AOBiome Therapeutics

Protocol No. ADB244-002
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STATISTICAL ANALYSIS PLAN

AN OPEN-LABEL, MULTICENTER, PHASE IB STUDY OF B244 DELIVERED AS A TOPICAL SPRAY TO ASSESS SAFETY IN PEDIATRIC SUBJECTS AGED 2 TO 17 YEARS WITH ATOPIC DERMATITIS

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List of Abbreviations and Definitions of Terms

Abbreviation	Definition
ADaM	Analysis dataset model
AE	Adverse event
ATC	Anatomical Therapeutic Chemical Classification System
BMI	Body mass index
BSA	Body surface area
EASI	Eczema Area Severity Index
eCRF	Electronic Case Report Form
EOS	End of study
ETV	Early termination visit
ITT	Intent To Treat
vIGA-AD	Validated Investigator Global Assessment for Atopic Dermatitis
IP	Investigational product
MedDRA	Medical Dictionary for Regulatory Activities
POEM	Patient Oriented Eczema Measure
PP	Per protocol
PT	Preferred Term
SAE	Serious adverse event
SAP	Statistical analysis plan
SD	Standard deviation
SDTM	Study data tabulation model
SOC	System Organ Class
TEAE	Treatment-emergent adverse event

1. STUDY SYNOPSIS

Protocol Title: An open-label, multicenter, Phase Ib study of B244 delivered as a topical spray to assess safety in pediatric subjects aged 2 to 17 years with atopic dermatitis

Rationale:

Clinical studies with topical administration of B244 have been conducted in subjects with acne, hypertension, atopic dermatitis, and rosacea. There have been no safety signals observed to date.

The aim of this study is to assess the safety of B244 in pediatric subjects aged 2 to 17 years with atopic dermatitis.

Objectives and Endpoints

Objectives	Endpoints
Primary	
Assessment of the safety and tolerability of B244 in pediatric subjects with atopic dermatitis.	Incidence of treatment-emergent adverse events (TEAEs). Change from Baseline in physical examination at each post baseline visit. Change from Baseline in vital signs at each post baseline visit.
Exploratory	
Efficacy of B244 on signs and symptoms of atopic dermatitis.	Changes from Baseline to post baseline visits in: Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) scale. Area Severity Index (EASI) score and each component of EASI from Baseline to post baseline visits.
Efficacy of B244 on patient oriented measure of atopic dermatitis.	Changes is Patient Oriented Eczema Measure (POEM total score and each of the 7 components) from Baseline to post baseline visits.
Efficacy of B244 on patient reported assessment of atopic dermatitis.	Changes in patient reported outcome (self-reported ItchMan questionnaire).from Baseline to post baseline visits.

Overall Design:

This is a Phase 1b, open-label, multiple site study assessing twice daily B244 application for 28 days in pediatric subjects with atopic dermatitis.

The study will enroll approximately 36 subjects in 3 cohorts of 12 subjects:

- Cohort 1: subjects aged 2 to 5 years.
- Cohort 2: subjects aged 6 to 11 years.
- Cohort 3: subjects aged 12 to 17 years.

Number of Investigators and Study Centers:

Approximately 6 Investigators and study centers are expected to participate in this study.

Number of Subjects:

The study will enroll approximately 36 subjects in 3 cohorts of 12 subjects:

- Cohort 1: subjects aged 2 to 5 years.
- Cohort 2: subjects aged 6 to 11 years.
- Cohort 3, subjects aged 12 to 17 years.

Treatment Groups and Duration:

Subjects will attend a Screening visit between Days -21 and -14. If all eligibility criteria and none of the exclusion criteria are met, subjects will be enrolled into the study and will be required to undergo a 14 day washout period (Days-14 to -1). Subjects will attend the study center on Day 1 (-1 to 1) and the Baseline assessments will be performed before application of the first dose. On confirmation of continued eligibility the subject and parent or guardian of the subject will be coached on how to apply medication, depending on the affected areas. They will be instructed to apply B244 twice daily (approximately 12 hours apart) for 28 days. The first dose will be applied in the clinic under the supervision of clinical staff. Details of dose administration will be recorded in the study diary provided.

