INTEGRIUM, LLC

BIOMETRICS DEPARTMENT

Clinical Study Protocol: ARB244-001

A Prospective, Controlled, Double Blind, Single Center, Randomized, 3 Arm, Phase 1b/2a Study to Assess the Safety, Tolerability, and Preliminary Efficacy of B244 Delivered as an Intranasal Spray in Healthy Volunteers and Subjects with Seasonal Allergic Rhinitis

Statistical Analysis Plan (SAP) Documentation

Author(s): Kenneth E. Homer

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Statistical Analysis Plan for Clinical Study Protocol: ARB244-001

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Approved by:

S. Jamas. 1/3/2018

Spiros Jamas, ScD
Founding CEO
AOBiome, LLC

Date

Hyun Kim 03 JAN 2018

Hyun Kim, PhD.
Head of Clinical Operations
AOBiome, LLC

Date

Melissa Vrabel 03Jan2018

Melissa Vrabel, MS
Project Leader
Integrium, LLC

Date

Author(s):

Kenneth E Homer 03Jan2018

Kenneth E. Homer, MS
Director of Biometrics
Integrium, LLC

Date

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Glossary of Abbreviations

ABPM	Ambulatory Blood Pressure Monitoring
AE	Adverse Event
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
CTR	Clinical Trial Report
eCRF	Electronic Case Report Form
MedDRA	Medical Dictionary of Regulatory Activities
NAC	Nasal Allergen Challenge
nNO	Intranasal Nitric Oxide
PNIF	Peak Nasal Inspiratory Flow
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Seasonal Allergic Rhinitis
SAS®	Statistical Analysis Software
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TNSS	Total Nasal Symptom Score
WHO	World Health Organization

Table of Contents

1. Introduction

1.1. Scope

This document contains detailed information to aid the production of the Clinical Trial Report (CTR) including summary tables and listings for trial ARB244-001**.** The contents of this document were reviewed by the sponsor AOBiome, LLC., and the trial biostatistician at Integrium.

1.2. Study Background/Plan

This is a prospective, controlled, double blind, single center, randomized, 3 arm, parallel assignment, phase 1b/2a study to assess the safety, tolerability, and preliminary efficacy of B244 delivered as an intranasal spray in healthy volunteers and subjects with seasonal allergic rhinitis. This will be a 2-part study. In Part 1, safety and tolerability will be evaluated during 14 days of study treatment twice-a-day followed by 4 weeks of follow-up in healthy volunteers. In Part 2, preliminary efficacy will be evaluated in subjects with a history of seasonal allergic rhinitis outside of the local pollen season.

Part 1 (safety and tolerability evaluation in healthy volunteers) will enroll 24 subjects. Up to 12 subjects per dose cohort (n=8 active n=4 vehicle) will be enrolled, with a target of 20 subjects completed (10 subjects per dose cohort) assuming a 16.7% drop out rate.

Subjects will be dispensed study medication for 14 days of at home dosing. While at home, subjects will dose twice daily (am and pm), and record their dosing, any occurrence of an AE, and Total Nasal Symptom Score (TNSS) using a study diary. In addition to the screening, pre-dose and initial dose visits, subjects will be asked to visit the site at Day 14 (Week 2) and at follow-up visits at Day 21 (Week 3) and Day 42 (Week 6) for safety assessments and will additionally obtain Peak Nasal Inspiratory Flow (PNIF), intranasal fluid (collected on days 14 and 42), intranasal nitric oxide (nNO) and nasal inflammation score.

During the 2 week safety phase (Part 1), a continuous Ambulatory Blood Pressure Monitoring (ABPM) device will monitor blood pressure of each subject for 24 hours at baseline and Day 14. ABPM would be worn for 24 hours prior to the baseline visit and again for 24 hours prior to the Day 14 visit.

Part 2 (preliminary efficacy evaluation in subjects with a history of SAR to ragweed pollen) will enroll 42 subjects. Up to 14 subjects per arm ($1x10^9$ cells/ml; $4x10^9$ cells/ml or vehicle) will be enrolled, with a target of 12 subjects per arm for a total of 36 subjects completed, assuming a 10-15% dropout rate.

Safety and tolerability will be assessed in subjects with allergic rhinitis by reporting of AEs, physical examination and vital signs (blood pressure, heart rate, respiratory rate) during 14 days of treatment.

