Protocol B7541013

A PHASE 1, RANDOMIZED, DOUBLE-BLIND, THIRD-PARTY OPEN, PLACEBO CONTROLLED STUDY TO EVALUATE THE PHARMACOKINETICS, SAFETY AND TOLERABILITY FOLLOWING SINGLE SUBCUTANEOUS DOSE OF PF-06480605 IN CHINESE HEALTHY PARTICIPANTS

Statistical Analysis Plan
(SAP)

Version: 2

Date: 25 Apr 2022

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APPENDICES

1. VERSION HISTORY

Table 1. Summary of Changes

Version/ Date	Associated Protocol Amendment	Rationale	Specific Changes
1/ 08 Feb 2021	Original 29 Dec 2020	N/A	N/A
2/ 25 Apr 2022	Original 29 Dec 2020	To respond to the additional comments	• Section 3.4: changed the wording for the baseline to be more precise. • Section 3.5.1: changed the wording for the definition of TEAE to be consistent with the algorithm of TEAE defined in the newest version of CaPS. • Sections 3.5.2, 3.5.3: removed the hours of collection days to be flexible in the analyses. • Section 3.5.5: removed the hours of collection days to be flexible in the analyses, and added "The full list of …" in the end of second paragraph for clarification. • Section 4: added content and modified the format of table to be consistent with the newest SAP template. • Section 5.2: removed "or summaries". • Section 6.1.2: added injection site reactions to the endpoint of AEs. • Section 6.2.1: removed "AUC_{14days}(dn)" and added content for completeness of section. • Section 6.3: removed this section and re-number the subsequent sections. • Section 6.4.1: added more demographic examples. • Section 6.4.2: removed "for safety". • Section 6.5: added COVID-19 related safety analyses • Section 9, Appendix 1: added and removed abbreviations to adjust to the content of SAP.

2. INTRODUCTION

PF-06480605 is a fully human IgG1 monoclonal antibody against Tumor Necrosis Factor like Ligand 1A (TL1A), a member of the tumor necrosis factor (TNF) family of cytokines, that is currently in development for the treatment of Crohn's disease (CD) and ulcerative colitis (UC). The mechanism of action of PF-06480605 is to neutralize the binding and subsequent signaling of TL1A to its functional receptor Death Receptor 3 (DR3) on immune cells of the innate and adaptive immune system.

The purpose of the study is to evaluate the PK, safety, tolerability, immunogenicity, and PD of PF-06480605 in Chinese healthy adult participants. The information of the PK, safety, tolerability, immunogenicity, and PD in Chinese healthy participants is being collected to support further clinical development as well as drug registration in China.

This statistical analysis plan (SAP) provides the detailed methodology for summary and statistical analyses of the data collected in Study B7541013. This document may modify the plans outlined in the protocol; however, any major modifications of the primary endpoint definition or its analysis will also be reflected in a protocol amendment.

2.1. Study Objectives, Endpoints, and Estimands

Estimands are not applicable to this Phase 1 study.

Objectives	Endpoints
Primary:	**Primary:**
• To characterize the PK of PF-06480605 following administration of single SC dose of PF-06480605 450 mg and 150 mg (if needed) in Chinese healthy adult participants. • To evaluate the safety and tolerability following administration of single SC dose of PF-06480605 450 and 150 mg (if needed) in Chinese healthy adult participants.	• Serum PF-06480605 primary PK parameters, as permitted by data: C_{max}, T_{max}, $AUC_{14\ days}$, AUC_{inf}, and $t_{½}$. • Assessment of AEs, vital signs, 12-lead electrocardiograms, physical examination findings and clinical safety laboratory measurements.
Secondary:	**Secondary:**
• To further evaluate the PK of PF-06480605. • To evaluate the immunogenicity of PF-06480605. • To evaluate the PD biomarker (if feasible) which may be informative in demonstrating the pharmacologic effect of PF-06480605.	• Serum PF-06480605 PK parameters, as permitted by data: AUC_{last}, C_{max}(dn), AUC_{inf}(dn), and AUC_{last}(dn), V_z/F and CL/F. • Incidence of the development of ADA and NAb. • Total sTL1A protein concentration in serum.