The subjects with their parent or guardian will return to the study center on Days 7, 14, and 21 for completion of study assessments. There will be a final study visit on Day 28, this will be defined as the end of the study for the subjects. A time window of ±2 day will be permitted for these 4 visits. There will not be a period of confinement in the study center all visits will be outpatient visits.

Safety monitoring will include review of TEAEs, vital signs and physical examination.

Efficacy will be assessed using EASI, vIGA-AD scale, POEM and ItchMan scores.

Statistical Methods:

All subjects who are enrolled and take at least 1 dose of study treatment will be included in the Intent to Treat (ITT) population. The ITT population will be the primary population for safety and efficacy assessments.

All subjects in the ITT population without any protocol deviations that may have an impact on the efficacy assessments will be included in the Per Protocol (PP) population. The PP population will be the supportive population for efficacy assessments.

The sample size is not based on statistical considerations but is typical for studies of this nature and is considered adequate to characterize the distribution of the planned endpoints. Any statistical testing will be considered exploratory and descriptive.

Data Monitoring Committee: No

Table Error! No text of specified style in document.**.1 Schedule of Assessments**

Visit Name	**Screening**	**Washout**	**Baseline (Day 1)**	**Day 7**	**Day 14**	**Day 21**	**Day 28 Final Visit**	**Early Termination Visit**
Study Center Visit	**1**		**2**	**3**	**4**	**5**	**6**	
Visit Window in Days	**-21 to -14**	**-14 to -1**	**-1 to 1**	**±2**	**±2**	**±2**	**±2**	
Informed Consent	X							
Inclusion/Exclusion Criteria	X		X					
Demographics	X							
Medical History	X							
Hanifin and Rajka Criteria	X		X					
Physical Examination	X		X	X	X	X	X	X
Urine Pregnancy Test[1]	X		X				X	X
Body Weight	X						X	X
Height	X						X	X
Vital Signs[2]	X		X	X	X	X	X	X
Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) Scale	X		X	X	X	X	X	X
Eczema Area Severity Index	X		X	X	X	X	X	X

Visit Name	**Screening**	**Washout**	**Baseline (Day 1)**	**Day 7**	**Day 14**	**Day 21**	**Day 28 Final Visit**	**Early Termination Visit**
Study Center Visit	**1**		**2**	**3**	**4**	**5**	**6**	
Visit Window in Days	**-21 to -14**	**-14 to -1**	**-1 to 1**	**±2**	**±2**	**±2**	**±2**	
(EASI)								
Patient Oriented Measure (POEM)[3]	X		X	X	X	X	X	X
ItchMan Questionnaire	X		X	X	X	X	X	X
Dispense Investigational Product to Subject[4]			X	X	X	X		
Investigational Product Application[5]			X	X	X	X	X	
Collect Investigational Product from Subject[6]				X	X	X	X	
Investigational Product Compliance[6]				X	X	X	X	X
Counseling[7]			X	X	X	X		
Study Cleanser[8]	X	X	X	X	X	X	X	X
Moisturizer[8]	X	X	X	X	X	X	X	X
Study Diary[9]			X	X	X	X	X	X
Adverse Events Recording[10]	X	X	X	X	X	X	X	X
Concomitant Medications	X		X	X	X	X	X	X

1. Urine pregnancy test will be administered to females 11 years of age or older.
2. Pulse rate, temperature and blood pressure will be obtained. Subject should be allowed to rest for >5 minutes sitting, then a single blood pressure and pulse rate measurement will be performed, using the non-dominant arm with a calibrated electronic sphygmomanometer.
3. Patient Oriented Measure questionnaire is to be filled out by the subject or the parent or guardian.