A preliminary efficacy assessment will be performed in response to nasal allergen challenge (NAC) in a prophylaxis treatment setting.

Subjects will be asked to report for a screening visit (Visit 1) and if all inclusion/exclusion criteria are met, subjects will be asked to report for a NAC titration (ragweed pollen nasal

allergen titration) visit to administer a single provocative challenge dose for each subject (Visit 2). Subjects will then return 14 days after the washout period for basic health checks and baseline assessments (intranasal fluid, TNSS, PNIF, intranasal nitric oxide, and have a nasal inflammation score) followed by confirmatory NAC (NAC #1) (Visit 3). During this time subjects will use a study diary to complete TNSS at -30 (30 minutes prior to NAC), 0 (baseline prior to NAC), 15, 30, 45, 60, 90 and 120 minutes. PNIF at -30, 0, 15, 30, 60 and 120 minutes will also be obtained. TNSS is the sum of four individual symptom scores (running nose, congestion, itchy nose and sneezing) rated on a four point scale (0-3). Subjects will also provide samples for intranasal fluid at 0, 20 and 120 minutes, measure intranasal nitric oxide (nNO) and have a nasal inflammation score assessed by the investigator using a nasal otoscope at 0 and 120 minutes, in addition to blood collection at 120 min for biomarkers. Randomized subjects will be dispensed study medication for 14 days of at home dosing. While at home, subjects will dose twice daily (am and pm), and record their dosing, and any occurrence of an AE and TNSS using a study diary.

Subjects will return to the clinic for the last dose following the 14 days of at home dosing for their final visit (Visit 4). During this time subjects will again have their baseline assessments and be exposed to ragweed pollen challenge (NAC #2), and will use a study diary to complete TNSS at -30, 0, 15, 30 45, 60, 90 and 120 minutes and PNIF at -30, 0, 15, 30, 60 and 120 minutes. Prior to and 20 and 120 minutes after NAC #2, subjects will additionally provide samples for intranasal fluid, and have nNO measured and nasal inflammation score assessed by the investigator using a nasal otoscope at 0 and 120 min, in addition to blood collection at 120 min for biomarkers.

1.3. Trial Objectives and Purpose

The primary objective of the study is to assess the safety and tolerability of B244 relative to vehicle in healthy volunteers during 14 days of treatment and up to 28 days of follow-up.

The secondary objectives of the study are:

- To evaluate the efficacy of B244 relative to vehicle in treating Total Nasal Symptom Score (TNSS) in subjects with seasonal allergic rhinitis evaluated in a nasal allergen challenge model as a prophylaxis therapy after 14 days of treatment.
- To evaluate the safety and tolerability of B244 relative to vehicle in subjects with allergic rhinitis after 14 days of treatment.
- To evaluate the efficacy of B244 relative to vehicle in treating individual nasal symptom scores in subjects with allergic rhinitis evaluated in a nasal allergen challenge model as a prophylaxis therapy after 14 days of treatment.

The exploratory objective is to test the hypothesis that B244 inhibits airway inflammation driven by nasal allergen challenge.

1.3.1. Primary Endpoints

Safety and tolerability will be assessed by reporting of AEs, physical examination and vital signs (blood pressure, heart rate, respiratory rate) during 14 days of treatment and up to 28 days of follow-up (Part 1).

1.3.2. Secondary Endpoints

The secondary endpoints are:

- Change in TNSS from baseline to 14 days of prophylaxis treatment.
- Change in subjective nasal symptom scores of nasal congestion, rhinorrhea, nasal itching and sneezing from baseline to 14 days of prophylaxis treatment.
- Nasal symptom-free response rate within each individual symptom score and TNSS after 14 days of prophylaxis treatment.
- Safety and tolerability will be assessed in subjects with allergic rhinitis by reporting of AEs, physical examination and vital signs (blood pressure, heart rate, respiratory rate) during 14 days of treatment (Part 2).

1.3.3. Exploratory Endpoints

The exploratory endpoints are:

- Change in Peak Nasal Inspiratory Flow (PNIF),
- Nasal inflammation score using otoscope,
- Intranasal nitric oxide levels, and
- Cytokine concentration in nasal cavity and blood from baseline to 14 days of B244 application and during prophylaxis treatment setting.

2. Detailed Statistical Methods

2.1. General Statistical Methods

This is a two-part study. Each of the two parts have 2 levels of active therapy ($1x10^9$ cells/ml and $4x10^9$ cells/ml) versus vehicle. The listings and tables will be presented separately for each of the two parts.

