STATISTICAL ANALYSIS PLAN

Protocol Number:	BTX.2018.003
Study Title:	A Randomized, Double-Blind, Vehicle-Controlled Study of the Safety, Tolerability and Efficacy of BTX 1204 in Patients with Moderate Atopic Dermatitis
Development Phase of Study:	2a
Sponsor:	Botanix Pharmaceuticals Ltd
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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	13DEC2019	Original document	Laura Cole

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AD	atopic dermatitis
AE(s)	adverse event(s)
ANCOVA	analysis of covariance
ATC	anatomical therapeutic chemical
AUS	Australia
BID	twice daily
BSA	Body Surface Area
CBC	Complete Blood Count
CBD	Cannabidiol
eCRF(s)	Electronic case report form(s)
CRO	Clinical research organization
g	grams
g/day	grams/day
IGA	Investigator's Global Assessment
IL	Interleukin
I-NRS	Itching-Numerical Rating Score
ITT	Intent-to-Treat
IWRS	Interactive Web-based Randomization System
kg	kilograms
LOCF	last observation carried forward
LSMean	least squares mean
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified Intent-to-Treat
n	number of observations
N	number of subjects (sample size)
NZ	New Zealand
PP	per-protocol
PT(s)	preferred term(s)
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)
US	United States
WHO-DDE	World Health Organization Drug Dictionary

2. INTRODUCTION

Atopic dermatitis (AD) is an inflammatory cutaneous disease which may co-exist with other immunoglobulin E (IgE)-dependent atopic diseases such as allergic rhinitis, bronchial asthma, and food allergy. [14] The disease is a skin disorder which presents itself as itchy, inflamed, red, and possibly lichenified (i.e. thickened) skin with affected areas potentially distributed widely over the body. [13] The pathogenesis of the disease is thought to involve an acute T-helper 2 (Th2) cell response followed by a chronic response involving additional T-helper populations; although more recent research suggests that Th2 cells and a more generalized T-cell response are present during both acute and chronic phases. [6] The importance of Th2 cells and interleukin (IL)-4 and IL-13 signaling in the disease is supported by the effectiveness of dupilumab, a human monoclonal antibody specific to IL-4Rα that can block IL-4 and IL-13 signaling, to improve many symptoms of AD including pruritus, and reduction in AD area and severity. [6]

Literature indicates that Cannabidiol (CBD) can inhibit the migration, proliferation and cell maturation processes involved in Th17, Th1, and Th2 immune responses. [9, 10, 11] These are considered critical immune pathways involved in the pathophysiology of AD. [8] CBD may have beneficial effects on AD due to direct antioxidant effects, and ability to improve antioxidant status in models of inflammation and autoimmune disease. [1, 2, 3, 4, 12, 5, 7, 11] Finally, CBD may also provide a therapeutic benefit for the treatment of AD by modulating the inflammatory response regulated by keratinocytes. CBD inhibited the production of monocyte chemotactic protein-2 (MCP-2), IL-6, IL-8, and tumor necrosis factor-α in polyinosinic-polycytidylic acid stimulated human keratinocyte (HaCaT) cells. [16] CBD has also been shown to directly inhibit the proliferation of keratinocytes. [17]

This study is the second study in evaluating the use of BTX 1204 4% (w/w) in subjects with AD.

Botanix Pharmaceuticals' BTX 1204 contains the active pharmaceutical ingredient, cannabidiol (CBD; 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol). CBD is a member of a broader family of compounds known as cannabinoids, a class of compounds originally derived from the cannabis sativa plant. [15]

The preliminary efficacy of BTX 1204 4% (w/w) was evaluated in a Phase 1b, randomized, double-blind, vehicle-controlled study. After only 4 weeks of treatment, subjects receiving BTX 1204 4% (w/w) had improvements in the Signs of AD score compared to treatment with Vehicle. A total of 34.8% of subjects receiving BTX 1204 had a ≥ 4-point improvement in the Signs of AD score compared to 18.2% of subjects receiving vehicle. Improvement was observed primarily in erythema, exudation and lichenification.

This study is intended to establish safety, tolerability and efficacy in subjects with moderate AD treated twice daily (BID) with BTX 1204 4% (w/w) Liquid Formulation compared to subjects treated with Vehicle for 12 weeks.

3. STUDY OBJECTIVES

The objective of this study is to determine the safety, tolerability and efficacy of BTX 1204 4% (w/w) in subjects with moderate atopic dermatitis.

4. STUDY DESIGN

4.1 Overall Study Design

This is a randomized, double-blind, vehicle-controlled, Phase 2a study in subjects with moderate AD. Approximately two hundred (200) subjects randomized 1:1 (100 active: 100 vehicle) will be enrolled.

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

- BTX 1204 4% BID, or
- Vehicle BID

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 112 days in duration; screening period (up to 28 Days), and 84 days of treatment. During the study, subjects will return to the study clinic at Days 15, 29, 57, and 84 (Study Exit).

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 6.3.9 of the protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

A randomization scheduled will be generated by a statistician(s) from QST Consultations, Ltd. (QST) Statistical Services department who is not associated with the day-to-day conduct of the study, using a validated system. The randomization list will not be stratified, but stratification by site will be accomplished within the 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 1:1 (100 active: 100 vehicle).

4.1.3 Blinding

Botanix, the clinical research organization (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, evaluability confirmed, and the study database locked will the randomization schedule be released 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 Botanix to discuss if there are options other than unblinding. If the site and Botanix 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

5.1.1 Primary Efficacy Endpoints

The primary efficacy endpoint for the study is:

- The proportion of subjects with Investigator Global Assessment (IGA) success defined as an IGA score of “Clear” (0) or “Almost Clear” (1) with at least a 2-grade improvement from Baseline at Day 85

5.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints for the study are:

- The change from Baseline in the total Signs of AD score at Day 85,
- The proportion of subjects with an IGA of Clear or Almost Clear at Day 85,
- The proportion of subjects with at least a 2-grade improvement in IGA from Baseline at Day 85,
- The change from Baseline in the percent of total body surface area (BSA) affected by AD at Day 85,
- The time to achieve IGA success, and
- The change from Baseline to Day 85 in the Itch-Numerical Rating Scale (I-NRS).

5.1.3 Exploratory Efficacy Endpoints

The exploratory endpoints for the study are:

- The change from Baseline in the total Signs of AD score at Day 15, Day 29, and Day 57,
- The change from Baseline in the percent of total BSA affected by AD at Day 15, Day 29, and Day 57
- The proportion of subjects with IGA success defined as an IGA score of "Clear: (0) or "Almost Clear" (1) with at least a 2-grade improvement from Baseline at Day 15, Day 29, and Day 57,
- The change from Baseline to Day 29 and Day 57, and Day 85 in the Signs of AD score for the target lesion (at selected sites only).

5.2 Safety Endpoints

Safety will be assessed through adverse events (AEs), complete blood count (CBC), chemistry, and urinalysis laboratory tests, and reports of burning/stinging obtained during visits on Day 1, Day 15, Day 29, Day 57, and Day 85 (within AEs).

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® 9.4 or higher. No interim analyses are planned. This Phase 2 study is designed to identify the response of BTX 1204 4.0% BID compared to Vehicle BID. Statistical tests 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 Intent-to-Treat (ITT) and modified Intent-to-Treat (mITT) analysis sets 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.

