STATISTICAL ANALYSIS PLAN

Protocol Number:	BTX.2018.001
Study Title:	A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of BTX 1503 in Patients with Moderate to Severe Acne Vulgaris
Development Phase of Study:	2
Sponsor:	Botanix Pharmaceuticals Ltd.
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Statistical Analysis Plan based on Protocol Version:	2.4 (07JUN2018)
Statistical Analysis Plan Date:	24 MAY 2019
Statistical Analysis Plan Version:	v1

NCT03573518

SAP Approval

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Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

SAP Change History

Version	Date	Summary of Changes	Author
1	ddmmmyyyy	Original document	Laura Hatsis

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	adverse event(s)
ANCOVA	analysis of covariance
ATC	anatomical therapeutic chemical
AUS	Australia
BP	blood pressure
BPM	beats per minute
cm	centimeters
CRF(s)	case report form(s)
eCRF(s)	electronic case report form(s)
FDA	Food and Drug Administration
GCP	good clinical practice
HEENT	head, eyes, ears, nose, and throat
HR	heart rate
hr(s)	hour(s)
ICH	International Conference on Harmonization
ITT	intent-to-treat
kg	kilograms
LOCF	last observation carried forward
LSMean or LSM	least squares mean
max	maximum
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
min	minimum
n	number of observations
N	number of subjects (sample size)
PP	per-protocol
PT	preferred term
QST	QST Consultations, Ltd.
SAE(s)	serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	standard deviation
SOC	system organ class

TEAE(s)	treatment-emergent adverse event(s)
TEMP	temperature
US	United States
WHO	World Health Organization
WHO-DDE	World Health Organization Drug Dictionary

2. INTRODUCTION

Acne is the most common skin disease in the world and is characterized by partial obstruction of the pores and associated local skin lesions that can appear on the face, chest or back [1, 2]. Obstructed pores can become enlarged and inflamed as sebum and its breakdown products accumulate, resulting in visible lesions that can be unsightly and cause permanent scarring [1, 2]. Acne usually begins in puberty and affects many adolescents and young adults, but it can occur at any stage of life. Approximately 85 percent of people between the ages of 12 and 24 experience at least minor acne [3]. Acne often causes significant physical and psychological problems such as permanent scarring, poor self-image, depression and anxiety [4].

Botanix Pharmaceuticals' BTX 1503 containing the active pharmaceutical ingredient, cannabidiol (CBD) in a topical liquid formulation, is being developed for the treatment of acne vulgaris. CBD is a member of a broader family of compounds knowns as cannabinoids, a class of compounds originally derived from the *cannabis sativa* plant [5].

No known well-controlled, human clinical studies have ever been conducted using CBD to treat skin disease, and no CDB containing pharmaceuticals have been approved to treat skin disease. Researchers have found that CBD may play a beneficial role in regulating the cutaneous endocannabinoid system by decreasing unwanted skin cell growth, sebum production and skin inflammation associated with many human skin diseases [5].

BTX 1503 is a formulation of active synthetic CBD and inactive excipients designed to deliver a consistent dose of CBD to directly treat patients with acne. It is considered that CBD may:

- normalize excessive lipid synthesis of human sebocytes;
- decrease proliferation (but not the viability) of these human sebocytes;
- inhibit hyperproliferation of keratinocytes;
- exert anti-inflammatory actions; and
- have anti-bacterial effects [5, 6].

This study is designed to investigate the efficacy, safety and tolerability of BTX 1503 in subjects with moderate to severe acne.

3. STUDY OBJECTIVES

The objective of this study is to assess safety and efficacy of various doses of BTX 1503 liquid formulation in subjects with moderate to severe acne vulgaris of the face.

4. STUDY DESIGN

4.1 Overall Study Design

This will be a multi-center, randomized, double-blind, vehicle-controlled, parallel group, dose-finding study in pediatrics, adolescents, and adults (aged 12 to 40 years). Approximately 360 subjects will be enrolled.

There will be five dose groups. All subjects will apply study drug for 84 days.

- BTX 1503 5% twice daily (BID),
- BTX 1503 5% once daily (QD),
- BTX 1503 2.5% once daily (QD),
- Vehicle BID, or
- Vehicle QD.

At the Baseline visit, qualified subjects will be randomized to treatment using an Interactive Web-based Randomization System (IWRS). The study will be a total of up to 17 weeks in duration; screening period up to 35 days (5 weeks) and 84 days (12 weeks) of treatment. During the study subjects will return to the study clinic at Day 14, 28, 56, and 84 (Study Exit).

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 7.3.8 of the protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

A randomization schedule will be generated by a member in the QST Consultations, Ltd. (QST) Statistical Services department who is not associated with the conduct or analysis of the study, using a validated system. The randomization list will not be stratified, but stratification by site will be accomplished within the Interactive Web-based Randomization System (IWRS).

Once a subject is deemed eligible to enroll, randomization will occur using an IWRS. The IWRS will assign a study drug kit number based on a predetermined randomization schedule. The kit number will be recorded in the electronic case report form (eCRF). Randomization will be 2:2:2:1:1 (90 subjects in each active group and 45 in each vehicle group) and done by site.

4.1.3 Blinding

The Sponsor, the CRO, the investigator, study site personnel and subjects will be blinded to the treatment assignment. The randomization schedule will be kept strictly confidential and accessible only to authorized persons. Only when the study has been completed, the protocol violations determined, and the study database locked will the randomization schedule be made available for analysis.

During the study, the randomization code will not be broken except in the case of a safety concern, either for an individual subject or for the entire study. If a subject has an adverse event (AE) that may necessitate unblinding of the randomization code, the site will contact the CRO and sponsor to discuss if there are options other than unblinding. If the site and sponsor agree that unblinding is in the best interests of the subject, the IWRS system will be used to obtain treatment assignment information. The Medical Monitor must be notified whenever study medication is unblinded, preferably prior to unblinding a subject.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

For all efficacy evaluations the measurement endpoint is defined at Day 84.

5.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint for the study is:

- Absolute change from Baseline in inflammatory lesion counts at Day 84.

5.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints for the study are:

- Absolute change from Baseline in non-inflammatory lesion counts at Day 84,
- The percent change from Baseline in the inflammatory lesion counts at Day 84,
- The percent change from Baseline in the non-inflammatory lesion counts at Day 84,

- The proportion of subjects with at least a 2-grade reduction from the Baseline IGA score at Day 84,
- The proportion of subjects with an IGA score of "clear" or "almost clear" at Day 84, and
- The proportion of subjects with an IGA score of "clear" or "almost clear" at Day 84 and at least a 2-grade reduction from the Baseline IGA score.

5.1.3 Exploratory Efficacy Endpoints

The exploratory efficacy endpoints are:

- The change from Baseline in the total lesion count at Day 84,
- The percent change from Baseline in the total lesion count at Day 84,
- The change from Baseline in the IGA scores at Day 84,
- The absolute and percent change from Baseline in inflammatory, non-inflammatory, and total lesion counts at Day 14, Day 28, and Day 56,
- The proportion of subjects with an IGA score of "clear" or "almost clear" at Day 14, Day 28, and Day 56,
- The proportion of subjects with at least a 2-grade reduction from the Baseline IGA score at Day 14, Day 28, and Day 56,
- The proportion of subjects with an IGA score of "clear" or "almost clear" at Day 14, Day 28, and Day 56 and at least a 2-grade reduction from the Baseline IGA score,
- The change from Baseline in the Acne-QoL at Day 84, and
- Subject's assessment of the change in their acne from Baseline to Day 84 (Patient Reported Outcome [PRO]).

5.2 Safety Endpoints

Safety will be assessed through adverse events (AEs), cutaneous tolerability (erythema, scaling, dryness, pruritus, and burning/stinging), complete blood count (CBC), chemistry, and urinalysis laboratory testing, and physical exam.

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® 9.3 or higher. No interim analyses are planned. This Phase 2 study is designed to identify the response to two different dosing frequencies and two concentrations of BTX 1503. Statistical tests applied to the outcomes will be exploratory. No adjustments for Type I error will occur.

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. For continuous parameters, descriptive statistics will include n (number of subjects), mean, standard deviation (SD), median, minimum and maximum.

The primary method of handling missing efficacy data in the ITT analysis set will be based on last observation carried forward (LOCF). Repeated measures analyses will be used on the observed data as a sensitivity analysis on the primary endpoint and the first secondary endpoint.

The efficacy analysis performed on the ITT population is considered the primary analysis. The efficacy analysis performed on the per-protocol (PP) population is considered supportive analysis.

The number of subjects in each analysis set will be summarized. Reasons for study withdrawal during the study will be summarized using frequencies and percentages by treatment group.

Reported AEs, medical history terms, and prior and concomitant procedures and therapies will be classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Prior and concomitant medications will be classified on the basis of World Health Organization Drug Dictionary (WHO-DDE) terminology.

6.1.1 Statistical Analysis

All analyses will be performed by QST using SAS® Version 9.3 or later. All summary tables and data listings will be prepared utilizing SAS® software.

The standard operating procedures (SOPs) of QST will be followed in the creation and quality control of all data displays and analyses.

6.1.2 Baseline Definition

Baseline is defined as the last non-missing assessment prior to first application of study drug.

6.1.3 Visit Windowing

Data will be summarized based on nominal visit indications with the exception of data captured at early termination and unscheduled visits. Data from early termination and unscheduled visits will be summarized based on mapped visit values. The analysis windows for early termination and unscheduled visits are presented in the following table.

Analysis Windows

Scheduled Visit	Target Study Day	Window (Days)
Day 14	15	9 to 21
Day 28	29	22 to 42
Day 56	57	43 to 70
Day 84	85	71 to 98

Data collected at early termination and unscheduled visits prior to study day 9 will not be analyzed, with the exception of those identified as baseline values. Data collected at early termination and unscheduled visits after study day 98 will not be included in analyses.

The definition for the study day included in each study window is defined as below:

Study Day prior to Day 1 = Visit Date – Day 1 Date

Study Day on or after Day 1 = Visit Date – Day 1 Date + 1

If an assessment's mapped visit is a visit at which the subject has data from a scheduled visit present, or if no analyses are planned for the assessment at the mapped visit, the data collected at the early termination or unscheduled visit will not be included in analyses.

In the event of multiple values from unscheduled or early termination assessments within an analysis window, the value closest to the scheduled visit target study day will be used for analyses. If two values tie as closest to the time point (for example, one value is before and the other value is after the time point), then the later value will be selected.

Data collected at all visits will be included in the data listings with visit presented as reported by the site.

6.1.4 Adjustments for Covariates

Baseline lesion count will be a covariate for the efficacy endpoints for acne lesion counts. No other covariates are planned to be used in the analyses for this study.