The collected data will be summarized using descriptive statistics (sample size, mean, standard deviation, median, minimum and maximum) or frequency counts, where appropriate, by treatment and overall.

For continuous variables, an Analysis of Covariance (ANCOVA) may be performed to test for significant differences between treatment groups. For discrete variables, the Cochran-Mantel-Haenszel Row Mean Score test will be used to test for significant differences between treatment groups.

2.2. Study Populations

Intent-to-Treat Population

All randomized patients will be included in the Intent-to-Treat Population.

Safety Population

All subjects who received a single dose of the study medication will be included in the safety analysis population.

Per Protocol Population

All subjects who administered at least 50% of study medication by weight, have at least one baseline and post baseline in clinic visit and did not have any major protocol violations will be included in the per protocol population.

2.3. Study Conduct and Baseline Characteristics

2.3.1. Demographics and Subject Baseline Characteristics

Demographic and subject baseline characteristics will be presented by treatment group and overall for each of the study populations. All continuous variables (age, baseline weight, height and body mass index (BMI)) will be summarized by descriptive statistics (number of observations, mean, standard deviation, median, minimum, maximum and coefficient of variation). All discrete variables (sex, race, ethnicity, childbearing status and tobacco/nicotine use) will be summarized by frequency counts and percentages. Data will also be shown in data listings by subject.

2.3.2. Study Drug Compliance

The amount of study drug used by weight and the percent compliance by weight (actual weight of doses administered / expected weight of dose administered) will be summarized using descriptive statistics (number of observations, mean standard deviation, median, minimum and maximum) for each treatment group and overall. The number of doses administered will be summarized by frequency counts for each treatment group and overall.

2.3.3. Prior and Concomitant Medications

Prior and concomitant medications will be summarized by frequencies and percentages. All medications will be coded using the World Health Organization (WHO) Drug dictionary September 2017 version.

Prior medications will be defined as any medication that started prior to the first day of administration. Concomitant medications will be defined as any medication that starts or is ongoing on or after the first day of administration. A medication may qualify as both a prior and concomitant medication if it started prior to first day of administration and is ongoing or stopped after the first day of administration.

Section 2.8 describes the imputation rules for partial dates. All medications will be presented in a data listing.

2.3.4. Total Nasal Symptom Score (TNSS) During Treatment

The total nasal symptom score during treatment is collected for both part 1 and part 2 via subject diary. The total nasal symptom score is for monitoring purposes only and is part of study conduct (separate from the efficacy and safety assessments).

The total nasal symptom score will be summarized by each individual score (nasal congestion, sneezing, nasal itching and rhinorrhea) and total nasal symptom score for each study day by treatment group and overall.

The individual items will be summarized using frequency counts for each study day. Observed values and change from baseline (day 0 for Part 1, and the 0 minutes pre-NAC on day 14 for Part 2) will be summarized. A Cochran-Mantel-Haenszel test will be conducted at each study day to test for treatment effect.

The total nasal symptom score will be summarized using summary statistics for each study day. Observed values and change from baseline (if appropriate) will be summarized. An Analysis of Covariance with treatment as the factor and baseline value as a covariate will be used to test for treatment effect.

2.4. Safety Evaluations

Safety is a primary endpoint for Part 1 of the study and is a secondary endpoint for Part 2 of the study. All of the safety tables will be presented in a similar fashion with the emphasis on primary and secondary endpoints covered in the CSR.

The following safety parameters will be tracked at designated intervals throughout the trial:

- Adverse Events,
- Laboratory Evaluations,
- Vital Signs,
- Physical Examinations,
- 12-Lead Electrocardiograms,
- Ambulatory Blood Pressure Monitoring, and
- Nasal Inspections.

2.4.1. Adverse Events / Serious Adverse Events

Adverse events will be coded using the medical dictionary of regulatory activities (MedDRA Version 20.1) dictionary.

Treatment-emergent adverse events (TEAEs) will be defined as any AE that starts on or after the first administration of study medication. Any event that started prior to the first administration of study medication but worsened in severity after the first administration will be recorded as a new event so that it may be captured as a TEAE. AEs with an unknown onset date will be counted as treatment-emergent unless the event resolved prior to the first administration. Section 2.8 describes the imputation rules for partial dates.

