1.0 Title Page

Statistical Analysis Plan

Study M11-617

A Phase 3, Prospective, Open-Label, Multicenter Study to Evaluate the Safety, Efficacy and Pharmacokinetics of Paricalcitol Oral Solution for the Treatment of Secondary Hyperparathyroidism in Pediatric Subjects Ages 0 to 9 Years with Stage 5 Chronic Kidney Disease Receiving Peritoneal Dialysis or Hemodialysis

Date: 07 November 2025

Version 3.0

2.0 Table of Contents

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3.0 Introduction

This statistical analysis plan (SAP) describes the statistical analyses to be completed by AbbVie's Data and Statistical Sciences (DSS) for paricalcitol oral solution Study Protocol M11-617 Amendment 2 dated 13 July 2023. It provides details to further elaborate statistical methods as outlined in the protocol and describes analysis conventions to guide the statistical programming work. Analyses will be performed using SAS version 9.4 or higher (SAS Institute Inc., Cary, NC 27513).

Study M11-617 has been terminated with two subjects enrolled and treated. [redacted]

Of note, due to the old protocol standards, while efficacy endpoints were still defined on a population level ("proportion of subjects who achieved...") the data collected will be presented for endpoints defined on a subject level ("achievement of...").

The R&D number for the Study M11-617 clinical study report is R&D/25/2686. Table headers for each table will appear as:

```
DDMMYYYY 11:32 <! xxx.sas DBV xx >
PARICALCITOL (ABT-358) (Secondary Hyperparathyroidism)
STUDY M11-617
R&D/25/2686 - CLINICAL/STATISTICAL
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4.0 Study Objectives, Design and Procedures

4.1 Objectives

4.1.1 Study Objective

To evaluate the safety, efficacy and pharmacokinetics of paricalcitol oral solution for the treatment of secondary hyperparathyroidism (SHPT) in pediatric Subjects 0 to 9 years of age with stage 5 chronic kidney disease (CKD), receiving peritoneal dialysis (PD) or hemodialysis (HD).

4.1.2 Efficacy Variables

Primary:

- The proportion of subjects who achieve a positive response, defined as having two consecutive ≥ 30% reductions from baseline in iPTH or two consecutive iPTH values in the target range between 150 pg/mL to 300 pg/mL (16.5 – 33.0 pmol/L) during Dosing Period 1.

Secondary:

- Proportion of subjects who achieve a positive response (as defined for the primary endpoint) during Dosing Period 2.
- Proportion of subjects who achieve a positive response (as defined for the primary endpoint) during the Dosing Periods 1 and 2 combined (24 weeks).
- Proportion of subjects who achieve two consecutive ≥ 30% reductions in iPTH from baseline during Dosing Period 1.
- Proportion of subjects who achieve two consecutive ≥ 30% reductions in iPTH from baseline during Dosing Period 2.
- Proportion of subjects who achieve two consecutive ≥ 30% reductions in iPTH from baseline during the Dosing Periods 1 and 2 combined (24 weeks).
- Proportion of subjects who achieve two consecutive iPTH values between 150 pg/mL to 300 pg/mL (16.5 – 33.0 pmol/L) during Dosing Period 1.
- Proportion of subjects who achieve two consecutive iPTH values between 150 pg/mL to 300 pg/mL (16.5 – 33.0 pmol/L) during Dosing Period 2.
- Proportion of subjects who achieve two consecutive iPTH values between 150 pg/mL to 300 pg/mL (16.5 – 33.0 pmol/L) during the Dosing Periods 1 and 2 combined (24 weeks).

Of note, due to the old protocol standards, while efficacy endpoints were still defined on a population level ("proportion of subjects who achieved...") in the protocol, the data collected will be presented for endpoints defined on a subject level (i.e., for endpoints "achievement of...").

4.1.3 Safety Variables

Primary: The incidence of hypercalcemia, defined as two consecutive, post-baseline, corrected calcium measurements (see below for details) above the normal subject's age-specific upper limit (see Table 1), during Dosing Period 1.

Secondary:

- The incidence of hypercalcemia (as defined above) during Dosing Period 2.
- The incidence of hypercalcemia (as defined above) during the Dosing Periods 1 and 2 combined (24 weeks).

