Statistical Analysis Plan

A Phase 1, Open-label, Fixed-sequence Study to Investigate the Effect of the Moderate CYP3A Inducer Rifabutin on the Pharmacokinetics of Zanubrutinib in Healthy Male Subjects

SAP Status: Final
SAP Version: 1.0
SAP Date: 12OCT2020

Investigational Product: Zanubrutinib (BGB-3111)

Protocol Reference: BGB-3111-112
Covance Study: 8426473

Sponsor:
BeiGene, Ltd.
c/o BeiGene USA, Inc.
2955 Campus Drive, Suite 200
San Mateo, California 94403
USA

Study Site:
Covance Clinical Research Unit, Inc.
1900 Mason Ave. Suite 140
Daytona Beach, Florida 32117
USA

Principal Investigator:
[redacted]

NCT04470908

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LIST OF ABBREVIATIONS

Abbreviations pertain to the statistical analysis plan (SAP) only (not the tables, figures, and listings [TFLs]).

ADaM	analysis data model
AE	adverse event
AUC	area under the concentration-time curve
$AUC_{0-\infty}$	area under the concentration-time curve from time zero to infinity
AUC_{0-t}	area under the concentration-time curve from time zero to the time of the last quantifiable concentration
BLQ	below the limit of quantification
CDISC	Clinical Data Interchange Standards Consortium
CI	confidence interval
CL/F	apparent oral clearance
C_{max}	maximum observed concentration
CSR	clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
CV	coefficient of variation
ECG	electrocardiogram
GLSM	geometric least squares mean
ICH	International Council for/Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ln	natural log
LSM	least squares mean
MedDRA	Medical Dictionary for Regulatory Activities
PK	pharmacokinetic(s)
SAP	statistical analysis plan
SD	standard deviation
$t_{1/2}$	apparent terminal elimination half-life
TEAE	treatment-emergent adverse event
TFL	table, figure, and listing
T_{max}	time of the maximum observed concentration
T_{last}	time of the last quantifiable concentration
V_z/F	apparent volume of distribution
WHODrug	World Health Organization Drug Dictionary
$\%AUC_{extrap}$	percentage of AUC due to extrapolation from the last quantifiable concentration to infinity

1. INTRODUCTION

This SAP has been developed after review of the clinical study protocol (Final Version 2 dated 16 July 2020) and electronic case report form.

This SAP describes the planned analysis of the pharmacokinetic (PK) and safety and tolerability data from this study. A detailed description of the planned TFLs to be presented in the clinical study report (CSR) is provided in the accompanying TFL shells document.

In general, the analyses are based on information from the protocol, unless they have been modified by agreement with BeiGene, Ltd. A limited amount of information about this study (eg, objectives, study design) is given to help the reader's interpretation. This SAP must be finalized prior to the lock of the clinical database for this study. When the SAP and TFL shells are approved, they will serve as the template for this study's CSR.

This SAP supersedes any statistical considerations identified in the protocol; where considerations are substantially different, they will be so identified. If additional analyses are required to supplement the planned analyses described in this SAP, they may be performed and will be identified accordingly in the CSR. Any substantial deviations from this SAP will be agreed with BeiGene, Ltd. and identified in the CSR.

This SAP is written with consideration of the recommendations outlined in the International Conference on Harmonisation (ICH) E9 guideline *Statistical Principles for Clinical Trials* and ICH E3 guideline *Structure and Content of Clinical Study Reports*.[1,2]

The document history is presented in Appendix 1.

2. STUDY OBJECTIVES

The primary objective of the study is:

- to determine the effect of the moderate CYP3A inducer rifabutin on the PK of zanubrutinib in healthy male subjects.

The secondary objective of the study is:

- to evaluate the safety and tolerability of zanubrutinib when co-administered with rifabutin in healthy male subjects.

3. STUDY ENDPOINTS

3.1. Primary Endpoints

The PK outcome endpoints of zanubrutinib derived from the plasma concentration-time profiles following oral administration of zanubrutinib on Days 1 and 11 are as follows:

- area under the concentration-time curve (AUC) from time zero to the time of the last quantifiable concentration (AUC_{0-t})
- AUC from time zero to infinity ($AUC_{0-\infty}$)

- maximum observed concentration (C_{max})
- time of the maximum observed concentration (T_{max})
- apparent terminal elimination half-life ($t_{1/2}$)
- apparent oral clearance (CL/F)
- apparent volume of distribution (V_z/F).