Treatment-emergent adverse events that are documented as occurring within 30 minutes after any of the doses will be summarized with the other TEAEs and separately from the other TEAEs.

The incidence of TEAEs will be presented by system organ class (SOC) and preferred term (PT). Events will also be summarized by severity and relationship. The incidence of TEAEs leading to withdrawal from the study and SAEs, including deaths, will be presented in both summary tables and data listings.

All AEs will be presented in data listings.

2.4.2. Laboratory Evaluations

Laboratory results for hematology, chemistry and urinalysis will be presented in data listings. Observed values and change from baseline values for hematology and chemistry parameters will also be summarized using descriptive statistics. Observed values for urinalysis will be summarized using frequency counts.

Values outside the normal range will be presented in a separate data listing.

2.4.3. Vital Signs

Blood pressure, heart rate, and respiration rate will be measured at each visit. Observed and change from baseline values will be summarized using descriptive statistics. All vital signs will be shown in data listings.

2.4.4. Physical Exam and Nasal Inspection

Physical examination and nasal inspection data will be presented in data listings.

2.4.5. 12-Lead Electrocardiogram

ECG Diagnosis, ventricular rate, RR interval, PR interval, QRS interval, QT Interval and QTcF Interval will be collected each time the ECG is performed. Observed and change from baseline values will be summarized using descriptive statistics. All electrocardiogram results will be shown in data listings.

2.4.6. Ambulatory Blood Pressure Monitoring (ABPM)

The average 24-hour, daytime (8AM to 4PM), waking hours (6AM to 10PM) and nighttime (10PM to 6AM) systolic and diastolic measurements will be listed and summarized. Observed and change from baseline values will be summarized using descriptive statistics. All ABPM parameters will be shown in data listings.

2.5. Efficacy

The collected data will be summarized using descriptive statistics (sample size, mean, standard deviation, median, minimum and maximum) or frequency counts, where appropriate, by treatment group and overall.

Area under the Curve (AUC) values will be derived using the trapezoidal rule with each observed value being an endpoint for the trapezoids. Thus (assuming that an

individual has all of the expected measurements), the AUC for 0 to 120 minutes Post NAC (as an example) would be derived by adding the areas of the following trapezoids: 0 to 15 minutes, 15 to 30 minutes, 30 to 45 minutes, 45 to 60 minutes, 60 to 90 minutes and 90 to 120 minutes.

2.5.1. Total Nasal Symptom Score (TNSS) During NAC

The total nasal symptom score during NAC is collected for part 2 only.

The total nasal symptom score will be summarized by each individual score (nasal congestion, sneezing, nasal itching and rhinorrhea) and total nasal symptom score for each time point by each treatment group individually and both active groups combined.

The individual items will be summarized using frequency counts for each time point. Observed values and change from baseline will be summarized. A Cochran-Mantel-Haenszel test will be conducted at each time point to test for treatment effect.

Pre-NAC adjusted value is defined as the observed value minus the 0 minutes prior NAC value.

The total nasal symptom score will be summarized using summary statistics for:

- The observed Total Nasal Symptom Score at each time point,
- The Pre-NAC adjusted Total Nasal Symptom Score at each time point,
- The observed individual symptom scores (nasal congestion, sneezing, nasal itching and rhinorrhea) at each time point,
- The Pre-NAC adjusted individual symptom scores (nasal congestion, sneezing, nasal itching and rhinorrhea) at each time point
- The Observed Area Under the Curve in Total Nasal Symptom Score from 0 to 120 minutes Post NAC, and
- The Pre-NAC adjusted Area Under the Curve in Total Nasal Symptom Score from 0 to 120 minutes Post NAC.
- The Observed Area Under the Curve for each individual symptom score (nasal congestion, sneezing, nasal itching and rhinorrhea) from 0 to 120 minutes Post NAC, and
- The Pre-NAC adjusted Area Under the Curve for each individual symptom score (nasal congestion, sneezing, nasal itching and rhinorrhea) from 0 to 120 minutes Post NAC.
- Nasal symptom-free response rate (defined as a value of 0) for each individual symptom score and the Total Nasal Symptom Score at Visit 4.

For Part 2, observed values and change between Visits 3 and 4 will be summarized for the indicated items.

In addition to the items indicated above, the following items will also be analyzed:

- Percent of subjects with 25% reduction in Total Nasal Symptom Score between Visits 3 and 4.

