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STATISTICAL ANALYSIS PLAN

Protocol Number:	NI-AC202
Title:	A Phase 2, Multi-Center, Randomized, Evaluator-Blinded, Vehicle-Controlled Study Comparing the Efficacy, Tolerability, and Safety of SB204 Gel and Vehicle Gel Once or Twice Daily in the Treatment of Acne Vulgaris
Study Phase:	II
Expected Sample Size:	200 subjects
Sponsor:	Novan, Inc.
Sponsor Representative:	Carolyn Enloe, MPH
Date:	May 19, 2015
Protocol Version:	Amendment 1, Version 2.0 (October 16, 2014)
SAP Version Number:	Version 1
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Approved by:	**Signature**	**Date**
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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.

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2. ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
IB	Investigator's Brochure
ICF	Informed Consent Form
IGA	Investigator's Global Assessment
ITT	Intent to Treat
LOCF	Last Observation Carried Forward
MCMC	Markov Chain Monte Carlo
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over-the-Counter
PP	Per-Protocol
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis Software
UPT	Urine Pregnancy Test
WHO-DD	World Health Organization Drug Dictionary
WOCBP	Women of Child-Bearing Potential

3. INTRODUCTION

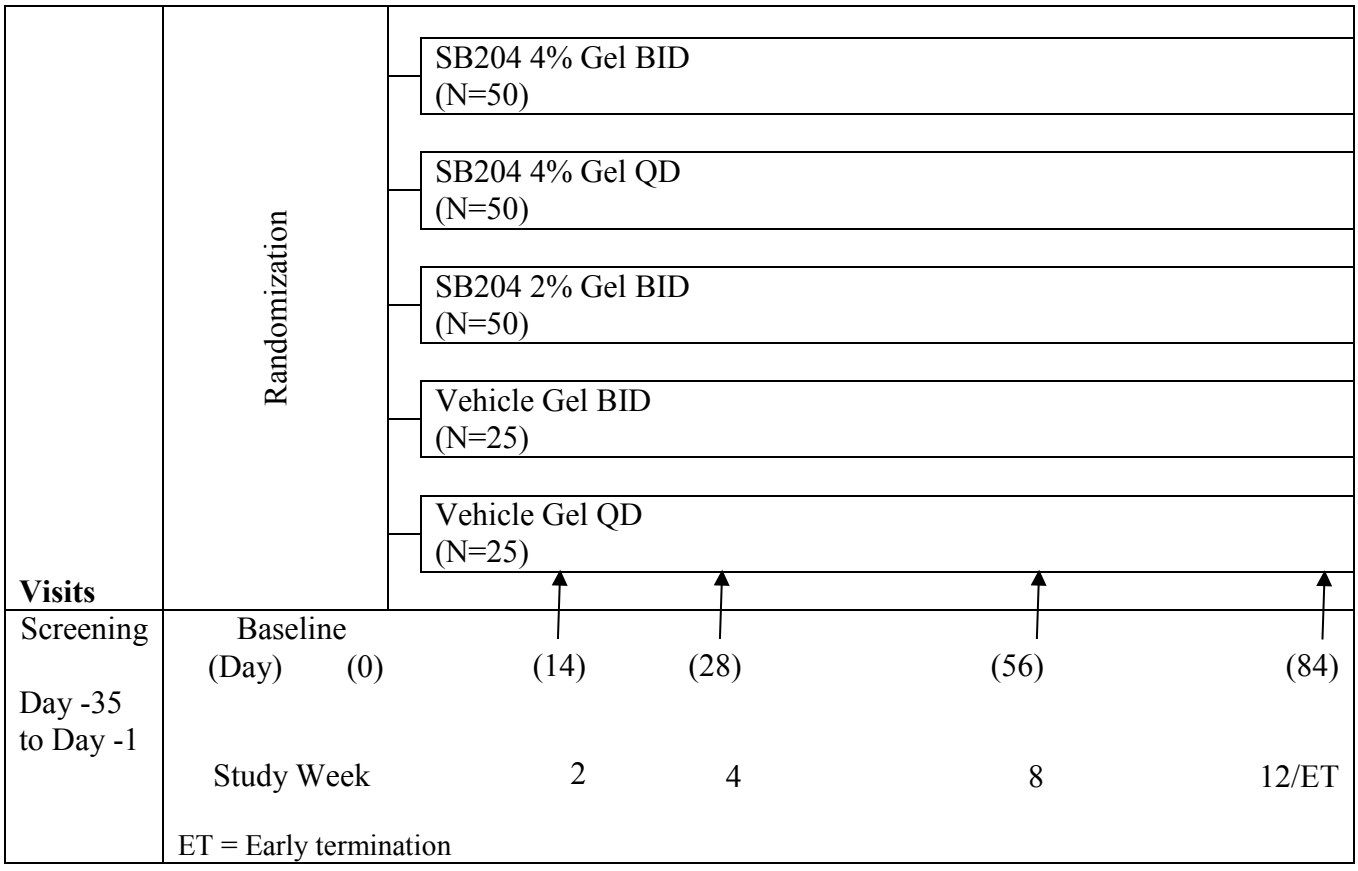
3.1 Study Objectives

The primary objective of this study is to compare efficacy, tolerability and safety of two concentrations of SB204 (NVN1000) Gel and Vehicle Gel once or twice daily for 12 weeks in subjects with acne vulgaris.

3.2 Design

Figure 1 depicts the overall study design for this 12-week, 5-arm, randomized, evaluator-blinded study in subjects with moderate to severe acne vulgaris dosed once or twice daily with SB204 and Vehicle Gel. Subjects receiving current treatment for acne vulgaris may enter a wash out period after screening of up to 35 days prior to randomization.

Figure 1: Study Diagram



3.2.1 Schedule of Visits and Assessments

PROCEDURES	Screening (Day -35 to Day -1)	Baseline (Day 0)	Week 2[1] ±3 days (Day 14)	Week 4 ±3 days (Day 28)	Week 8 ±5 days (Day 56)	Week 12/ET[2] ±5 days (Day 84)
Informed Consent/Assent	X					
Demographics	X					
Medical History	X	X				
Medication History	X	X				
Inclusion/Exclusion Criteria	X	X				
Brief Physical Examination	X	X[3]				X
Chemistry, Hematology, PT/PTT	X	X[3]				X
Urine Pregnancy Test (all WOCBP)	X	X[3]		X	X	X
Methemoglobin	X	X	X			X
Blood Pressure and Pulse	X	X	X	X	X	X
IGA	X	X	X	X	X	X
Lesion Counts	X	X	X	X	X	X
Cutaneous Tolerability Evaluation		X	X	X	X	X
Instruct on Study Drug Application and Provide Subject Instructions		X				
Study Drug and Diary Dispensed		X	X	X	X	
Study Drug and Diary Collected			X	X	X	X
Subject Compliance Reviewed			X	X	X	X
Photography		X				X
Concomitant Medications	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X

[1] All visit dates are in reference to Baseline, e.g., Visit 2 occurs two weeks (14 days) after Baseline visit.

[2] All Week 12 procedures should be completed for subjects who prematurely discontinue.

[3] If the Baseline Visit is within 3 calendar days of the Screening visit, Physical Examination, Chemistry, Hematology, PT/PTT and Urine Pregnancy Test do not need to be repeated.

3.3 Expected Sample Size

Approximately 200 subjects will be randomized into the study in a 2:2:2:1:1 ratio (~ 50 in each active arm and ~25 in each vehicle arm) at approximately 20 sites in North America.

3.4 Inclusion/Exclusion Criteria

Each subject must fulfill all of the following inclusion criteria to participate in the study:

1. Have a signed written informed consent form (ICF). Subjects less than 18 years of age or the age of majority in their state must sign an assent form for the study and a parent or a legal guardian must sign the informed consent;
2. Be male or female, 12 to 40 years of age, inclusive and in good general health;
3. Have a baseline IGA score of moderate (3) or severe (4);
4. Have a minimum of 25 but not more than 70 non-inflammatory lesions (open and closed comedones) on the face;
5. Have a minimum of 20 but no more than 40 inflammatory lesions (papules and pustules) on the face;
6. Have no more than two nodules or cysts on the face;
7. Women of childbearing potential (WOCBP) must have a negative urine pregnancy test (UPT) prior to randomization;
8. WOCBP must agree to use an effective method of birth control during the course of the study and for 30 days after their final study visit; females taking hormonal contraceptives must have taken the same type for at least three months (90 days) prior to entering the study and must not change type during the study. Those who have used hormonal contraceptives in the past and stopped must have discontinued usage at least three months prior to the start of the study;
9. Males must agree to avoid fathering a child during the study and for 60 days after the last dose of the study drug by ensuring one of the acceptable methods of contraception listed is used and not donating sperm; and
10. Be willing and able to follow study instructions and likely to complete all study requirements. Subjects under 18 years of age or age of majority must be accompanied by the parent or legal guardian at the time of assent/consent signing.