Serum calcium results will be reported as corrected calcium results using the following formula for albumin levels < 4.0 g/dL: corrected calcium (mg/dL) = [(4.0 – subject's albumin level measured in g/dL) × 0.8] + serum total calcium (uncorrected) measured in mg/dL.

Table 1. Age-Specific Limit for Phosphorus and Total Calcium

Age (yrs.)	Serum Phosphorus (mg/dL)	Serum Total Calcium (mg/dL)
< 1	7.4	11.0
1 – 5	6.5	10.8
6 – 9	5.8	10.3

Safety will also be assessed through adverse events, changes from baseline in chemistry and hematology laboratory variables, ECG, and changes from baseline in vital signs.

4.1.4 Other Variable of Interest

Individual paricalcitol plasma concentrations during Dosing Period 1 at each visit will be listed for each subject.

4.2 Study Design

This is a Phase 3, open-label, single-arm, multicenter study evaluating the safety, efficacy and pharmacokinetics of paricalcitol oral solution in pediatric subjects with SHPT associated with Stage 5 CKD receiving PD or HD. Approximately 12 sites in the United States (US) and Puerto Rico (PR) will be selected to enroll approximately 16 evaluable subjects aged 0 to 9 years in Dosing Period 1, of which at least 4 will be between 0 to 5 years of age and 4 between 6 to 9 years of age, inclusive at screening.

Eligible subjects will receive paricalcitol oral solution three times a week (TIW) but no more frequently than every other day for 24 weeks, divided into two 12-week dosing periods (Dosing Period 1 followed by Dosing Period 2).

Enrollment of a minimum of 16 subjects to complete the 12-week Dosing Period 1 will occur in two consecutive parts (Part 1 and Part 2) that are summarized below.

Part 1 will enroll only subjects aged 2 to 9 years with the initial paricalcitol dose (in mcg)

[redacted]

Part 2 will enroll subjects aged < 2 years. This part will not be initiated until after the data and results from Part 1 have been submitted to the FDA and were reviewed from approximately 12 subjects enrolled (age 2 to 9) with a minimum of 8 subjects and a maximum of 12 subjects who completed Dosing Period 1 in Part 1.

Based on the 2 to 9 year old data that will be submitted to the FDA for review, AbbVie will make a recommendation for the initial paricalcitol dose in subjects < 2 years of age based on a downward trend in iPTH levels while maintaining normal serum calcium

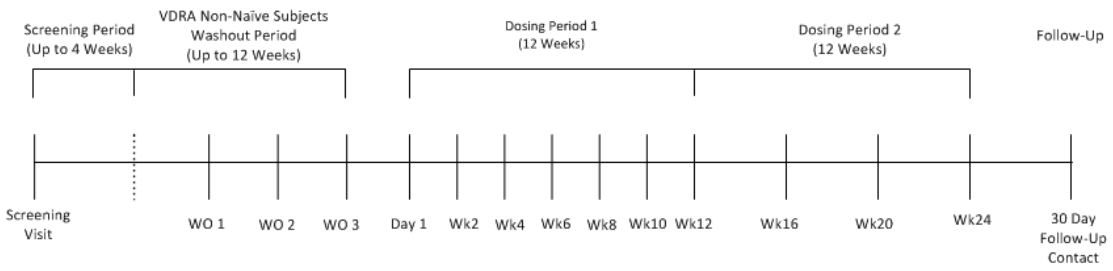
levels (for their age) for the 12 week duration. While FDA reviews the data, enrollment will continue for children aged 2 to 9 years, up to a maximum of 14 children that complete Dosing Period 1. Depending on the overall number and age range of subjects enrolled in Study M11-617 when FDA's feedback on Part 1 is received, AbbVie anticipates having future discussions with the FDA to meet the enrollment target goals and complete the study.

The study consists of four Periods:

- Screening Period
- Washout Period (if applicable)
- Dosing Period 1 (Parts 1 and 2)
- Dosing Period 2

A schematic of the study design is shown below in Figure 1.

Figure 1. Study Schematic



Note: Eligible subjects are to be enrolled into Dosing Period 1 within 4 weeks of the qualifying Screening or Washout visit, as applicable.

Descriptions of study visit, procedures, and selection of dose are included in Section 5.0 of the Protocol. The study procedures for each visit are outlined in Table 4.