- Percent of subjects with 50% reduction in Total Nasal Symptom Score between Visits 3 and 4.

For Total Nasal Symptom Score and Area Under the Curve analyses, an Analysis of Covariance with treatment as the factor and Visit 3 value as a covariate will be used to test for treatment effect at Visit 4.

For response rates, individual item scores and percent reduction, a Cochran-Mantel-Haenszel test will be conducted to test for treatment effect.

2.5.2. Peak Nasal Inspiratory Flow

Peak nasal inspiratory flow is collected in both Part 1 and Part 2, but the timing of the collection is different between the parts. For Part 1, the data is collected for observation only. For Part 2, the data is collected as an exploratory efficacy endpoint.

Pre-NAC adjusted value is defined as the observed value minus 0 minutes prior NAC value.

The peak nasal inspiratory flow will be summarized using summary statistics for:

- The observed value at each time point,
- The Pre-NAC adjusted value at each time point,
- the Observed Area Under the Curve from 0 to 120 minutes Post NAC, and
- the Pre-NAC adjusted Area Under the Curve from 0 to 120 minutes Post NAC.

For Part 2, observed values and change between Visits 3 and 4 will be summarized for the indicated items.

The collected data will be summarized using descriptive statistics at each time point in which the assessment was collected. Observed and change from baseline values will be summarized. Post-baseline values will be analyzed using an Analysis of Covariance to test for treatment effect where treatment is the main factor and Visit 3 value as the covariate.

2.5.3. Nasal Inflammation Score

The nasal inflammation score is collected in both Part 1 and Part 2, but the timing of the collection is different between the parts. For Part 1, the data is collected for observation only. For Part 2, the data is collected as an exploratory efficacy endpoint.

Pre-NAC adjusted value is defined as the observed value minus 0 minutes prior NAC value.

The nasal inflammation score will be summarized using summary statistics for:

- The observed value at Pre-NAC and 120 minutes Post-NAC, and
- The Pre-NAC adjusted value at 120 minutes Post-NAC,

For Part 2, observed values and change between Visits 3 and 4 will be summarized for the indicated items.

The collected data will be summarized using frequency counts at each time point in which the assessment was collected. Observed values will be summarized. A Cochran-Mantel-Haenszel test will be conducted at each post-baseline visit to test for treatment effect.

2.5.4. Intranasal Nitric Oxide

Intranasal nitric oxide is collected in both Part 1 and Part 2, but the timing of the collection is different between the parts. For Part 1, the data is collected for observation only. For Part 2, the data is collected as an exploratory efficacy endpoint.

Pre-NAC adjusted value is defined as the observed value minus 0 minutes prior NAC value.

Intranasal Nitric Oxide will be summarized using summary statistics for:

- The observed value at Pre-NAC and 120 minutes Post-NAC, and
- The Pre-NAC adjusted value at 120 minutes Post-NAC,

For Part 2, observed values and change between Visits 3 and 4 will be summarized for the indicated items.

The collected data will be summarized using descriptive statistics at each time point in which the assessment was collected. Observed and change from baseline values will be summarized. Post-baseline values will be analyzed using an Analysis of Covariance to test for treatment effect where treatment is the main factor and Visit 3 value as the covariate.

2.6. Interim Analyses and Database Lock

There are no interim analyses planned for this study. There will be a database lock after each of the parts are completed. The unblinding and analysis of the data will be performed for each part after their respective database lock.

2.6.1. Part 1 Database Lock

The Part 1 database lock will take place after all part 1 subjects have completed the study.

2.6.2. Part 2 Database Lock

The Part 2 database lock will take place after all part 2 subjects have completed the study.

2.7. Sample Size and Power Considerations

Part 1 (safety and tolerability evaluation in healthy volunteers) will enroll 24 subjects. Up to 12 subjects per dose cohort (n=8 active, n=4 vehicle) will be enrolled, with a target of 20 subjects completed (10 subjects per dose cohort; n=7 active, n=3 vehicle) assuming a 16.7% drop out rate. The two dose cohorts are $1x10^9$ cells/ml and $4x10^9$ cells/ml.

Part 2 (preliminary efficacy evaluation in subjects with a history of SAR to ragweed pollen) will enroll 42 subjects. Up to 14 subjects per arm ($1x10^9$ cells/ml; $4x10^9$ cells/ml or vehicle) will be enrolled, with a target of 12 subjects per arm for a total of 36 subjects completed, assuming a 10-15% drop-out rate.