Subjects will not be enrolled if they meet any of the following exclusion criteria:

1. Have any dermatological conditions on the face that could interfere with clinical evaluations such as acne conglobata, acne fulminans, acne secondary to medications or other medical conditions, perioral dermatitis, clinically significant rosacea, or gram-negative folliculitis;
2. Have any underlying disease(s) or some other dermatological condition of the face that requires the use of interfering topical or systemic therapy or makes evaluations and lesion count inconclusive;
3. Have a history of experiencing significant burning or stinging when applying any facial treatment (e.g., make-up, soap, masks, washes, sunscreens, etc.) to their face;
4. Female subjects who are pregnant, nursing mothers, or planning to become pregnant during the study;
5. Have used estrogens (e.g., Depogen, Depo-Testadiol, Gynogen, Valergen, etc.) or oral contraceptives for less than 12 weeks immediately preceding Baseline, discontinued use of estrogens or oral contraceptives less than 12 weeks prior to Baseline, or planning to begin or discontinue use of this therapy during the treatment period;
6. Have used medications or vitamins which are reported to exacerbate acne during the 12 weeks immediately preceding Baseline (e.g. azothioprine, haloperidol, halogens such as iodides or bromides, lithium, anabolic steroids, systemic corticosteroids, phenytoin and phenobarbital). The subject must not have had a severe acne flare for at least 12 weeks preceding Baseline. Daily use of a multi-vitamin is acceptable.
7. Have a history of hypersensitivity or allergic reactions to any of the ingredients in the SB204 Gel or Vehicle Gel as described in the Investigator's Brochure;
8. Subjects using or requiring short- or long-acting nitrates, nitric oxide donor drugs or supplements (eg; arginine, citrulline) or drugs associated with methemoglobinemia;
9. Have used the following <u>topical</u> preparations within the time specified prior to Baseline or require the concurrent use of any of the following topical agents:

Topical astringents/abrasives	1 week
Other topical anti-acne medications*	2 weeks
Antibiotics	2 weeks
Moisturizers or sunscreens containing antibacterials	2 weeks
Anti-inflammatory products or corticosteroids	4 weeks
Retinoids or retinol-containing products or corticosteroids	4 weeks

* Includes benzoyl peroxide, salicylic acid, dapsone, alpha-hydroxy acid, or glycolic acids

10. Have used the following <u>systemic</u> medications within the time specified prior to Baseline or require the concurrent use of any of the following systemic medications:

Systemic antibiotics+	4 weeks
Other systemic acne treatments	4 weeks
Corticosteroids*	12 weeks
Systemic retinoids	24 weeks
Therapeutic Vitamin A Supplements > 10,000 IU/day	24 weeks

+ Short courses (≤10 days) of antibiotics if needed during the treatment phase of the study for non-acne related illnesses are allowed.
* Intranasal and inhaled corticosteroids may be used throughout the trial if the subject is on a stable dose.

11. Have had the following procedures on the face, including treatment area within the time specified prior to Baseline:

Cryodestruction/Chemo-destruction	4 weeks
Dermabrasion	4 weeks
Photodynamic Therapy	4 weeks
Acne Surgery	4 weeks
Intralesional Corticosteroids	4 weeks
X-ray, Laser Therapy, or Other Device	4 weeks

12. Have a methemoglobin value of > 3.0% at Screening or Baseline;

13. Have clinically significant anemia at Screening as determined by the Investigator;

14. Intend to use a tanning booth or sunbathe during the study;

15. Have any condition or situation which, in the Investigator's opinion, puts the subject at significant risk, could confound the study results, or may interfere significantly with the subject's participation in the study. Subjects scheduled for endoscopy with use of topical anesthetics should not be enrolled.

16. Are unable to communicate or cooperate with the Investigator due to language problems, poor mental development, or impaired cerebral function;

17. Have used an investigational drug or device within 30 days of Baseline or concurrent participation in a different research study;

18. Have participated in a previous study with SB204 Gel or NVN1000 Gel.

3.5 Treatments

- SB204 4% Gel BID
- SB204 4% Gel QD
- SB204 2% Gel BID
- Vehicle Gel BID

- Vehicle Gel QD

3.6 Efficacy Assessments

The same blinded evaluator will perform Investigator Global Assessments and lesion counting at Screening, Baseline and Weeks 2, 4, 8, and 12. In the event that this is not possible due to unforeseen circumstances, a different blinded evaluator will evaluate the subject. However, the same evaluator should evaluate subjects at the Baseline and Week 12 evaluations.

3.6.1 Investigator Global Assessment

The Investigator Global Assessment (IGA) Score will be a static assessment that is independent of the Baseline score. The Investigator will make the assessment without referring to the Baseline value and prior to performing lesion counts. The assessment should be made approximately three feet from the subject. The same investigator will perform each study assessment for each study subject, for consistency in evaluations.

Subjects are eligible to participate in the study if they have a Baseline IGA score of 3 (moderate) or 4 (severe).

The following scores will be used to assign IGA scores:

Grade	Description
0	Clear: Clear skin with no inflammatory or non-inflammatory lesions.
1	Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red).
2	Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions.
3	Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion.
4	Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

3.6.2 Lesion Counts

The facial area lesion counts will be taken from the forehead, right and left cheeks, chin and nose. The lesion count groups will be inflammatory and non-inflammatory. Facial inflammatory lesions (pustules, papules, nodules and cysts) will be counted and recorded separately. Non-inflammatory lesions (open and closed comedones) will be counted and recorded separately. The following are definitions of each lesion type:

Inflammatory lesions are defined as follows:

Papule –A small, superficial, circumscribed, palpable lesion elevated above the skin surface, less than 10 mm in diameter

Pustule –A superficial elevated lesion that contains yellow fluid (pus) within or beneath the epidermis

Nodule –A firm (indurated) lesion greater than 10 mm in diameter and that is thicker or deeper than the average papule

Cyst - Spherical swelling that contains fluid or semisolid material

Non-inflammatory lesions are defined as follows:

Open comedones (blackhead) –Plugged follicular units with brown/black central debris

Closed comedones (whitehead) –Plugged follicular units with white central debris

3.7 Safety Assessments

3.7.1 Cutaneous Tolerability Evaluations

The Investigator will evaluate the subject's face prior to the first application of investigational product in addition to evaluating at each study visit. The cutaneous tolerability assessment for visits other than Baseline should be performed at least 30 minutes after study drug application. Cutaneous tolerability evaluations will include erythema, scaling, dryness, pruritus and burning/stinging. Pruritus and burning/stinging will be based on the subject's report for the previous 24 hours. Cutaneous tolerability endpoints will not be reported as an AE unless they reach severe and/or result in subject's discontinuation from the study. Cutaneous tolerability assessments will be performed according to the following scales:

Erythema

Score	Description
0-None	No evidence of erythema present
1-Mild	Slight pink coloration
2-Moderate	Definite redness
3-Severe	Marked erythema, bright red to dusky dark red in color

Scaling

Score	Description
0-None	No scaling
1-Mild	Fine scales present to limited areas of the face, barely perceptible
2-Moderate	Fine scale generalized to all areas of the face
3-Severe	Scaling and peeling of skin over all areas of the face

Dryness

Score	Description
0-None	No dryness
1-Mild	Slight but definite roughness
2-Moderate	Moderate roughness
3-Severe	Marked roughness

Pruritus

Score	Description
0-None	No itching
1-Mild	Slight itching, not very bothersome
2-Moderate	Moderate amount of itching, somewhat bothersome
3-Severe	Severe amount of itching, definite discomfort and sleep may be disturbed

Burning/Stinging

Score	Description
0-None	No burning/stinging
1-Mild	Slight warm, burning/stinging sensation; not very bothersome
2-Moderate	Definite warm, burning/stinging sensation that is somewhat bothersome
3-Severe	Hot, tingling/sensation that has caused definite discomfort and may have disturbed sleep

3.7.2 Adverse Events

3.7.2.1 Definition of Adverse Events

An adverse event (AE) is any untoward medical occurrence (e.g., sign, symptom, disease, syndrome, intercurrent illness, clinically significant abnormal laboratory finding, injury or accident) whether or not considered drug related. Any AE that emerges or worsens following administration of the informed consent and until the end of study participation will be collected. A pre-existing condition is one that is present prior to the start of the study and is to be reported as part of the subject's medical history. It should be reported as an AE only if the frequency, intensity, or the character of the condition worsens during the study.