2.2. Study Design

This is a Phase 1, single-center, randomized, double-blind, third-party open (participant blind, investigator blind, sponsor open), placebo -controlled study to investigate PK, safety, tolerability, immunogenicity, and PD of PF-06480605 following a single subcutaneous dose of PF-06480605 450 mg and 150 mg (if needed) in Chinese healthy adult participants. Optional 150 mg cohort will be conducted only if data from 450 mg cohort does not confirm expected PK based on previous studies in healthy Western and Japanese participants as well as UC patients.

A maximum of approximately 24 participants (18 with active treatment and 6 with placebo) will be randomized and receive the investigational product such that approximately 12 participants are assigned to each cohort (450 mg and 150 mg) to ensure that 11 evaluable participants per cohort will complete the study. Participants will be enrolled to both cohorts sequentially, starting with the 450 mg cohort first. When the 150 mg cohort is determined to be needed, the 150 mg cohort with entirely new participants will be opened.

The 150 mg cohort will be started only if it indicates the ethnic PK difference (eg, more than two-fold higher exposure) based on all available serum concentrations data of PF-06480605 obtained until the timing when the PK sample is collected at Day 14 after administration, by comparing the dose-normalized mean exposures (or dose-normalized mean concentrations profiles) in this study versus dose-normalized mean exposures in Western study B7541001 and Japanese study B7541006.

Table 2. Randomization Scheme

Cohort	Treatment	Number of participants
1	PF-06480605 450 mg	9
	Placebo	3
2 (optional)	PF-06480605 150 mg	9
	Placebo	3

Participants, who drop out from the study if the number of participants completing at least the follow-up visit at Day 57 per cohort decreases to 10 or lower, will be replaced.

If a participant discontinues before completing the part of the study to which they have been randomized, or withdraws for reasons unrelated to the safety of the investigational product, the participant may be replaced at the discretion of the investigator upon consultation with the sponsor.

Within 28 days of successful completion of the screening process, eligible participants will be enrolled and randomized to receive a single dose of PF-06480605 450 mg or 150 mg (if needed) or placebo. Participants will be admitted into the CRU approximately 1 day prior to dosing and required to stay overnight in the CRU at least through completion of the Day 5 evaluations. Participants will return for outpatient follow-up visits through Day 114.

3. ENDPOINTS AND BASELINE VARIABLES: DEFINITIONS AND CONVENTIONS

3.1. Primary Endpoint(s)

The primary endpoints consist of PK and safety endpoints.

- Serum PF-06480605 primary PK parameters, as permitted by data: C_{max}, T_{max}, $AUC_{14\ days}$, AUC_{inf}, and $t_{½}$.
- Assessment of AEs, vital signs, 12 lead electrocardiograms, physical examination findings and clinical safety laboratory measurements.

3.2. Secondary Endpoint(s)

The secondary endpoints are additional PK, immunogenicity and PD biomarker endpoints defined as follows.

- Serum PF-06480605 PK parameters, as permitted by data: AUC_{last}, C_{max}(dn), AUC_{inf}(dn), and AUC_{last}(dn), V_z/F and CL/F.
- Incidence of the development of ADA and Nab.
- Total sTL1A protein concentration in serum.

3.3. Other Endpoint(s)

There are no other endpoints defined in this study.

3.4. Baseline Variables

Baseline value is defined as the latest value before receiving the dose of study intervention.

3.5. Safety Endpoints

3.5.1. Adverse Events

An adverse event is considered treatment emergent if the event starts during the effective study period (CRU confinement and follow-up visits).

All events that start on or after the dosing day and time, if collected, but before the end of study will be flagged as TEAEs. The algorithm will not consider any events that started prior to the dose date. If an AE starts on the same day as the dose date, it will be considered treatment emergent unless the CRF data indicates otherwise via explicitly recording time for AE onset and treatment dosing.

3.5.2. Vital Signs

Supine BP, PR measurements and axillary temperature are collected during the CRU confinement on Day 1 and Day 5, and during the follow-up visits on Day 10 and Day 114/ET.

3.5.3. Electrocardiograms

Single 12-Lead ECGs are collected during the CRU confinement on Day 1 and Day 5, and during the follow-up visits on Day 10 and Day 114/ET. Repeat ECGs may be taken following the study protocol at each assessment time.

Changes from baseline for the ECG parameters: QT interval, heart rate, QTc interval, PR interval, and QRS complex will be summarized by treatment and time.