4. At Baseline, depending on the age of the participant, 1 or 2 bottles will be supplied. Total number of bottles to be dispensed to the subjects for the duration of the study will depend upon the body surface area affected by atopic dermatitis. At each visit, study staff will determine each subject's usage and supply additional investigational product if necessary.
5. The first investigational product application will happen in the study center under clinical staff supervision after completion of the baseline assessments. Subjects and parent or guardian will be coached on how to apply the study treatment depending on the affected area and will be asked to apply the study treatment twice daily.
6. Weight of an investigational product kit will be obtained at the at the Baseline visit. Study staff will be asked to weigh dispensed bottles PRE FIRST DOSE. Weight will be recorded in grams. Subjects will be asked to bring their bottles back for every visit. Upon return for the study visit, bottles will be weighed again.
7. Subjects will be counseled on the use of the study treatment, study diary and any questions the subject, parent or guardian may have will be answered.
8. The Sponsor will provide a biome friendly, preservative-free moisturizer and cleanser to be used as needed, at the discretion of the parent or guardian. Any remaining moisturizer or cleanser will be returned to the Investigator at the Final Visit (Day 28) or the Early Termination Visit.
9. The subject, parent or guardian will be asked to fill out a daily study diary.
10. Adverse events will be monitored throughout the trial, starting with the time informed consent form has been signed.

2. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study Protocol Amendment 1 dated February 25, 2019 .

This document provides additional details concerning the statistical analyses outlined in the protocol and reflects any changes to the protocol from any amendments. This plan will not repeat all the definitions given in the protocol but will provide further details of the summaries and analyses planned therein.

3. STUDY OBJECTIVES

The primary objectives:

To assess the safety and tolerability of B244 in pediatric subjects with atopic dermatitis.

The exploratory objectives:

To assess the efficacy of B244 on signs and symptoms of atopic dermatitis.

To assess the efficacy of B244 on patient oriented measure of atopic dermatitis.

To assess the efficacy of B244 on patient reported assessment of atopic dermatitis.

4. STUDY DESIGN

This is a Phase 1b, open-label, multiple site study assessing twice daily B244 application for 28 days in pediatric subjects with atopic dermatitis.

The study will enroll approximately 36 subjects in 3 cohorts of 12 subjects:

Cohort 1: subjects aged 2 to 5 years.
Cohort 2: subjects aged 6 to 11 years.
Cohort 3: subjects aged 12 to 17 years.

At Screening and Baseline, all subjects must have confirmed diagnosis of atopic dermatitis, as defined by the Hanifin and Rajka criteria, which involves a minimum of 10% but no more than 60% body surface area and a Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) scale of 2 or 3.

Subjects will attend a Screening visit between Day -21 and -14. If all eligibility criteria and none of the exclusion criteria are met, subjects will be enrolled into the study and will be required to undergo a 14 day washout period (Day-14 to -1). After that, subjects will be assigned to one of the cohorts based on their age.

Subjects will attend the study center on Day 1 where the first dose will be administered and the Baseline assessments will be conducted. Subject and parent or guardian of the subject will be instructed to apply B244 twice daily (approximately 12 hours apart) for 28 days and record the details of the application in the study diary provided. They will return to the study center on Days 7, 14, 21 and end of the study (EOS) on Day 28. Subjects who do not complete all required study visits and withdraw from the study before Day 28 final visit, will be asked to complete the ETV (Early Termination Visit).

5. HARDWARE AND SOFTWARE

Statistical analysis will be performed following IQVIA Biotech standard operating procedures and on the IQVIA Biotech computer network. All statistical analysis will be performed using SAS Version 9.3 or higher with program code prepared specifically for the project by qualified IQVIA Biotech statisticians and SAS programmers.

6. DATABASE CLOSURE

After completion of all data review and cleaning procedures and approval of the sponsor, the clinical database will be closed. Any change to the clinical database after this time will require written authorization, with explanation, by the Sponsor and the Biostatistician.

7. RANDOMIZATION

Not applicable as this is an open-label study.

8. SAMPLE SIZE DETERMINATION

The sample size is not based on statistical considerations but on the desire for each cohort to obtain adequate safety and tolerability data to achieve the objectives of the study while exposing as few subjects as possible to B244 and study procedures.

No formal statistical hypothesis testing is planned for this study. All statistical analyses will be considered exploratory and descriptive.

9. ANALYSIS POPULATIONS

The following analysis sets/populations will be used in this trial:

ITT population: All subjects who are enrolled and take at least 1 dose of study cohort will be included in the Intent to Treat (ITT) population. The ITT population will be the primary population for safety and efficacy assessments.