Other PK parameters may also be reported.

3.2. Secondary Endpoints

The safety outcome measures for this study are as follows:

- incidence and severity of adverse events (AEs)
- incidence of laboratory abnormalities, based on hematology, clinical chemistry, and urinalysis test results
- vital sign measurements
- 12-lead electrocardiogram (ECG) parameters
- physical examinations.

4. STUDY DESIGN

This is an open-label, fixed-sequence study in healthy male subjects to investigate the effect of CYP3A induction by steady-state rifabutin on the single-dose PK of zanubrutinib.

All subjects will receive the following treatments:

- Day 1: single oral dose of 320 mg zanubrutinib after overnight fast of 8 to 10 hours
- Days 3 to 10: oral dose of 300 mg rifabutin QD with food (standard meal)
- Day 11: single oral dose of 320 mg zanubrutinib and QD dose of 300 mg rifabutin after overnight fast of 8 to 10 hours.

5. SAMPLE SIZE JUSTIFICATION

Approximately 15 subjects will be enrolled to ensure that 12 subjects complete the study.

The sample size chosen for this study was based on precedent set by other PK studies of similar nature and was not based on power calculations.

6. STUDY TREATMENTS

All summaries will be provided for the total number of treated subjects. For the summaries of AEs, summaries will also be provided according to the study day of onset of the AE. The study treatment sequence name to be used in the AE summaries is presented in Table 1.

Table 1: Presentation of Study Treatment Sequence for AE summaries

Study Treatment Sequence	Includes AEs with Onset on Study Day:
320 mg Zanubrutinib on Day 1	1-2
300 mg Rifabutin on Days 3 to 10	3-10
320 mg Zanubrutinib + 300 mg Rifabutin on Day 11	11-study completion

The study days described above are the planned study days. The AE summaries according to treatment sequence will reflect the actual study days on which treatments were received.

The study treatment names and ordering to be used in the TFLs are presented in Table 2.

Table 2: Presentation of Study Treatments in TFLs

Study Treatment	Order in TFLs
320 mg Zanubrutinib	1
300 mg Rifabutin	2
320 mg Zanubrutinib + 300 mg Rifabutin	3

7. DEFINITIONS OF POPULATIONS

7.1. All Subjects Population

The all subjects population will include all subjects who signed the informed consent form and had any study assessment recorded in the database per the protocol.

7.2. Safety Population

The safety population will include all subjects who received at least 1 dose of zanubrutinib and/or rifabutin.

7.3. Pharmacokinetic Population

The PK population will include all subjects who received at least 1 dose of zanubrutinib and have evaluable PK data (at least 1 PK parameter can be calculated). A subject may be excluded from the PK summary statistics and statistical analysis if the subject has an AE of vomiting that occurs at or before 2 × median T_{max}.

8. STATISTICAL METHODOLOGY

8.1. General

Listings will be provided for all data captured in the database. Listings will include all subjects assigned to the all subjects population and include data up to the point of study completion or discontinuation. Subjects are generally considered to have completed the study if they completed all protocol-specified procedures and assessments for the follow-up visit. Any subject who discontinued the study will be identified accordingly in the listings.

Summaries and statistical analyses will include the subjects assigned to the relevant population based on data type.

Data analysis will be performed using the SAS® statistical software package Version 9.4 (or higher if up-versioned during the study).

Analysis Data Model (ADaM) datasets will be prepared using Clinical Data Interchange Standards Consortium (CDISC) ADaM Version 2.1 (or higher if up-versioned during the study) and CDISC ADaM Implementation Guide Version 1.2 (or higher if up-versioned during the study). Pinnacle 21 Community Validator Version 2.2.0 (or higher if up-versioned during the study) will be utilized to ensure compliance with CDISC standards.

Where reference is made to 'all calculations', this includes, but is not limited to, summary statistics and statistical analyses.

8.1.1. Calculation of the Summary Statistics

For continuous data the following rules will be applied:

- Missing values will not be imputed, unless specifically stated otherwise.
- Unrounded data will be used in the calculation of summary statistics.
- If the number of subjects with valid observations (n) <3, summary statistics will not be calculated, with the exception of n, minimum, and maximum.
- As Early Termination data is not associated with any scheduled timepoint, it will be excluded from all calculations of summary statistics.