The efficacy analysis performed on the ITT population is considered the primary analysis. The efficacy analyses performed on the mITT and per-protocol (PP) populations are considered supportive analyses.

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 9.4 or later. All summary tables and data listings will be prepared utilizing SAS® software.

The standard operating procedures 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 for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Window (Days)
Day 15	15	9 to 21
Day 29	29	22 to 42
Day 57	57	43 to 70
Day 85	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. Efficacy and safety 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 total BSA affected by AD will be a covariate for the secondary efficacy endpoint, change from Baseline in total BSA affected by AD. Baseline Signs of AD total score will be a covariate for the secondary and exploratory efficacy endpoints change from Baseline in total Signs of AD. 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 and mITT analysis set will be based on LOCF. Summary of efficacy 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. Blinded subject data will be reviewed as it is generated to monitor for any safety signals and to ensure that the study is being appropriately executed.

6.1.7 Multicenter Studies

This study will be conducted at multiple investigational sites in the United States (US), Australia (AUS) and New Zealand (NZ) with the intention of pooling the results for analysis.

6.1.8 Multiple Comparisons/Multiplicity

This Phase 2a study is designed to identify the response to BTX 1204 relative to vehicle. Statistical tests applied to the outcomes will be exploratory. No adjustments for Type 1 error will occur.

6.1.9 Use of an Efficacy Subset of Subjects

One subset of interest is the mITT population. This subset is defined in order to better assess the effects of treatment on target areas; see Section 6.4.3 for definition.

Subjects randomized to study drug who complete the Day 85 visit without noteworthy study protocol violations, including compliance with study drug application, and completion of efficacy evaluations on Day 85 will form the PP population. Any noteworthy protocol violations will be defined at the time of evaluability evaluation, the time between the database soft lock and hard lock before unblinding.

Both mITT and PP analyses will allow for a further exploration of overall efficacy of BTX 1204.

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 mITT and PP analysis sets on the primary efficacy endpoint. These analyses will be summarized using descriptive statistics. The specific subsets within the mITT and PP analysis sets that will be evaluated include:

- Geographical region (US vs AUS/NZ);
- Gender (Male vs. Female);
- Ethnicity (Hispanic or Latino vs Non-Hispanic or Latino);
- Race (White vs Non-White)
- Age (12 to < 18 Years vs. 18 to < 30 Years vs. ≥30 Years)

6.2 Disposition of Subjects

The number of subjects included in each analysis population (randomized, ITT, mITT, safety, PP) will be summarized by treatment group. The number of subjects completed, and

discontinued (including the primary reasons for discontinuation) will be summarized for each treatment group.

Subjects who are excluded from an analysis population will be summarized by the primary 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 and summaries will be provided for all randomized subjects.

6.4.2 Intent-to-Treat Population

All subjects in the randomized population who receive at least one application of study drug and have at least one post-Baseline efficacy assessment 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 Modified Intent-to-Treat Population

All subjects in the ITT population with no new areas of AD post-Baseline compared to Baseline BSA areas of AD will be included in the mITT population and analyzed according to the randomized treatment group. All efficacy analyses will be presented using the mITT population as supportive.

6.4.4 Safety Population

All subjects who receive at least one application of study drug and have at least one post-Baseline safety assessment will be included in the Safety population and analyzed according to the treatment received. All safety analyses will be performed using the Safety population.

6.4.5 Per-Protocol Population

All subjects in the ITT population who complete the Day 85 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;
- Has missing IGA assessment at the Day 85 visit;
- Have missed both the Day 29 and Day 57 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 85 visit by ±7 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 with results considered as supportive.

6.5 Demographic and Other Baseline Characteristics

All Baseline summaries will be done on the ITT, mITT, 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.

Baseline total BSA affected by AD and duration of AD will be summarized with descriptive statistics. Baseline IGA will be summarized by counts and percentages.

The duration of AD will be calculated as follows:

Duration of AD = year of Baseline visit – year of AD diagnosis + 1.

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 WHO-DDE terminology.

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 Botanix 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 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), mITT (supportive), and PP (supportive) populations. The IGA, total BSA affected by AD, Signs of AD total score, and I-NRS analyses will employ the methods for handling missing data as described in Section 6.1.5. IGA, total BSA affected by AD, Signs of AD score, and I-NRS data will also be shown in by-subject listings.

6.8.1 Primary Efficacy Analysis

The proportion of subjects with IGA success defined as an IGA score of Clear (0) or Almost Clear (1) with at least a 2-grade improvement from Baseline at Day 85 will be analyzed using logistic regression with a term for treatment.

6.8.2 Secondary Efficacy Analysis

6.8.2.1 Signs of Atopic Dermatitis at Day 85

The Signs of AD total score will be calculated based on the sum of the score for each component (erythema, exudation, excoriation, induration/papulation, and lichenification). Each component will be scored as 0, 1, 2, or 3. The total score therefore ranges from 0 to a maximum score of 15.

The change from Baseline to Day 85 in the total Signs of AD score will be analyzed using analysis of covariance (ANCOVA) with Baseline Signs of AD as covariate and treatment as a factor.

6.8.2.2 Proportion of Subjects with an IGA of Clear (0) or Almost Clear (1) at Day 85

The proportion of subjects with an IGA of Clear (0) or Almost Clear (1) at Day 85 will be analyzed analogously to the primary endpoint.

6.8.2.3 Proportion of Subjects with at least a 2-Grade Improvement in IGA at Day 85

The proportion of subjects with at least a 2-grade improvement from Baseline at Day 85 will be analyzed analogously to the primary endpoint.

6.8.2.4 Percent of Total Body Surface Area Affected by Atopic Dermatitis at Day 85

The change from Baseline to Day 85 in percent of total BSA affected by AD will be analyzed using ANCOVA with Baseline total BSA affected by AD as covariate and treatment as a factor.

6.8.2.5 Time to Achieve IGA Success

Time to achieve IGA success will be summarized using the Kaplan-Meier method and displayed graphically. Medians, as well as 25% and 75% percentiles will be presented. Elapsed times will be computed from the date of first dose to the date of IGA assessment. Subjects not achieving the event by the time of completion/discontinuation will be right censored using the date of the last recorded non-missing assessment.

6.8.2.6 I-NRS at Day 85

The change from Baseline to Day 85 in the I-NRS score will be summarized with descriptive statistics.

Summary statistics will also be presented for the change from Baseline in I-NRS at each timepoint (Day 15, Day 29, Day 57 and Day 85). Additionally, summary statistics for I-NRS will be presented at each timepoint (Baseline, Day 15, Day 29, Day 57 and Day 85).

6.9 Exploratory Efficacy Analysis

6.9.1.1 Signs of Atopic Dermatitis at Days 15, 29 and 57

The change from Baseline in the Signs of AD total score for the target lesion at Day 15, Day 29, and Day 57 will be analyzed using ANCOVA with Baseline score as a covariate and treatment as a factor.

Summary statistics will also be presented for the change from Baseline in each of the Signs of AD scores (erythema, exudation, excoriation, induration/papulation, and lichenification) and total score at each timepoint (Day 15, Day 29, Day 57 and Day 85).