3.5.4. Physical Examination

Height and body weight are only collected at screening. A full physical examination may be done at screening or Day -1. Brief physical examination to follow up open AEs after Day -1 may be done.

3.5.5. Laboratory Data

The safety laboratory tests of hematology, chemistry and urinalysis are performed during the screening, the CRU confinement on days: -1, 2 and 5, and the follow-up visits on days: 10, 15, 57, 85 and 114/ET.

Additional laboratory results may be reported on these samples as a result of the method of analysis or the type of analyzer used by the clinical laboratory, or as derived from calculated values. These additional tests would not require additional collection of blood. The full list of laboratory tests/assessments is shown in Table 4 in the protocol.

Hematology	Chemistry	Urinalysis
Hemoglobin Hematocrit RBC count MCV MCH MCHC Platelet count WBC count Total neutrophils (Abs) Eosinophils (Abs) Monocytes (Abs) Basophils (Abs) Lymphocytes (Abs)	BUN and creatinine Glucose (fasting) Calcium Sodium Potassium Chloride Total CO_2 (bicarbonate) AST, ALT Total bilirubin Alkaline phosphatase Uric acid Albumin Total protein	pH Glucose (qual) Protein (qual) Blood (qual) Ketones Nitrites Leukocyte esterase Urobilinogen Urine bilirubin Microscopy[a]
	Additional Tests (Needed for Hy's Law)	
	AST, ALT (repeat) Total bilirubin (repeat) Albumin (repeat) Alkaline phosphatase (repeat) Direct bilirubin Indirect bilirubin Creatine kinase GGT PT/INR	

a. Only if urine dipstick is positive for blood, or leukocyte esterase.

To determine if there are any abnormalities of potential clinical concern, the hematology, chemistry and urinalysis safety tests will be assessed against the criteria specified in the CDISC and Pfizer standards (CaPS). The assessment will take into account whether each participant's baseline test result is within or outside the laboratory reference range for the particular laboratory parameter.

4. ANALYSIS SETS (POPULATIONS FOR ANALYSIS)

Data for all participants will be assessed to determine if participants meet the criteria for inclusion in each analysis set prior to unblinding and releasing the database and classifications will be documented per standard operating procedures.

For purposes of PK/PD, safety and immunogenicity analyses, the following analysis sets are defined:

Population	Description	Applicable Analysis (for additional information refer to section 6)
Safety	All randomized participants who applied at least 1 dose of study intervention.	Analysis for safety endpoints
PK Concentration	All randomized participants who applied at least 1 dose of study intervention and for whom at least 1 concentration value is reported.	Analysis for PK concentration
PK Parameter	All randomized participants who applied at least 1 dose of study intervention and for whom at least 1 of the PK parameters of interest (e.g., AUC_{inf} and C_{max}) is calculated.	Analysis for PK parameters
Immunogenicity	All randomized participants who applied at least 1 dose of study intervention with at least 1 post-treatment anti-drug (PF-06480605) antibody determination.	Analysis for immunogenicity endpoints
PD	All randomized participants who have at least 1 PD assessment.	Analysis for PD biomarkers

All analyses will not include data from participants who are randomized but not treated. If a participant receives a treatment that is not consistent with the treatment they were randomly assigned to, then the participant will be reported under the treatment that the participant actually received for all PK/PD, safety and immunogenicity analyses, where applicable.

5. GENERAL METHODOLOGY AND CONVENTIONS

5.1. Hypotheses and Decision Rules

No formal statistical hypothesis testing will be conducted the analyses in this study.

5.2. General Methods

No formal statistical tests will be performed. Descriptive analyses will be provided for all endpoints by treatment for each cohort.

Additionally, a population PK model will be developed to characterize the PK and assess the effect of ethnicity on PK using all available data. The detailed analysis plans will be described in a separate pharmacometric analysis plan.

5.2.1. Analyses for Binary Endpoints

Number and percentage of participants in each category will be used to summarize the endpoints, if not otherwise specified.

5.2.2. Analyses for Continuous Endpoints

The summary statistics n, arithmetic mean, median, standard deviation (SD), minimum and maximum will be used to summarize the endpoints, if not otherwise specified.

The summary statistics for PK parameters are described in Section 6.2.

5.2.3. Analyses for Categorical Endpoints

Number and percentage of participants in each category will be used to summarize the endpoints, if not otherwise specified.