For categorical data the following rules will be applied:

- If the categories of a parameter are ordered (eg, AE severity), all categories between the possible minimum and maximum categories will be included, even if n = 0 for a given category. If the categories are not ordered (eg, race), only those categories for which there is at least 1 subject represented will be included.
- Missing values will not be imputed, with the exception of AEs where the 'worst-case' approach will be taken (see Section 8.6.1), or unless specifically stated otherwise. A 'missing' category will be included for any parameter for which information is missing. This will ensure that the population size totals are consistent across different parameters.

8.1.2. Repeat and Unscheduled Readings

For vital signs and ECG data only, any predose value recorded in addition to the original value or a postdose value recorded within 15 minutes of the original value will be defined as a repeat value. Any value recorded in addition to the original value and repeat value will be defined as an unscheduled value.

The original value will be replaced by the last associated repeat value in all calculations.

As unscheduled values are not associated with any scheduled timepoint, they will be excluded from all calculations.

8.1.3. Definitions of Baseline and Change from Baseline

For laboratory data, vital signs, and ECG data, the baseline will be defined as the last non-missing value recorded prior to the first dose of zanubrutinib. If the date/time of the value is incomplete or missing, it will be excluded from the baseline calculation, unless the incomplete date/time or nominal time point indicates the value was recorded prior to the first dose.

Individual changes from baseline will be calculated by subtracting the individual subject's baseline value from the value at the timepoint. The mean change from baseline will be defined as the mean of the individual changes from baseline for all subjects.

See Section 8.1.2 for more detail on handling repeat and unscheduled readings in the calculations.

For laboratory data, vital signs, and ECG data, a baseline value is defined as the last non-missing value collected before the time of first dose of zanubrutinib.

8.2. Subject Disposition, Population Assignment, and Protocol Deviations

Subject disposition and population assignment will be listed.

A summary table will be provided, based on the all subjects population.

Any protocol deviations will be considered prior to database lock for their importance and taken into consideration when assigning subjects to populations. A listing of protocol deviations will be provided. Important protocol deviations will be noted in the listing.

8.3. Demographics

Demographics including age, sex, race, ethnicity, height, body weight, and body mass index will be listed.

A summary table by will be provided, based on the safety population.

8.4. Prior and Concomitant Medication

Prior medication will be defined as medication that starts prior to the first dose. Concomitant medication will be defined as medication that starts during or after the first dose or starts but does not end prior to the first dose. Medications that start prior to the first dose but do not end prior to the first dose will be classified as both prior and concomitant medications.

Prior and concomitant medications will be coded using the World Health Organization Drug Dictionary (WHODrug) Global, Format B3, Version March 2020 (or later if up-versioned during the study). Prior and concomitant medications will be listed.

8.5. Pharmacokinetic Assessments

8.5.1. Pharmacokinetic Analysis

The following PK parameters will be determined where possible from the plasma concentrations of zanubrutinib using noncompartmental methods in validated software program Phoenix WinNonlin (Certara, Version 8.1 or higher):

Parameter	Units[a]	Definition
AUC_{0-t}	h*ng/mL	area under the concentration-time curve from time 0 to the time of the last quantifiable concentration (T_{last})[b]
$AUC_{0-\infty}$	h*ng/mL	area under the concentration-time curve from time 0 extrapolated to infinity[c]
$\%AUC_{extrap}$	%	percentage of AUC due to extrapolation from the last quantifiable concentration to infinity
C_{max}	ng/mL	maximum observed concentration
T_{max}	h	time of the maximum observed concentration
T_{last}	h	time of the last quantifiable concentration
$t_{1/2}$	h	apparent terminal elimination half-life
CL/F	L/h	apparent oral clearance
V_z/F	L	apparent volume of distribution

[a] Units are based on concentration units (provided by the bioanalytical lab or preferred units for presentation of PK parameters) and dose units used in the study.
[b] Area under the concentration-time curve will be calculated using the linear trapezoidal rule for increasing concentrations and the logarithmic rule for decreasing concentrations (linear up/log down rule).
[c] Based on the last observed quantifiable concentration

Additional PK parameters may be determined where appropriate.