Subjects may have to permanently discontinue study drug for reasons stated in Protocol Section 5.4.1. Subjects with study drug interruption for any other reason will be

encouraged to restart study drug as soon as practically and medically appropriate at the discretion of the Investigator.

The dates of study drug interruption and restart, and the reason for study drug interruption should be documented in the source document and eCRF(s). Study drug interruption should last no longer than 2 weeks. Subject who needs a study drug interruption lasting more than 2 weeks will be discontinued from study drug (see Protocol Section 5.4.1).

In order to minimize missing data for assessments, subjects who discontinue study drug treatment should continue to be followed for all regularly scheduled visits and procedures, unless subjects and their parent or legal guardian have decided to discontinue study participation entirely (withdrawal of informed consent). At a minimum, for subjects who discontinue study drug but do not withdraw consent, the Investigator will monitor each subject for AEs, including hypercalcemia, hyperphosphatemia, and low iPTH values, at 12 weeks after initial dose of study drug (for AEs: or 30 days after last dose of study drug, whichever is later) if discontinued during Dosing Period 1 and 24 weeks after initial dose of study drug (for AEs: or 30 days after last dose of study drug, whichever is later) if discontinued during Dosing Period 2.

4.3 Sample Size

The study is targeted to achieve a ≥ 50% positive response rate. If the observed response rate in Dosing Period 1 is 50% or higher (i.e., at least 8 out of the 16 subjects), the study is considered to meet the efficacy endpoint. With a sample size of 16 subjects and an assumed true underlying positive response rate of 65%, the study has an approximately 93% probability to meet the efficacy endpoint. Table 2 and Table 3 provide the probabilities of observing a ≥ 50% positive response rate under different scenarios.

Table 2. Probability of Observing a ≥ 50% Positive Response Rate Under Different Scenarios

Scenario	1	2	3	4	5
Number of subjects (n)	16	16	16	16	16
True underlying positive response rate (%)	55	60	**65**	70	75
Probability of observing a ≥ 50% positive response rate (%)	74.4	85.8	**93.3**	97.4	99.3

Table 3. Probability of Observing a ≥ 50% Positive Response Rate Under Different Scenarios – Taking Replacement of Subjects Into Account

Scenario	1	2	3	4	5
Completed DP1 (n)	**16**	16	16	16	16
Withdrawn in DP1 (n)[a]	**0**	4	4	10	10
Treated in DP1 (n) (primary analysis set)	**16**	20	20	26	26
True response rate in completers (%)	**65**	65	65	65	65
True response rate in withdrawn subjects (%)[a]	**n/a**	0	10	0	10
Probability of observing a ≥ 50% positive response rate (%)	**93.3**	68.8	74.6	13.4	30.4

DP1 = Dosing Period 1; n/a = not applicable

a. Subject withdrew from study drug.

Sixteen subjects will initially be enrolled in Dosing Period 1, and subjects that withdraw or discontinue will be replaced to ensure that 16 subjects complete Dosing Period 1. Subjects that complete Dosing Period 1 will continue into the 12 week Dosing Period 2.

Table 4. Study Activities

Activity	Screening Period[a] (Up to 4 Weeks)	Washout Period[b,c] (Up to 12 Weeks)			Dosing Period 1[b,d] (12 Weeks)			Dosing Period 2[d] (12 Weeks)		Unscheduled Visit	Premature Discontinuation Visit[e]	Follow-Up Contact[f]
	Screening Visit	WO 1	WO 2	WO 3	Day 1	Wks 2, 4, 6, 8, 10	Wk 12	Wks 16, 20	Wk 24			
Informed Consent/Assent[g]	X											
Medical History[h]	X				X							
Physical Exam	X				X		X		X		X	
ECG[i]	X				X		X		X		X	
Vital Signs[j]	X				X	X	X	X	X		X	
Height/Length[k]	X				X		X		X		X	
Weight[l]	X				X	X	X	X	X		X	
Hematology[m]	X				X		X		X		X	
Complete Chemistry[m]	X				X		X		X		X	
Limited Chemistry[m,n]		X	X	X		X		X		X		
iPTH[m,o]	X	X	X	X	X	X	X	X	X	X	X	
PK blood draw[m]					X[o]	X[q, r]	X[q, r]				X[q, r]	
Prior/Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X

Activity	Screening Period[a] (Up to 4 Weeks)	Washout Period[b,c] (Up to 12 Weeks)			Dosing Period 1[b,d] (12 Weeks)			Dosing Period 2[d] (12 Weeks)		Unscheduled Visit	Premature Discontinuation Visit[e]	Follow-Up Contact[f]
	Screening Visit	WO 1	WO 2	WO 3	Day 1	Wks 2, 4, 6, 8, 10	Wk 12	Wks 16, 20	Wk 24			
Monitor Adverse Events[s]	X	X	X	X	X	X	X	X	X	X	X	X
IRT Call	X				X	X	X	X	X		X	
Dispense Study Drug					X	X	X	X				
Monitor Study Drug Compliance[s]					X	X	X	X	X	X	X	

a. Tests for eligibility may be repeated within the subject's 4-week Screening Period, at the discretion of the Investigator.