An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed.

A serious adverse event (SAE) includes any event, if in the view of either the investigator or QST Medical Monitor results in any of the following outcomes:

- Death
- Life-threatening event (i.e., the subject was, in the opinion of the Investigator, at immediate risk of death from the event as it occurred. It does not apply to an AE that hypothetically might have caused death if it were more severe.)
- Persistent or significant disability/incapacity (i.e., the AE results in a substantial disruption of the subject's ability to carry out normal life functions)
- Requires in-patient hospitalization or prolongs hospitalization (i.e., the AE required at least a 24-hour in-patient hospitalization or prolonged a hospitalization beyond the expected length of stay; hospitalizations for elective medical/surgical procedures, scheduled treatments, or routine check-ups are not SAEs by this criterion)
- Congenital anomaly/birth defect (i.e., an adverse outcome in a child or fetus of a subject exposed to the molecule or investigational product before conception or during pregnancy)
- Does not meet any of the above serious criteria but may jeopardize the subject or may require medical or surgical intervention to prevent one of the outcomes listed above (i.e., is a significant or important medical event)

3.7.2.2 Adverse Event Severity Grades

The Investigator is responsible for evaluating all AEs and determining the severity of the event. Severity will be categorized according to the following definitions:

1. Mild: Event may be noticeable to subject; does not influence daily activities; usually does not require intervention

2. Moderate: Event may be of sufficient severity to make subject uncomfortable; performance of daily activities may be influenced; intervention may be needed
3. Severe: Event may cause severe discomfort; usually interferes with daily activities; subject may not be able to continue in the study; treatment or other intervention usually needed

The Investigator will follow all subjects who experience AEs until there is a return to the subject's baseline condition or until a clinically satisfactory resolution is achieved or the subject is lost to follow-up.

3.7.2.3 Investigational Product Causality

Relationship of an AE to investigational product will be assessed as follows:

- Definite: There is a clinically plausible time sequence between the onset of the AE and the application of investigational product; when the event responds to withdrawal of investigational product and recurs with re-administration of investigational product.
- Probable: There is a clinically plausible time sequence between the onset of the AE and the application of investigational product; the AE is unlikely to be caused by the concurrent/underlying illness, other drugs or procedures.
- Possible: There may or may not be a clinically plausible time sequence between the onset of the AE and the application of investigational product and a cause cannot be ruled out.
- Unlikely: There is no reasonable temporal association between the test material and the suspected event and the event could have been produced by the subject's clinical state or other modes of therapy administered to the Subject.
- Unrelated: This term should be reserved for those events that cannot be even remotely related to study participation.

3.7.3 Abbreviated Physical Examination

A brief physical exam will be performed at Screening, Baseline (Day 0) and Week 12/ET. If clinically significant changes in the physical examination from Baseline are noted at the Week 12/ET visit, these will be recorded as adverse events.

3.7.4 Vital Signs

Blood pressure and pulse rate will be collected at Screening, Baseline, and at Weeks 2, 4, 8, and 12. Any clinically significant changes in vital signs from Baseline will be recorded as adverse events whether or not drug related.

3.7.5 Laboratory Assessments

Chemistry, hematology, and PT/PTT will be collected at Screening, Baseline, and Week 12/ET. If clinically significant changes in lab results from Baseline are noted at the Week 12/ET visit, these will be recorded as adverse events. Subjects with clinically significant anemia at Screening as determined by the Investigator will not be eligible to participate.

3.7.6 Methemoglobin

Methemoglobin will be measured at Screening, Baseline, Week 2 and Week 12/ET using a Masimo Rainbow® SET® Rad-57™ pulse co-oximeter that analyzes methemoglobin levels. The

percent methemoglobin will be displayed on the pulse co-oximeter and recorded in the subject's study record and in the study database.

Subjects with methemoglobin values of > 3.0% at Screening or Baseline will not be eligible to participate in the study.

Clinically significant changes in methemoglobin will be recorded as adverse events. The adverse event term should reflect the underlying diagnosis or symptoms and not the pulse co-oximeter result itself.

Clinical symptoms and signs of methemoglobinemia in relation to the level of methemoglobin are listed in the following table.

Clinical Symptoms and Signs of Methemoglobinemia in Relation to the Level of Methemoglobin

Level of Methemoglobin	Clinical Symptoms and Signs
<10%	Frequently asymptomatic, occasionally grayish skin
10%-20%	Skin changes such as cyanosis
20%-30%	Dyspnea, headache, anxiety
30%-50%	Dizziness, palpitations, confusion, tachypnea
50%-70%	Seizures, cardiac arrhythmias, metabolic acidosis, coma
>70%	Death

Source: (Boylston, 2002)

3.7.7 Pregnancy Testing

All WOCBP must have a UPT at Screening and Baseline and if the result is positive, the subject will not be allowed to participate in the study.

A female is considered to be of childbearing potential UNLESS she is post-menopausal (no menses for 24 consecutive months), surgically sterilized, or without a uterus and/or both ovaries. Premenarchal subjects will be considered to be of childbearing potential.

Pregnancy tests will also be performed at Weeks 4, 8, and 12. If a subject is determined to be pregnant prior to Week 12, the subject will be discontinued from the study but followed until term.

3.8 Additional Assessments

3.8.1 Photography

Photographs of the face will be taken at Baseline and Week 12/ET. Baseline photographs may be reviewed by the sponsor or member of the study team to confirm appropriateness of enrolled subjects.

4. STATISTICAL METHODS

4.1 Statistical and Analytical Plans

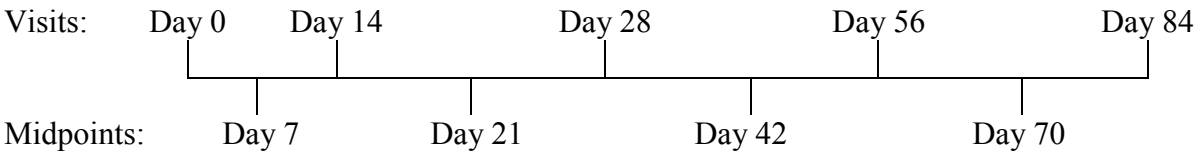
All statistical processing will be performed using SAS® version 9.3 unless otherwise stated. Statistical significance will be based on two-tailed tests of the null hypothesis resulting in p-values of ≤0.05 unless stated otherwise. Inferential testing will compare each active treatment group to the combined Vehicle treatment group. Comparisons will not be performed between active treatments.

Efficacy analyses will be performed for the intent-to-treat (ITT) and per-protocol (PP) populations. Safety analyses will be performed using the safety population. The combined Vehicle treatment group will be included in efficacy summaries. Safety summaries will include both the combined Vehicle treatment group and the combined SB204 treatment group.

For the dichotomized IGA, subjects will be considered a success if their IGA score is clear or almost clear and at least two grades less than Baseline.

For those subjects for whom no Week 12 assessments are available, the last observation will be carried forward (LOCF) in order to provide a value for efficacy parameters that are missing, primarily due to missed visits. Additionally, a sensitivity analysis to estimate missing efficacy data will be based on estimation using the method of Markov Chain Monte Carlo (MCMC) independently for each treatment group. All hypotheses will be two-sided at an alpha level of 0.05.

Information collected at early termination visits will be mapped to the most appropriate visit based on the midpoints between scheduled visits.



For example, if a subject terminates on or after Day 21 but before Day 42, data collected at the early termination visit will be mapped to the Day 28 evaluation for summaries. In addition, LOCF will be applied for efficacy parameters subsequent to mapping the information to the appropriate visit.