Pharmacokinetic analysis will be carried out where possible using actual blood sampling times post dose. If an actual time is missing, the sample concentration result will be treated as missing unless there is scientific justification to include the result using the nominal time.

The parameters C_{max}, T_{max} and T_{last} will be obtained directly from the concentration-time profiles. If C_{max} occurs at more than 1 timepoint, T_{max} will be assigned to the first occurrence of C_{max}.

8.5.1.1. Criteria for the Calculation of Apparent Terminal Elimination Rate Constant and Half-life

The start of the terminal elimination phase for each subject will be defined by visual inspection and generally will be the first point at which there is no systematic deviation from the log-linear decline in concentrations.

The apparent terminal elimination rate constant (λ_z) will only be calculated when a reliable estimate can be obtained using at least 3 data points, preferably not including C_{max}, and the adjusted coefficient for determination of exponential fit (R^2-adj) of the regression line is ≥ 0.7.

Parameters requiring λ_z for their calculation (eg, $AUC_{0-\infty}$, $t_{1/2}$, CL/F, and V_z/F) will only be calculated if the R^2-adj value of the regression line is ≥ 0.7.

The following regression-related diagnostic PK parameters will be determined, when possible:

Parameter	Units	Definition
λ_z	1/h	apparent terminal elimination rate constant
λ_z Upper	h	end of exponential fit
λ_z Lower	h	start of exponential fit
λ_z N	NA	number of data points included in the log-linear regression
λ_z Span Ratio	NA	time period over which λ_z was determined as a ratio of $t_{1/2}$
R^2-adj	NA	adjusted coefficient for determination of exponential fit

Where possible, the span of time used in the determination of λ_z (ie, the difference between λ_z Upper and λ_z Lower) should be ≥ 2 half-lives. If the λ_z Span Ratio is < 2, the robustness of the $t_{1/2}$ values will be discussed in the CSR.

8.5.1.2. Criteria for Calculation and Reporting of Area Under the Concentration-time Curve

The minimum requirement for the calculation of area under the concentration-time curve (AUC) will be the inclusion of at least 3 consecutive concentrations above the lower limit of quantification. If there are only 3 consecutive concentrations, at least 1 should follow C_{max}.

If the extrapolated area is > 20%, $AUC_{0-\infty}$ (and derived parameters) may be excluded from the summary statistics and statistical analysis at the discretion of the sponsor or pharmacokineticist.

If $AUC_{0-\infty}$ cannot be determined reliably for all subjects and/or treatments, an alternative AUC measure, such as AUC to a fixed time point or AUC_{0-t}, may be used in the statistical analysis.

8.5.1.3. Criteria for Handling Below the Limit of Quantification or Missing Concentrations for Pharmacokinetic Analysis

Plasma concentrations below the limit of quantification (BLQ) will be assigned a value of 0 before the first measurable concentration and thereafter BLQs will be treated as missing. The following rules apply with special situations defined below:

- If an entire concentration-time profile is BLQ, it will be excluded from PK analysis.
- Where 2 or more consecutive concentrations are BLQ at the end of a profile, the profile will be deemed to have terminated and any further quantifiable concentrations will be set to missing for the calculation of the PK parameters, unless they are considered to be a true characteristic of the profile of the drug.

- If a Day 1 predose plasma concentration is missing, it may be set to zero by default.

8.5.1.4. Treatment of Outliers in Pharmacokinetic Analysis

If a value is considered to be anomalous due to being inconsistent with the expected PK profile, it may be appropriate to exclude the value from the PK analysis. However, the exclusion of any data must have strong justification and will be documented in the CSR.

Any quantifiable predose concentration value in the first treatment period will be considered anomalous and set to missing for the PK analysis.

If the predose concentration is > 5% of C_{max} in the second treatment period, all PK concentration and parameter data will be excluded from the summary statistics and statistical analysis for that period.

8.5.2. Presentation of Pharmacokinetic Data

If the actual time of sample collection deviates from the nominal time by more than ± 10%, the concentration will be flagged and excluded from the summary statistics. Individual concentrations deemed to be anomalous will be flagged in the listings and excluded from the summary statistics.