5.3. Methods to Manage Missing Data

Missing data will not be imputed.

5.3.1. Concentrations Below the Limit of Quantification

In all data presentations (except listings), PK and PD concentrations below the limit of quantification (BLQ) will be set to zero. In listings, BLQ values will be reported as "<LLQ", where LLQ will be replaced with the value for the lower limit of quantification.

5.3.2. Deviations, Missing Concentrations and Anomalous Values

In summary tables, plots of mean profiles and plots of median profiles, summary statistics will be calculated by setting concentrations to missing if one of the following cases is true:

- A concentration has been collected as ND (Not Done) or NS (No Sample).
- A deviation in sampling time is of sufficient concern or a concentration has been flagged anomalous by the pharmacokineticist.

Note that summary statistics will not be presented at a particular time point if more than 50% of the data are missing.

5.3.3. PK Parameters

Actual PK sampling times will be used in the derivation of PK parameters.

If a PK parameter cannot be derived from a participant's concentration data, the parameter will be coded as NC (Not Calculated). Note that NC values will not be generated beyond the day a participant discontinues.

In summary tables, summary statistics will be calculated by setting NC values to missing; and summary statistics will not be presented at a particular time point if more than 50% of the data are missing.

If an individual participant has a known biased estimate of a PK parameter (eg, due to known loss of drug during SC administration), this will be footnoted in summary tables and will not be included in the calculation of summary statistics.

6. ANALYSES AND SUMMARIES

6.1. Primary Endpoint(s)

The primary endpoints include PK and safety endpoints.

The primary PK parameters will be calculated from the concentration-time values for each participant, as applicable, using noncompartmental analysis as described in the protocol. The primary PK parameters will be listed and summarized for participants in the PK parameter analysis set. Each PK parameter will be summarized by dose (450 mg, 150 mg [if needed]) and will include the set of summary statistics as specified in the table in Section 6.1.1.

The safety endpoints will be listed and summarized by treatment (450 mg, 150 mg [if needed] and placebo) for participants in the safety analysis set. All participants received placebo in either 450 mg or 150 mg (if needed) cohort will have a pooled placebo group.

6.1.1. Primary PK Parameters

Parameter	Summary statistics
C_{max}, $AUC_{14\ days}$, AUC_{inf}	n, arithmetic mean, median, SD, minimum, maximum, percent coefficient of variation (%CV), geometric mean and geometric %CV.
T_{max}	n, median, minimum, maximum.
$t_{½}$	n, arithmetic mean, median, SD, minimum, maximum, %CV.

There will be one summary table presenting all PK parameters for each dose (450 mg and 150 mg [if needed]). The PK concentrations will be listed and summarized for participants in the PK concentration analysis set. Presentations for PF-06480605 concentrations will include:

- A listing of all concentrations sorted by subject ID, dose and nominal time postdose. The concentration listing will also include the actual times. Deviations from the nominal time will be given in a separate listing.

- A summary of concentrations by dose and nominal time postdose, where the set of summary statistics will include n, arithmetic mean, median, SD, %CV, minimum, maximum and the number of concentrations above the lower limit of quantification.

- Individual concentration time plots by dose (on both linear and semi-log scales) against actual time postdose (there will be separate spaghetti plots for each dose per scale).

- Individual concentration time plots by participant (on both linear and semi-log scales) against actual time postdose (there will be separate plots for each participant per scale).

- Mean concentrations time plots (on both linear and semi-log scales) against nominal time postdose (all doses on the same plot per scale, based on the summary of concentrations by dose and time postdose).

- Median concentrations time plots (on both linear and semi-log scales) against nominal time postdose (all doses on the same plot per scale, based on the summary of concentrations by dose and time postdose).

Note that if the cohort of 150 mg is not needed, then all the presentations above will only be available for 450 mg. The length of time used for the x-axes of these plots will be decided on review of the data, and will depend on how long PF-06480605 concentration is quantifiable in the matrix.

For summary statistics, mean and median plots by sampling time, the nominal PK sampling time will be used. For individual participant plots by time, the actual PK sampling time will be used.

6.1.2. Adverse Events

AEs (including injection site reactions) will be listed and summarized following CaPS.

6.1.3. Vital Signs

Absolute values and changes from baseline on vital signs will be listed and summarized by treatment following CaPS. In addition, the maximum increase and decrease from baseline over all measurements taken postdose for supine systolic blood pressure (BP) and diastolic BP will also be determined.