Summary statistics for each of the Signs of AD scores (erythema, exudation, excoriation, induration/papulation, and lichenification) and total score at each timepoint will be presented (Baseline, Day 15, Day 29, Day 57 and Day 85).

6.9.1.2 Percent of Total Body Surface Area Affected by Atopic Dermatitis at Days 15, 29 and 57

Change from Baseline in the percent of total BSA affected by AD at Days 15, 29, and 57 will be analyzed using ANCOVA with Baseline percent of total BSA affected by AD as covariate and treatment as factor.

Summary statistics will be presented for the percent of total BSA affected by AD and change from Baseline at each timepoint (Day 15, Day 29, Day 57 and Day 85).

6.9.1.3 Investigator Global Assessment at Days 15, 29 and 57

The proportion of subjects with IGA success defined as an IGA score of Clear (0) or Almost Clear (1) with at least a 2-grade improvement from Baseline at Day 15, Day 29, and Day 57 will be analyzed using the same logistic regression method described for the primary endpoint.

Summary statistics by IGA Score at each timepoint (Baseline, Day 15, Day 29, Day 57 and Day 85) and dichotomized IGA at each post-Baseline timepoint (Day 15, Day 29, Day 57 and Day 85) will also be presented at each post-Baseline timepoint.

6.9.1.4 Signs of Atopic Dermatitis at Target Lesions (at selected photography sites only) at Days 29, 57 and 85

At selected sites, a target lesion will be identified, photographed and scored with the Signs of AD.

The change from Baseline to Day 29, and Day 57, and Day 85 Signs of AD total score at target lesions will be analyzed using an ANCOVA with Baseline score as a covariate and treatment as a factor.

Summary statistics for each of the Signs of AD scores (erythema, exudation, excoriation, induration/papulation, and lichenification) and total score at target lesions for each timepoint will be presented (Baseline, Day 15, Day 29, Day 57 and Day 85).

6.10 Sensitivity Analyses

The sensitivity analyses will be performed using the ITT population.

6.10.1 Repeated Measures

The first sensitivity analysis for the primary endpoint, IGA success, will be analyzed using a repeated measures logistic regression (generalized estimating equations), with dichotomized IGA success as the dependent variable and treatment group, visit, and treatment group by visit interaction as independent factors. In this analysis, data from all post-Baseline visits will be included with no imputation for missing data.

```
proc genmod data = datain;
      class SUBJECT TRT VISIT;
      model IGA SUCCESS = TRT VISIT TRT * VISIT / dist=bin;
      repeated subject = SUBJECT/type = cs;
      lsmeans TRT*VISIT / diff;
      estimate 'pval' TRT 1 -1 TRT*VISIT 0 0 1 0 0 -1;
run;
```

6.10.2 Tipping Point

A tipping point analysis of the primary endpoint, proportion of subjects with IGA success defined as an IGA score of Clear (0) or Almost Clear (1) with at least a 2-grade improvement from Baseline at Day 85, will be performed as a sensitivity analysis for the handling of missing data. Specifically, a range of response rates for both groups will be explored to determine the tipping point(s) at which the combinations result in no longer reaching statistical significance.

6.11 Safety Evaluation

6.11.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of applications, number of missed applications, number and percentage of subjects who are compliant, and amount of drug used total. Exposure and compliance will not be calculated for subjects who are lost to follow-up. A subject will be considered compliant with the dosing regimen if the subject applies 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 record using the recorded weights for subjects with an initial weight and return weight for all dispensed pumps of study drug. The difference between the dispensed weight and the returned weight for each pump will be summed over all pumps to calculate the total amount of study drug used.

Compliance will be calculated based on the applications of study drug. The total number of applications is as follows:

> If 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).
>
> If 1 application 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).

The total number of applications expected is as follows:

> 2*(Date Subject Ended Participation - Date of Randomization + 1).

If the total number of applications exceeds 178 then it will set to 178.

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.

6.11.2 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. Burning/stinging is a pre-defined safety endpoint; subjects' reports of burning/stinging will be reported as AEs and included in a separate summary.

An overall summary of TEAEs will be presented showing the number of subjects reporting at least one TEAE, number reporting at least one serious adverse event (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.

A summary of time until study discontinuation for subjects who discontinue due to a TEAE will also be presented.

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. A summary of subjects who discontinue the study due to AEs will be included.

No statistical inference between treatments will be performed on AEs.

6.11.3 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.

6.11.4 Clinical Laboratory Evaluation

Laboratory test results will be summarized with descriptive statistics at Baseline and Day 85. Additionally, shifts from Baseline to Day 85 in laboratory test results based on normal ranges will be summarized with frequency counts and percentages. Individual laboratory test results will be presented in a by-subject listing. A by-subject listing of abnormal lab findings will also be provided.

6.11.5 Other Observations Related to Safety

6.11.5.1 Physical Examination

Physical examination (review of systems) 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 1:1 with 100 subjects in each treatment group for a total 200 subjects. This is considered adequate to evaluate the safety and tolerability and preliminary information on efficacy of twice daily BTX 1204 4% in the treatment of moderate atopic dermatitis in subjects aged 12 to 70 years of age.

8. CHANGES IN THE PLANNED ANALYSES

Baseline IGA will not be used as a factor for the primary, secondary, and exploratory efficacy IGA endpoints as treatment was not stratified by IGA score.

The ITT population was updated to specify inclusion only of subjects with at least one post-Baseline efficacy assessment.

The mITT population was added to the SAP in order to assess efficacy for subjects with consistent areas of AD lesions.

A tipping point analysis was added as an additional sensitivity analysis on the ITT population.

9. REFERENCES

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10. INDEX OF PLANNED TABLES

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

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Completed Study	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)
No		
Reason for Discontinuation from Study		
Adverse Event	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)
Worsening Condition	xx (xx.x%)	xx (xx.x%)
Other		

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

Table 14.0.2: Summary of Subjects Excluded from Analyses
(Randomized Subjects)
(Page 1 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Number of Subjects Included in the ITT Population	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the ITT Population	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the ITT Population		
At Least One Post-Baseline Efficacy Assessment	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the mITT Population	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the mITT Population	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the mITT Population[a]		
Not in the ITT Population	xx (xx.x%)	xx (xx.x%)
No New Post-Baseline Areas of Atopic Dermatitis[b]	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Safety Population[a]		
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)
No Post Baseline Safety Assessment	xx (xx.x%)	xx (xx.x%)

[a] Table includes primary reason (assigned in order presented in table) subject was excluded.
[b] The presence of new areas of atopic dermatitis were determined by post-baseline reports compared to baseline reports of BSA.
[c] See Listing 16.2.3 for a complete list of all other reasons for exclusion from the PP population.
Note: The ITT exclusion of not being randomized is not presented as the table is on randomizied subjects.
Percentages are based on the number of randomized subjects.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2: Summary of Subjects Excluded from Analyses
(Randomized Subjects)
(Page 2 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Number of Subjects Included in the PP Population	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the PP Population	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the PP Population[a]		
Violated the Inclusion/Exclusion Criteria	xx (xx.x%)	xx (xx.x%)
Received an Interfering Medication	xx (xx.x%)	xx (xx.x%)
Missed Investigator Global Assessment at Day 85	xx (xx.x%)	xx (xx.x%)
Missed Both Day 29 and Day 57 Visits	xx (xx.x%)	xx (xx.x%)
Not Compliant with Dosing Regimen	xx (xx.x%)	xx (xx.x%)
Day 85 Visit not within +/- 7 days Window	xx (xx.x%)	xx (xx.x%)
Other[c]	xx (xx.x%)	xx (xx.x%)