b. Subjects should enter the next study period (Washout or Dosing, as applicable) within 4 weeks of the qualifying Screening or Washout visit.

c. Subjects will require Washout if the subject has current or previous exposure to a VDRA within 4 weeks of the Screening Visit. It is at the investigator's discretion to determine the timing of the WO visits, with a minimum of 2 weeks and a maximum of 4 weeks between visits.

d. Subjects are recommended to prospectively schedule their study visits from Week 2 through Week 12 to occur approximately 2 days following their last dose of study drug. Study visits should be conducted within ± 2 days of the expected visit date. All expected visit dates are calculated from Day 1.

e. Subjects that Prematurely Discontinue from the study and study drug should perform a premature discontinuation visit approximately 7 days (± 2 days) after their last dose of study drug. Subjects who discontinue study drug but remain in the study will continue with all visits and procedures as noted in Protocol, Section 5.4.1.

f. A Follow-Up Phone Contact will be completed between 30 – 35 days after the last dose of study drug.

g. Signed informed consent and assent, if applicable, can be collected up to 30 days prior to the conduct of any Screening procedures or discontinuation of medications.

h. Complete medical history from birth will be obtained at the initial Screening visit and updated at Day 1 prior to study drug administration.

i. All 12-lead resting ECGs will be obtained after vital signs are measured and prior to blood collection; ECGs could be obtained at or within 1 week prior to the visit.

j. Vital signs measurements (blood pressure, heart rate, respiratory rate and body temperature) will be collected at Screening and each visit during the Dosing Periods, prior to dialysis and any scheduled blood draws or ECGs. Blood pressure and heart rate will be measured after the subject has been sitting or in the supine position for at least 5 minutes, if possible.

k. Length will be measured for infants < 2 years of age or incapable for standing independently and height without shoes will be measure for children ≥ 2 years of age and that are capable of standing independently at the initial Screening visit, Day 1, Week 12, Week 24, and premature discontinuation visit.

l. Weight with lightweight clothing and no shoes will be measured for all subjects at Screening and at each visit during the Dosing Periods, preferably after dialysis session.

m. Blood draws should be performed following completion of vital signs assessment and ECG (if applicable for visit) and prior to the start of dialysis.

n. A blood draw will be completed to measure limited chemistry (Serum Albumin, Calcium, and Phosphorus) every 2 weeks during Dosing Period 1 and every 4 weeks during Dosing Period 2.

o. A blood draw will be completed to measure iPTH every 2 weeks during Dosing Period 1 and every 4 weeks during Dosing Period 2.

p. Blood draw for PK on Study Day 1 should be collected immediately prior to (0 minutes) and 1 and 3 hours following the initial dose of study drug and before dialysis. Time of sample collection and time of initial dose of study drug will be recorded in the site source documentation.

q. Blood draw for PK on Dosing Period 1 (Study visits at Week 2, 4, 6, 8, 10 and 12) will be collected regardless of the study drug dosing time. Time of sample collection and time of two previous doses of study drug will be recorded in the site source documentation.

r. Blood draw for PK should only be performed at the premature discontinuation visit if the subject discontinues at any time during Dosing Period 1. Time of sample collection and time of two previous doses of study drug will be recorded in the site source documentation.

s. All adverse events reported from the time of the first dose of study drug administration (Day 1) until completion of the 30-day follow-up visit. In addition, serious adverse events and protocol-related non-serious adverse events will be collected from the time of the signature of the study-specific informed consent/assent.