The sample size for this study is not based on statistical considerations.

2.8. Handling Missing Data

Listings will be provided for all data. Descriptive statistics will be provided for all planned visits as provided on the eCRFs. No imputations for missing data will be used in the data displayed in the listings such that the listing will only show "observed data".

Safety and Other Rules

Per the protocol, visits are expected to occur within a given number days of the expected day of the visit. The visits will be analyzed as recorded. Likewise, unscheduled visits will not be reassigned a visit number based on the visit date.

Dates related to the adverse events and medications will be imputed using the rules below in an effort to categorize them properly into the summary tables.

Imputing partial or missing start dates:

- If the year is unknown, then the start date will not be imputed. The date will remain missing.
- If the month is unknown and the year is the same as the first injection date of the study, then impute the month and day of the date to be equal to the first injection month and day. Otherwise, impute the month as January.
- If the day is unknown and the month and year are the same as the first injection date of the study, then impute the day to be equal to the day of the first injection. Otherwise, impute the day as '01'.

Impute partial or missing stop dates:

- If the year is unknown, then the stop date will not be imputed. The date will remain missing.
- If the month is unknown, impute the month as December.
- If the day is unknown, impute the day to be the last day of the month.

If an imputed stop date is greater than the date of study completion/discontinuation date of the study, then the imputed stop date will be set equal to the date of completion/discontinuation date.

The imputed dates will be stored in the analysis datasets along with the original dates as recorded by the sites.

2.9. Subject Withdrawals

Subject withdrawals will be summarized in a disposition table for all subjects. The reasons for discontinuation will also be tabulated. Withdrawals due to AEs will be tabulated as discussed in the Adverse Event section above. A listing of the subjects who withdrew due to an AE will be presented as well as a listing of the subjects' completion and/or discontinuation status.

2.10. Protocol Deviations

Protocol deviations will be displayed in a data listing as provided by the clinical team.

2.11. Computer Systems and Packages Used for Statistical Analyses

SAS® version 9.4 or higher on the Microsoft Windows 7 64 bit platform will be used for all analyses. All computations will be performed using SAS®. The exact form of the various algorithms will be the SAS® defaults. The output from any SAS® procedure will be used in the tables using SAS® macros.

3. Data Listing Shells

3.1. Data Listings Table of Contents

The following post-text listings will be generated.

Listing Number	Listing Title
16.2.1-1	Subject Completion / Discontinuation – Part 1
16.2.1-2	Subject Completion / Discontinuation – Part 2
16.2.2-1	Protocol Deviations – Part 1
16.2.2-2	Protocol Deviations – Part 2
16.2.3.1-1	Demographics and Baseline Characteristics – Part 1
16.2.3.1-2	Demographics and Baseline Characteristics – Part 2
16.2.3.2-1	Subject Eligibility and Informed Consent – Part 1
16.2.3.2-2	Subject Eligibility and Informed Consent – Part 2
16.2.3.3-1	Medical History / Surgical History / Procedures – Part 1
16.2.3.3-2	Medical History / Surgical History / Procedures – Part 2
16.2.3.4-1	Prior and Concomitant Medications – Part 1
16.2.3.4-2	Prior and Concomitant Medications – Part 2
16.2.3.5-1	Substance Use – Part 1
16.2.3.5-2	Substance Use – Part 2
16.2.4.1-1	Study Drug Administration – Part 1
16.2.4.1-2	Study Drug Administration – Part 2
16.2.4.2-1	Dose Compliance Log – Part 1
16.2.4.2-2	Dose Compliance Log – Part 2
16.2.5.1-1	Total Nasal Symptom Score (TNSS) During Treatment – Part 1
16.2.5.1-2	Total Nasal Symptom Score (TNSS) During Treatment – Part 2
16.2.5.2-1	Individual Nasal Symptom Items During Treatment – Part 1
16.2.5.2-2	Individual Nasal Symptom Items During Treatment – Part 2