6.1.5 Handling of Dropouts or Missing Data

All efforts will be made to minimize the occurrence of missing data. It is not expected that dropout rates will differ between groups. Therefore, the primary method of handling missing efficacy data in the ITT analysis set will be based on last observation carried forward (LOCF). Summary of efficacy and pharmacology variables for the PP subjects will be based on available data. No imputation will be done for non-efficacy related variables.

If a partial date is reported where the day is missing, then the day will be imputed as the first day of the month unless the month is the same month as the first application of study drug then the day will be that of first application with the month and year remaining the same. If a partial date is reported where the month is missing, then the month will be imputed to January unless the year is the same year as the first application of study drug then the month will be that of first application with the year remaining the same. If a partial date where both the day and month is missing, follow details as stated previously.

Missing AE start dates will be imputed using partial date imputation rules as previously described in this Section.

6.1.6 Interim Analyses and Data Monitoring

No interim analysis or data monitoring is planned for this study.

6.1.7 Multicenter Studies

This study will be conducted at multiple investigational sites in the United States and Australia with the intention of pooling the results for analysis.

6.1.8 Multiple Comparisons/Multiplicity

This Phase 2 study is designed to identify the response to two different concentrations and dosing frequencies of BTX 1503. Statistical tests applied to the outcomes will be exploratory for establishing the dose and sample size for Phase 3 studies. No adjustments for Type I error will occur.

6.1.9 Use of an Efficacy Subset of Subjects

Subjects randomized to study drug who complete the Day 84 visit without noteworthy study protocol violations, including compliance with study drug application, Day 84 visit window, and completion of efficacy evaluations on Day 84 will form the PP Population. The noteworthy

protocol violations will be defined at the time of evaluability evaluation, the time between the database soft lock and hard lock before unblinding.

Excluding subjects who have noteworthy protocol violations will decrease the variability in treatment response and will allow for a better determination of dose-response relationship of BTX 1503.

6.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

6.1.11 Examination of Subgroups

Subset analyses will be conducted for the PP analysis set on the primary efficacy endpoint and for the secondary endpoints, absolute change from Baseline in non-inflammatory lesion counts at Day 84 and subjects with an IGA score of "clear" or "almost clear" at Day 84 and at least a 2-grade reduction from the Baseline IGA score. These analyses will be summarized using descriptive statistics. The specific subsets within the PP analysis set that will be evaluated include:

- Baseline inflammatory lesion count (< median vs ≥ median);
- Baseline non-inflammatory count (< median vs ≥ median);
- Baseline total lesion count (< median vs ≥ median and < 80th percentile vs ≥ 80th percentile);
- Baseline IGA (3 (Moderate) vs 4 (Severe));
- Baseline Acne-QoL:
    - Self-Perception domain (< median vs ≥ median),
    - Role-Social domain (< median vs ≥ median),
    - Role-Emotional (< median vs ≥ median), and
    - Acne Symptoms (< median vs ≥ median);
- PRO (Improved (includes responses of much better and slightly better) vs. Same (includes response of the same) vs Worsened (includes responses of slightly worse and much worse));
- Geographical region (US vs AUS);

- Gender (Male vs Female);
- Ethnicity (Hispanic or Latino vs Non-Hispanic or Latino);
- Race (White vs Non-White); and
- Age (12 to <18 vs 18 to <30 vs 30 to 40).

6.1.11.1 Examination of Responders

Responder analyses will be conducted for the primary efficacy endpoint and for the secondary endpoints, absolute change from Baseline in non-inflammatory lesion counts at Day 84 and subjects with an IGA score of "clear" or "almost clear" at Day 84 and at least a 2-grade reduction from the Baseline IGA score. Responders are defined as, 80th percentile showing absolute reduction in inflammatory lesions from Baseline. These analyses will be summarized using descriptive statistics. The specific subsets within the responder PP analysis set that will be evaluated include:

- Baseline inflammatory lesion count (< median vs ≥ median);
- Baseline non-inflammatory count (< median vs ≥ median);
- Baseline total lesion count (< median vs ≥ median and < 80th percentile vs ≥ 80th percentile);
- Baseline IGA (3 (Moderate) vs 4 (Severe));
- Compliance (percent compliance < median vs ≥ median)

6.2 Disposition of Subjects

The number of subjects included in each analysis population (randomized, ITT, safety, PP) will be summarized by treatment group. The number of subjects completed and discontinued (including the reasons for discontinuation) will be summarized for each treatment group.

Subjects who are excluded from an analysis population will be summarized by the reasons for exclusion.

6.3 Protocol Deviations

Protocol deviations will not be entered into the database. Deviations leading to exclusion from analysis populations will be identified and summarized.

6.4 Data Sets Analyzed

6.4.1 Randomized Population

All subjects who are randomized to study treatment will be included in the randomized population and will be analyzed according to the treatment group they were randomized. Listings will be presented for all randomized subjects.

6.4.2 Intent-to-Treat (ITT) Population

All subjects in the randomized population will be included in the ITT population and analyzed according to the randomized treatment group. All efficacy analyses will be presented using the ITT population.

6.4.3 Safety Population

All subjects in the ITT population, who have at least one confirmed dose of study drug, and have at least one post-Baseline assessment will be included in the safety population and analyzed according to the treatment group received. All safety analyses will be performed using the safety population.

6.4.4 Per-Protocol (PP) Population

All subjects in the ITT population who complete the Day 84 visit without noteworthy study protocol violations will be included in the PP population and analyzed according to the treatment group received. The PP population will include subjects in the ITT population who do not meet any of the following criteria:

- Violated the inclusion/exclusion criteria;
- Have taken any interfering concomitant medication;
- Did not complete both IGA and lesion count efficacy assessments at the Day 84 visit;
- Have missed both the Day 28 and Day 56 visits;
- Have not been compliant with the dosing regimen (i.e. subjects must apply 80-120% of the expected applications of study medication during participation in the study);
- Out of visit window at the Day 84 visit by ±5 days;

Subjects that discontinue from the study due to an AE related to study treatment or documented lack of treatment effect will be included in the PP population. Prior to breaking the blind, other

additional criteria may be added to the list to accommodate for unforeseen events that occurred during the conduct of the trial that result in noteworthy study protocol violations.

All efficacy analyses will be performed on the PP population.

6.5 Demographic and Other Baseline Characteristics

All demographic and Baseline summaries will be done on the ITT, PP, and safety populations.

Sex, race, and ethnicity will be summarized by counts and percentages. Age, height (cm), and weight (kg) will be summarized with descriptive statistics.

Tobacco and alcohol history will be summarized with counts and percentages. Baseline IGA and inflammatory and non-inflammatory lesion counts will be summarized with descriptive statistics.

Medical histories will be coded using the MedDRA dictionary and presented in a by-subject listing.

6.6 Prior and Concomitant Medications

Concomitant medications will be coded to preferred name and Anatomical Therapeutic Chemical (ATC) classification of ingredients using the World Health Organization (WHO) Drug dictionary (WHO-DDE).

Counts and percentages will be provided to summarize the use of concomitant medications other than the study drug reported throughout the study. The number and percent of subjects who took other therapy will be shown by ATC level 2 term and preferred name. Medications which start prior to first application will be considered prior medications. Ongoing medications and medications ending after the date of first application will be considered concomitant medications. Incomplete start and end dates which could be either prior to first application or after first application will be considered prior to first application.

A by-subject listing of all prior and concomitant medications will be presented.

6.7 Concomitant Antibiotic Therapies

Concomitant antibiotic therapies will be determined by the sponsor prior to database lock.

Counts and percentages will be provided to summarize the use of concomitant antibiotic therapies reported throughout the study. The number and percent of subjects who took concomitant antibiotic therapies will be shown by ATC level 2 term and preferred name.

A by-subject listing of all concomitant antibiotic therapies will be presented.

6.8 Analysis of Efficacy

The efficacy analyses will be performed using the ITT (primary) and PP (supportive) analysis sets. The lesion count and IGA analyses will employ the methods for handling missing data as described by Section 6.1.5. Lesion count and IGA data will also be shown in by-subject listings.

6.8.1 Primary Efficacy Analysis

Absolute change from Baseline to Day 84 in inflammatory lesion counts will be analyzed using either parametric or non-parametric methods consistent with the statistical assumptions required to support the analyses. Specifically, the tests of superiority will be based on an ANCOVA with factors of treatment (with the vehicle treatment groups combined) and the respective Baseline lesion count as a covariate, or on ranked data submitted to an ANCOVA with factors of treatment and the respective Baseline lesion count as a covariate.

A skewness test, based on the methods presented by J.H. Zar (1984), will be applied to the residuals resulting from an ANCOVA. A two-sided p-value for the skewness test significant at 0.01 will imply the use of the non-parametric method. If a parametric analysis is indicated, the results of the parametric analysis will be considered the primary analysis. Should a non-parametric analysis be indicated, the absolute changes in inflammatory lesions will be rank transformed prior to submitting them to the ANCOVA. Results of the rank-transformed analyses then will be considered the primary analysis; however, results of the non-ranked transformed analyses will also be presented.

6.8.2 Secondary Efficacy Analysis

6.8.2.1 Lesion Counts

The absolute change from Baseline in non-inflammatory lesion count at Day 84 will be summarized similarly as absolute change from Baseline for inflammatory lesion count (primary efficacy endpoint). Percent change from Baseline to Day 84 in inflammatory and non-inflammatory lesion counts will be analyzed using the same ANCOVA method described for the primary endpoint.

6.8.2.2 Investigator Global Assessment

The proportion of subjects with at least a 2-grade reduction from the Baseline IGA score at Day 84 will be analyzed with logistic regression. Pairwise tests will be conducted comparing the treated groups to a combined vehicle. The proportion of subjects with an IGA score of “clear” or “almost clear” at Day 84 will be analyzed using the same logistic method as described above.

The IGA will be dichotomized into "success" and "failure", with a subject considered a "success" at each individual visit if the IGA at that visit is Clear ("0") or Almost Clear ("1") and at least 2 grades less than the Baseline score. The proportion of subjects who are dichotomized to success at Day 84 will be analyzed using the same logistic method as described above.

6.8.3 Exploratory Efficacy Analysis

6.8.3.1 Lesion Counts

The absolute and percent change from Baseline in the total lesion count at Day 84 will be summarized with descriptive statistics.

Additional comparisons between vehicle BID to BTX 1503 BID and vehicle QD to each BTX 1503 QD group for the absolute and percent change from Baseline to Day 84 in inflammatory and non-inflammatory lesion counts will be analyzed using either parametric or non-parametric methods consistent with the approach used for the primary endpoint using an ANCOVA with factors of treatment where no treatment groups are combined and the respective Baseline lesion count as a covariate or on ranked data submitted to an ANCOVA with factors of treatment where no treatment groups are combined and the respective Baseline lesion count as a covariate.