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum) will be used to summarize continuous variables. Descriptive statistics for categorical variables will consist of frequency counts and percentages.

4.2 Populations Analyzed

The ITT population will include all study subjects who were randomized and dispensed study medication.

The safety population will include all randomized subjects with documented use of study medication (at least one application) and at least one post-baseline safety assessment.

The PP population will include subjects who complete the Week 12 evaluation without noteworthy study protocol violations (i.e., any subject or investigator activity that could have

possibly interfered with the therapeutic administration of the treatment or the precise evaluation of treatment efficacy). The PP population will include subjects in the safety population who do not meet any of the following criteria:

- Violated the inclusion/exclusion criteria;
- Have taken any interfering concomitant medications;
- Did not attend the Week 12 visit;
- Have missed more than one interim study visit;
- 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 Week 12 visit by ±5 days;

Subjects who are discontinued from the study due to an adverse event 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.

4.2.1 Subject Disposition and Evaluability

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

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

4.3 Background and Demographic Characteristics

Subject demographic (age, sex, ethnicity, race) and baseline characteristics (lesion counts, IGA) will be summarized by treatment group for the ITT, PP and safety populations.

4.4 Efficacy Analyses

Lesion counts will be summarized at each evaluation from Baseline through Week 12. Absolute and percent change in lesion counts will be summarized at Weeks 2, 4, 8, and 12. IGA scores will be summarized from Baseline through Week 12. The dichotomized IGA scores will be summarized at Weeks 2, 4, 8, and 12.

4.4.1 Primary Efficacy Analysis

The analysis of the absolute change in non-inflammatory lesion counts at Week 12 will be conducted using an analysis of covariance with factor of treatment and baseline non-inflammatory lesion count as the covariate.

The analysis of the absolute change in inflammatory lesion counts at Week 12 will use the same method as the analysis of the non-inflammatory lesions, with the baseline inflammatory lesion count as the covariate.

The analysis of the dichotomized IGA scores at Week 12 will be analyzed with a Cochran-Mantel-Haenszel test.

Pairwise comparisons of each active treatment group to the combined vehicle treatment group will be computed without concern for controlling for multiplicity.

4.4.2 Secondary Efficacy Analysis

The analyses of percent change in inflammatory and non-inflammatory lesion counts at Week 12 will use the same method as the analyses of the absolute changes in lesion counts.

The median time to improvement will be compared between each of the active treatment groups and the combined Vehicle treatment group. Improvement will be based on percent reduction from Baseline in inflammatory lesion counts. The analysis will be completed for six different levels of percent reduction. A subject will be considered to achieve improvement if the percent reduction from Baseline in inflammatory lesion counts reaches 25%, 30%, 35%, 40%, 45%, or 50%. Median time to improvement will be calculated using the Kaplan-Meier method, and the Kaplan-Meier curves will be presented for each active treatment group and the combined Vehicle treatment group. An observation will be censored if improvement is not achieved by the subject's time of completion/discontinuation. The log-rank test will be used to compare time to response between each active treatment group and the combined Vehicle treatment group.

4.4.3 Sensitivity Efficacy Analyses

The sensitivity analysis will use the method of Markov Chain Monte Carlo (MCMC) multiple imputation to impute missing data for the non-inflammatory and inflammatory lesion counts and IGA at Week 12. This method does not rely on the assumption of data missing at random. Additionally, imputation will be conducted within each treatment group independently, so the pattern of missing observations in one treatment group cannot influence missing value estimations in another. Note that the vehicle groups will be combined, so imputation will be performed in a total of four treatment groups.

For each efficacy variable (inflammatory lesion count, non-inflammatory lesion count and IGA), the following steps will be performed to impute missing data:

1. Calculate the number of missing Week 12 values to be estimated by MCMC in each treatment group. Let nmiss be the maximum number of missing Week 12 values among the treatment groups.
2. For each treatment group, create a data set containing subjects with observed values and those needing estimation by MCMC. The missing efficacy data in each data set will be filled in using the MCMC method '5 x nmiss' times to generate '5 x nmiss' data sets. The resulting data set for each treatment group will be combined into one complete data set for each imputation.

   Syntax:

   ```
   proc mi data=datain out=dataout seed=&seed. nimpute=5xnmiss <options>;
       where trtpn=(1, 2, 3 or 4);
       mcmc chain=multiple;
       var baseline week2 week4 week8 week12;
   run;
   ```

3. For lesion counts, absolute and percent change from Baseline to Week 12 will be computed from imputed data. Imputed IGA data will be used to determine dichotomized success/failure values.

4. Each complete data set will be analyzed as specified for the particular analysis.
5. The results from these analyses will be combined into a single inference using SAS® PROC MIANALYZE. The Cochran-Mantel-Haenszel statistics computed in the analyses of dichotomized IGA results will be normalized using the Wilson-Hilferty transformation prior to combining them using SAS® PROC MIANALYZE.

A total of 12 random seeds will be needed to impute inflammatory lesion counts, non-inflammatory lesion counts and IGA for all four treatment groups. Those 12 random seeds have been pre-specified by using a random number generator:

- Inflammatory Lesion Counts; SB 204 4% Gel BID: Seed = 30178369
- Inflammatory Lesion Counts; SB 204 4% Gel QD: Seed = 79613624
- Inflammatory Lesion Counts; SB 204 2% Gel BID: Seed = 129994208
- Inflammatory Lesion Counts; Vehicle Gel: Seed = 275
- Non-Inflammatory Lesion Counts; SB 204 4% Gel BID: Seed = 6146
- Non-Inflammatory Lesion Counts; SB 204 4% Gel QD: Seed = 1572
- Non-Inflammatory Lesion Counts; SB 204 2% Gel BID: Seed = 2857988
- Non-Inflammatory Lesion Counts; Vehicle Gel: Seed = 68275983
- IGA; SB 204 4% Gel BID: Seed = 17430239
- IGA; SB 204 4% Gel QD: Seed = 32629
- IGA; SB 204 2% Gel BID: Seed = 8565
- IGA; Vehicle Gel: Seed = 29838218

4.5 Safety Analyses

Safety analyses will be conducted on the safety population. No imputation will be made for missing safety data.

4.5.1 Extent of Exposure

The number of applications used and subject compliance will be summarized using descriptive statistics. A subject will be considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of expected applications. The number of applications will be calculated with the following assumptions:

For subjects assigned to once daily dosing:

- Subject will apply 1 dose each day from Day 0 to the date of last application

For subjects assigned to twice daily dosing:

- Subject will apply 1 dose on Day 0
- Subject will apply 2 doses on the date of last application (subjects are instructed to apply last dose the evening prior to the final study visit)

4.5.2 Cutaneous Safety and Tolerability Evaluations

Cutaneous tolerability assessments (erythema, scaling, dryness, pruritus, burning/stinging) will be summarized from Baseline to Week 12 by treatment group as frequency counts and percentages.

4.5.3 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 dose. 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.

All information pertaining to an AE noted during the study will be listed by subject, detailing verbatim term given by the PI or designee, preferred term, system organ class (SOC), onset date, resolution date, severity, seriousness, action taken, outcome, and drug relatedness. The event onset will also be shown relative (in number of days) to date of first dose.

Treatment-emergent AEs will be summarized by treatment group, the number of subjects reporting a TEAE, SOC, preferred term, severity, relationship to study drug (causality), and seriousness. When summarizing AEs by severity and relationship, each subject will be counted once within a system organ class or a preferred term by using the event with the highest severity and greatest relationship within each classification.

Serious AEs will be summarized by treatment group, severity, and relationship to study drug, and individual SAEs will be listed by subject. In addition, a list of subjects who prematurely discontinue from the study due to an AE will be provided.

4.5.4 Abbreviated Physical Examinations

Results of physical examinations will be presented in data listings by subject.

4.5.5 Vital Signs

Blood pressure and pulse rate will be summarized by treatment group from Baseline through Week 12. Additionally, change from Baseline in vital signs will be summarized by treatment group at Weeks 2, 4, 8, and 12.

4.5.6 Laboratory Assessments

Blood chemistry, hematology, and PT/PTT values will be reported individually at Screening, Baseline, and Week 12. Laboratory test results will be summarized descriptively at Baseline and Week 12. Additionally, shifts from Baseline to Week 12 in laboratory test results based on normal ranges will be summarized with descriptive statistics. The last laboratory evaluation prior to the first dose of study drug will be used as Baseline for all laboratory analyses.