Listing Number	Listing Title
16.2.5.3-2	Total Nasal Symptom Score (TNSS) During NAC – Part 2
16.2.5.4-2	Individual Nasal Symptom Items During NAC – Part 2
16.2.5.3-1	Peak Nasal Inspiratory Flow – Part 1
16.2.5.3-2	Peak Nasal Inspiratory Flow – Part 2
16.2.5.4-1	Nasal Inflammation Score – Part 1
16.2.5.4-2	Nasal Inflammation Score – Part 2
16.2.5.5-1	Intranasal Nitric Oxide – Part 1
16.2.5.5-2	Intranasal Nitric Oxide – Part 2
16.2.6.1-1	Adverse Events – Part 1
16.2.6.1-2	Adverse Events – Part 2
16.2.6.2-1	Adverse Events Leading to Discontinuation of Study – Part 1
16.2.6.2-2	Adverse Events Leading to Discontinuation of Study – Part 2
16.2.6.3-1	Serious Adverse Events – Part 1
16.2.6.3-2	Serious Adverse Events – Part 2
16.2.7.1-1	Laboratory Results – Hematology – Part 1
16.2.7.1-2	Laboratory Results – Hematology – Part 2
16.2.7.2-1	Laboratory Results – Chemistry – Part 1
16.2.7.2-2	Laboratory Results – Chemistry – Part 2
16.2.7.3-1	Laboratory Results – Urinalysis – Part 1
16.2.7.3-2	Laboratory Results – Urinalysis – Part 2
16.2.7.4-1	Laboratory Results – Other – Part 1
16.2.7.4-2	Laboratory Results – Other – Part 2
16.2.7.5-1	Laboratory Results – Abnormal Lab Results – Part 1
16.2.7.5-2	Laboratory Results – Abnormal Lab Results – Part 2
16.2.7.6-1	Vital Signs – Part 1
16.2.7.6-2	Vital Signs – Part 2
16.2.7.7-1	Electrocardiogram Results – Part 1
16.2.7.8-1	Physical Examination and Nasal Inspection – Part 1
16.2.7.8-2	Physical Examination and Nasal Inspection – Part 2
16.2.7.9-1	Ambulatory Blood Pressure Monitoring – Part 1

3.2. Data Listings

All subjects and all data will be presented in the listings. The listings will be sorted by treatment and subject number.

4. Summary Table and Figure Shells

4.1. Post-text Table of Contents

The following post-text tables will be generated.

Table Number	Table Title
14.1.1.1-1	Summary of Subject Disposition – Intent-to-Treat Population - Part 1
14.1.1.1-2	Summary of Subject Disposition – Intent-to-Treat Population - Part 2
14.1.1.2-1	Summary of Subject Disposition – Safety Population - Part 1
14.1.1.2-2	Summary of Subject Disposition –Safety Population - Part 2
14.1.1.3-1	Summary of Subject Disposition – Per Protocol Population - Part 1
14.1.1.3-2	Summary of Subject Disposition – Per Protocol Population - Part 2
14.1.2.1-1	Summary of Demographics and Baseline Characteristics – Intent-to-Treat Population - Part 1
14.1.2.1-2	Summary of Demographics and Baseline Characteristics – Intent-to-Treat Population - Part 2
14.1.2.2-1	Summary of Demographics and Baseline Characteristics – Safety Population - Part 1
14.1.2.2-2	Summary of Demographics and Baseline Characteristics – Safety Population - Part 2
14.1.2.3-1	Summary of Demographics and Baseline Characteristics – Per Protocol Population - Part 1
14.1.2.3-2	Summary of Demographics and Baseline Characteristics – Per Protocol Population - Part 2
14.1.3-1	Summary of Medical History – Safety Population - Part 1
14.1.3-2	Summary of Medical History – Safety Population - Part 2
14.1.4.1-1	Summary of Prior Medications – Safety Population - Part 1
14.1.4.1-2	Summary of Prior Medications – Safety Population - Part 2
14.1.4.2-1	Summary Concomitant Medications – Safety Population - Part 1
14.1.4.2-2	Summary Concomitant Medications – Safety Population - Part 2
14.1.5.1-1	Summary of Study Medication Usage – Intent-to-Treat Population - Part 1
14.1.5.1-2	Summary of Study Medication Usage – Intent-to-Treat Population - Part 2

Table Number	Table Title
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4.3. Table Shells

The following number of decimal places will be used when presenting summary statistics:

- N to 0 decimal places
- Minimum and maximum to the same number of decimal places as recorded in the raw data.
- Means and medians to 1 more decimal place than is recorded in the raw data. Standard deviations to 2 more decimal places than is recorded in the raw data.
- Percentages to 1 decimal place.

The precision may be changed for individual endpoints as needed.