A further comparison will be made between vehicle QD to a combined BTX 1503 QD group for the absolute and percent change from Baseline to Day 84 in inflammatory and non-inflammatory lesion counts using an ANCOVA with factors of treatment where the two BTX 1503 QD treatment groups are combined and the respective Baseline lesion count as a covariate or on ranked data submitted to an ANCOVA with factors of treatment where the two BTX 1503 QD treatment groups are combined and the respective Baseline lesion count as a covariate.

The absolute and percent change from Baseline in inflammatory, non-inflammatory, and total lesion counts will be summarized at Day 14, Day 28, and Day 56. The absolute and percent change from Baseline in inflammatory, non-inflammatory, and total lesion counts at Day 14, Day 28, and Day 56 will be analyzed using the same ANCOVA method used for the primary endpoint as well as the additional testing described above in this section.

6.8.3.2 Investigator Global Assessment

The dichotomized IGA success at Day 84 will be analyzed with an additional logistic regression analysis where no treatment groups are combined. Pairwise tests will be conducted comparing the vehicle BID to BTX 1503 BID and comparing the vehicle QD to each BTX 1503 QD group. The dichotomized IGA success at Day 84 will additionally be analyzed with a logistic regression

where the two BTX 1503 QD treatment groups are combined. Pairwise tests will be conducted comparing the vehicle QD to BTX 1503 QD combined.

The change from Baseline in the IGA scores at Day 14, Day 28, Day 56, and Day 84 will be summarized with descriptive statistics. The proportion of subjects who are dichotomized to success at Day 14, Day 28, and Day 56 will be summarized with proportions. The dichotomized success at Day 14, Day 28, and Day 56 will also be analyzed using the same logistic method as in the secondary efficacy analysis as well as the additional testing described above in this section.

6.8.3.3 Acne-QoL

The change from Baseline in the Acne-QoL domain scores at Day 84 will be summarized with descriptive statistics by domain score and treatment group. Domains for the Acne-QoL include Self-Perception, Role-Social, Role-Emotional, and Acne Symptoms. Responses will be coded numerically on a scale from 0 (‘extremely’ or ‘extensive’) to 6 (‘not at all’ or ‘none’) within each domain. All questions in each domain will be summed to get the total domain score.

Self-Perception includes Q1, Q2, Q3, Q6, and Q10; Role-Social includes Q11, Q12, Q13, and Q14; Role-Emotional includes Q4, Q5, Q7, Q8, and Q9; and Acne Symptoms includes Q15, Q16, Q17, Q18, and Q19 (Martin 2001).

Domain scores as well as individual question responses will be listed in a by-subject listing.

6.8.3.4 Patient Reported Outcome (PRO)

The PRO will be summarized with counts and percentages by treatment group.

PRO results will also be shown in a by-subject listing.

6.9 Sensitivity Analyses

A sensitivity analysis will be performed using the ITT population. The primary and the first secondary endpoints (change from Baseline in inflammatory and non-inflammatory lesion counts) will be analyzed using a repeated measures ANCOVA, with treatment group and visit as independent factors and the Baseline value as a covariate.

```
proc mixed data = datain method = ML;
   class SUBJECT TRT VISIT;
   model CHG = TRT VISIT TRT * VISIT BASE / solution;
   repeated VISIT / subject = SUBJECT type = cs;
   lsmeans TRT | VISIT / diff;
run;
```

6.10 Safety Evaluation

6.10.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of days of exposure, total number of applications, number of missed applications, number and percentage of subjects who are compliant, average amount of study drug used per day (g/day), and amount of drug used total (g). A subject will be considered compliant with the dosing regimen if the subject applied 80% to 120% of the expected number of applications while enrolled in the study.

The total amount of study drug used will be calculated from the drug accountability using the recorded weights. The difference between the dispensed weight and the returned weight for each pump will be summed over all pumps to get the total amount of study drug used. The total amount of study drug used will be divided by the total number of exposure days to get the average amount of study drug used per day.

The total number of days of exposure is as follows:

> Date of Last Application – Date of First Application + 1.

It will be assumed the BID subjects were expected to have 2 applications on the Date of First Application. It will also be assumed the BID subjects were expected to have only 1 application on the Date of Last Application unless there is evidence to suggest otherwise (i.e. dosing deviation log indicates 2 doses were expected).

The total number of applications taken for BID subjects is as follows:

> 2 applications expected on Date of Last Application: 2*(Date of Last Application – Date of First Application + 1) – (Number of doses marked as missed on the CRF);
>
> 1 application expected on Date of Last Application: 2*(Date of Last Application – Date of First) + 1 – (Number of doses marked as missed on the CRF).

The total number of applications taken for QD subjects is as follows:

> (Date of Last Application – Date of First Application + 1) – (Number of doses marked as missed on the CRF).

The total number of applications expected for BID subjects is as follows:

> 2 applications expected on Date of Last Application: 2*(Date Subject Ended Participation – Date of Randomization + 1);

1 application expected on Date of Last Application: 2*(Date Subject Ended Participation – Date of Randomization) + 1.

The total number of applications expected for QD subjects is as follows:

Date Subject Ended Participation – Date of Randomization + 1.

If the total number of applications for BID subjects exceeds 178 then it will be set to 178.

If the total number of applications for QD subjects exceeds 89 then it will be set to 89.

Compliance will be calculated as a percentage as 100 times the total number of applications taken divided by the total number of applications expected while enrolled in the study.

6.10.2 Adverse Events

All AEs that occur during the study will be recorded and classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Treatment-emergent AEs (TEAEs) are defined as AEs with an onset on or after the date of the first study drug application. Adverse events noted prior to the first study drug administration that worsen after Baseline will also be reported as AEs and included in the summaries.

An overall summary of TEAEs will be presented showing the number of subjects reporting at least one TEAE, number reporting at least one SAE, number reporting at least one TEAE leading to study discontinuation, and number of TEAEs by severity and by relationship for each treatment group. The total number of AEs will also be presented as part of the overall summary of TEAEs. Treatment-emergent AEs will be summarized by system organ class and preferred name. Serious TEAEs, Related TEAEs, Severe TEAEs, and TEAEs leading to study discontinuation will also be summarized by system organ class and preferred name.

In addition, a listing of all AEs, a listing of Serious AEs, and a listing of subjects who prematurely discontinue from the study due to an AE will be provided.

No statistical inference between treatments will be performed on AEs.

6.10.2.1 Drug Abuse and Liability Assessments

Adverse events associated with potential abuse or overdose will be recorded and classified by MedDRA System Organ Classifications (SOC) and MedDRA Preferred Terms (PTs) as outlined in the Safety Management Plan. The incidence of abuse related AEs will be summarized by treatment group using frequency counts and percentages.

A by-subject listing of abuse related AEs will also be presented.

6.10.3 Clinical Laboratory Evaluation

Laboratory test results will be summarized with descriptive statistics at Baseline and Day 84. Additionally, shifts from Baseline to Day 84 in laboratory test results based on normal ranges will be summarized with frequency counts and percentages. Individual laboratory test results as well as pregnancy test results will be presented in a by-subject listing.

6.10.4 Other Observations Related to Safety

6.10.4.1 Cutaneous Tolerability Assessments

Cutaneous tolerability (erythema, scaling, dryness, pruritus, and burning/stinging) will be summarized at each visit using counts and percentages by treatment group. In addition, worst post-Baseline grade will be summarized by treatment group using counts and percentages. Any incident of mild, moderate, or severe post-Baseline results will be summarized by treatment group using counts and percentages.

6.10.4.2 Physical Examination

Physical examination data will be presented in a by-subject listing.

7. DETERMINATION OF SAMPLE SIZE

The sample size for this study is based on clinical considerations only. Subjects will be randomized 2:2:2:1:1 with 90 subjects in each active treatment group and 45 subjects in each vehicle group for a total 360 subjects. This is considered adequate to evaluate the safety and tolerability of BTX 1503 in the treatment of acne vulgaris.

8. CHANGES IN THE PLANNED ANALYSES

There are no changes in the conduct of the study or planned analyses.

9. REFERENCES

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4. Strauss JS, Krowchuk DP, Leyden JJ, Lucky AW, Shalita AR, Siegfried EC et al. Guidelines of care for acne vulgaris management. *Journal of the American Academy of Dermatology* 2007;56:651-6

5. Olah A, Toth B, Borbiro I, et al, Cannabidiol exerts sebostatic and anti-inflammatory effects on human sebocytes, J Clin Invest 2014; 124(9); 3713-3724

6. van Klingeren B, ten Ham M, Antibacterial activity of Δ9-tetrahydrocannabionol and cannabidiol *Antoine van Leeuwenhoek* 1976; 42: 9-12

10. INDEX OF PLANNED TABLES

Table 14.0.1: Summary of Subject Completion/Discontinuation
(Randomized Subjects)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Completed Study							
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation from Study							
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Worsening Condition	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2: Summary of Subjects Excluded from Analyses
(Randomized Subjects)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Number of Subjects Included in the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Safety Population							
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Post Baseline Assessment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the PP Population							
Violated the Inclusion/Exclusion Criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Received an Interfering Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Has not been Compliant with the Dosing Regimen	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missed IGA or Lesion Count assessment at Day 84	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missed Both Day 28 and Day 56 Visits	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Compliant with Dosing Regimen	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 84 Visit not within +/- 5 days Window	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other[a]							

[a] See Listing 16.2.3 for a complete list of all other reasons for exclusion from the PP population.
Note: ITT exclusion of not being randomized not presented due to requirement of needing to be randomized to be summarized in the table.
Percentages are based on the number of randomized subjects.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.3: Summary of Reasons for Screen Failure
(Non-Randomized Subjects)

	Total (N=xx)
Reason for Screen Failure	
Adverse Event	xx (xx.x%)
Inclusion and/or Exclusion Criteria	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)
Withdrawal by Legally Authorized Representive	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)
Other	xx (xx.x%)

Note: Percentages are based on the number of non-randomized subjects.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(ITT Population)
(Page 1 of 2)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Age (years)							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Sex							
n	xx	xx	xx	xx	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity							
n	xx	xx	xx	xx	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Percentages are based on the number of subjects in the ITT population with a non-missing response.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(ITT Population)
(Page 2 of 2)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Race							
n	xx	xx	xx	xx	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Percentages are based on the number of subjects in the ITT population with a non-missing response.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.1.1 for the following:

Table 14.1.1.2: Summary of Subject Demographics (PP Population)
Table 14.1.1.3: Summary of Subject Demographics (Safety Population)

Table 14.1.2.1: Summary of Baseline Characteristics
(ITT Population)
(Page 1 of 3)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Height (cm)							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg)							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Alcohol History							
n	xx	xx	xx	xx	xx	xx	xx
Drinker	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-drinker	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Smoking History							
n	xx	xx	xx	xx	xx	xx	xx
Non-smoker	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ex-smoker	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Smoker	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Baseline Characteristics
(ITT Population)
(Page 2 of 3)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Inflammatory Lesion Count							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Non-Inflammatory Lesion Count							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Total Lesion Count							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Baseline Characteristics
(ITT Population)
(Page 3 of 3)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Investigator Global Assessment							
n	xx	xx	xx	xx	xx	xx	xx
Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.2.1 for the following:

Table 14.1.2.2: Summary of Baseline Characteristics (PP Population)
Table 14.1.2.3: Summary of Baseline Characteristics (Safety Population)

Table 14.1.3.1: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Name
(ITT Population)

ATC Level 2 Term Preferred Name[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Subjects with at Least One Concomitant Medication Reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name x	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…							

[a] WHO-DDE, Format B2, Version MAR 2017.
Note: Concomitant medications are those used on or after the date of first application of study medication.
Percentages are based on the number of subjects in each treatment group in the ITT population.
Subjects are only counted once per ATC Level 2 Term and once per Preferred Name.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.3.1 for the following:

Table 14.1.3.2: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Name (PP Population)
Table 14.1.3.3: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Name (Safety Population)

Table 14.1.4.1: Summary of Concomitant Antibiotic Therapies by ATC Level 2 Term and Preferred Name
(ITT Population)

ATC Level 2 Term Preferred Name[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Subjects with at Least One Concomitant Antibiotic Therapy Reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name x	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…							

[a] WHO-DDE, Format B2, Version MAR 2017.
Note: Concomitant antibiotic therapies are those used on or after the date of first application of study medication
Percentages are based on the number of subjects in each treatment group in the ITT population.
Subjects are only counted once per ATC Level 2 Term and once per Preferred Name.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.4.1 for the following:

Table 14.1.4.2: Summary of Concomitant Antibiotic Therapies by ATC Level 2 Term and Preferred Name (PP Population)
Table 14.1.4.3: Summary of Concomitant Antibiotic Therapies by ATC Level 2 Term and Preferred Name (Safety Population)

Table 14.2.1.1: Primary Efficacy Endpoint: Summary of Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Skewness P-value
Change from Baseline in Inflammatory Lesion Counts							
n	xx	xx	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	
LSMean[a]			xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]			xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]				0.xxxx	0.xxxx	0.xxxx	

[a] Least squares mean, standard deviation, and contrast p-values from an analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
[b] Skewness test is based on methods presented by J.H. Zar (1984).
[c] Contrast p-values from a ranked analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.1.1 for the following:

Table 14.2.1.2: Primary Efficacy Endpoint: Summary of Absolute Change from Baseline in Inflammatory Lesion Count at Day 84 (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.1.3: Sensitivity Analysis of Primary Efficacy Endpoint: Summary of Absolute Change from Baseline in Inflammatory Lesion Count at Day 84 (ITT Population)

Repeated Measures Analysis on Observed Data	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
LSMean[a]			xx.x	xx.x	xx.x	xx.x
LSSD[a]			xx.xx	xx.xx	xx.xx	xx.xx
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values from a repeated measures analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group), visit, treatment by visit interaction, and corresponding baseline lesion count as the covariate.
Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 1 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Inflammatory Lesion Count < median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 2 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Non-Inflammatory Lesion Count < median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Non-Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 3 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Total Lesion Count < median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Total Lesion Count ≥ median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 4 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline IGA of 3 (Moderate)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline IGA of 4 (Severe)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 5 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Self-Perception Domain < median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Self-Perception Domain ≥ median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 6 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Role-Social Domain < median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Role-Social Domain ≥ median (xxx)						
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Role-Emotional Domain < median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Role-Emotional Domain ≥ median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 8 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Acne Symptoms < median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Acne Symptoms ≥ median (xxx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
			PRO: Improved			
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
			PRO: Same			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
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			PRO: Worsened			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
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	US					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

	AUS					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 12 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
			Male			
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
			Female			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 13 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Hispanic or Latino						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Non-Hispanic or Latino						
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 14 of 16)

	White					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

	Non-White					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 15 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Age 12 to < 18 years						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Age 18 to < 30 years						
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.3: Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population)
(Page 16 of 16)

	Age 30 to 40 years					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Responder Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 1 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Inflammatory Lesion Count < median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Responder Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 2 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Non-Inflammatory Lesion Count < median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Non-Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Responder Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 3 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Total Lesion Count < median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Total Lesion Count ≥ median (xx)						
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Responder Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 4 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
			Baseline IGA of 3 (Moderate)			
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
			Baseline IGA of 4 (Severe)			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Responder Subgroup Summary of the Primary Endpoint: Absolute Change from Baseline in Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 5 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
			Percent Compliance < median (xx.x%)			
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
			Percent Compliance ≥ median (xx.x%)			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.1: Secondary Efficacy Endpoint: Summary of Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Skewness P-value
Change from Baseline in Non-Inflammatory Lesion Counts							
n	xx	xx	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	
LSMean[a]			xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]			xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]				0.xxxx	0.xxxx	0.xxxx	

[a] Least squares mean, standard deviation, and contrast p-values from an analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
[b] Skewness test is based on methods presented by J.H. Zar (1984).
[c] Contrast p-values from a ranked analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.1.1 for the following:

Table 14.2.2.1.2: Secondary Efficacy Endpoint: Summary of Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84 (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.2.1.3: Sensitivity Analysis of Secondary Efficacy Endpoint: Summary of Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(ITT Population)

Repeated Measures Analysis on Observed Data	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
LSMean[a]			xx.x	xx.x	xx.x	xx.x
LSSD[a]			xx.xx	xx.xx	xx.xx	xx.xx
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values from a repeated measures analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group), visit, treatment by visit interaction, and corresponding baseline lesion count as the covariate.
Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Inflammatory Lesion Count < median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Non-Inflammatory Lesion Count < median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Non-Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Total Lesion Count < median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Total Lesion Count ≥ median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline IGA of 3 (Moderate)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline IGA of 4 (Severe)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
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	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Self-Perception Domain < median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Self-Perception Domain ≥ median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 6 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Role-Social Domain < median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Role-Social Domain ≥ median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 7 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Role-Emotional Domain < median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Role-Emotional Domain ≥ median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 8 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Acne Symptoms < median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Acne-QoL: Acne Symptoms ≥ median (xxx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 9 of 16)

			PRO: Improved			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

			PRO: Same			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
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			PRO: Worsened			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 11 of 16)

				US		
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

				AUS		
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 12 of 16)

	Male					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

	Female					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 13 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
			Hispanic or Latino			
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
			Non-Hispanic or Latino			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 14 of 16)

	White					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

	Non-White					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 15 of 16)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
			Age 12 to < 18 years			
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
			Age 18 to < 30 years			
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.4: Subgroup Summary of Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population)
(Page 16 of 16)

	Age 30 to 40 years					
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.5: Responder Subgroup Summary of the Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 1 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Inflammatory Lesion Count < median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.5: Responder Subgroup Summary of the Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 2 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Non-Inflammatory Lesion Count < median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Non-Inflammatory Lesion Count ≥ median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.5: Responder Subgroup Summary of the Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 3 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Total Lesion Count < median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Total Lesion Count ≥ median (xx)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.5: Responder Subgroup Summary of the Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 4 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline IGA of 3 (Moderate)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline IGA of 4 (Severe)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.5: Responder Subgroup Summary of the Secondary Efficacy Endpoint: Absolute Change from Baseline in Non-Inflammatory Lesion Count at Day 84
(PP Population - Responders)
(Page 5 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Percent Compliance < median (xx.x%)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Percent Compliance ≥ median (xx.x%)						
Change from Baseline in Non-Inflammatory Lesion Counts						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2.1: Secondary Efficacy Endpoint: Summary of Percent Change from Baseline in Inflammatory and Non-Inflammatory Lesion Count at Day 84
(ITT Population)
(Page 1 of 2)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Skewness P-value
Percent Change from Baseline in Inflammatory Lesion Counts							
n	xx	xx	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	
LSMean[a]			xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]			xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]				0.xxxx	0.xxxx	0.xxxx	

[a] Least squares mean, standard deviation, and contrast p-values from an analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
[b] Skewness test is based on methods presented by J.H. Zar (1984).
[c] Contrast p-values from a ranked analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2.1: Secondary Efficacy Endpoint: Summary of Percent Change from Baseline in Inflammatory and Non-Inflammatory Lesion Count at Day 84
(ITT Population)
(Page 2 of 2)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Skewness P-value
Percent Change from Baseline in Non-Inflammatory Lesion Counts							
n	xx	xx	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	
LSMean[a]			xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]			xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]				0.xxxx	0.xxxx	0.xxxx	

[a] Least squares mean, standard deviation, and contrast p-values from an analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
[b] Skewness test is based on methods presented by J.H. Zar (1984).
[c] Contrast p-values from a ranked analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.2.1 for the following:

Table 14.2.2.2.2: Secondary Efficacy Endpoint: Summary of Percent Change from Baseline in Inflammatory and Non-Inflammatory Lesion Count at Day 84 (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.2.3.1: Secondary Efficacy Endpoint: Summary of Dichotomized IGA at Day 84
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Treatment P-value
>= 2 Grade Reduction from Baseline in IGA							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	

[a] P-value from a logistic regression with factor of treatment group (vehicle treatment groups included as single combined treatment group).
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.3.1 for the following:

Table 14.2.2.3.2: Secondary Efficacy Endpoint: Summary of Dichotomized IGA at Day 84 (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 1 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Inflammatory Lesion Count < median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Inflammatory Lesion Count ≥ median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 2 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Non-Inflammatory Lesion Count < median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Non-Inflammatory Lesion Count ≥ median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 3 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Total Lesion Count < median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Total Lesion Count ≥ median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 4 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline IGA of 3 (Moderate)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline IGA of 4 (Severe)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 5 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Self-Perception Domain < median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Acne-QoL: Self-Perception Domain ≥ median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 6 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Role-Social Domain < median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Acne-QoL: Role-Social Domain ≥ median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 7 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Role-Emotional Domain < median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Acne-QoL: Role-Emotional Domain ≥ median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 8 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Acne-QoL: Acne Symptoms < median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Acne-QoL: Acne Symptoms ≥ median (xxx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 9 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
PRO: Improved						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
PRO: Same						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
PRO: Worsened						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 10 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
US						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
AUS						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 11 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Male						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Female						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 12 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Hispanic or Latino						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Non-Hispanic or Latino						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 13 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
White						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Non-White						
	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.3: Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population)
(Page 14 of 14)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Age 12 to < 18 years						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Age 18 to < 30 years						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Age 30 to 40 years						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.4: Responder Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population - Responders)
(Page 1 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Inflammatory Lesion Count < median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Inflammatory Lesion Count ≥ median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.4: Responder Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population - Responders)
(Page 2 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Non-Inflammatory Lesion Count < median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Non-Inflammatory Lesion Count ≥ median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.4: Responder Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population - Responders)
(Page 3 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline Total Lesion Count < median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline Total Lesion Count ≥ median (xx)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.4: Responder Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population - Responders)
(Page 4 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline IGA of 3 (Moderate)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Baseline IGA of 4 (Severe)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.4: Responder Subgroup Summary of Secondary Efficacy Endpoint: Dichotomized IGA at Day 84
(PP Population - Responders)
(Page 5 of 5)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Percent Compliance < median (xx.x%)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Percent Compliance ≥ median (xx.x%)						
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1						
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: Responder is defined as upper 80th percentile showing absolute reduction in inflammatory lesions from Baseline.
No imputations were made for missing data.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1.1: Exploratory Efficacy Endpoint: Summary of Inflammatory Lesion Count by Visit
(ITT Population)
(Page x of y)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1.1: Exploratory Efficacy Endpoint: Summary of Inflammatory Lesion Count by Visit
(ITT Population)
(Page x of y)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Day 14						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Change from Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Percent Change from Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[*Continue for Day 28, Day 56, and Day 84*]

Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.1.1 for the following:

Table 14.2.3.1.2: Exploratory Efficacy Endpoint: Summary of Inflammatory Lesion Count by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.2.1: Exploratory Efficacy Endpoint: Summary of Non-Inflammatory Lesion Count by Visit (ITT Population)

Table 14.2.3.2.2: Exploratory Efficacy Endpoint: Summary of Non-Inflammatory Lesion Count by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.3.1: Exploratory Efficacy Endpoint: Summary of Total Lesion Count by Visit (ITT Population)

Table 14.2.3.3.2: Exploratory Efficacy Endpoint: Summary of Total Lesion Count by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.4.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count at Day 84 (Comparing Dose Frequencies)
(ITT Population)
(Page 1 of 2)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Table 14.2.3.4.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count at Day 84 (Comparing Dose Frequencies)
(ITT Population)
(Page 2 of 2)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Repeat Table 14.2.3.4.1 for the following:

Table 14.2.3.4.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count at Day 84 (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.5.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Non-Inflammatory Lesion Count at Day 84 (Comparing Dose Frequencies) (ITT Population)

Table 14.2.3.5.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Non-Inflammatory Lesion Count at Day 84 (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.6.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit
(ITT Population)
(Page 1 of 2)

	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Skewness P-value
Change from Baseline in Inflammatory Lesion Counts					
Day 14					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]		0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]		0.xxxx	0.xxxx	0.xxxx	
Day 28					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]		0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]		0.xxxx	0.xxxx	0.xxxx	
Day 56					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]		0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]		0.xxxx	0.xxxx	0.xxxx	

[a] Least squares mean, standard deviation, and contrast p-values from an analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
[b] Skewness test is based on methods presented by J.H. Zar (1984).
[c] Contrast p-values from a ranked analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.6.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit
(ITT Population)
(Page 2 of 2)

	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Skewness P-value
Percent Change from Baseline in Inflammatory Lesion Counts					
Day 14					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]		0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]		0.xxxx	0.xxxx	0.xxxx	
Day 28					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]		0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]		0.xxxx	0.xxxx	0.xxxx	
Day 56					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	0.xxxx[b]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Combined Vehicle[a]		0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Combined Vehicle[c]		0.xxxx	0.xxxx	0.xxxx	

[a] Least squares mean, standard deviation, and contrast p-values from an analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
[b] Skewness test is based on methods presented by J.H. Zar (1984).
[c] Contrast p-values from a ranked analysis of covariance with factors of treatment group (vehicle treatment groups included as single combined treatment group) and corresponding baseline lesion count as the covariate.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.6.1 for the following:

Table 14.2.3.6.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.7.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Non-Inflammatory Lesion Count by Visit (ITT Population)

Table 14.2.3.7.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Non-Inflammatory Lesion Count by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.8.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Total Lesion Count by Visit (ITT Population)

Table 14.2.3.8.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Total Lesion Count by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.9.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies)
(ITT Population)
(Page 1 of 6)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
Day 14						
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Table 14.2.3.9.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies)
(ITT Population)
(Page 2 of 6)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
Day 28						
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Table 14.2.3.9.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies)
(ITT Population)
(Page 3 of 6)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
Day 56						
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Table 14.2.3.9.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies)
(ITT Population)
(Page 4 of 6)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
Day 14						
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Table 14.2.3.9.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies)
(ITT Population)
(Page 5 of 6)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
Day 28						
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Table 14.2.3.9.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies)
(ITT Population)
(Page 6 of 6)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)
Day 56						
LSMean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	
Unranked P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx	
Ranked P-value vs. Vehicle[b]			0.xxxx	0.xxxx	0.xxxx	
LSMean[c]	xx.x					xx.x
LSSD[c]	xx.xx					xx.xx
Unranked P-value vs. Vehicle[c]						0.xxxx
Ranked P-value vs. Vehicle[d]						0.xxxx

[a] Least squares mean, standard deviation, and contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from an analysis of variance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[b] Contrast p-values (BTX 1503 BID group compared to vehicle BID and each BTX 1503 QD group compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (no treatment groups combined) and corresponding baseline lesion count as the covariate.
[c] Least squares mean, standard deviation, and contrast p-values (BTX 1503 QD combined compared to vehicle QD) from an analysis of variance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion count as the covariate.
[d] Contrast p-values (BTX 1503 QD combined compared to vehicle QD) from a ranked analysis of covariance with factors of treatment group (BTX 1503 QD treatment groups combined) and corresponding baseline lesion counts as the covariate.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming Note: Only present Unranked if primary endpoint used parametric approach, only present ranked if primary endpoint used non-parametric approach. Adjust the footnotes as appropriate.

Repeat Table 14.2.3.9.1 for the following:

Table 14.2.3.9.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Inflammatory Lesion Count by Visit (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.10.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Non-Inflammatory Lesion Count by Visit (Comparing Dose Frequencies) (ITT Population)

Table 14.2.3.10.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Non-Inflammatory Lesion Count by Visit (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.11.1: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Total Lesion Count by Visit (Comparing Dose Frequencies) (ITT Population)

Table 14.2.3.11.2: Exploratory Efficacy Endpoint: Analysis of Absolute and Percent Change from Baseline in Total Lesion Count by Visit (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.12.1: Exploratory Efficacy Endpoint: Summary of IGA Score by Visit
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[Repeat for Day 14, Day 28, Day 56, and Day 84]

Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.12.1 for the following:

Table 14.2.3.12.2: Exploratory Efficacy Endpoint: Summary of IGA Score by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.13.1: Exploratory Efficacy Endpoint: Analysis of Dichotomized IGA at Day 84 (Comparing Dose Frequencies)
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)	Treatment P-value
>= 2 Grade Reduction from Baseline in IGA							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx		
P-value vs. Vehicle[b]						0.xxxx	
IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failuire	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx		
P-value vs. Vehicle[b]						0.xxxx	
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx		
P-value vs. Vehicle[b]						0.xxxx	

[a] P-value from a logistic regression with factor of treatment group (no treatment groups combined) where BTX 1503 BID group is compared to vehicle BID and each BTX 1503 QD group is compared to vehicle QD.
[b] P-value from a logistic regression with factor of treatment group (BTX 1503 QD treatment groups combined) where BTX 1503 combined QD group is compared to vehicle QD.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.13.1 for the following:

Table 14.2.3.13.2: Exploratory Efficacy Endpoint: Analysis of Dichotomized IGA at Day 84 (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.14.1: Exploratory Efficacy Endpoint: Analysis of Dichotomized IGA by Visit
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	Treatment P-value
Day 14							
>= 2 Grade Reduction from Baseline in IGA							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Combined Vehicle[a]				0.xxxx	0.xxxx	0.xxxx	

[*repeat for Day 28 and Day 56*]

[a] P-value from a logistic regression with factor of treatment group (vehicle treatment groups included as single combined treatment group).
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.14.1 for the following:

Table 14.2.3.14.2: Exploratory Efficacy Endpoint: Analysis of Dichotomized IGA by Visit (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.15.1: Exploratory Efficacy Endpoint: Analysis of Dichotomized IGA by Visit (Comparing Dose Frequencies)
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 QD Combined (N=xx)	Treatment P-value
Day 14							
>= 2 Grade Reduction from Baseline in IGA							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx		
P-value vs. Vehicle[b]						0.xxxx	
IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failuire	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx		
P-value vs. Vehicle[b]						0.xxxx	
>= 2 Grade Reduction from Baseline and IGA Grade of 0 or 1							0.xxxx[a]
Success	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	
P-value vs. Vehicle[a]			0.xxxx	0.xxxx	0.xxxx		
P-value vs. Vehicle[b]						0.xxxx	

[*repeat for Day 28 and Day 56*]

[a] P-value from a logistic regression with factor of treatment group (no treatment groups combined) where BTX 1503 BID group is compared to vehicle BID and each BTX 1503 QD group is compared to vehicle QD.
[b] P-value from a logistic regression with factor of treatment group (BTX 1503 QD treatment groups combined) where BTX 1503 combined QD group is compared to vehicle QD.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.15.1 for the following:

Table 14.2.3.15.2: Exploratory Efficacy Endpoint: Analysis of Dichotomized IGA by Visit (Comparing Dose Frequencies) (PP Population)
Programming note: replace last footnote with:
Note: No imputations were made for missing data.