[a] Table includes primary reason (assigned in order presented in table) subject was excluded.
[b] The presence of new areas of atopic dermatitis were determined by post-baseline reports compared to baseline reports of BSA.
[c] See Listing 16.2.3 for a complete list of all other reasons for exclusion from the PP population.
Note: The ITT exclusion of not being randomized is not presented as the table is on randomizied subjects.
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)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Age (years)		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
12 to < 18 Years	xx (xx.x%)	xx (xx.x%)
18 to < 30 Years	xx (xx.x%)	xx (xx.x%)
≥ 30 Years	xx (xx.x%)	xx (xx.x%)
Sex		
n	xx	xx
Male	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)
Ethnicity		
n	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)
Race		
n	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)
Multiple/Other	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 (mITT Population)
Programming note: *Replace footnote with* - Note: Percentages are based on the number of subjects in the mITT population with a non-missing response.

Table 14.1.1.3: Summary of Subject Demographics (PP Population)
Programming note: *Replace footnote with* - Note: Percentages are based on the number of subjects in the PP population with a non-missing response.

Table 14.1.1.4: Summary of Subject Demographics (Safety Population)
Programming note: *Replace footnote with* - Note: Percentages are based on the number of subjects in the Safety population with a non-missing response.

Table 14.1.2.1: Summary of Baseline Characteristics
(ITT Population)
(Page 1 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Height (cm)		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Weight (kg)		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Investigator Global Assessment		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
Total Body Surface Area Affected by AD		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

[a] Duration of AD is calculated as year of Baseline visit – year of AD diagnosis.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Duration of AD (Years)[a]		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

[a] Duration of AD is calculated as year of Baseline visit – year of AD diagnosis + 1.
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 (mITT Population)
Table 14.1.2.3: Summary of Baseline Characteristics (PP Population)
Table 14.1.2.4: 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)
(Page 1 of x)

ATC Level 2 Term Preferred Name[a]	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Subjects with at Least One Concomitant Medication Reported	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term 1	xx (xx.x%)	xx (xx.x%)
Preferred Name 1	xx (xx.x%)	xx (xx.x%)
Preferred Name 2	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)
Preferred Name x	xx (xx.x%)	xx (xx.x%)
…		

[a] WHO-DDE, Format B2, Version xxxxx.

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 (mITT Population)
Programming note: *Replace 3rd footnote with* - Percentages are based on the number of subjects in each treatment group in the mITT population.

Table 14.1.3.3: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Name (PP Population)
Programming note: *Replace 3rd footnote with* - Percentages are based on the number of subjects in each treatment group in the PP population.

Table 14.1.3.4: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Name (Safety Population)
Programming note: *Replace 3rd footnote with* - Percentages are based on the number of subjects in each treatment group in the Safety population.

Table 14.1.4.1: Summary of Concomitant Antibiotic Therapies by ATC Level 2 Term and Preferred Name
(ITT Population)
(Page 1 of x)

ATC Level 2 Term Preferred Name[a]	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Subjects with at Least One Concomitant Antibiotic Therapy Reported	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term 1	xx (xx.x%)	xx (xx.x%)
Preferred Name 1	xx (xx.x%)	xx (xx.x%)
Preferred Name 2	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)
Preferred Name x	xx (xx.x%)	xx (xx.x%)
…		

[a] WHO-DDE, Format B2, Version xxxxx.

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 (mITT Population)
Programming note: *Replace 3rd footnote with* - Percentages are based on the number of subjects in each treatment group in the mITT population.

Table 14.1.4.3: Summary of Concomitant Antibiotic Therapies by ATC Level 2 Term and Preferred Name (PP Population)
Programming note: *Replace 3rd footnote with* - Percentages are based on the number of subjects in each treatment group in the PP population.

Table 14.1.4.4: Summary of Concomitant Antibiotic Therapies by ATC Level 2 Term and Preferred Name (Safety Population)
Programming note: *Replace 3rd footnote with* - Percentages are based on the number of subjects in each treatment group in the Safety population.

Table 14.2.1.1: Primary Efficacy Endpoint: Dichotomized IGA Success at Day 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value[a]
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	

[a] Estimates and p-value from a logistic regression with a term for treatment group.
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: Dichotomized IGA Success at Day 85 (mITT Population)

Table 14.2.1.3: Primary Efficacy Endpoint: Dichotomized IGA Success at Day 85 (PP Population)
Programming note: *Replace last footnote with* - Note: No imputations were made for missing data.

Table 14.2.1.4: Sensitivity Analysis of Primary Efficacy Endpoint: Dichotomized IGA Success at Day 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value[a]
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	

[a] Estimates and p-value from a repeated measures logistic regression with .factors of treatment group, visit and treatment group by visit interaction.
Note: No imputations were made for missing data.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.6: Subgroup Summary of the Primary Endpoint: Dichotomized IGA Success at Day 85
(mITT Population)
(Page 1 of 5)

	Geographical Region: US	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

	Geographical Region: AUS/NZ	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: No imputations were made for missing data.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.1.6: Subgroup Summary of the Primary Endpoint: Dichotomized IGA Success at Day 85
(mITT Population)
(Page 2 of 5)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Gender: Male		
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
Gender: Female		
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: No imputations were made for missing data.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.1.6: Subgroup Summary of the Primary Endpoint: Dichotomized IGA Success at Day 85
(mITT Population)
(Page 3 of 5)

	Ethnicity: Hispanic or Latino	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

	Ethnicity: Non-Hispanic or Latino	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: No imputations were made for missing data.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.1.6: Subgroup Summary of the Primary Endpoint: Dichotomized IGA Success at Day 85
(mITT Population)
(Page 4 of 5)

	Race: White	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

	Race: Non-White	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: No imputations were made for missing data.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.1.6: Subgroup Summary of the Primary Endpoint: Dichotomized IGA Success at Day 85
(mITT Population)

	Age: 12 to < 18 Years	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
	Age: 18 to < 30 Years	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
	Age: ≥ 30 Years	
	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
n	xx	xx
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: No imputations were made for missing data.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Repeat Table 14.2.1.6 for the following:

Table 14.2.1.7: Subgroup Summary of the Primary Endpoint: Dichotomized IGA Success at Day 85 (PP Population)

Table 14.2.2.1.1: Secondary Endpoint: Change from Baseline in Signs of AD Total Score at Day 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Total Signs of AD			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
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 Endpoint: Change from Baseline in Signs of AD Total Score at Day 85 (mITT Population)

Table 14.2.2.1.3: Secondary Endpoint: Change from Baseline in Signs of AD Total Score at Day 85 (PP Population)
Programming note: *Replace last footnote with* - Note: No imputations were made for missing data.

Table 14.2.2.2.1: Secondary Endpoint: Dichotomized IGA at Day 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value[a]
IGA Grade of 0 or 1			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	
At Least a 2 Grade Improvement from Baseline in IGA			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	

[a] Estimates and p-value from a logistic regression with a term for treatment group and adjusted for baseline IGA.
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 Endpoint: Dichotomized IGA at Day 85 (mITT Population)

Table 14.2.2.2.3: Secondary Endpoint: Dichotomized IGA at Day 85 (PP Population)
Programming note: *Replace last footnote with* - Note: No imputations were made for missing data.