Per Protocol (PP) population: All subjects in the ITT population without any protocol deviations that may have an impact on the efficacy assessments will be included in the Per Protocol (PP) population. The PP population will be the supportive population for efficacy assessments. Major protocol violations will include but not be restricted to the following:

Failure to meet the inclusion/exclusion criteria

Usage of any prohibited concomitant medications or procedures

Failure to be compliant with treatment regimen

Non-compliance with study drug application (applied <50% of the total number of expected applications)

Additional criteria may be added to determine PP population.

10. HANDLING OF MISSING DATA

No imputation will be used.

11. INTERIM ANALYSIS

No interim analysis is planned.

12. DATA CONVENTIONS FOR ANALYSIS

12.1 General Statistical Principles

All observed and derived variables (e.g., change from baseline, percentage change from baseline, response status) used in the summaries of analyses will be presented in by-cohort and by-subject listings. Descriptive statistics will be used to provide an overview of the efficacy and safety results. For categorical parameters, the number and percentage of subjects in each category will be presented. The denominator for percentage will be based on the number of subjects appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include number of subjects (n), mean, standard deviation (SD), median, minimum (min), and maximum (max).

12.2 Study Day

Day 1 is defined as the date of first study drug application. Study day is calculated relative to the date of Day 1.

12.3 Baseline and Change from Baseline

Baseline value is defined as the last non-missing value prior to the first dose of study drug. Change from baseline is defined as: post-baseline value – baseline value.

12.4 Analysis Visit Window

Where applicable, all efficacy and safety data will be analyzed according to the nominal study visits, for Baseline/Day 1, Day 7, Day 14, Day 21, Day 28 (excluding ETV), and EOS (including Day 28 and ETV).

13. STATISTICAL EVALUATION

13.1 Subject Disposition

The number and percentage of subjects screened, enrolled, included in each analysis population, completing the study, withdrawing from the study (together with the reasons for withdrawal), and subjects excluded from PP population (together with the reasons for exclusion) will be summarized using frequencies and percentages by Cohort and overall. A by-cohort and by-subject listing will be presented for all subject enrollment and disposition. Screen failures will also be presented in by-cohort and by-subject listings.

13.2 Protocol Deviation

Protocol deviations will be logged into the IL2 database and displayed in a by-cohort and by-subject listing.

13.3 Demographic and Baseline Characteristics

Demographics and baseline characteristics will be summarized overall and by cohort and overall for the ITT and PP populations. The following demographic and baseline variables will be included:

Age
Gender
Race
Ethnicity
Weight
Height
BMI
Total Body Surface Area
Baseline vIGA-AD scale

13.4 Study Medication Exposure and Compliance

Subjects will apply IP B244 suspension twice a day approximately 12 hours apart, for 28 days (Day 1 to 28) and record the date of each trial medication application in the subject diary. The Med ID (kit number), the corresponding date dispensed and returned will be recorded, the weight of the IP for each bottle in grams pre- and post-application at each visit will also be collected. The Investigator will review the completed subject diary and record number of missed applications at each visit.

The following exposure and compliance parameters will be summarized for the ITT population by cohort and overall using descriptive statistics:

Total number of days of exposure to the study drug, defined as the date of last application of study drug minus date of first application plus one

Total number of applications taken during the treatment period, defined as the summation of number of applications used between each two visits, as reviewed and recorded on the CRF by the Investigator. If the number of applications between any two visits is missing, the subject will be assumed to have used 0 application.

Total amount of drug used (g), defined as the summation of amount of drug used per kit for all dispensed kits. Amount of drug used per kit is defined as the difference in weight

between the returned and dispensed kits, where weight of dispensed kits is a unit value. Amount of drug used for sealed and unreturned kits will be assumed to be 0.0 g.

Percent compliance, defined as the total number of applications used divided by total number of expected applications times 100%. The total number of expected applications is defined as the total number of days of exposure times 2.

Percent study drug applied, defined as total amount of drug applied divided by the expected weight of study drug applied times 100%. The expected weight of study drug applied is calculated as number of pumps per day times 0.14g per pump and multiply by total number of days of exposure assuming that subject applies the same amount of pumps per day during the treatment period. Table 13.1 gives the suggested number of pumps to be applied on each application based on cohort and baseline affected body surface area.