Table 14.2.3.16.1: Exploratory Efficacy Endpoint: Summary of Acne Patient Self-Questionnaire
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Self-Perception						
Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 84						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Change from Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[*Repeat for Role-Social, Role-Emotional, and Acne Symptoms*]

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.16.1 for the following:

Table 14.2.3.16.2: Exploratory Efficacy Endpoint: Summary of Acne Patient Self-Questionnaire (PP Population)

Table 14.2.3.17.1: Exploratory Efficacy Endpoint: Summary of Patient Reported Outcome
(ITT Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Compared to the beginning of treatment, my acne is:						
n	xx	xx	xx	xx	xx	xx
Much Better	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Slightly Better	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
The Same	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Slightly Worse	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Much Worse	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.17.1 for the following:

Table 14.2.3.17.2: Exploratory Efficacy Endpoint: Summary of Patient Reported Outcome (PP Population)

Table 14.3.0.1: Summary of Extent of Exposure
(Safety Population)
(Page 1 of 2)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Exposure (Days)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Amount of Study Drug Used Total (g)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Average Amount of Study Drug Used Per Day (g/day)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[a] Compliant with the dosing regimen is if the subject applied at least 80% but no more than 120% of expected applications while enrolled in the study.
[b] Percentages based on the number of subjects in the safety population with percent compliance calculated.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.0.1: Summary of Extent of Exposure
(Safety Population)
(Page 2 of 2)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)
Number of Applications					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Number of Missed Applications					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Percent Compliance					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Compliant[a]					
Yes[b]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No[b]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Compliant with the dosing regimen is if the subject applied at least 80% but no more than 120% of expected applications while enrolled in the study.
[b] Percentages based on the number of subjects in the safety population with percent compliance calculated.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.0.2.1: Summary of Cutaneous Tolerability Assessments
(Safety Population)
(Page x of y)

Burning/Stinging	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Baseline							
n	xx	xx	xx	xx	xx	xx	xx
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1 – 15 Mins Post-Dose							
n	xx	xx	xx	xx	xx	xx	xx
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 14 – Pre-Dose							
n	xx	xx	xx	xx	xx	xx	xx
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderare	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[*Repeat for Day 14 – 15 Mins Post-Dose, Day 56 – Pre-Dose, Day 56 – 15 Mins Post-Dose, Day 84 – Pre-Dose, and Day 84 – 15 Mins Post-Dose*]

[*Repeat for Pruritus, Erythema, Dryness, and Scaling*]

Note: Percentages are based on the number of subjects in each treatment group in the Safety population with a non-missing assessment at the given visit.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.0.2.2: Summary of Cutaneous Tolerability Assessments Worst Post-Baseline Grades
(Safety Population)
(Page x of y)

Worst Post-Baseline Grade	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Burning/Stinging							
n	xx	xx	xx	xx	xx	xx	xx
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pruritus							
n	xx	xx	xx	xx	xx	xx	xx
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Erythema							
n	xx	xx	xx	xx	xx	xx	xx
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[*Repeat for Dryness and Scaling*]

Note: Percentages are based on the number of subjects in each treatment group in the Safety population with at least one post-baseline assessment for the given category.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.0.2.3: Summary of Mild, Moderate, or Severe Post-Baseline Cutaneous Tolerability Assessments
(Safety Population)
(Page x of y)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Post-Baseline							
n	xx	xx	xx	xx	xx	xx	xx
Burning/Stinging	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pruritus	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Erythema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Dryness	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scaling	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Percentages are based on the number of subjects in each treatment group in the Safety population with at least one post-baseline assessment.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Number (%) of Subjects Reporting At Least One Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events	xx	xx	xx	xx	xx	xx	xx
Number (%) of Subjects Reporting At Least One Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events	xx	xx	xx	xx	xx	xx	xx
Number (%) of Subjects who Discontinued Study Due to At Least One Treatment-Emergent Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events Leading to Discontinuation of Study	xx	xx	xx	xx	xx	xx	xx
Maximum Severity							
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongest Relationship to Study Drug							
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first application of study drug.
Percentages are based on the number of subjects in each treatment group in the Safety population.
Related adverse events include possibly, probably, and definitely responses to relationship to study drug question.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of y)

System Organ Class[a] Preferred Term	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
System Organ Class 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term x	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

…

[a] At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: MedDRA Version 20.0.
Treatment-emergent adverse events are those with an onset on or after the date of first application of study drug.
Percentages are based on the number of subjects in each treatment group in the Safety population.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.1.2 for the following:

Table 14.3.1.1.3: Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.1.4: Summary of Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)
Programming note: Add footnote –
Related adverse events include possibly, probably, and definitely responses to relationship to study drug question.

Table 14.3.1.1.5: Summary of Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.1.6: Summary of Treatment-Emergent Adverse Events Leading to Study Discontinuation by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.1.7: Summary of Treatment-Emergent Abuse-Related Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.2.1.1: Summary of Chemistry Results by Visit
(Safety Population)
(Page 1 of y)

Test Name (*Units*)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Baseline							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 84							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Change from Baseline							
n	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min., Max.	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[*repeat for each test*]

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Programming note: Chemistry tests include: Glucose, Albumin, Total Protein, Calcium, Sodium, Potassium, Chloride, CO_2 (bicarbonate), BUN, Creatinine, Alkaline Phosphatase, ALT, AST, and Total Bilirubin. Test names will be standardized to CDISC Controlled Terminology.

Table 14.3.1.2.1.2: Shift Table for Chemistry Results
(Safety Population)
(Page 1 of y)

Test Name (*Units*)		Baseline (N=xx)		
Vehicle QD (N=xx)	Day 84 (N[a]=xx)	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Vehicle BID (N=xx)	Day 84 (N[a]=xx)			
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Vehicle Combined (N=xx)	Day 84 (N[a]=xx)			
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Number of subjects with both Baseline and Day 84 results for the given treatment group.
Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
Percentages are based on the number of subjects in the Safety population with both Baseline and Day 84 results.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1.2: Shift Table for Chemistry Results
(Safety Population)
(Page 2 of y)

Test Name (*Units*)		Baseline		
BTX 1503 5% BID (N=xx)	Day 84 (N[a]=xx)	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
BTX 1503 5% QD (N=xx)	Day 84 (N[a]=xx)			
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
BTX 1503 2.5% QD (N=xx)	Day 84 (N[a]=xx)			
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
BTX 1503 Combined (N=xx)	Day 84 (N[a]=xx)			
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[*Repeat for all tests*]

[a] Number of subjects with both Baseline and Day 84 results for the given treatment group.
Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
Percentages are based on the number of subjects in the Safety population with both Baseline and Day 84 results.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.2.1.1 for the following:

Table 14.3.1.2.2.1: Summary of CBC Results by Visit (Safety Population)

Programming note: CBC tests include: WBC (with differentials for ANC, Lymphocytes, monocytes, eosinophils, and basophils), RBC, Hemaglobin, Hematocrit, MCV, MCH, MCHC, and Platelet Count. Test names will be standardized to CDISC Controlled Terminology.

Repeat Table 14.3.1.2.1.2 for the following:

Table 14.3.1.2.2.2: Shift Table for CBC Results (Safety Population)

Repeat Table 14.3.1.2.1.1 for the following:

Table 14.3.1.2.3.1: Summary of Numeric Urinalysis Results by Visit (Safety Population)

Repeat Table 14.3.1.2.1.2 for the following:

Table 14.3.1.2.3.2: Shift Table for Numeric Urinalysis Results (Safety Population)

Table 14.3.1.2.3.3: Summary of Character Urinalysis Results by Visit
(Safety Population)
(Page 1 of y)

Test Name (*Units*)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Vehicle Combined (N=xx)	BTX 1503 5% BID (N=xx)	BTX 1503 5% QD (N=xx)	BTX 1503 2.5% QD (N=xx)	BTX 1503 Combined (N=xx)
Baseline							
n	xx	xx	xx	xx	xx	xx	xx
xxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 84							
n	xx	xx	xx	xx	xx	xx	xx
xxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[*repeat for each test*]

Note: Percentages are based on the number of subjects in the Safety population with a non-missing result for the given test and visit.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

11. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Randomization Scheme
(Page xx of yy)

Subject	Age/Sex	Evaluable	Randomization Number	Randomization Date	Assigned Treatment Group	Kit Dispensed at Baseline
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxx-xx-xx	xxxxxxx xxxxxx xxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxx-xx-xx	xxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxx-xx-xx	xxxxxxx xxxxxx xxxx	xxxxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.1.1: Subject Disposition Information
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date (Day)[1] of Last Dose	Completion Status	E: Date (Day)[1] of Completion/Discontinuation R: Reason for Study Discontinuation	Additional Information[2]
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxx xxxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxx xxxxxxx xxxxxxx	Cause of Death: xxxxxxxxxxxxx Date of Death: xxxx-xx-xx If Lost to follow-up date of last contact: xxxx-xx-xx Lost to follow-up comment: xxxxxxx xxxxx Date the blind was broken: xxxx-xx-xx Reason for breaking the blind: xxxxxx xxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxx xxxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxx xxxxxxx xxxxxxx	Cause of Death: xxxxxxxxxxxxx Date of Death: xxxx-xx-xx If Lost to follow-up date of last contact: xxxx-xx-xx Lost to follow-up comment: xxxxxxx xxxxx Date the blind was broken: xxxx-xx-xx Reason for breaking the blind: xxxxxx xxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Additional information is collected on a conditional basis, all information collected is included in the listing.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.1.2: Discontinued Subjects
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date (Day)[1] of Last Dose	Completion Status	E: Date (Day)[1] of Completion/Discontinuation R: Reason for Study Discontinuation	Additional Information[2]
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxx xxxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxx xxxxxxx xxxxxxx	Cause of Death: xxxxxxxxxxxxx Date of Death: xxxx-xx-xx If Lost to follow-up date of last contact: xxxx-xx-xx Lost to follow-up comment: xxxxxxx xxxxx Date the blind was broken: xxxx-xx-xx Reason for breaking the blind: xxxxxx xxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx (xx)	xxxxx xxxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxx xxxxxxx xxxxxxx	Cause of Death: xxxxxxxxxxxxx Date of Death: xxxx-xx-xx If Lost to follow-up date of last contact: xxxx-xx-xx Lost to follow-up comment: xxxxxxx xxxxx Date the blind was broken: xxxx-xx-xx Reason for breaking the blind: xxxxxx xxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Additional information is collected on a conditional basis, all information collected is included in the listing.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.1.3: Screen Failures
(Page x of xx)

Subject	Age/Sex	Date of Screen Failure	Reason for Screen Failure
xxxxxxxxx	xxxx	xxxx-xx-xx	xxxxxxxxx xx xxxxxxx
xxxxxxxxx	xxxx	xxxx-xx-xx	xxxx xx xxxxxx xx
xxxxxxxxx	xxxx	xxxx-xx-xx	xxxxxxx xxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.2: Inclusion/Exclusion Criteria Not Met
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Study Visit D: Date	Inclusion/Exclusion Criteria not met	Reason eligibility criteria not met
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxx xxxxxxxx
		xxxxxx	xxxxx xxxxxxxx xx xxxxxxxx xxxxxxx
		xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxxx
		xxxxxx	xxxx xxx xxxxxxxxxxxxx xxxxxxx xxxxxxxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Criterion Failed.

Listing 16.2.3: Analysis Populations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Population	Included	Reason(s) Excluded
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Population (as ordered above).

Listing 16.2.4.1: Subject Demographic Information
Treatment Group
(Page xx of yy)

Subject	Evaluable	B: Date of Birth A: Age S: Sex	R: Race E: Ethnicity	I: Date of Informed Consent A: Date of Assent	Childbearing Potential	Photography Consent	Protocol Version
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	I: xxxx-xx-xx A: xxxx-xx-xx	xx	xxx	xxxxxxxxxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	I: xxxx-xx-xx A: xxxx-xx-xx		xxx	xxxxxxxxxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	I: xxxx-xx-xx A: xxxx-xx-xx	xxx	xx	xxxxxxxxxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.4.2.1: Unique Medical History Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Medical History Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by System Organ Class, Preferred Term, and Medical History.