Table 14.2.2.3.1: Secondary Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Day 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Total BSA Affected by AD			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total BSA Affected by AD and treatment as covariates.
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 Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Day 85 (mITT Population)

Table 14.2.2.3.3: Secondary Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Day 85 (PP Population)
Programming note: *Replace last footnote with* - Note: No imputations were made for missing data.

Table 14.2.2.4.1: Secondary Endpoint: Time to IGA Success
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Subjects with a Non-Missing Post-Baseline IGA	xx	xx
Subjects with IGA Success[a]	xx (xx.x%)	xx (xx.x%)
Subjects Censored	xx (xx.x%)	xx (xx.x%)
Time to IGA Success[a] (Days)		
Minimum[b]	xx	xx
25th Percentile[c]	xx.x	xx.x
50th Percentile[c]	xx.x	xx.x
75th Percentile[c]	xx.x	xx.x
Maximum[b]	xx	xx

[a] IGA Success is defined as an IGA score of Clear or Almost Clear with at least a 2-grade improvement from baseline.
[b] Observed time to event.
[c] Estimated using Kaplan-Meier methods.
Note: Elasped times are computed from the date of first dose to the date of IGA assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Programming note: *Minimum and Maximum values are among subjects achieving the event. Censored subjects are not considered.*

Repeat Table 14.2.2.4.1 for the following:

Table 14.2.2.4.2: Secondary Endpoint: Time to IGA Success (mITT Population)
Table 14.2.2.4.3: Secondary Endpoint: Time to IGA Success (PP Population)

Table 14.2.2.5.1: Secondary Endpoint: Summary of Itching-Numerical Rating Score by Visit
(ITT Population)
(Page 1 of 3)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
How would you rate your average itch in the past 24 hours?		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 15		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.5.1: Secondary Endpoint: Summary of Itching-Numerical Rating Score by Visit
(ITT Population)
(Page 2 of 3)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
How would you rate your average itch in the past 24 hours?		
Day 29		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 57		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.5.1: Secondary Endpoint: Summary of Itching-Numerical Rating Score by Visit
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
How would you rate your average itch in the past 24 hours?		
Day 85		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.5.1 for the following:

Table 14.2.2.5.2: Secondary Endpoint: Summary of Itching-Numerical Rating Score by Visit (mITT Population)

Table 14.2.2.5.2: Secondary Endpoint: Summary of Itching-Numerical Rating Score by Visit (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.1.1: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Days 15, 29 and 57
(ITT Population)
(Page 1 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Signs of AD Total Score			
Day 15			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		
Day 29			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.3.1.1: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Days 15, 29 and 57
(ITT Population)
(Page 2 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Signs of AD Total Score			
Day 57			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
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 Endpoint: Change from Baseline in Signs of AD Total Score at Days 15, 29 and 57 (mITT Population)

Table 14.2.3.1.3: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Days 15, 29 and 57 (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.2.1: Exploratory Efficacy Endpoint: Summary of Signs of AD Score by Visit
(ITT Population)
(Page 1 of x)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Erythema		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 15		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2.1: Exploratory Efficacy Endpoint: Summary of Signs of AD Score by Visit
(ITT Population)
(Page 2 of x)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Erythema		
Day 29		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 57		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming note: *Continue for Exudation, Excoriation, Induration/Papulation, Lichenification, and Total Score*

Repeat Table 14.2.3.2.1 for the following:

Table 14.2.3.2.2: Exploratory Efficacy Endpoint: Summary of Signs of AD Score by Visit (mITT Population)

Table 14.2.3.2.3: Exploratory Efficacy Endpoint: Summary of Signs of AD Score by Visit (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.3.1: Exploratory Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Days 15, 29 and 85
(ITT Population)
(Page 1 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Total BSA affected by AD			
Day 29			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		
Day 57			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.3.3.1: Exploratory Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Days 15, 29 and 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Total BSA affected by AD			
Day 57			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Repeat Table 14.2.3.3.1 for the following:

Table 14.2.3.3.2: Exploratory Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Days 15, 29 and 85 (mITT Population)

Table 14.2.3.3.3: Exploratory Endpoint: Change from Baseline in Percent of Total BSA Affected by AD at Days 15, 29 and 85 (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.4.1: Summary of Percent of Total BSA Affected by AD by Visit
(ITT Population)
(Page 1 of 3)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Total BSA Affected by AD		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 15		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4.1: Summary of Percent of Total BSA Affected by AD by Visit
(ITT Population)
(Page 2 of 3)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Total BSA Affected by AD		
Day 29		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 57		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4.1: Summary of Percent of Total BSA Affected by AD by Visit
(ITT Population)
(Page 3 of 3)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Total BSA Affected by AD		
Day 85		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.4.1 for the following:

Table 14.2.3.4.2: Summary of Percent of Total BSA Affected by AD by Visit (mITT Population)

Table 14.2.3.4.3: Summary of Percent of Total BSA Affected by AD by Visit (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.5.1: Exploratory Efficacy Endpoint: Summary of Dichotomized IGA Success at Days 15, 29 and 57
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value[a]
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1			
Day 15			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	
Day 29			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	
Day 57			
n	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	
Success[a]	xx.x%	xx.x%	x.xxx
Failure[a]	xx.x%	xx.x%	

[a] Estimates and p-value from a logistic regression with a term for treatment group and adjusted for baseline IGA.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.5.1 for the following:

Table 14.2.3.5.2: Exploratory Efficacy Endpoint: Summary of Dichotomized IGA Success at Days 15, 29 and 57 (mITT Population)

Table 14.2.3.5.3: Exploratory Efficacy Endpoint: Summary of Dichotomized IGA Success at Days 15, 29 and 57 (PP Population)
Programming note: *Replace last footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.6.1: Summary of Investigator Global Assessment by Visit
(ITT Population)
(Page 1 of 4)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Baseline		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
Day 15		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.6.1: Summary of Investigator Global Assessment by Visit
(ITT Population)
(Page 2 of 4)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Day 29		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.6.1: Summary of Investigator Global Assessment by Visit
(ITT Population)
(Page 3 of 4)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Day 57		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.6.1: Summary of Investigator Global Assessment by Visit
(ITT Population)
(Page 4 of 4)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Day 85		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)
At Least a 2 Grade Improvement from Baseline and IGA Grade of 0 or 1		
Success	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)

Note: Missing values are 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: Summary of Investigator Global Assessment by Visit (mITT Population)

Table 14.2.3.6.3: Summary of Investigator Global Assessment by Visit (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.7.1: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Target Lesions at Days 29, 57 and 85
(ITT Population)
(Page 1 of 2)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Total Signs of AD			
Day 29			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		
Day 57			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Table 14.2.3.7.1: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Target Lesions at Days 29, 57 and 85
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)	Treatment P-Value
Change from Baseline in Total Signs of AD			
Day 29			
n	xx	xx	
Mean	xx.x	xx.x	
SD	xx.xx	xx.xx	
Median	xx.x	xx.x	
Min., Max.	xx, xx	xx, xx	
LSMean[a]	xx.x		x.xxx[a]
LSSD[a]	xx.xx		