For PK concentration data the following rules will apply:

- Values that are BLQ will be set to 0 for the calculation of summary statistics.
- Arithmetic mean or median values that are BLQ will be presented as 0.
- If any BLQ results (treated as 0) are in a series of summarized data, geometric mean and CV% of geometric mean will be reported as not calculated (NC).

For PK parameters the following rule will apply:

- Geometric mean and coefficient of variation will not be calculated for T_{max} or T_{last}.

8.5.3. Pharmacokinetic Statistical Methodology

All PK concentrations and parameters will be listed.

Summary tables, mean (+ standard deviation [SD]) figures, overlaying individual figures, and individual figures by treatment and time postdose will be provided for plasma PK concentrations. All figures will be produced on both linear and semi-logarithmic scales. The +SD bars will only be displayed on the linear scale.

Summary tables by treatment will be provided for all PK parameters, with the exception of diagnostic regression-related PK parameters.

A statistical analysis will be conducted to investigate the drug-drug interaction on the PK of zanubrutinib by comparing zanubrutinib co-administered with rifabutin (test treatment) to zanubrutinib alone (reference treatment) for AUC_{0-t}, $AUC_{0-\infty}$, and C_{max}.

The natural log (ln)-transformed[3] PK parameters will be analyzed using a mixed model.[4] The model will include treatment as a fixed effect, and subject as a random effect.

For each PK parameter separately, the least squares mean (LSM) for each treatment, difference in LSMs between the test and reference treatments, and corresponding 90% confidence interval (CI) will be calculated; these values will then be back-transformed to give the geometric least square mean (GLSM), ratio of GLSMs for zanubrutinib+ rifabutin (Day 11) to zanubrutinib alone (Day 1), and corresponding 90% CI.

Additionally, the pooled estimate (across all treatments) of the within-subject coefficient of variation (CV) will be calculated, and residual plots will be produced to assess the adequacy of the model(s) fitted.

Examples of the SAS code that will be used are as follows:

Mixed Model Analysis

```
proc mixed data = <data in>;
  by parcat1n parcat1 pkday paramn param;
  class trtan aperiod trtseqp usubjid;
  model lpk = trtan aperiod trtseqp / cl residual ddfm = kr2;
  lsmeans trtan / cl pdiff = control('1') alpha = 0.1;
  random intercept / subject = usubjid(trtseqp);
  ods output lsmeans = <data out>;
  ods output diffs = <data out>;
  ods output covparms = <data out>;
run;
```

8.6. Safety and Tolerability Assessments

8.6.1. Adverse Events

All AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 23.0 (or higher if upversioned during the study). All AEs will be assigned severity grade using Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 (or higher if upversioned during the study).

A treatment-emergent adverse event (TEAE) will be defined as an AE that starts during or after the first dose, or starts prior to the first dose and increases in severity after the first dose.

A treatment-related TEAE will be defined as a TEAE with a relationship of related to the study treatment, as determined by the investigator.

The assignment of TEAEs to treatments will be as follows:

- A TEAE with onset during or after Day 1 dosing and prior to Day 3 dosing will be assigned to zanubrutinib
- A TEAE with onset during or after Day 3 dosing and prior to Day 11 dosing will be assigned to rifabutin
- A TEAE with onset during or after Day 11 dosing will be assigned to rifabutin co-administered with zanubrutinib

All AEs will be listed.

The frequency of subjects with TEAEs and the number of TEAEs will be summarized for the following categories:

- TEAEs (overall, serious, leading to discontinuation, and leading to death) by treatment and overall (total safety population)
- TEAEs according to maximum severity by treatment and overall
- Treatment-related TEAEs (overall, serious, leading to discontinuation, and leading to death) by treatment and overall
- Treatment-related TEAEs according to maximum severity by treatment and overall

The frequency of subjects will be summarized by treatment and overall for TEAEs and treatment-related TEAEs using the following classifications:

- System organ class, preferred term by decreasing incidence of system organ class and preferred term within system organ class overall
- Preferred term by decreasing incidence overall

For the AE data the following rules will apply:

- For the derivation of TEAE status: If the start date/time of an AE is incomplete or missing, an AE will be assumed to be a TEAE, unless the incomplete start date/time or the end date/time indicates an AE started prior to the first dose.
- For the derivation of treatment-related TEAE status: If the study treatment relationship for a TEAE is missing, a TEAE will be assumed to be a treatment-related TEAE.
- For the calculation of summary statistics: If the severity of a TEAE is missing, no imputation of grade will be performed. The AE will only be counted under the ”all grades” category.
- For the calculation of summary statistics: If a subject experienced multiple TEAEs with the same preferred term for the same treatment, this will be counted as 1 TEAE for that treatment under the maximum severity recorded.