Listing 16.2.4.2.2: Medical History
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Condition/Surgery Verbatim Term	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Start Date (Day)[1] E: End Date (Day)[1]
xxxxxx	xxxx	xxxxxxxx	xxxxxx xxxxxxx xxxxxxxxxxxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxx-xx-xx (xx) E: xxxxxxx
			xxxxxxxx xxxxxxxxxx	P: xxxxxxx xxxxxxxx S: xxxxxxxx xxx xxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: System Organ Class and Preferred Term map to MedDRA (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Medical Condition/Surgery, Start Date, and End Date.

Listing 16.2.4.2.3: Substance Use History
Treatment Group
(Page xx of yy)

			Alcohol History			Smoking History			
Subject	Age/Sex	Evaluable	Status	Type of Alcohol[2]	Number of Units[1] consumed per week	Status	Smoking Type[3]	Number per day	End Date for Ex-Smoker
xxxxxx	xxxx	xxxxx	DRINKER	Wine	x	EX-SMOKER			xxxx-xx-xx
				Beer	x				
				Spirits	x				
xxxxxx	xxxx	xxxxxxxx	NON-DRINKER			NON-SMOKER			
xxxxxx	xxxx	xxxxxxxx	NON-DRINKER			SMOKER	Cigarettes	x	
							E-Cigarettes	x	
							Cigars	x	
							Pipes	x	
							Smokeless tobacco	x	
xxxxxx	xxxx	xxxxx	DRINKER	Wine	x	SMOKER	Cigarettes	x	
				Beer	x		E-Cigarettes	x	
				Spirits	x		Cigars	x	
							Pipes	x	
							Smokeless tobacco	x	

[1] Number of units consumed per week (1 unit = 150 mL wine, 360 mL beer, 45 mL spirits)
[2] Type of Alcohol is collected on a conditional basis, if "DRINKER", then the number of units consumed per week is collected for each type of alcohol.
[3] Smoking Type is collected on a conditional basis, if "SMOKER", then the number of Cigaretts, E-Cigarettes, Cigars, Pipes, and Smokeless tobacco is collected on a per day basis.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.4.1: Unique Medication/Therapy Names Coded to WHO-DDE ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Preferred Name	Medication/Therapy Name	I: Indication R: Route
xxxxxx xxxxxx xx xxx	xxxxxxxxxx	xxxxxxxxxx	I: xxxxxxx xxxxxxxx R: xxxx
	xxxxxxx x	xxxxxx	I: xxxxxxx xxxxxxxx xxxxxxxxxxxx R: xxxx
	xxxxxxxxx	xxxxxxxxx	I: xxxxxxx xxxxxxxx xxxx xxxxx xxxxxxxx R: xxxx

Note: Preferred Name and ATC Level 2 Term map to the WHO-DDE MAR 2017.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by ATC Level 2 Term, Standardized Medication Name, Medication Name, Indication, and Route.

Listing 16.2.4.4.2: Prior and Concomitant Medications/Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medication/Therapy Name P: Standardized Name A: ATC Level 2 Term I: Indication	T: Prior/Concomitant S: Start Date/Time (Day)[1] E: End Date/Time (Day)[1]	D: Dose U: Units F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx S: xxxx-xx-xxTxx:xx:xx (xx) E: xxxx-xx-xxTxx:xx:xx (xx)	D: xx U: xx F: xxxx R: xxxxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx S: xxxx-xx-xxTxx:xx:xx (xx) E: xxxx-xx-xxTxx:xx:xx (xx)	D: xxxxx U: xx F: xx R: xxxx
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx S: xxxx-xx-xxTxx:xx:xx (xx) E: xxxxxxx	D: xxx U: xx F: xx R: xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: Standardized Medication Name and ATC Level 2 Term map to the WHO-DDE (Version MAR 2017).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route. If ongoing, include 'Ongoing' in place of End Date.

Listing 16.2.4.4.3: Unique Antibiotic Therapy Names Coded to WHO-DDE ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Preferred Name	Medication/Therapy Name	I: Indication R: Route
xxxxxx xxxxxx xx xxx	xxxxxxxxxx	xxxxxxxxxx	I: xxxxxxx xxxxxxxx R: xxxx
	xxxxxxx x	xxxxxx	I: xxxxxxx xxxxxxxx xxxxxxxxxxxx R: xxxx
	xxxxxxxxx	xxxxxxxxx	I: xxxxxxx xxxxxxxx xxxx xxxxx xxxxxxxx R: xxxx

Note: Preferred Name and ATC Level 2 Term map to the WHO-DDE MAR 2017.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by ATC Level 2 Term, Standardized Medication Name, Medication Name, Indication, and Route.

Listing 16.2.4.4.4: Concomitant Antibiotic Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medication/Therapy Name P: Standardized Name A: ATC Level 2 Term I: Indication	T: Prior/Concomitant S: Start Date/Time (Day)[1] E: End Date/Time (Day)[1]	D: Dose U: Units F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx S: xxxx-xx-xxTxx:xx:xx (xx) E: xxxx-xx-xxTxx:xx:xx (xx)	D: xx U: xx F: xxxx R: xxxxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx S: xxxx-xx-xxTxx:xx:xx (xx) E: xxxx-xx-xxTxx:xx:xx (xx)	D: xxxxx U: xx F: xx R: xxxx
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx S: xxxx-xx-xxTxx:xx:xx (xx) E: xxxxxxx	D: xxx U: xx F: xx R: xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: Standardized Medication Name and ATC Level 2 Term map to the WHO-DDE (Version MAR 2017).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route. If ongoing, include 'Ongoing' in place of End Date.

Listing 16.2.4.6: Physical Examination
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date of Exam	H: Height (cm) W: Weight (kg)	Body System Assessed	Result	Abnormal Description	Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	H: xxx W: xx	General Appearance	xxxxxxxxx		
			Cardiovascular	xxxxxxxxx		
			Neurological	xxxxxxxxxxx	xxxxxx xxxxxxxxx	
			Musculoskeletal	xxxxxxxxx		
			Extremities/Skin	xxxxxxxxx		
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	H: xxx W: xx	General Appearance	xxxxxxxxx		
			Cardiovascular	xxxxxxxxx		
			Neurological	xxxxxxxxx		
			Musculoskeletal			xxxxxxx xxxxx xxxx
			Extremities/Skin	xxxxxxxxxxx	xxxxxxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D:	H: W:				xxx xxx xxxx xx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Body System Assessed.

Listing 16.2.5.1: Study Drug Administration
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date/Time of Administration	Where was the Study Drug Administered?	Reason Not Administered
xxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
xxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxx	
			xxx xx		xxx xxxxxxxxxx	xx xxxxx xxxxxxxxxx
xxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxx	
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, visit, Date/Time.

Listing 16.2.5.3: Drug Accountability
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Kit Number	Date Dispensed	Date Returned	Pump ID	Dispensed Weight (units)	Returned Weight (units)
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
			xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
			xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
			xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx
						x	xx.xx	xx.xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Kit Number, Date Dispensed, Date Returned.

Listing 16.2.5.4: Dosing Compliance
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	D: Date of First Dose R: Date of Last Dose	Number of Days of Exposure	Calculated[1] Number of Doses	Amount of Study Drug Used (g)	Number of Missed Doses	Percent Complaint	Compliant?[2]
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxx-xx-xx R: xxxx-xx-xx	xx	xx	xxxx		xxx	xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxx-xx-xx R: xxxx-xx-xx	xx	xx	xxxx	x	xxx	xx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxx-xx-xx R: xxxx-xx-xx	xx	xx	xxxx		xxxx	xxx

[1] The total number of doses was calculated from the date of first dose and the date of last known dose minus the missed doses.
[2] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of the expected applications.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.5.5: Dosing Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date (Day)[1] of Missed Dose	Morning or Afternoon dose?	Reason for Missed Dose
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx (xx)	xx	xxxxx xxxxxxxxx xxxxxxxx
			xxxx-xx-xx (xx)	xx	xxxxxxxx
			xxxx-xx-xx (xx)	xx	xxxxxxx xx
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx (xx)	xx	xxxxxxxxx xxxxxxxxxxx xx xxxxx x xxxxxxx
			xxxx-xx-xx (xx)	xx	xxxxxxxxx xxxxxxxxxxx xx xxxxx x xxxxxxx
			xxxx-xx-xx (xx)	xx	xxxxxxxxx xxxxxxxxxxx xx xxxxx x xxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx (xx)	xx	xxxxxxx xx
			xxxx-xx-xx (xx)	xx	xxx xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.1: Lesion Count Evaluations
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date/Time E: Evaluator Initials	Lesion Category	Count	Change from Baseline	Percent Change from Baseline	Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxx	V: SCREENING D: xxxx-xx-xxTxx:xx:xx E: xx	Inflammatory	xx			
		Non-Inflammatory	xx			
		Total Lesions	xxx			
	V: BASELINE D: xxxx-xx-xxTxx:xx:xx E: xx	Inflammatory	xx			
		Non-Inflammatory	xx			
		Total Lesions	xxx			
	V: DAY 14 D: xxxx-xx-xxTxx:xx:xx E: xx	Inflammatory	xx	xx	xxx	
		Non-Inflammatory	xx	x	xxxx	
		Total Lesions	xx	xx	xxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.2: Investigator Global Assessment
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	Visit	Date/Time	Result	Two Grade Reduction from Baseline	Two Grade Reduction from Baseline and Achieving Clear or Almost Clear	Evaluator Initials or Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxx	SCREENING	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx			xxx
	BASELINE	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx			xxx
	DAY 14	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
	DAY 28	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
	DAY 56	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
	DAY 84	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
S: xxxxxx A: xxxx E: xxxxxxxx	SCREENING	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx			xxx
	BASELINE	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx			xxx
	DAY 14	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
	DAY 28	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
	DAY 56	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx
	DAY 84	xxxx-xx-xxTxx:xx:xx	x x xxxxxxxx	xx	xx	xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.3: Patient Reported Outcome Assessment
Treatment Group
(Page x of xx)