The maximum increase from baseline will be calculated by first subtracting the baseline value from each postdose measurement to give the change from baseline. The maximum of these values over all measurements will then be selected, except for cases in which a participant does not show an increase. In such an instance, the minimum decrease should be taken.

Similarly, the maximum decrease from baseline will be determined by selecting the minimum value of the changes from baseline. In cases where a participant does not show a decrease, the minimum increase should be taken.

6.1.4. Electrocardiograms

A listing of all ECG data sorted by subject ID, treatment and nominal time postdose will be produced.

Absolute values and changes from baseline for the ECG parameters (ie, QT interval, QTc interval, PR interval, and QRS interval) will be summarized by treatment and time postdose following CaPS. Average values of the ECG parameters for a participant will be calculated for summarization when ECG repeated at any assessment time for the participant.

The number and percentage of participants with maximum postdose QTc values and maximum increase from baseline in the following categories will be tabulated by treatment:

Safety QTc Assessment

Degree of Prolongation	Mild (msec)	Moderate (msec)	Severe (msec)
Absolute value	>450 – 480	>480 – 500	>500
Increase from baseline		30 – 60	>60

In addition, the number of participants with uncorrected QT values >500 msec will be summarized.

6.1.5. Physical Examination

Absolute values of height and body weight at baseline will be listed and summarized by treatment following CaPS.

6.1.6. Laboratory Data

Absolute values and changes from baseline on laboratory data will be listed and summarized by treatment following CaPS.

6.2. Secondary Endpoint(s)

The secondary endpoints are additional PK, immunogenicity and PD biomarker endpoints.

6.2.1. Secondary PK Parameters

Each PK parameter will be summarized as described in Section 6.1.1 and will include the set of summary statistics as specified in the table below:

Parameter	Summary statistics
C_{max}(dn), AUC_{last}, AUC_{inf}(dn), AUC_{last}(dn), V_z/F, CL/F	n, arithmetic mean, median, SD, minimum, maximum, %CV, geometric mean and geometric %CV.

dn = dose normalized to 1 mg

To assess the relationship between the PK parameters and dose, dose normalized parameters C_{max}(dn), AUC_{last}(dn) and AUC_{inf}(dn) (if data permitted) will be plotted against dose (using a logarithmic scale) and will include individual participants values and the geometric means for each dose. Geometric means will have a different symbol than the individual values. The values will be dose normalized to 1 mg by dividing the individual values and raw geometric means by dose. A footnote will be added to the plots to indicate that geometric means are presented. Note that if the cohort of 150 mg is needed, then the dose will include both 450 mg and 150 mg and perform a within-study comparison; if the cohort of 150 mg is not needed, then the analyses will only be based on dose of 450 mg and no within-study comparison will be performed.

6.2.2. Immunogenicity Endpoints

The incidence of the development of ADA and NAb will be listed and summarized for participants in the immunogenicity analysis set. Presentations for PF-06480605 concentrations will include:

- Listing of ADA and NAb incidence sorted by subject ID and dose.
- Summary of ADA and NAb incidence by dose and time.
- Summary of ADA and NAb incidence by overall postdose measurements (if 150 mg is conducted).
- Summary of treatment emergent ADA and NAb positive participants. An ADA incidence is considered treatment emergent if any ADA positive occurs for the first time after dosing and was negative at Day 1 (0 hr predose). An NAb incidence is considered treatment emergent if any NAb positive occurs for the first time after dosing and was negative at Day 1 (0 hr predose).
- Summary of mean PK concentrations by ADA and NAb status, dose and time postdose.
- Summary of mean PK parameters by ADA and NAb status and dose.

Immunogenicity assay titers will be used to determine incidence for ADA and NAb. Titer values will also be listed.

6.2.3. PD Biomarker

The PD biomarker endpoints will be listed and summarized for participants in the PD analysis set. Presentations for total sTL1A protein concentration in serum will include:

- A listing of sTL1A observed value, change and percent change from baseline sorted by subject ID and treatment (450 mg, 150 mg [if needed] and placebo). The sTL1A listing will also include the actual test times.