[a] Least squares mean, standard deviation, and p-value from an analysis of covariance with baseline Total Signs of AD and treatment as covariates.
Note: Missing values imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Repeat Table 14.2.3.7.1 for the following:

Table 14.2.3.7.2: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Target Lesions at Days 29, 57 and 85 (mITT Population)

Table 14.2.3.7.3: Exploratory Endpoint: Change from Baseline in Signs of AD Total Score at Target Lesions at Days 29, 57 and 85 (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

Table 14.2.3.8.1: Exploratory Efficacy Endpoint: Summary of Signs of AD Score at Target Lesions by Visit
(ITT Population)
(Page 1 of x)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Erythema		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 15		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.8.1: Exploratory Efficacy Endpoint: Summary of Signs of AD Score at Target Lesions by Visit
(ITT Population)
(Page 2 of x)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Erythema		
Day 29		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 57		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

Note: Missing values are imputed using LOCF.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Programming note: *Continue for Exudation, Excoriation, Induration/Papulation, Lichenification, and Total Score*

Repeat Table 14.2.3.8.1 for the following:

Table 14.2.3.8.2: Exploratory Efficacy Endpoint: Summary of Signs of AD Score at Target Lesions by Visit (mITT Population)

Table 14.2.3.8.3: Exploratory Efficacy Endpoint: Summary of Signs of AD Score at Target Lesions by Visit (PP Population)
Programming note: *Replace footnote with* - Note: No imputations were made for missing data.

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

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Total Amount of Study Drug Used (g)		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Number of Applications		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Number of Missed Applications		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	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 subject 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)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Percent Compliance		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Compliant[a]		
Yes[b]	xx (xx.x%)	xx (xx.x%)
No[b]	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 subject in the safety population with percent compliance calculated.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Number (%) of Subjects Reporting At Least One Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events	xx	xx
Number (%) of Subjects Reporting At Least Once Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events	xx	xx
Number (%) of Subjects who Discontinued Study Due to At Least One Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events Leading to Discontinuation of Study	xx	xx
Maximum Severity		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Stongest Relationship to Study Drug		
Related	xx (xx.x%)	xx (xx.x%)
Not Related	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 14.3.1.2: Summary of Treatment-Emergent Adverse Event by MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class[a] Preferred Term	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
System Organ Class 1	xx (xx.x%)	xx (xx.x%)
Preferred Term 1	xx (xx.x%)	xx (xx.x%)
Preferred Term 2	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%)

[a] At each level of summarization (System Organ Class or Preferred Term) subjecs are counted once.

Note: MedDRA Version xx.x.

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 14.3.1.2 for the following:

Table 14.3.1.3: Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.4: 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 14.3.1.5: Summary of Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.6: Summary of Treatment-Emergent Adverse Events Leading to Study Discontinuation by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.1.7: Summary of Time to Study Discontinuation for Subjects Who Discontinue Due to Treatment-Emergent Adverse Events
(ITT Population)

	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Time to Study Discontinuation[a]		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

[a] Time to Study Discontinuation is calculated as study discontinuation date – date of first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.2 for the following:

Table 14.3.1.8: Summary of Treatment-Emergent Abuse-Related Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.2.1.1: Summary of Chemistry Results by Visit
(Safety Population)
(Page 1 of y)

Test Name (Units)	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Day 85		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min., Max.	xx, xx	xx, xx

[*repeat for each test*]

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

Table 14.3.2.1.2: Shift Table for Chemistry Results
(Safety Population)
(Page 1 of y)

Test Name (*Units*)		Baseline		
BTX 1204 4% BID (N=xx)	Day 85 (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 85 (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 each test*]

[a] Number of subjects with both Baseline and Day 85 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 14.3.2.1.1 for the following:
Table 14.3.2.2.1: Summary of CBC Results by Visit (Safety Population)
***Programming note**: CBC tests include: WBC (with differentials for ANC, Neutrophils,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 14.3.2.1.2 for the following:
Table 14.3.2.2.2: Shift Table for CBC Results (Safety Population)

Repeat Table 14.3.2.1.1 for the following:
Table 14.3.2.3.1: Summary of Numeric Urinalysis Results by Visit (Safety Population)

Repeat Table 14.3.2.1.2 for the following:
Table 14.3.2.3.2: Shift Table for Numeric Urinalysis Results (Safety Population)

Table 14.3.2.3.3: Summary of Character Urinalysis Results by Visit
(Safety Population)
(Page 1 of y)

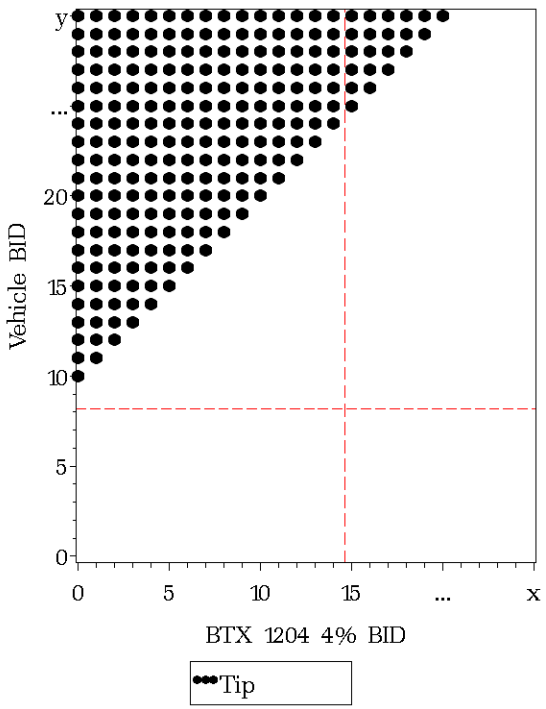
Test Name (Units)	BTX 1204 4% BID (N=xxx)	Vehicle BID (N=xxx)
Baseline		
n	xx	xx
xxxxxxx	xx (xx.x%)	xx (xx.x%)
xxxxxxx	xx (xx.x%)	xx (xx.x%)
xxxxxxx	xx (xx.x%)	xx (xx.x%)
Day 85		
n	xx	xx
xxxxxxx	xx (xx.x%)	xx (xx.x%)
xxxxxxx	xx (xx.x%)	xx (xx.x%)
xxxxxxx	xx (xx.x%)	xx (xx.x%)

[*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)