4.5.7 Methemoglobin

Methemoglobin will be reported as a percentage of hemoglobin. Methemoglobin will be summarized descriptively by treatment group at Baseline and Weeks 2 and 12 and will include sample size, mean, median, standard deviation, minimum and maximum. Additionally, the change from baseline in methemoglobin at Weeks 2 and 12 will be summarized.

4.5.8 Urine Pregnancy Tests

Urine pregnancy tests results for WOCBP will be presented in data listings by subject.

4.6 Sample Size Determination

Approximately 200 subjects will be randomized into the study in a 2:2:2:1:1 ratio (~ 50 in each active arm and ~25 in each vehicle arm) at approximately 20 sites in North America. The main objective of this study is to evaluate the efficacy, tolerability and safety of SB204 with respect to vehicle.

5. CHANGES TO THE PLANNED ANALYSES

Definition of PP population was clarified to include "Subjects who are discontinued from the study due to an adverse event related to study treatment or documented lack of treatment effect/worsening of condition will be included in the PP population."

A second definition of dichotomized IGA will be summarized, where subjects will be considered a success if their IGA score is at least two grades less than Baseline.

Subgroup summaries by age (< median age, >= median age) and gender (female, male) will be included.

6. INDEX OF TABLES AND FIGURES

Table 14.0.1.1: Summary of Subject Enrollment and Evaluability

	Vehicle QD	Vehicle BID	Combined Vehicle	SB204 2% BID	SB204 4% QD	SB204 4% BID	Combined SB204
Number of Subjects Randomized	xx	xx	xx	xx	xx	xx	xx
ITT Population							
Number of Subjects Included	xx	xx	xx	xx	xx	xx	xx
Number of Subjects Excluded	xx	xx	xx	xx	xx	xx	xx
PP Population							
Number of Subjects Included	xx	xx	xx	xx	xx	xx	xx
Number of Subjects Included with Violations[a]	xx	xx	xx	xx	xx	xx	xx
Number of Subjects Excluded	xx	xx	xx	xx	xx	xx	xx
Safety Population							
Number of Subjects Included	xx	xx	xx	xx	xx	xx	xx
Number of Subjects Excluded	xx	xx	xx	xx	xx	xx	xx

[a] Subjects who are discontinued from the study due to an adverse event related to study treatment or documented lack of treatment effect/worsening of condition are included in the PP population

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

Table 14.0.1.2: Summary of Subject Evaluability by Investigational Site
(Randomized Subjects)

		Vehicle QD			Vehicle BID			Combined Vehicle			SB204 2% BID			SB204 4% QD			SB204 4% BID			Combined SB204		
Inv. Site	Number Rand.	ITT	PP	Saf.	ITT	PP	Saf.	ITT	PP	Saf.	ITT	PP	Saf.	ITT	PP	Saf.	ITT	PP	Saf.	ITT	PP	Saf.
101	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
102	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
103	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
104	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
105	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
106	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
107	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
108	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
109	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
110	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
111	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
112	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
113	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
114	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
116	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
117	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
118	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
119	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
120	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
121	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

Inv. = Investigational, Rand. = Randomized, Saf. = Safety, ITT = Intent-to-Treat, PP = Per-Protocol

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

Table 14.0.2: Summary of Subject Completion/Discontinuation
(Randomized Subjects)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Completed Study							
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation							
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Worsening of Condition	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.xxx for other discontinuation reasons.

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

Table 14.0.3: Summary of Subjects Excluded from Analyses
(Randomized Subjects)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Number of Subjects Excluded from the ITT Population	xx	xx	xx	xx	xx	xx	xx
Reason for Exclusion from ITT							
Not Dispensed Study Medication	xx	xx	xx	xx	xx	xx	xx
Number of Subjects Excluded from the Safety Population	xx	xx	xx	xx	xx	xx	xx
Reason for Exclusion from Safety							
No Documented Use of Study Medication	xx	xx	xx	xx	xx	xx	xx
No Post-Baseline Safety Assessments	xx	xx	xx	xx	xx	xx	xx
Number of Subjects Excluded from the PP Population[a]	xx	xx	xx	xx	xx	xx	xx
Reason for Exclusion from PP							
Violated Inclusion/Exclusion	xx	xx	xx	xx	xx	xx	xx
Took Interfering Medications	xx	xx	xx	xx	xx	xx	xx
Did Not Attend Week 12 Visit	xx	xx	xx	xx	xx	xx	xx
Missed More than One Interim Study Visit	xx	xx	xx	xx	xx	xx	xx
Not Compliant with Dosing Regimen	xx	xx	xx	xx	xx	xx	xx
Week 12 Visit Out of Window	xx	xx	xx	xx	xx	xx	xx

[a] Subjects may have more than one deviation.

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

Table 14.1.1.1: Summary of Subject Demographic Characteristics
(Intent-to-Treat Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Age (years)							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Sex							
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity							
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race							
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing xx for a complete list of all other races.

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

Table 14.1.1.2: Summary of Subject Demographic Characteristics
(Per-Protocol Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Age (years)							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Sex							
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity							
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race							
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing xx for a complete list of all other races.

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

Table 14.1.1.3: Summary of Subject Demographic Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Age (years)							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Sex							
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity							
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race							
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing xx for a complete list of all other races.

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

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Non-Inflammatory Lesion Count							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Inflammatory Lesion Count							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Investigator's Global Assessment							
N	xx	xx	xx	xx	xx	xx	xx
Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.1.2.2: Summary of Subject Baseline Characteristics
(Per-Protocol Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Non-Inflammatory Lesion Count							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Inflammatory Lesion Count							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Investigator's Global Assessment							
N	xx	xx	xx	xx	xx	xx	xx
Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.1.2.3: Summary of Subject Baseline Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Non-Inflammatory Lesion Count							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Inflammatory Lesion Count							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Investigator's Global Assessment							
N	xx	xx	xx	xx	xx	xx	xx
Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.2.1.1.1: Summary of Lesion Counts at Baseline and Week 12
(Intent-to-Treat Population)
(Page 1 of 3)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Absolute Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline. Percent change from Baseline calculated as 100*(follow-up minus Baseline)/Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Summary of Lesion Counts at Baseline and Week 12
(Intent-to-Treat Population)
(Page 2 of 3)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Absolute Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline. Percent change from Baseline calculated as 100*(follow-up minus Baseline)/Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Summary of Lesion Counts at Baseline and Week 12
(Intent-to-Treat Population)
(Page 3 of 3)

Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Absolute Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline. Percent change from Baseline calculated as 100*(follow-up minus Baseline)/Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Summary of Lesion Counts at Baseline and Week 12
(Per-Protocol Population)
(Page 1 of 3)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Absolute Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline. Percent change from Baseline calculated as 100*(follow-up minus Baseline)/Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Summary of Lesion Counts at Baseline and Week 12
(Per-Protocol Population)
(Page 2 of 3)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Absolute Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline. Percent change from Baseline calculated as 100*(follow-up minus Baseline)/Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Summary of Lesion Counts at Baseline and Week 12
(Per-Protocol Population)
(Page 3 of 3)

Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Absolute Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline. Percent change from Baseline calculated as 100*(follow-up minus Baseline)/Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.2.1.1: Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.2.1.1: Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.2.1.2: Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)
(Page 1 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.2.1.2: Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)
(Page 2 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.2.2.1: Summary of Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)

Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.1.2.2.2: Summary of Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)

Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.1.2.3.1: Summary of Percent Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)

Percent Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.1.2.3.2: Summary of Percent Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)

Percent Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.1.3.1.1: Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.3.1.1: Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.3.1.2: Summary of Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)
(Page 1 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.3.1.2: Summary of Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)
(Page 2 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.3.2.1: Summary of Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.1.3.2.2: Summary of Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.1.3.3.1: Summary of Percent Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.1.3.3.2: Summary of Percent Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Per-Protocol Population)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.1.4.1.1: Summary of Total Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.4.1.1: Summary of Total Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.4.1.2: Summary of Total Lesion Counts at Each Evaluation
(Per-Protocol Population)
(Page 1 of 2)

Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.4.1.2: Summary of Total Lesion Counts at Each Evaluation
(Per-Protocol Population)
(Page 2 of 2)

Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.1.4.2.1: Summary of Change from Baseline in Total Lesion Counts at Each Evaluation
(Intent-to-Treat Population)