t. Each dose of study drug will be administered to study subjects by a parent or legal guardian following the instructions for use (Protocol, Appendix E), with supervision from either a study nurse or a home health nurse.

5.0 Analysis Set

The All Treated Dataset is defined as the set of all subjects who take at least one dose of study drug including those who prematurely discontinued study treatment. All efficacy and safety analyses will be conducted on the All Treated Dataset, unless otherwise specified.

6.0 Analysis Conventions

General Considerations

Continuous variables will be summarized by sample size (N), mean, standard deviation, median, minimum, and maximum. Frequency and percentages will be provided for the categorical variables. As only 2 subjects were enrolled and took at least one dose of study drug, summary statistics will be reduced to a minimum and supplemented by data listings as specified below.

Definition of Baseline Measurement

Unless otherwise specified, the baseline measurement is defined as the last non-missing measurement collected prior to the first dose of study drug (i.e., at or before the Day 1 Visit). The baseline iPTH for the efficacy endpoint analysis is defined as the average of the last measurement in the screening or washout period and Day 1, if both are non-missing, otherwise the last non-missing measurement collected prior to the first dose of study drug.

Definition of Rx Days (Days Relative to the First Dose of Study Drug)

Rx days are calculated for each time point relative to the date of first dose of study drug. They are defined as the number of days between the day of the first dose of study drug and the specific time point. Rx days are negative values when the time point of interest is prior to the first study drug dose day. Rx days are positive values when the time point of interest is after the first study drug dose day. The day of the first dose of study drug is

defined as Rx Day 1, while the day prior to the day of the first study drug dose is defined as Rx Day –1 (there is no Rx Day 0).

Definition of Analysis Windows

To perform visit wise data summaries for the assessments taken at each scheduled visit the corresponding windows and nominal days are given in the table below.

Scheduled Visits	Nominal Days	Visit Window (Days)
Baseline	1	≤ 1
2	15	[2, 22]
4	29	[23, 36]
6	43	[37, 50]
8	57	[51, 64]
10	71	[65, 78]
12	85	[79, 99]
16	113	[100, 127]
20	141	[128, 155]
24	169	[156, 182]

For the assessments taken at baseline, Week 12 and Week 24 only, corresponding windows and nominal days are given in the table below.

Scheduled Visits	Nominal Days	Visit Window (Days)
Baseline	1	≤ 1
12	85	[2, 127]
24	169	[128, 210]

For the assessments taken at baseline and Week 24 only, corresponding windows and nominal days are given in the table below.

Scheduled Visits	Nominal Days	Visit Window (Days)
Baseline	1	≤ 1
24	169	[2, 336]

When there is more than one measurement taken within a specific window, the one taken on a day closest to the nominal day will be chosen for the analysis. If two values are equidistant from the nominal day, one being before and one being after the nominal day, then the later measurement will be considered the measurement for that visit. For any given variable, if more than one measurement exists for a subject on the same day, the average of the measurements will be considered to be that subject's measurement for that day.

Definition of Missing Data Imputation

There will be no imputation of missing values. For the definition of endpoints in the presence of missing visits, see Section 10.1 and Section 11.4.

Other General Analysis Conventions

All data will be converted into SI units for statistical analyses and data presentations, including data listings.

Multiplicity Adjustment

Not applicable as no confirmatory testing is planned.

7.0 Demographics, Baseline Characteristics, Medical History, and Previous/Concomitant Medications

Data for demographics, baseline characteristics, medical history, and previous/concomitant medications will be summarized on the All Treated Dataset.

7.1 Demographic and Baseline Characteristics

The following demographic information and baseline characteristics will be included in listings.

- Demographics
  - Age (years)

- Weight (kg)
- Height/Length (cm)
- Sex
- Race
- Ethnicity
- Dialysis modality (HD/PD)
- Length of time on dialysis (years; last date prior to or on Day 1 – earliest date on dialysis + 1)
- VDRA naïve (yes/no)

- Laboratory Characteristics
  - iPTH

Note: Baseline information for hematology and chemistry as well as for vital signs and ECG will only be included in the respective safety tables (14.3__4 and 14.3__5, but not listed separately for 14.1).