8.6.2. Clinical Laboratory Parameters

All clinical laboratory parameters and changes from baseline will be listed; any value outside the clinical reference range will be flagged. Separate listings will be provided for any parameter for which there is any individual subject value outside the respective clinical reference range.

Summary tables by treatment and timepoint will be provided for observed value and change from baseline for all clinical chemistry and hematology parameters.

Values recorded as <x, ≤x, >x, or ≥x will be displayed in the listings as recorded. For the derivation of listing flags, calculation of summary statistics, and presentation in the figures, <x and ≤x values will be imputed to one less value in the maximum decimal place (e.g. '< 5.2' imputed to '5.1'), whereas >x and ≥x values will be imputed to one higher value in the

maximum decimal place. The maximum decimal place will be determined to be the maximum number of decimal places from all records of a parameter.

8.6.3. Vital Signs Parameters

All vital signs parameters and changes from baseline will be listed; any value outside the clinical reference range will be flagged.

Summary tables will be provided for observed value and change from baseline for all vital signs parameters.

8.6.4. 12-lead Electrocardiogram Parameters

All 12-lead ECG parameters and changes from baseline will be listed; any value outside the clinical reference range will be flagged.

Summary tables will be provided for observed value and change from baseline for all 12-lead ECG parameters.

8.6.5. Other Assessments

All other safety and tolerability assessments not detailed in the above sections will be listed only.

8.6.6. Safety and Tolerability Statistical Methodology

No inferential statistical analyses are planned.

9. INTERIM ANALYSES

No interim analyses are planned for this study.

10. SIGNIFICANT CHANGES FROM THE PROTOCOL-SPECIFIED ANALYSES

There were no significant changes from the protocol-specified analyses.

11. REFERENCES

1. ICH. ICH Harmonised Tripartite Guideline: Statistical principles for clinical trials (E9). 5 February 1998.

2. ICH. ICH Harmonised Tripartite Guideline: Structure and content of clinical study reports (E3). 30 November 1995.

3. Keene ON. The log transformation is special. *Stat Med*. 1995;14(8):811-819.

4. Brown H, Prescott R. *Applied Mixed Models in Medicine*. Chichester: John Wiley & Sons, 1999.

12. APPENDICES

Appendix 1: Document History

Status, Version	Date of Change	Summary/Reason for Changes
Final, Version 1.0	NA	NA; the first version.

NA = not applicable

[redacted]

Statistical Analysis Plan Approval Form

Sponsor Name:	BeiGene, Ltd.
Sponsor Protocol ID:	BGB-3111-112
Covance Study ID:	8426473
SAP Text Filename:	BeiGene_BGB-3111-112_8426473_SAP_Final_V1.docx
TFL Shells Filename:	BeiGene_BGB-3111-112_8426473_TFL_Shells_Final_V1.docx
Version:	1.0
Date:	14OCT2020

Covance Approval(s):

[redacted] 22-Oct-2020 | 16:12:03 PDT

Signature Date

[redacted]

Printed Name/Title - [redacted]

[redacted] 22-Oct-2020 | 11:13:11 PDT

Signature Date

[redacted]

Printed Name/Title

Sponsor Approval(s):

By signing below when the statistical analysis plan (SAP) is considered final, the signatories agree to the analyses to be performed for this study; and to the format of the associated tables, figures, and listings (TFLs). Once the SAP has been signed, programming of the TFLs based on this document can proceed. Any modifications to the SAP and TFLs made after signing may result in a work-scope change.

[redacted] 22-Oct-2020 | 13:12:38 PDT

Signature Date

[redacted]

Printed Name/Title

[redacted] 22-Oct-2020 | 12:03:46 PDT

Signature Date

[redacted]

Printed Name/Title

[redacted]

Statistical Analysis Plan Approval Form

Please scan/email completed form(s) to the Lead Statistician listed below:

Printed Name/Title:	[redacted]
Email:	[redacted]

16.1.9.2. Quality Tolerance Limit Definitions

Not applicable.