Change from Baseline in Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.1.4.2.2: Summary of Change from Baseline in Total Lesion Counts at Each Evaluation
(Per-Protocol Population)

Change from Baseline in Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.1.4.3.1: Summary of Percent Change from Baseline in Total Lesion Counts at Each Evaluation
(Intent-to-Treat Population)

Percent Change from Baseline in Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.1.4.3.2: Summary of Percent Change from Baseline in Total Lesion Counts at Each Evaluation
(Per-Protocol Population)

Percent Change from Baseline in Total Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.2.1.1: Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.1.1: Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 8						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.1.2: Summary of Investigator's Global Assessment at Each Evaluation
(Per-Protocol Population)
(Page 1 of 2)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.1.2: Summary of Investigator's Global Assessment at Each Evaluation
(Per-Protocol Population)
(Page 2 of 2)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 8						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.2.1: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population)

Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.2.1: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population)

Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.2.2: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Per-Protocol Population)
(Page 1 of 2)

Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.2.2.2: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Per-Protocol Population)
(Page 2 of 2)

Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.3.1.1: Primary Efficacy Analysis: Absolute Change from Baseline in Lesion Counts and Dichotomized IGA at Week 12
(Intent-to-Treat Population)
(Page 1 of 2)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Change from Baseline in Non-Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	
Change from Baseline in Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing SB204 treatment group with Combined Vehicle treatment group.
[b] P-value from a Cochran-Mantel-Haenszel test.

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.3.1.1: Primary Efficacy Analysis: Absolute Change from Baseline in Lesion Counts and Dichotomized IGA at Week 12
(Intent-to-Treat Population)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Dichotomized Investigator's Global Assessment -					
Clear or Almost Clear and at Least 2 Grades Less than Baseline					
N	xx	xx	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
P-Value[b]		x.xxx	x.xxx	x.xxx	
Dichotomized Investigator's Global Assessment -					
At Least 2 Grades Less than Baseline					
N	xx	xx	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
P-Value[b]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing SB204 treatment group with Combined Vehicle treatment group.
[b] P-value from a Cochran-Mantel-Haenszel test.

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.3.1.2: Primary Efficacy Analysis: Absolute Change from Baseline in Lesion Counts and Dichotomized IGA at Week 12
(Per-Protocol Population)
(Page 1 of 2)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Change from Baseline in Non-Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	
Change from Baseline in Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing SB204 treatment group with Combined Vehicle treatment group.
[b] P-value from a Cochran-Mantel-Haenszel test.

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.3.1.2: Primary Efficacy Analysis: Absolute Change from Baseline in Lesion Counts and Dichotomized IGA at Week 12
(Per-Protocol Population)
(Page 2 of 2)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Dichotomized Investigator's Global Assessment -					
Clear or Almost Clear and at Least 2 Grades Less than Baseline					
N	xx	xx	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
P-Value[b]		x.xxx	x.xxx	x.xxx	
Dichotomized Investigator's Global Assessment -					
At Least 2 Grades Less than Baseline					
N	xx	xx	xx	xx	
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
P-Value[b]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing SB204 treatment group with Combined Vehicle treatment group.
[b] P-value from a Cochran-Mantel-Haenszel test.

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.3.2: Sensitivity Analysis of Primary Endpoints: Absolute Change from Baseline in Lesion Counts and Dichotomized IGA at Week 12
(Intent-to-Treat Population)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Change from Baseline in Non-Inflammatory Lesion Counts					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	
Change from Baseline in Inflammatory Lesion Counts					
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	
Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline					
Success	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	
P-Value[b]		x.xxx	x.xxx	x.xxx	
Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline					
Success	xx.x%	xx.x%	xx.x%	xx.x%	
Failure	xx.x%	xx.x%	xx.x%	xx.x%	
P-Value[b]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing SB204 treatment group with Combined Vehicle treatment group. Values have been adjusted for multiple imputation.

[b] P-value from a Cochran-Mantel-Haenszel test. Value has been adjusted for multiple imputation.

Note: Missing values imputed using Markov Chain Monte Carlo (MCMC) multiple imputation.

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

Table 14.2.4.1.1: Secondary Efficacy Analysis: Percent Change from Baseline in Lesion Counts at Week 12
(Intent-to-Treat Population)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Percent Change from Baseline in Non-Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	
Percent Change from Baseline in Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing SB204 treatment group with Combined Vehicle treatment group.

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.4.1.2: Secondary Efficacy Analysis: Percent Change from Baseline in Lesion Counts at Week 12
(Per-Protocol Population)

	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Overall P-Value
Percent Change from Baseline in Non-Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	
Percent Change from Baseline in Inflammatory Lesion Counts					
N	xx	xx	xx	xx	
Mean	xx.x	xx.x	xx.x	xx.x	
SD	xx.xx	xx.xx	xx.xx	xx.xx	
Median	xx.x	xx.x	xx.x	xx.x	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
LSMean[a]	xx.x	xx.x	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	xx.xx	xx.xx	
Contrast P-Value[a]		x.xxx	x.xxx	x.xxx	

[a] Least squares mean, standard deviation and p-value from an analysis of covariance with factors of treatment group and corresponding baseline lesion count as the covariate. Contrast p-value from comparing each SB204 treatment group with Combined Vehicle treatment group.

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.4.2.1: Secondary Efficacy Analysis: Time to Improvement
(Intent-to-Treat Population)

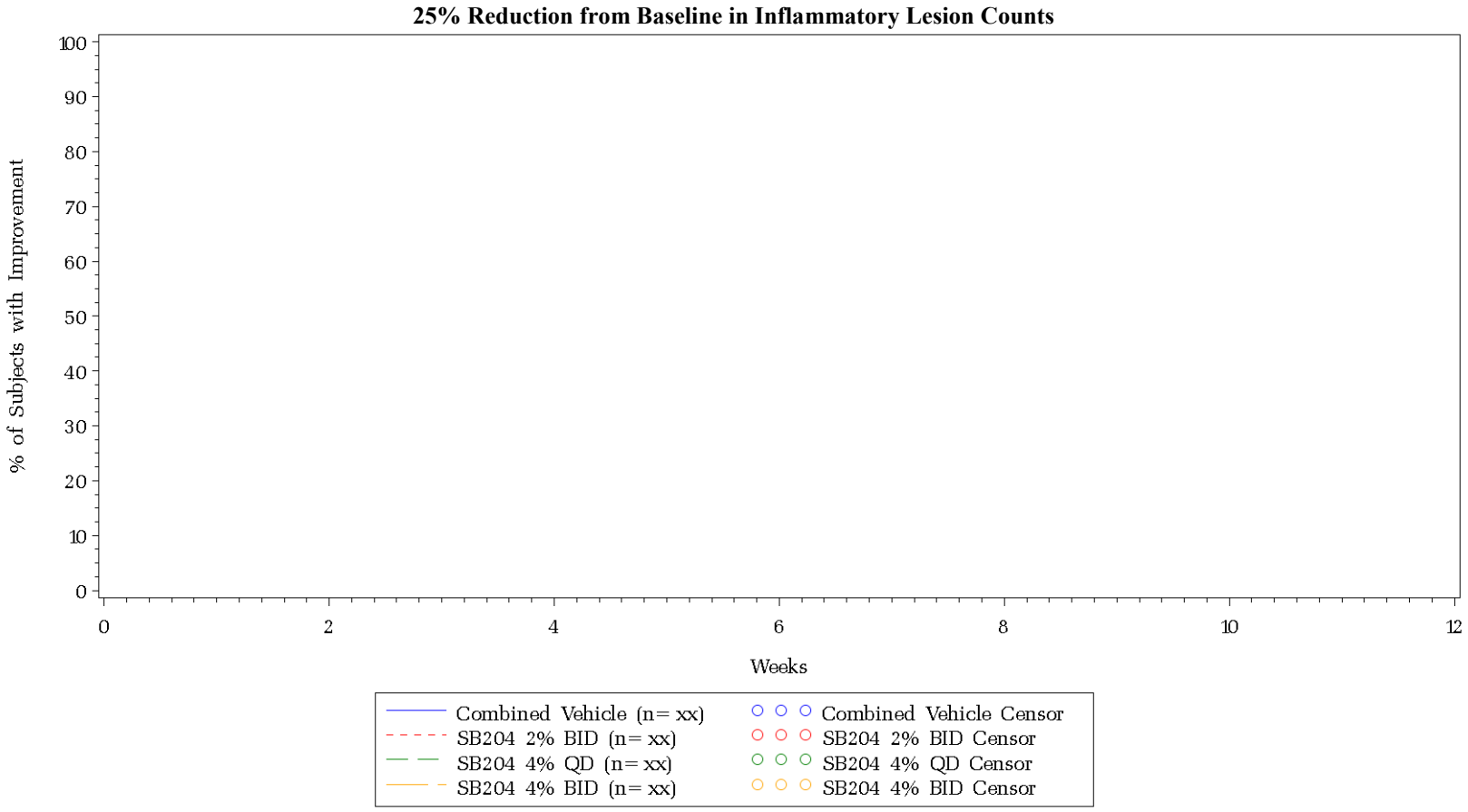
Time to Improvement	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
25% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
30% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
35% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
40% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
45% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
50% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx

[a] Median based on Kaplan-Meier method.
[b] P-value from a log-rank test comparing SB204 treatment group with Combined Vehicle treatment group.