7.2 Medical History

Medical history data will be summarized and presented using System Organ Class (SOC) and Preferred Terms (PT) according to the Medical Dictionary for Regulatory Activities (MedDRA) dictionary. The SOCs will be presented in alphabetical order and the PTs will be presented in alphabetical order within each SOC. The number and percentage of subjects with a particular PT will be summarized. Subjects reporting more than one PTs within a SOC will be counted only once for that SOC.

7.3 Prior and Concomitant Medications

Concomitant medications are those medications, other than study drug, taken after the first dose of study drug and collected on the case report forms.

Concomitant medications will be summarized by generic name assigned by the World Health Organization (WHO) dictionary and will include the number and percentage of subjects that take the medications.

Subjects reporting the same medication generic name two or more times will be counted only once for that generic name. Subjects reporting more than one medication will be counted only once in the total number of subjects taking a concomitant medication.

A similar summarization will be performed for prior medications. Prior medications are those medications taken within 4 weeks of the initial screening visit and prior to the first dose of study drug and collected on the case report forms.

As none of the two enrolled subjects received phosphate binders, no additional analyses will be done.

8.0 Subject Accountability and Disposition

For subject accountability the following information will be listed per subject:

- Entered screening period (yes/no)
- Entered washout period (yes/no)
- Received at least one dose of study drug (yes/no)
- Prematurely discontinued study drug (During Period 1/ During Period 2/ Completed)
- Reason for Discontinuation from study drug
- Subjects who prematurely discontinued study (Washout Period/ During Dosing Period 1/ During Dosing Period 2/ Completed)
- Reason for Discontinuation from study

9.0 Study Drug Exposure, Observation Time and Compliance

The study drug exposure and observation time will be presented in a listing for the All Treated Dataset.

Study drug exposure for each subject will be calculated as follows:

last dose date – first dose date + 1 – cumulative duration of study drug interruptions.

Duration of an individual study drug interruption is defined as

date of restart of study drug – date of last dose of study drug prior to the corresponding interruption.

Cumulative duration of study drug interruptions is the sum of durations of individual study drug interruptions.

Observation time for each subject will be calculated as follows:

last study day – first dose date + 1.

10.0 Efficacy Analysis

Efficacy analyses described below will be performed on the All Treated Dataset, unless otherwise noted.

10.1 Analysis for iPTH

Primary endpoint: The number and percentage of subjects who achieve a positive response, defined as having either two consecutive ≥ 30% reductions from baseline in iPTH or two consecutive iPTH values in the target range between 150 pg/mL to 300 pg/mL (16.5 – 33.0 pmol/L) (defined as positive response) during the 12-weeks of Dosing Period 1 will be presented in a listing that includes all available iPTH measurements.

Of note, due to the old protocol standards, while efficacy endpoints were still defined on a population level ("proportion of subjects who achieved...") in the protocol, the data collected will be presented for endpoints on a subject level (i.e., for endpoints "achievement of...").

Similarly, the secondary endpoints will be included in a listing.

'Two consecutive values' means two consecutive non-missing iPTH assessment, i.e., without a missing iPTH value in between.

All subjects who cannot be classified as 'responder' per above definition will be considered 'non-responder' (including patients who do not have two consecutive values for the primary endpoint (i.e., one value is missing from two consecutive visits but the other value is non-missing), or patient who have no assessment at all, or the response status cannot be derived due to either missing baseline or missing all post-baseline status).

10.2 Sensitivity Efficacy Analyses

No sensitivity analyses will be done.

11.0 Safety Analysis

Safety analyses described below will be performed on the All Treated Dataset.

11.1 Analysis of Adverse Events

The summary of adverse events will include "treatment-emergent" events (i.e., those that first occur or worsen after the first dose of study drug and with an onset date no more than 30 days after the last dose of study drug) Events where the onset date is the same as the study drug start date are assumed to be treatment-emergent. If an incomplete onset date was collected for an adverse event, the event will be assumed to be treatment emergent unless there is other evidence that confirms that the event was not treatment-emergent (e.g., the event end date was prior to the study drug start date).

Of note: The study protocol also specified the assessment of "observational" events (i.e., those that first occur or worsen after the first dose of study drug up to the last day in the study). These analyses will not be performed.