Table 13.1 Body Surface Area and Suggested Application of Investigational Product

Affected Body Surface Area	Approximate Number of Pumps per application		
	2 to 5 years old	6 to 11 years old	12 to- 17 years old
10% (>=10% - <20%)	2	2	3
20% (>=20% - <30%)	3	4	7
30% (>=30% - <50%)	4	6	10
50% (>=50% - <60%)	7	10	16

13.5 Prior and Concomitant Medications

Prior (within the previous 30 days and with stop dates prior to first dose of study drug) and concomitant (ongoing or with stop dates on or after first dose of study drug) medications or vaccines will be presented for the ITT population in a by-cohort and by-subject listing. If the medication is ongoing or the stop year is missing, the medication will be considered as received for the entire duration of the study. Medications will be coded using WHO-DD terminology.

For the determination of prior vs concomitant medications, the following rules regarding the stop date will be applied:

If only year was recorded, and it is before Baseline, it is a prior medication; if year is same or after Baseline, it is assumed to be a concomitant medication.

If day is missing, but month and year are before Baseline, it is a prior medication; if month and year are the same as Baseline, it is assumed to be a concomitant medication; if month and year are after Baseline, it is a concomitant medication.

If start date is after Baseline, it is a concomitant medication regardless.

In addition, concomitant medications will be summarized by WHO-DD Anatomical-Therapeutic-Chemical (ATC) classification and preferred term (PT) for each cohort and overall.

The use of medications to treat a subject's atopic dermatitis during the study will be permitted if deemed necessary and it will be indicated in the CRF. Rescue medication will be indicated in the concomitant medication listing.

13.6 Medical History and Concurrent Procedures

Medical history (including previous and ongoing medical conditions) will be coded using MedDRA and presented in a by-cohort and by-subject listing.

Concurrent procedures will be coded using MedDRA and presented in a by-cohort and by-subject listing.

13.7 Efficacy Endpoints

The efficacy assessments are as follows:

Changes from Baseline to post baseline visits in Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) scale.

The vIGA-AD is a 5-point scale that evaluates overall severity assessment of AD: 0=Clear, 1=Almost Clear, 2=Mild, 3=Moderate, and 4=Severe.

Number and proportion of subjects with a vIGA-AD of 0 (Clear) or 1 (Almost Clear) at each post baseline visit.

Changes from Baseline to post baseline visits in Area Severity Index (EASI) score (total and each component).

The EASI assesses the extent of disease (% involvement) at 4 body sites (head/neck, trunk, upper extremities, and lower extremities) and measures 4 clinical signs: erythema, edema/papulation, excoriation, and lichenification, and is graded on a severity scale of 0 to 3 (half points may be used): 0=None, 1=Mild, 2=Moderate, and 3=Severe.

Number and proportion of subjects with ≥30% EASI score reduction from Baseline to each post baseline visit

Changes from Baseline to post baseline visits in Patient Oriented Eczema Measure (POEM total score and each of the 7 components).

The POEM consists of 7 questions and each question carries equal weight and is scored from 0 to 4, and yield a total score of 0 to 28; higher scores mean the greater the severity of atopic dermatitis.

Changes from Baseline to post baseline visits in self-reported ItchMan scale.

The ItchMan Scale ranges from 0 to 4: no itch to itches most terribly.

Number and proportion of subjects with ≥0, 1, 2, 3 grade reduction in ItchMan Scale from Baseline to each post baseline visit

13.8 Efficacy Analyses

All efficacy analyses will be exploratory and performed on the ITT and PP populations, for overall and by age cohorts (2 to 5 years, 6 to 11 years, and 12 to 17 years).

Summary statistics will be provided for scheduled visits (Baseline/Day 1, Day 7, Day 14, Day 21, Day 28 [excluding ETV]) and the EOS visit (including Day 28 and ETV). Frequency counts and percentages will be provided for vIGA-AD Scale, POEM component scores, and ItchMan Scale, including absolute values and changes from baseline. The frequency and percentage of subjects who have achieved clear (0) or almost clear (1) on the vIGA-AD scale will also be provided at each post-baseline visit. Descriptive statistics for continuous parameters will be provided for EASI (total and by component), and POEM total score.

13.9 Safety Analyses

All safety analyses will be performed on the ITT population.

Safety endpoints include the following:

Incidence of treatment-emergent adverse events (TEAEs).