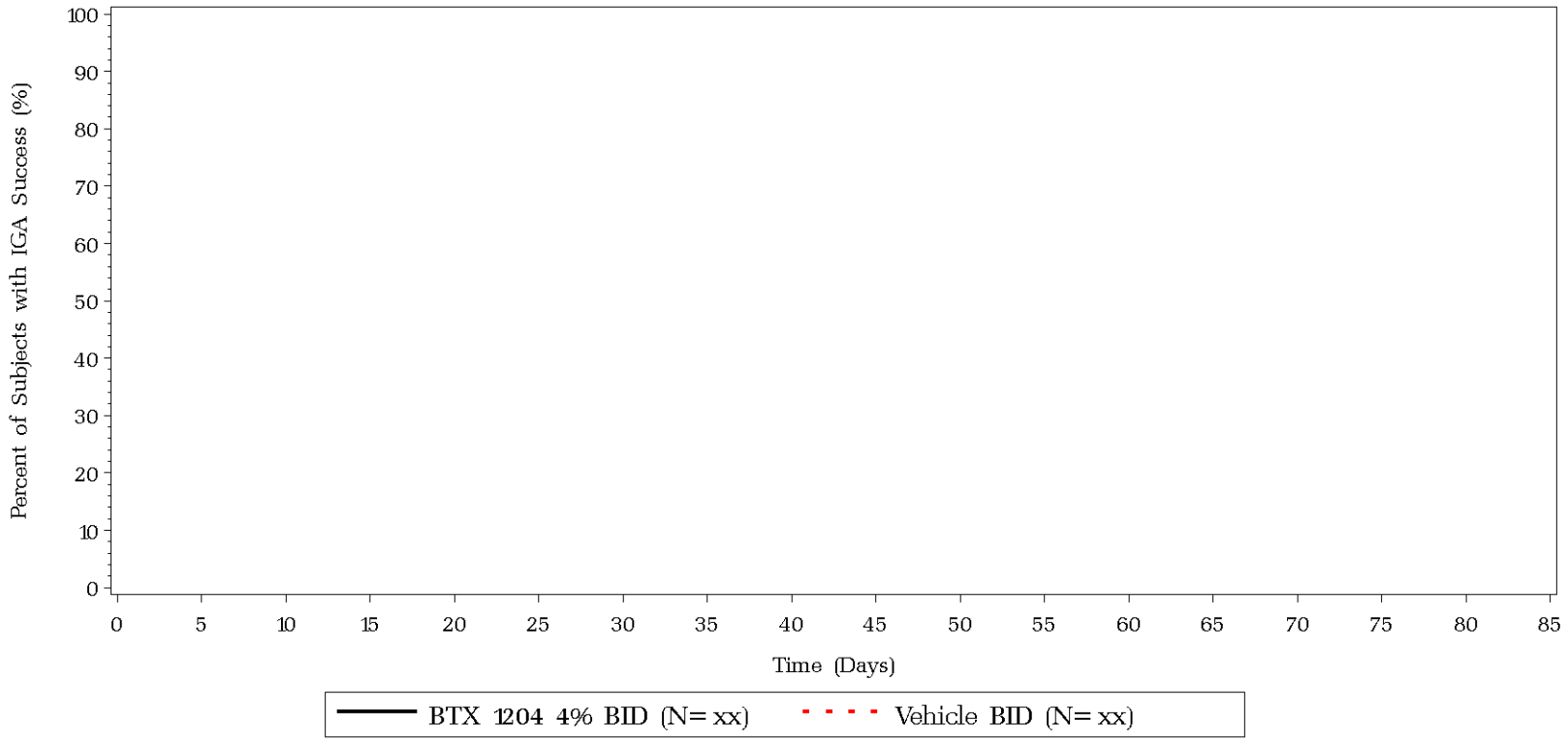
11. INDEX OF PLANNED FIGURES

Figure 14.2.1.5: Sensitivity Tipping-Point Analyses of the Primary Efficacy Endpoint: Dichotomized IGA Success at Day 85
(Intent-to-Treat Population)



Note: The horizontal and vertical axes indicate the potential number of successes among subjects with missing data in each treatment group.
Each plotted point indicates the number of imputed successes in each treatment group that results in a p-value greater than 0.05.
The red lines represent the number of imputed successes from the primary analysis using last observation carried forward (LOCF) to impute missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.2.4.4: Secondary Endpoint: Kaplan Meier Curves for Time to IGA Success
(ITT Population)



Note: Circles represent censored observations.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.4.4 for the following:

Figure 14.2.2.4.5: Secondary Endpoint: Kaplan Meier Curves for Time to IGA Success (mITT Population)
Figure 14.2.2.4.6: Secondary Endpoint: Kaplan Meier Curves for Time to IGA Success (PP Population)

12. 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; mITT = modified 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 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 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 = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of first dose).
[2] Additional information is collected on a conditional basis. All information collected is included in the listing verbatim.
Note: ITT = Intent-to-Treat Population; mITT = modified Intent-To-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)
Listing sorted by Subject.

Listing 16.2.1.2: 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 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 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 = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of first dose).
[2] Additional information is collected on a conditional basis. All information collected is included in the listing verbatim.
Note: ITT = Intent-to-Treat Population; mITT = modified Intent-To-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)
Listing sorted by Subject.

Listing 16.2.1.3: 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 xxxxxx xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxx xxxxxxxx xx xxxxxxxx xxxxxxx xxxxx xxx xx xxxxxxxx xxxx xxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D: xxxx-xx-xx	xxxxxx xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxxx xxxx xxx xxxxxxxxxxxxx xxxxxxx xxxxxxxx

Note: ITT = Intent-to-Treat Population; mITT = modified 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	Exceptions
xxxxxx	xxxx	Intent-to-Treat	xxx		
		modifed Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	
xxxxxx	xxxx	Intent-to-Treat	xxx		
		modifed Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	
xxxxxx	xxxx	Intent-to-Treat	xxx		
		modifed Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xxx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	xxxx xxxx xx

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	Date of Informed Consent	Date of Assesnt	Childbearing Potential	Photography Consent
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xxx

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

Listing sorted by Subject.
Note to Programmer: Race will be displayed as the mapped CDISC version of the verbatim text.

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	Condition/Surgery 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 xx.x).
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 = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of first dose).
Note: System Organ Class and Preferred Term map to MedDRA (Version xx.x).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.4.3.1: 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, Format B2, Version xxxxx.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.4.3.2: Prior and Concomitant Medications/Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medication/Therapy Name P: Preferred 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 = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of first dose).
Note: Preferred Name and ATC Level 2 Term map to the WHO-DDE, Format B2, Version xxxxx.
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 16.2.4.3.3: 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, Format B2, Version xxxxx.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.4.3.4: Concomitant Antibiotic Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medication/Therapy Name P: Preferred 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 = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of first dose).
Note: Preferred Name and ATC Level 2 Term map to the WHO-DDE, Format B2, Version xxxxx.
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: 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	xxx xxxx		xxxxxxx xxxxx xxxx
			Extremities/Skin	xxxxxxxxxxx	xxxxxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxxx D:	H: W:		xxx xxxx		xxx xxx xxxx xx

[1] Day = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of 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 16.2.5.2: Drug Accountability
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Kit Number	Date Dispensed	Date Returned	Pump ID	Dispensed Weight (g)	Where was IP Applied	Returned Weight (g)
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxx xxxxxx	xx.x
						x	xx.x	xxxxx xxxxxx	xx.x
						x	xx.x	xxxxx xxxxxx	xx.x
			xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
			xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxx-xx-xx	xxx xxxx	x	xx.x		
						x	xx.x		
						x	xx.x		
						x	xx.x		
			xxxxx	xxxx-xx-xx	xxxx-xx-xx	x	xx.x		
						x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x
						x	xx.x	xxxxxx xxxxxx	xx.x