Adverse event data will be summarized and presented using primary Medical Dictionary for Regulatory Activities (MedDRA) system organ classes (SOCs) and preferred terms (PTs) according to the most recent version of the MedDRA coding dictionary. The SOCs will be presented in alphabetical order, and the PTs will be presented in alphabetical order within each SOC. Subjects reporting more than one adverse event for a given MedDRA preferred term will be counted only once for that term (most severe incident for the severity tables and most related incident for the relationship tables). Subjects reporting more than one type of adverse event within a SOC will be counted only once for that SOC. Subjects reporting more than one type of adverse event will be counted only once in the overall total.

The following outlines the ways in which treatment-emergent and observational adverse events will be summarized.

1. An overview of the number and percentage of subjects with adverse events as well as an overview of incidence rates (events per 100 patient-years (PYs) of study drug exposure [for treatment-emergent event analyses] or observation time [for observational event analyses], respectively), including:
    - Any adverse event
    - Any adverse event that was rated to be related to study drug by the investigator (reasonable possibility of being related to study drug)
    - Any severe adverse event
    - Any serious adverse event
    - Any adverse event leading to discontinuation of study drug
    - Any adverse event leading to death
    - Any adverse event leading to hospitalization
    - Deaths

2. A summary of the number and percentage of subjects with adverse events by MedDRA system organ class and preferred term.

11.2 Listings of Adverse Events

Listings for all adverse events will be provided.

11.3 Analysis of Laboratory Data

Clinical laboratory variables are listed in Table 5.

Table 5. Clinical Laboratory Tests

Hematology	Complete Chemistry	Limited Chemistry
Hematocrit Hemoglobin Red Blood Cell (RBC) count White Blood Cell (WBC) count Neutrophils Bands (if detected) Lymphocytes Monocytes Basophils (if detected) Eosinophils (if detected) Platelet count (estimate not acceptable)	Albumin Alkaline Phosphatase Bicarbonate Blood Urea Nitrogen (BUN) Calcium[a] Chloride Creatinine Sodium Potassium Phosphorus Uric acid Total protein Glucose Magnesium Lactic Dehydrogenase (LDH)	Albumin Calcium[a] Phosphorus
		Hormonal Test
		iPTH

a. All serum calcium results will be corrected to an albumin level of 4.0 g/dL if the subject's reported albumin level is < 4.0 g/dL (40 g/L). Corrected calcium will be reported to the investigator by the central laboratory and all clinical decisions will be made based on the corrected calcium value.

Laboratory data will be presented in listing format, including the change from baseline for all post-baseline measurements.

For serum phosphorus and total calcium levels, the listings will also include the information whether each value is above the ULN and whether it is outside the age specific limits provided in Table 1.

For total calcium, the listing will also contain the information whether the subject experienced a hypercalcemia [defined as having 2 consecutive post baseline corrected calcium measurements above the subject's age-specific limit (see Table 1)] during the 12-week Dosing Period 1, during the 12-week Dosing Period 2 or during Dosing Periods 1 and 2 combined.

'Two consecutive measurements' means two successive measurements, even if there is a missing corrected calcium value in between.

11.4 Analysis of Vital Signs

Vital signs measurements (blood pressure, heart rate, respiratory rate and body temperature) will be presented in a listing (values only, no changes from baseline).

11.5 Analyses of Weight and Height/Length

Weight and height/length will be presented in a listing (values only, no changes from baseline).

11.6 Analysis of ECG

ECG variables will be presented in a listing (values only, no changes from baseline).