Change from Baseline in physical examination at each post baseline visit.

Change from Baseline in vital signs at each post baseline visit

13.9.1 Adverse Events

AE terms will be coded using MedDRA dictionary. Treatment-emergent adverse events (TEAEs) are defined as AEs that first occurred or worsened in severity after the first administration of study treatment. If relationship to treatment is missing, the event will be conservatively considered as being related to study drug. If severity is missing, a separate category of missing severity will be included in the summary table, and no imputation of severity will be performed.

For the determination of TEAEs, the following rules regarding the start date will be applied:

If only year was recorded, and it is before Baseline, it is a non-TEAE; if year is same or after Baseline, it is assumed to be a TEAE.

If day is missing, but month and year are before Baseline, it is a non-TEAE; if month and year are the same as Baseline, it is assumed to be a TEAE; if month and year are after Baseline, it is a TEAE.

If start date is after Baseline, it is a TEAE regardless.

All AEs will be presented in a by-cohort and by-subject listing, detailing the verbatim term given by the investigator, the preferred term (PT), system organ class (SOC), onset date and time, end date and time, intensity, outcome, relationship to study drug, action taken with study drug, other action taken to treat the event, seriousness and criteria for seriousness. Serious AEs (SAEs), TEAEs leading to death, and TEAEs leading to discontinuation of study treatment will also be presented in a separate listing. An overall summary of AEs will be presented by age cohort and overall. The summary will include the total number of events, frequency counts and percentages for:

Any AE
Any SAE
Any TEAE
Any TEAE leading to death
Any TEAE leading to discontinuation of study treatment

The number of the TEAEs and the incidence rate of TEAEs will be displayed by cohort and overall according to the following:

All TEAEs by SOC in alphabetical order and PT in descending order of frequency (the frequency in the overall group)

All TEAEs by SOC, PT, and maximum severity (mild, moderate, or severe)

All TEAEs by SOC, PT, and maximum causality (not related, related) to the study drug

SAEs, TEAEs leading to death, and TEAEs leading to discontinuation of study treatment by SOC and PT

At each level of summarization of incidence rates, a subject will be counted once if he/she reported one or more events. In the counts of subjects with TEAEs, each subject will contribute only once (maximum severity) regardless of the number of occurrences (events).

13.9.2 Clinical Laboratory Testing

A urine pregnancy test will be performed at all visits for females 11 years of age or older. The results will be presented in a by-cohort and by-subject listing.

13.9.3 Vital Signs

Vital signs including blood pressure (systolic and diastolic), pulse rate, and body temperature will be presented in a by-cohort and by-subject listing. Absolute values and change from baseline value will be summarized by cohort using descriptive statistics for scheduled visits (Baseline/Day 1, Day 7, Day 14, Day 21, Day 28 [excluding ETV], and the EOS visit [including Day 28 and ETV]).

13.9.4 Physical Examination

Number and frequency of subjects with abnormal findings for physical examination (including general appearance, dermatological, musculoskeletal, thyroid, HEENT, lymphatic, respiratory, gastrointestinal, cardiovascular, neurologic, extremities and Overall) will be summarized by-cohort and overall for scheduled visits.

The abnormality status will also be summarized in a shift table for all post-baseline visits by cohort and overall.

All abnormal results (including verbatim comments) will be presented in a by-cohort and by-subject listing.

14. CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

Not applicable.

15. FORMATTING

Each page of the analysis will show the sponsor's name, the investigational product, and the protocol number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). The summary tables and listings will be formatted using the Times New Roman 9-point font.

Datasets will be created and taken as input to validated SAS programs to generate the report-ready tables, listings, and figures. Each output display will show the names of the data sets and SAS program used to produce it.

16. ARCHIVING AND RETENTION OF DOCUMENTS

After finalization of the analysis, the following will be archived at IQVIA Biotech and/or with the study sponsor:

SAP and any amendments

All SAS code used in the project for statistical analysis, report tables generation, and analysis data set creation

Tables, listings and figures as included in the clinical study report

SAS study data tabulation model (SDTM) and analysis dataset model (ADaM) datasets

17. OUTLINE OF PROPOSED TABLES, LISTINGS AND FIGURES