Note: Subjects censored if improvement is not achieved by time of completion/discontinuation.

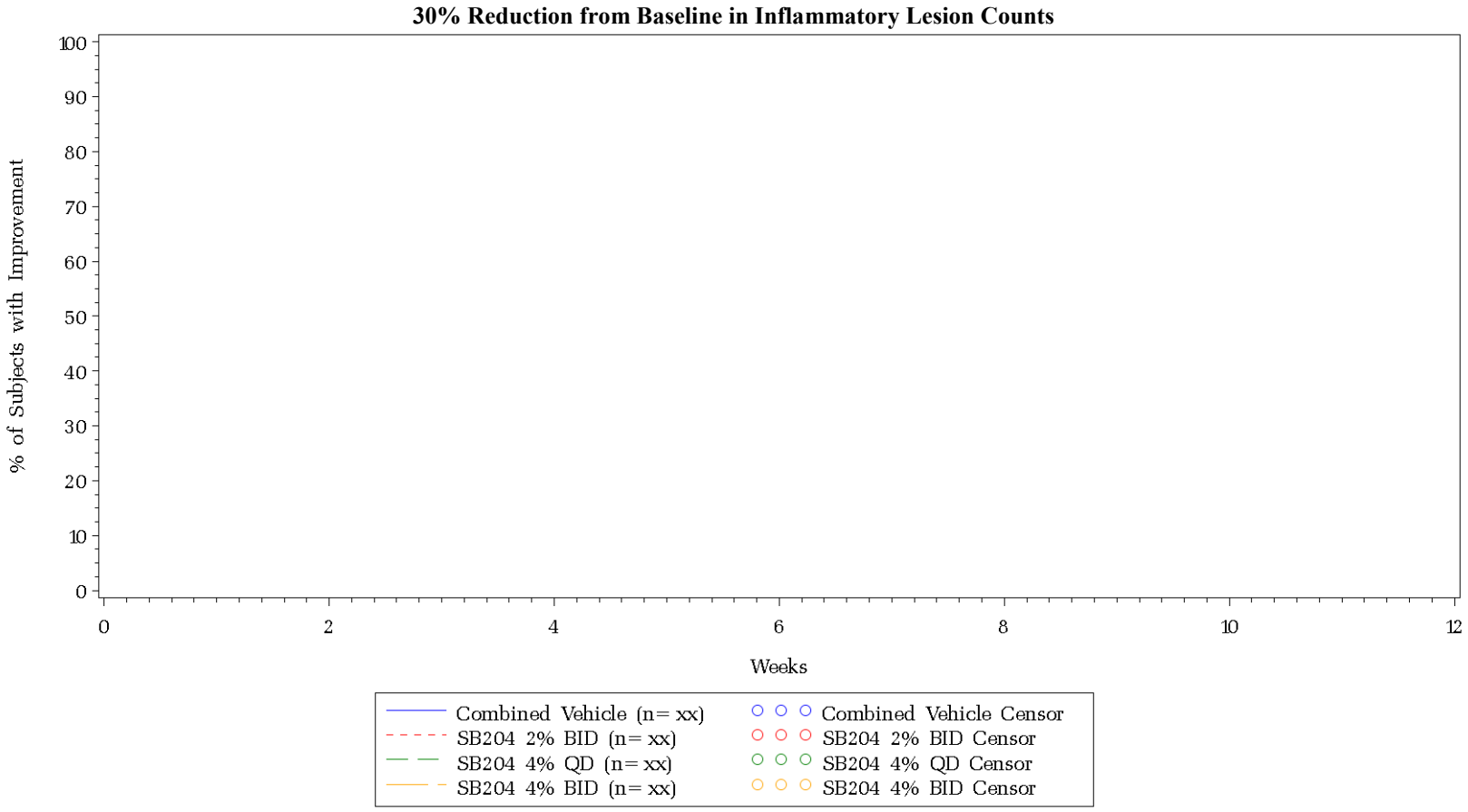
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Intent-to-Treat Population)
(Page 1 of 6)



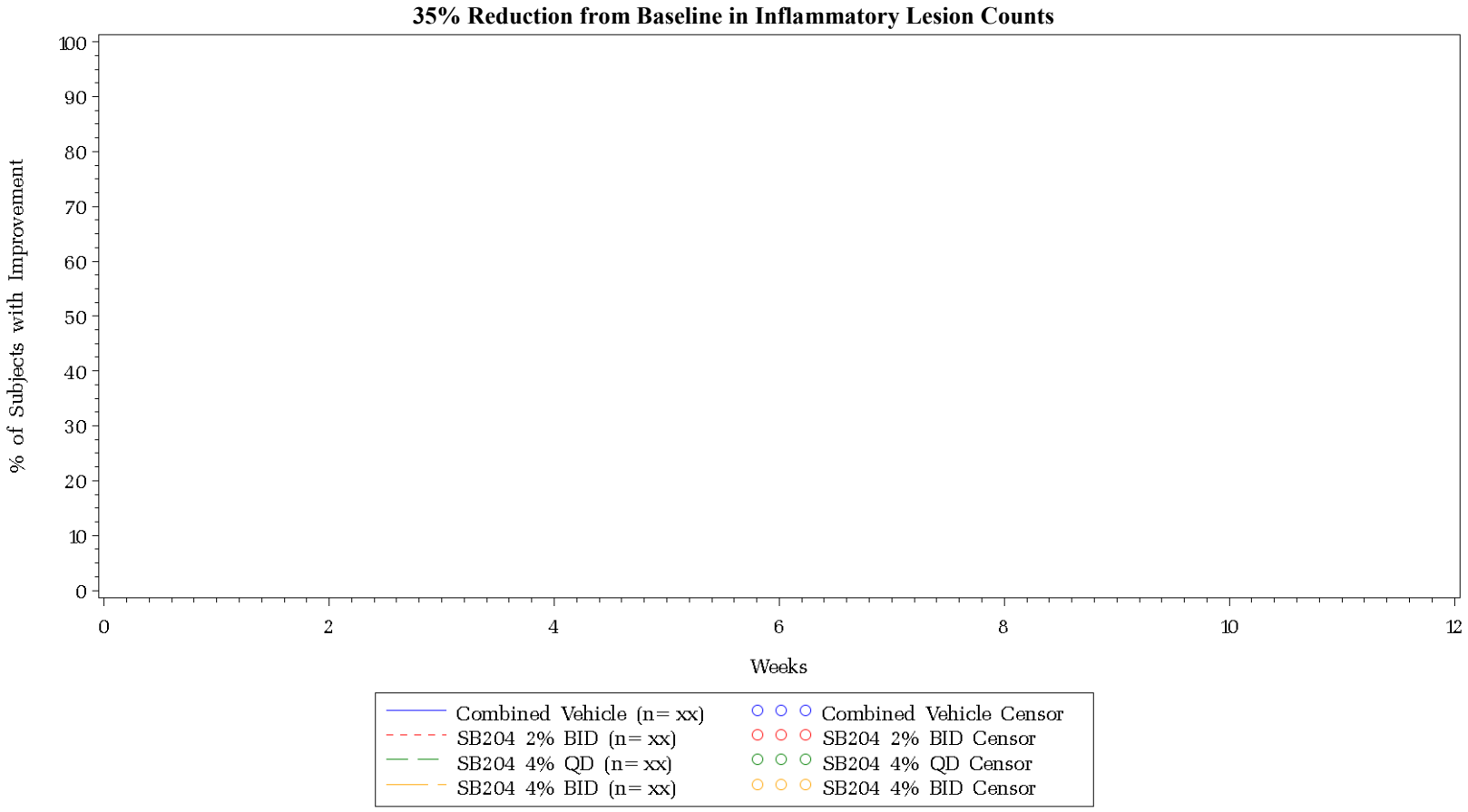
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Intent-to-Treat Population)
(Page 2 of 6)



