups.

Listing 16.2.9.7
Local Site Pain Assessment: Visual Analogue Scale (VAS)
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/ Race	Treatment Period II Subset [1]	Visit	Assessment Performed? (Yes / No, specify)	Assessment Date/Time	Result (mm)	Total Length (mm)	Standardized Result (mm)
XXXX-XXXX	XX/X/X	C	Week 0	Yes	DDMMMYYYY/HH:MM	XX	XXX	XX.X
			Week 4	No, XXXXXXXXXXXX				
			Week 16	Yes	DDMMMYYYY/HH:MM	XX	XXX	XX.X
			…					

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No., Date and Visit. Repeat for Stelara treatment groups.

Listing 16.2.9.8
Serum Pregnancy Test
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II Subset [1]	Fertility Status	Visit	Test Performed? (Yes / No, specify)	Sampling Date	Result
XXXX-XXXX	XX/X/X	C	Potentially Able to Bear Children	Screening #	Yes	DDMMMYYYY	XXXXXX
				EOS	Yes	DDMMMYYYY	XXXXXX
				…			

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
EOS = End-of-Study. # = Baseline Visit.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment groups.

Listing 16.2.9.9
Urine Pregnancy Test
Safety Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Treatment Period II Subset [1]	Fertility Status	Visit	Test Performed? (Yes / No, specify)	Sampling Date	Result
XXXX-XXXX	XX/X/X	C	Potentially Able to Bear Children	Week 0	Yes	DDMMMYYYY	XXXXXX
				Week 4	Yes	DDMMMYYYY	XXXXXX
				Week 16	No, XXXXXXXXXXXX		
				…			

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

Programming Note: Sort by Patient No. and Visit. Repeat for Stelara treatment groups.

Listing 16.2.9.10
Immunogenicity Results
Safety Set

Treatment Group: CT-P43

Patient No.	Age/ Gender/ Race	Treatment Period II Subset [1]	Visit	Sample collected? (Yes / No, specify)	Sampling Date	ADA SCR [2]	ADA CON [3]	ADA Result	NAb SCR [4]	ADA Titer
XXXX-XXXX	XX/X/X	C	XXXX	Yes	DDMMMYYYY	XXXX	XXXX	XXXX	XXXX	XXXX
			XXXX	Yes	DDMMMYYYY	XXXX	XXXX	XXXX	XXXX	XXXX
			XXXX	No, XXXXXXX						
			XXXX	Yes	DDMMMYYYY	XXXX	XXXX			
			Unscheduled *							
…										

Gender: M=Male, F=Female. Race: AI=American Indian or Alaska Native, AS=Asian, B=Black or African American, PI=Native Hawaiian or Other Pacific Islander, W=White, NI=Not allowed by investigator country regulation, O=Other. N/A=Not Applicable.
[1] Displayed only for Safety – Treatment Period II subset. C = CT-P43 Maintenance, S =Stelara Maintenance, SW = Switched to CT-P43

[2] ADA SCR = Anti-drug antibody screening assay result.
[3] ADA CON = Anti-drug antibody specificity/confirmatory assay result.
[4] NAb SCR = Neutralizing antibody (NAb) screening assay result.

Programming Note: Sort by Patient No., and Visit. Repeat for Stelara treatment groups.

Listing 16.2.11.1
General Comments
ITT Set

Treatment Group: CT-P43

Patient No.	Age/Gender/Race	Visit/Date	Category	COVID-19 [1]	Comment
XXXX-XXXX	XX/X/X	XXXXXXXX/DDMMMYYYY	XXXXXX	*	XXXXXXXXXX
XXXX-XXXX	XX/X/X	XXXXXXXX//DDMMMYYYY	XXXXXX		XXXXXXXXXX
XXXX-XXXX	XX/X/X	XXXXXXXX	XXXXXX		XXXXXXXXXX

Note: Gender: M=Male, F=Female. Race: W=White, B=Black or African American, AI=American Indian or Alaska Native, AS=Asian, PI=Native Hawaiian or Other Pacific Islander, NI= Not Allowed by Investigator Country Regulation, O=Other.
[1] Are the comments associated with COVID-19? * = Yes
Programming Note: Sort by Patient No.. Repeat for Stelara treatment groups.

CELLTRION Inc.

CT-P43 3.1

A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients with Moderate to Severe Plaque Psoriasis

22th June 2022

Statistical Analysis Plan Addendum

Final Version 1.0 (B)

Prepared by:

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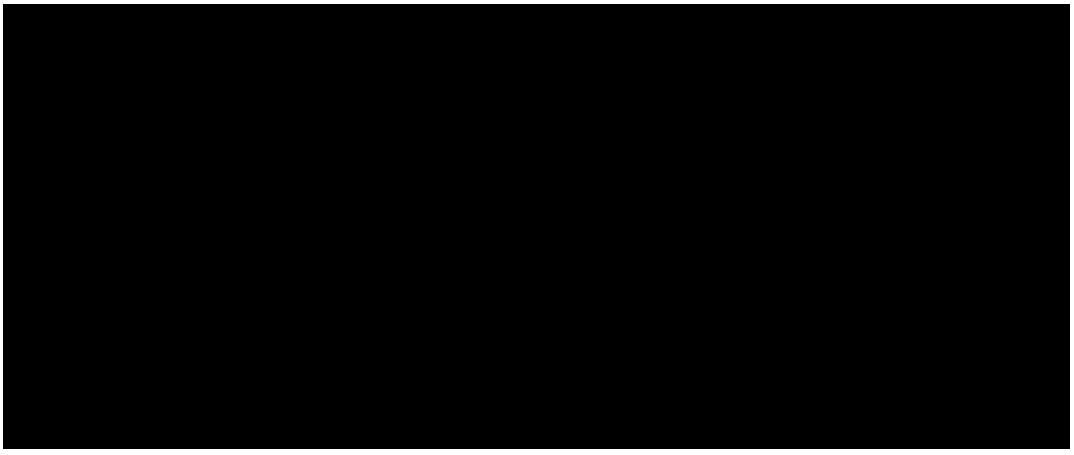

Approved by:

The undersigned agree to the changes to the statistical analyses and procedures outlined in this Statistical Analysis Plan Addendum.

TABLE OF CONTENTS

1. Statistical Analysis Addendum

This Statistical Analysis Plan (SAP) Addendum describes the changes and/or modifications from SAP final version 1.0 (B) dated 19th May 2022.

2. Overview of Changes Required

In this SAP addendum, it is described that the results of ADA titration recorded a below lower limit of quantification (BLQ) will be set to the respective limit for descriptive summary. The purpose of this addendum is to include the patients whose ADA titration results are BLQ even though their ADA results are positive in summarization. Also, both descriptive summary and proportion will be summarized by each scheduled visit.

2.1. Immunogenicity

2.1.1. Change of: Section 12.9

The method of summary will be changed as follows:
"In addition, the results of ADA titration will be summarized by treatment group and visit using descriptive statistics including interquartile range (IQR) for Overall Period on the Safety Set. In case the result of ADA titration is BLQ, it will be set to the respective limit for the descriptive summary. The proportion of patients who report ADA positive result ~~after first administration~~ will be summarized by treatment group and original scale at each scheduled visit for Overall Period on the Safety Set."