12.0 Version History

Table 6. SAP Version History Summary

Version	Date	Description of Change	Brief Rationale
1.0	15 July 2019	Original version	
2.0	01 July 2020	Update due to protocol amendment 1	Protocol amendment
3.0	07 November 2025	As only 2 subjects were enrolled and took at least one dose of study drug, summary statistics have been reduced to a minimum and supplemented by data listings (Changes were made to Section 4.1, Section 6.0 to Section 11.0).	Termination of the study with only 2 subjects enrolled

Appendix A. List of SAP Signatories

Appendix B. Table Shells for Non-Standard Tables, Listings and Figures

DDMMYYYY 11:32 <! xxx.sas DBV xx >
PARICALCITOL (ABT-358) (Secondary Hyperparathyroidism)
STUDY M11-617
R&D/XX/XXX - CLINICAL/STATISTICAL
TABLE PAGE 1 OF X

REF# LIST_EXP

TABLE 14.1__2.1

Listing of Drug Exposure and Observation Time
(Analysis Population)

Subject Number	Drug Exposure Duration(days)	Observation Time (days)
INV: XXX, XXXXXXX (XXXXXX)		
TRT: XXX		
999999# Age:XX Sex: Female Race:XX Weight:XXX.X KG Country: XX		
	xx	

 # Subject prematurely discontinued

DDMMYYYY 11:32 <! xxx.sas DBV xx >
PARICALCITOL (ABT-358) (Secondary Hyperparathyroidism)
STUDY M11-617
R&D/XX/XXX - CLINICAL/STATISTICAL
TABLE PAGE 1 OF X

REF# LIST_AE

TABLE 1.2__1.1.3

Listing of Treatment-Emergent Serious Adverse Events
(Study MXX-XXX – Incremental from DDMMMYYYY through DDMMMYYYY)

Subject Number	Epoch Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA XX.X Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Concomitant Medication or Therapy Started?	S: Serious AE? O: Other Cause of Event E: Event Related to COVID-19 Infection?
[redacted]								
TRT: PLACEBO								
[redacted]	DB	1 TO 62	62	62	R: SARS-COV-2 S: Infections and Infestations P: COVID-19 L: SARS-CoV-2 Infection	E: 79 L: 18 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NON-STUDY HCP C: YES	S: YES HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: NO REASONABLE CAUSALITY. E: YES

Screen = Screening, DB = Treatment.
# Subject prematurely discontinued

Program Source Code: XXXXX

DDMMMYYYY HH:MM <! xxx.sas DBV X>DDMMYYYY 11:32 <! xxx.sas DBV xx >
PARICALCITOL (ABT-358) (Secondary Hyperparathyroidism)
STUDY M11-617
R&D/XX/XXX - CLINICAL/STATISTICAL
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REF# LIST_IPTH

TABLE 14.1__1

Listing of iPTH values over time
(Analysis Population)

Subject Number	iPTH value	Unit	≥ 30% reduction from baseline	Value in target range*
INV: XXX, XXXXXXX (XXXXXX) TRT: XXX				
999999# Age:XX Sex: Female Race:XX Weight:XXX.X KG Country: XX				
	xx	x	No	no
11111 Age:XX Sex: Female Race:XX Weight:XXX.X KG Country: XX				
	xx	x	yes	yes

Subject prematurely discontinued
* Target range between 150 pg/mL to 300 pg/mL (16.5 – 33.0 pmol/L)

DDMMYYYY 11:32 <! xxx.sas DBV xx >
PARICALCITOL (ABT-358) (Secondary Hyperparathyroidism)
STUDY M11-617
R&D/XX/XXX - CLINICAL/STATISTICAL
TABLE PAGE 1 OF X

Ref# LIST_ENDP

TABLE 14.1__2

Listing of Efficacy Endpoints
(Analysis Population)

Subject Number	Primary endpoint: Two consecutive ≥ 30% reductions from baseline in iPTH or two consecutive iPTH values in the target range in Period 1*	Secondary endpoint: Two consecutive ≥ 30% reductions from baseline in iPTH or two consecutive iPTH values in the target range in Period 2*	Secondary endpoint: Two consecutive ≥ 30% reductions from baseline in iPTH or two consecutive iPTH values in the target range in Period 1 and 2*	Secondary endpoint: Two consecutive ≥ 30% reductions from baseline in iPTH in Period 1	Secondary endpoint: Two consecutive ≥ 30% reductions from baseline in iPTH in Period 2	Secondary endpoint: Two consecutive ≥ 30% reductions from baseline in iPTH in Period 1 and 2	Secondary endpoint:Two consecutive iPTH values in the target range in Period 1*	Secondary endpoint:Two consecutive iPTH values in the target range in Period 2*	Secondary endpoint:Two consecutive iPTH values in the target range in Period 1 and 2*
xxx	responder	non-responder	responder	responder	non-responder	responder	responder	non-responder	responder
yyy	Non-responder	NA	NA	Non-responder	NA	NA	Non-responder	Responder	responder

Subject prematurely discontinued
* Target range between 150 pg/mL to 300 pg/mL (16.5 - 33.0 pmol/L)