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

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

Listing 16.2.5.3: 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	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	xxxx	x	xxx	xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxx-xx-xx R: xxxx-xx-xx	xx	xxxx	x	xxx	xx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxx-xx-xx R: xxxx-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 16.2.5.4: 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 = (date – date of first dose + 1) for dates on or after first dose. Otherwise, Day = (date – date of first dose).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.1: 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	xxxxxxxx	xxxx-xx-xxTxx:xx	x - xxxx			xxx
	xxxxxxxx	xxxx-xx-xxTxx:xx	x - xxxxxx			xxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxxxxxx	xx	xx	xxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxx	xx	xx	xxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxx	xx	xx	xxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxxxx xxxxx	xx	xx	xxx
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxx	xxxx-xx-xxTxx:xx	x - xxxxxxxx			xxx
	xxxxxxxx	xxxx-xx-xxTxx:xx	x - xxxxxxxx			xxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxxxxxx	xx	xx	xxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxx	xx	xx	xxx
	xxxxxx		xxx xxxx			xxx xxxxxx xxx xx xxxxxxxxxx
	xxxxxx	xxxx-xx-xxTxx:xx	x - xxxx	xx	xx	xxx

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

Listing 16.2.6.2: Body Surface Area Affected by Atopic Dermatis
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	Visit	Date	Evaluator Initials	Location	Result	Change from Bsaeline	Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xxx	Head and Neck	x.x%		
				Right Arm	x.x%		
				Left Arm	x.x%		
				Right Leg	x.x%		
				Left Leg	x.x%		
				Trunk Front	x.x%		
				Trunk Back	x.x%		
				Total Body Surface Area	x.x%		
	xxxxxxxx	xxxx-xx-xx	xxx	Head and Neck	x.x%		
				Right Arm	x.x%		
				Left Arm	x.x%		
				Right Leg	x.x%		
				Left Leg	x.x%		
				Trunk Front	x.x%		
				Trunk Back	x.x%		
				Total Body Surface Area	x.x%		
	xxxxxx	xxxx-xx-xx	xxx	Head and Neck	x.x%		
				Right Arm	x.x%		
				Left Arm	x.x%		
				Right Leg	x.x%		
				Left Leg	x.x%		
				Trunk Front	x.x%		
				Trunk Back	x.x%		
				Total Body Surface Area	x.x%	x.x	
	xxxxx	xxxx-xx-xx	xxx	Head and Neck	x.x%		
				Right Arm	x.x%		
				Left Arm	x.x%		
				Right Leg	x.x%		
				Left Leg	x.x%		
				Trunk Front	x.x%		
				Trunk Back	x.x%		
				Total Body Surface Area	x.x%	x.x	

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

Listing 16.2.6.3: Investigator Assessed Signs of Atopic Dermatitis
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	Visit	Date	Evaluator Initials	Signs of Atopic Dermatitis	Result	Change from Baseline	Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xxx	Erythema	x - xxxx		
				Exudation	x		
				Excoriation	x		
				Induration/papulation	x		
				Lichenification	x		
				Total Score	x		
	xxxxxxxx	xxxx-xx-xx	xxx	Erythema	x		
				Exudation	x		
				Excoriation	x		
				Induration/papulation	x		
				Lichenification	x		
				Total Score	x		
	xxxxxx	xxxx-xx-xx		All Signs of AD	xxx xxxx		xxxxxx xxxx xxx
	xxxxxx	xxxx-xx-xx	xxx	Exudation	x		
				Excoriation	x		
				Induration/papulation	x		
				Lichenification	x		
				Total Score	x	x	

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

Listing 16.2.6.3: Signs of Atopic Dermatitis Based on Photography
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	Visit	Date	Evaluator Initials	Signs of Atopic Dermatitis	Result	Change from Baseline	Reason Not Done
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xxx	Erythema	x - xxxx		
				Exudation	x		
				Excoriation	x		
				Induration/papulation	x		
				Lichenification	x		
				Total Score	x		
	xxxxxxxx	xxxx-xx-xx	xxx	Erythema	x		
				Exudation	x		
				Excoriation	x		
				Induration/papulation	x		
				Lichenification	x		
				Total Score	x		
	xxxxxx	xxxx-xx-xx		All Signs of AD	xxx xxxx		xxxxxx xxxx xxx
	xxxxxx	xxxx-xx-xx	xxx	Exudation	x		
				Excoriation	x		
				Induration/papulation	x		
				Lichenification	x		
				Total Score	x	x	

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

Listing 16.2.6.4: Itch Numeric Rating Score
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date	How Would You Rate Your Average Itch in the Past 24 Hours	Change from Baseline	Reason Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	x		
			xxxxxxxx	xxxx-xx-xx	x		
			xxxxxx	xxxx-xx-xx	x	xx	
			xxxxxx	xxxx-xx-xx	x	xx	
			xxxxxx	xxxx-xx-xx	x	xx	
			xxxxxx	xxxx-xx-xx	x	xx	
S: xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	x		
			xxxxxxxx	xxxx-xx-xx	x		
			xxxxxx	xxxx-xx-xx	x	xx	
			xxxxxx	xxxx-xx-xx	x	xx	
			xxxxxx		xxx xxxx		xxx xxxxxxxxxx xxxxxxxxxx
			xxxxxx	xxxx-xx-xx	x	xx	

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

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

Subject	Age/Sex	Evaluable	Visit	Were Photographs of the Target Lesions 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 16.2.7.1.1: 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
	xxxxxxxxxxxx	xxxxxxxxxxxx
xxx xxx xxxxxxxxx xxxxxxxxx	xxxxxxx	xxxxxxx
xxx xxxxxxxxx	xxxxxx xxxxxx xxxxxxx	xxxxxxxxx xxxxxx xxxxxx
xxxxxxxxxxxxxxx xxxxxxxxx	xxxxxxxxx xxxx	xxxxxxxxx xxxx
	xxxxxxxxx xxxxxxxxxxxx	xxxxx xxxxxxxxx xxxxxxxxxxxx

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

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

Listing 16.2.7.1.2: 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] A: Action Take with Study Treatment	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) A: xxxx xxx xxxxxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: 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) A: xxxx xxx xxxxxxx	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) A: xxxx xxx xxxxxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx xxxxxxxxx T: xxx

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

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

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 16.2.7.1.3: 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] A: Action Take with Study Treatment	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) A: xxxx xxx xxxxxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: 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) A: xxxx xxx xxxxxxx	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) A: xxxx xxx xxxxxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx xxxxxxxxx T: xxx

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

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

Listing 16.2.7.1.4: 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] T: Time to Discontinuation (days) A: Action Take with Study Treatment	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) T: xx A: xxxx xxx xxxxxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: 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) A: xx A: xxxx xxx xxxxxxx	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) T: xx A: xxxx xxx xxxxxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx R: xxxxxxxxx T: xxx

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

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

Listing 16.2.7.1.5: 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
	xxxxxxxxxxxx	xxxxxxxxxxxx
xxx xxx xxxxxxxxx xxxxxxxxx	xxxxxxx	xxxxxxx
xxx xxxxxxxxx	xxxxxx xxxxxx xxxxxxx	xxxxxxxxx xxxxxx xxxxxx
xxxxxxxxxxxxxxx xxxxxxxxx	xxxxxxxxx xxxx	xxxxxxxxx xxxx
	xxxxxxxxx xxxxxxxxxxxx	xxxxx xxxxxxxxx xxxxxxxxxxxx

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

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

Listing 16.2.7.1.6: 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 xx.x).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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 16.2.8.3.1.1: 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 16.2.8.3.1.2: Chemistry Laboratory Test Results
Listing 16.2.8.3.1.3: Urinalysis Laboratory Test Results
```