Subject	Age/Sex	Evaluable	Date of Assessment	Compared to the beginning of treatment, my acne is:	Reason Not Done
xxxxxxxxx	xxxx	xxxxxxxxxx	xxxx-xx-xx	xxxxx xxxxxxxx	
xxxxxxxxx	xxxx	xxxxxxxxxx	xxxx-xx-xx	xxxxxxx xxxxxxx	
xxxxxxxxx	xxxx	xxxxxxxxxx	xxxx-xx-xx	xxxxx xxxxxxxx	
xxxxxxxxx	xxxx	xxxxxxxxxx			xxxxx xxxxxxxx xxxxx
xxxxxxxxx	xxxx	xxxxxxxxxx	xxxx-xx-xx	xxxxx xxxxxxxx	
xxxxxxxxx	xxxx	xxxxxxxxxx	xxxx-xx-xx	xxx xxxxxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.4: Acne-QoL Questionnaire
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date/Time	AQOL Question	Result	Reason Not Done
S: xxxxxx A: xxx xx E: xxxxxxxx	V: xxxxxxxx D: xxxx-xx-xxTxx:xx:xx			xxxxxx xxxx xxx xxxx xx xxxxxx
S: xxxxxx A: xxx xx E: xxxxxxxx	V: xxxxxxxx D: xxxx-xx-xxTxx:xx:xx	5. xxxxxxxxxx xx xx xxx xxxx xxxxx xxx xxxxxxxxxxxx xxx xxx	xxxxx x xxx	
		6. xx xxx xxxx xxxx xxx xxx xxxxxxxxxxx xxx xxx xxxx xxxxxxx xx	xxxx x x	
		7. xx xx xxx xxxx xxxxx xxx xxxxxxxxxxxxxx xxxxxxx xxxxx xxxxx xxx xxx xxxx xxxxx xxxx xxxxxx xxxxx	xxx xx xxx	
		8. xx xx xxx xxxx xxxxx xxx xxxxx xxxx xxx xxxxx xxxxxx xxxxxx	xxx xx xxx	
		9. xx xx xxx xxxx xxxxx xxx xxxxxxx xxx xxx xxxx xx xxxxxx xx xxxx xxxxx xxx xxxxxxxx xxx xxxxxxxx xxxx xxxx xxxxxxx xx xxxx	x xxxx xxx	
		10. xx xx xxx xxxx xxxxx xxx xxxxxxxxxxx xxxx xxxx xxxxxxxxxxx xxx xxx xxxx xxxxxxx xx xxxx xxxxxx xxxxx	xxxxxx x	
		11. xx xx xxx xxxx xxxxx xxx xxxxxxxxx xx xxxxxxx xxxx xxx xxxxx xxxxxxx xxxx xxxx xxxxxxx xx xxxx xxxxxx xxxxx	xxxxxx x	
		12. xx xx xxx xxxx xxxxx xxx xxxxxxxxx xx xxxxxxx xxxx xxx xxxx xxxx xxxxxxxxxx xxxxxxxx xxxx xxxxxxx xxxx xxxxxx xx xxxxxxxx xx xxx xxxx xx xxxx xxxxx	xxxxxx x	
		13. xx xx xxx xxxx xxxxx xxx xxxxxxxx xxx xxx xxxx xxxxx xxx xxx xxxxxx xxxx xxxxxxxxxx xx xxxxxxxx xxxxxxxxx xxx xxx xxxx xx	xxxxx x	
		14. xxx xx xxx xxxx xxxxx xxx xxxx xxx xxxx xxxxxxxxxxxxxx xxxx xxxxxxxxx xxxxxxxxxx xxxxxxxx xxxxxxx xx xxxx xxxxxx xxxxx	xxxxxx xxx	
		15. xxx xx xxx xxxx xxxxx xxx xxxxxxxxx xx xxxxxxx xxxx xxx xxxx xxxxxxx xxx xxxxxx xxxxxxx xx xxxx xxxxxx xxxxx	xxxxxx xxx	
		16. xxx xx xxx xxxx xxxxx xxx xxxxxxxxx xx xxxxxxx xxxx xxx xxxx xxxxx xxx xx xxxxxx xxxxxxx xx xxxx xxxxxx xxxxx	xxx xx xxx	
		17. xxx xx xxx xxxx xxxxx xxx xxxx xxx xxxxxxxxxxx xxxx xxxxxx x xxxxxxx xxx xxx xxxxxxx xx xxxx xxxxxx xxxxx	x xxxxxx x	
		18. xxx xx xxx xxxx xxxxx xxx xxxx xxx xxxxxxxxxxx xxxx xxx xxxx	x xxxxxx x	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, AQOL Question.

Listing 16.2.6.5: Photography Information
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Were Photographs of the Face Obtained?	Reason Photographs Not Obtained	Date of Photograph
xxxxxx	xxxx	xxxxx	xxxxxxxx	xxx		xxxx-xx-xx
			xxxx xxxxxxxxx	xxx		xxxx-xx-xx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxx		xxxx-xx-xx
			xxxx xxxxxxxxx	xx	xxxxx xxxxxx xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxx		xxxx-xx-xx
			xxxx xxxxxxxxx	xxx		xxxx-xx-xx
xxxxxx	xxxx	xxxxx	xxxxxxxx	xxx		xxxx-xx-xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.1: Cutaneous Tolerability Assessment
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date of assessment E: Evaluator Initials	Timepoint	Assessment	Severity Grade[1]	Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxx-xx-xx E: xxx	Pre-Dose	Burning/Stinging	x	
			Dryness	x	
			Erythema	x	
			Pruritus	x	
			Scaling	x	
		15 Minutes Post-Dose	Burning/Stinging	x	
			Dryness	x	
			Erythema	x	
			Pruritus	x	
			Scaling	x	

[1] Grade 0 = None; Grade 1 = Slight; Grade 2 = Moderate; Grade 3 = Severe.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Timepoint, Assessment.

Listing 16.2.7.2.1: Unique Adverse Events Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxx xxxxxxxxx xxxxxx xxxxxxxxx	xxxxxxx	xxxxxx
		xxxxxx
	xxxxxxxxxxx	xxxxxxxxxxx
xxx xxx xxxxxxxxx xxxxxxxxx	xxxxxxx	xxxxxxx
xxx xxxxxxxxx	xxxxxx xxxxxx xxxxxxx	xxxxxxxxx xxxxxx xxxxxx
xxxxxxxxxxxxxxx xxxxxxxxx	xxxxxxxxx xxxx	xxxxxxxxx xxxx
	xxxxxxxxx xxxxxxxxxxx	xxxxx xxxxxxxxx xxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, Preferred Term, and Adverse Event.

Listing 16.2.7.2.2: Treatment-Emergent Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Adverse Event C: System Organ Class P: Preferred Term	S: Start Date (Day)[1] E: End Date (Day)[1]	S: Severity R: Relationship to Study Drug O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Medical Treatment Received?
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxx xxxxxxxx T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx xxxxxxxxx T: xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: System Organ Class and Preferred Term map to MedDRA (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Programming Notes: If an adverse event is indicated as serious the reason(s) for the event being serious will be listed under the R: Reason(s) for Serious column and serperated by a comma. Possible reason(s) include: Fatal, Life-threatening event, Hospitalization or prolongation of hospitalization, Persistent or significant disability/incapacity, Congenital Anomaly or Birth Defect, Important Medical Event.
Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.2.3: Serious Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Adverse Event C: System Organ Class P: Preferred Term	S: Start Date (Day)[1] E: End Date (Day)[1]	S: Severity R: Relationship to Study Drug O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Medical Treatment Received?
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxxxx xxxxx xxxxxxx T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxx xxxxxxxx T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx xxxxxxxxx T: xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: System Organ Class and Preferred Term map to MedDRA (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.2.4: Subjects Who Permanently Discontinued Study Drug and/or Discontinued from the Study Due to Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Adverse Event C: System Organ Class P: Preferred Term	S: Start Date (Day)[1] E: End Date (Day)[1]	S: Severity R: Relationship to Study Drug O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Medical Treatment Received?
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxxxx xxxxx xxxxxxx T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxx xxxxxxxx T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx xxxxxxxxx T: xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: System Organ Class and Preferred Term map to MedDRA (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.2.5: Unique Abuse-Related Adverse Events Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxx xxxxxxxxx xxxxxx xxxxxxxxx	xxxxxxx	xxxxxx
		xxxxxx
	xxxxxxxxxxx	xxxxxxxxxxx
xxx xxx xxxxxxxxx xxxxxxxxx	xxxxxxx	xxxxxxx
xxx xxxxxxxxx	xxxxxx xxxxxx xxxxxxx	xxxxxxxxx xxxxxx xxxxxx
xxxxxxxxxxxxxxx xxxxxxxxx	xxxxxxxxx xxxx	xxxxxxxxx xxxx
	xxxxxxxxx xxxxxxxxxxx	xxxxx xxxxxxxxx xxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, Preferred Term, and Adverse Event.

Listing 16.2.7.2.6: Treatment-Emergent Abuse-Related Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Adverse Event C: System Organ Class P: Preferred Term	S: Start Date (Day)[1] E: End Date (Day)[1]	S: Severity R: Relationship to Study Drug O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Medical Treatment Received?
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxx xxxxxxxx T: xxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx xxxxxxxxx T: xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: System Organ Class and Preferred Term map to MedDRA (Version 20.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Programming Notes: If an adverse event is indicated as serious the reason(s) for the event being serious will be listed under the R: Reason(s) for Serious column and serperated by a comma. Possible reason(s) include: Fatal, Life-threatening event, Hospitalization or prolongation of hospitalization, Persistent or significant disability/incapacity, Congenital Anomaly or Birth Defect, Important Medical Event.
Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.8.1: Urine Pregnancy Test Results
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date/Time	Results
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxxx xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxx xx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx
			xxxx xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date.

Listing 16.2.8.2: Urine Drug Screen Results
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date/Time	Results	Positive Drugs	Reason Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx	xxxxxxxxxxx	
			xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx		
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx		
			xxxxxxxxx				xxxxx xxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx		
			xxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xxxxxxxx	xxxxxxxxx xxxxxxx xxxxxxxxxxxxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Programming Notes: The Positive Drugs column will list all of the drugs that apply as positive or (Yes) for the drug screen, each separated by a comma. For example if the Result is Positive and the drug screen found Amphetamines and Methamphetamines as Positive then they will be listed as Amphetamines, Methamphetamines.
Listing sorted by Subject, Visit, Date.

Listing 16.2.8.2.1.1: Complete Blood Count Laboratory Test Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date/Time	Laboratory Test	Results (Units)	Reference Range Low	Reference Range High	Reference Range Indicator(CS[1])	Reason Not Done/ Comments
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx	xxxxxxxxxxxxxxxxx	xxx xxx	x	xx	xxxxxx xxxx	
		xxxxxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
		xxxxxxxxxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
		xxxxxxxxxxxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx	xxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
		xxxxxxxxxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
		xxxxxxxxxxxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
		xxxxxxxxxxxxxxxxx					xxx xxx xxxxx xxxxxxxxxx xxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx	xxxxxxxxxxxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxxx	
		xxxxxx xxxxxxxx	xxx xxxxxx	xx	xx	xxxxxx xxxx	
		xxxxxxxxxxxx	xxx xxx	x	xx	xxxxxx xxxx	
		xxxxxxxxxxxxxxxxx	xxx xxx	x	xx	xxxxxx xxxx	

[1] Clinically Significant per Investigator
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date/Time, and Lab Test.

Repeat Listing 16.2.8.2.1.1: for the following listings:

Listing 16.2.8.2.1.2: Chemistry Laboratory Test Results

Listing 16.2.8.2.1.3: Urinalysis Laboratory Test Results