- A summary of sTL1A observed value, change and percent change from baseline sorted by time postdose and treatment, where the set of summary statistics will include n, arithmetic mean, SD, median, 25% quantile and 75% quantile.
- Individual plots of sTL1A against actual time postdose (there will be separate plots for each dose per scale).
- Individual plots of change from baseline in sTL1A against actual time postdose (there will be separate plots for each dose per scale).
- Individual plots of percent change from baseline in sTL1A against actual time postdose (there will be separate plots for each dose per scale).
- Mean sTL1A time plots against nominal time postdose (all treatments on the same plot per scale, based on the summary of concentrations by treatment and time postdose).
- Median sTL1A time plots against nominal time postdose (all treatments on the same plot per scale, based on the summary of concentrations by treatment and time postdose).

6.3. Subset Analyses

No formal subset analysis will be conducted for this study.

6.4. Baseline and Other Summaries and Analyses

6.4.1. Baseline Summaries

Demographic data (age, sex, ethnicity and race etc.) will be summarized following CaPS.

6.4.2. Study Conduct and Participant Disposition

The following participant dispositions will be summarized.

- A summary of participant discontinuations up to end of study;
- Summary of participant disposition;
- Summary of numbers of participant treated by treatment group.

Data will be reported following CaPS.

6.4.3. Concomitant Medications and Nondrug Treatments

All concomitant medications as well as nondrug treatments will be summarized following CaPS.

6.5. Safety Summaries and Analyses

In order to report the impact of COVID-19 on clinical trial populations and study data, the following additional listings and summaries will be produced:

- Listing of participants affected by COVID-19 related study disruption;
- Protocol deviations related to COVID-19;
- Discontinuations from study drug due to COVID-19 related AEs.

7. INTERIM ANALYSES

No formal interim analysis will be conducted for this study. As this is a sponsor-open study, the sponsor may conduct unblinded reviews of the data of 450 mg SC cohort through Day 14 and during the course of the study for the purpose of determining whether or not to conduct 150 mg SC cohort, and preliminarily assess any ethnic differences between Chinese and non-Chinese, thus to support China joining further global Phase 2 or Phase 3 studies.

The 150 mg cohort will be started only if it indicates the ethnic PK difference (eg, more than two-fold higher exposure) based on all available serum concentrations data of PF-06480605 obtained until the timing when the PK sample is collected at Day 14 after administration, by comparing the dose-normalized mean exposures (or dose-normalized mean concentrations profiles) in this study versus dose-normalized mean exposures in Western study B7541001 and Japanese study B7541006.

8. REFERENCES

Not applicable.

9. APPENDICES

Appendix 1. List of Abbreviations

Abbreviation	Term
AE	adverse event
AUC	area under the curve
BLQ	below the limit of quantitation
BP	blood pressure
CaPS	CDISC & Pfizer Standards
CD	Crohn's disease
CDARS	Clinical Data Analysis and Reporting System (of US Food and Drug Administration)
CDISC	Clinical Data Interchange Standard Consortium
C_{max}	maximum observed concentration
CRF	case report form
CRU	Clinical research unit
CSR	clinical study report
DMC	data monitoring committee
DR3	Death Receptor 3
EAC	event adjudication committee
ECG	electrocardiogram
E-DMC	external data monitoring committee
ET	Early termination
FDA	Food and Drug Administration (United States)
GCP	Good Clinical Practice
ICD	informed consent document
ICH	International Council for Harmonisation
IgG	immunoglobulin G
IRC	internal review committee
LLOQ	lower limit of quantitation
LOD	limit of detection
MedDRA	Medical Dictionary for Regulatory Activities
N/A	not applicable

Abbreviation	Term
NC	Not Calculated
ND	Not Done
NS	No Sample
PD	pharmacodynamic(s)
PK	pharmacokinetic(s)
PRO	patient-reported outcome
PR	Pulse rate
PT	preferred term
QTc	corrected QT
QTcF	corrected QT (Fridericia method)
qual	qualitative
RCDC	reverse cumulative distribution curve
RR	relative risk
SAE	serious adverse event
SAP	statistical analysis plan
SC	subcutaneous
SD	standard deviation
SGS	Statistical Guidance Standards
SOP	standard operating procedure
TA	therapeutic area
TL1A	Tumor Necrosis Factor like Ligand 1A
TNF	tumor necrosis factor
UC	ulcerative colitis
ULN	upper limit of normal
%CV	percent coefficient of variation