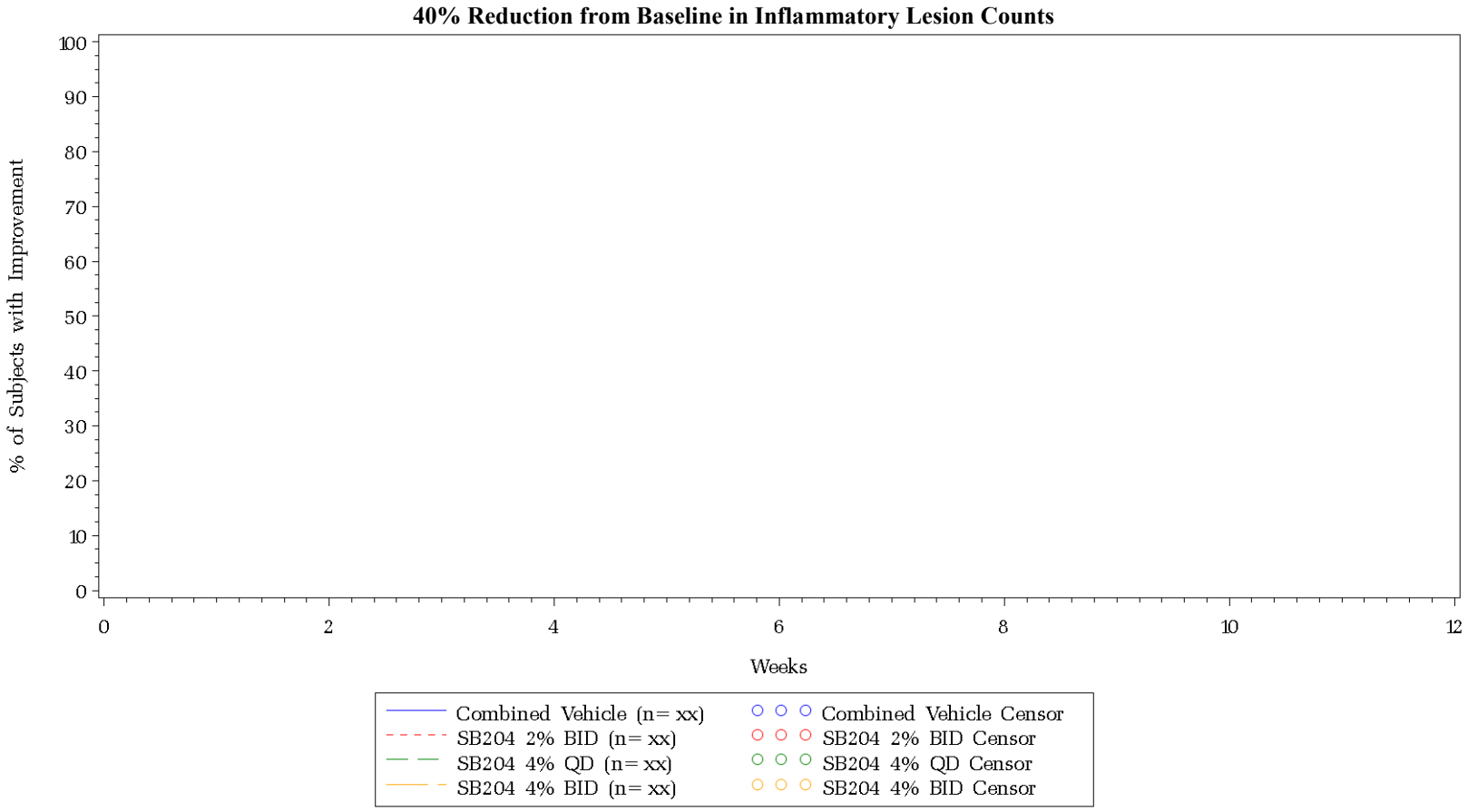
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Intent-to-Treat Population)
(Page 3 of 6)



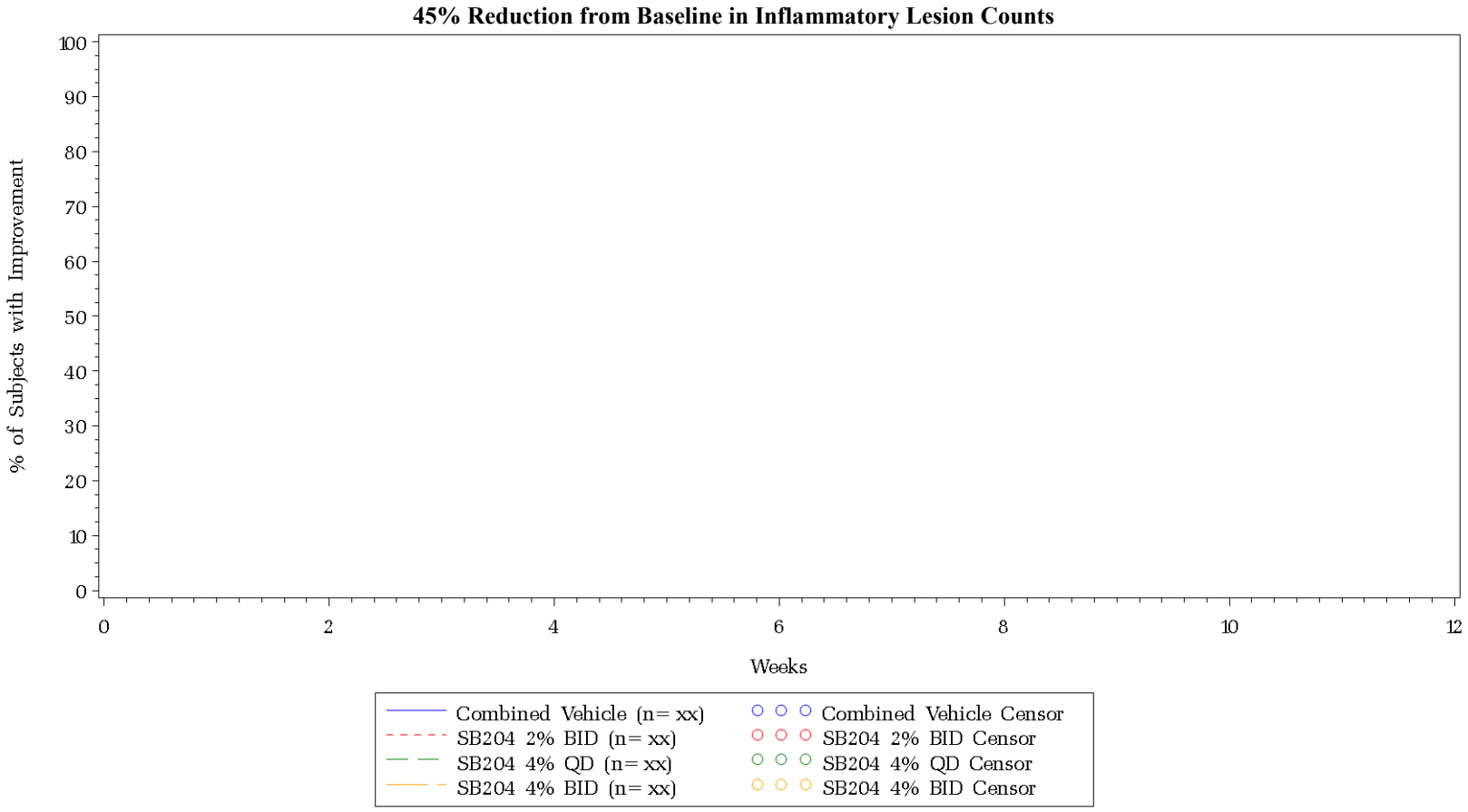
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Intent-to-Treat Population)
(Page 4 of 6)



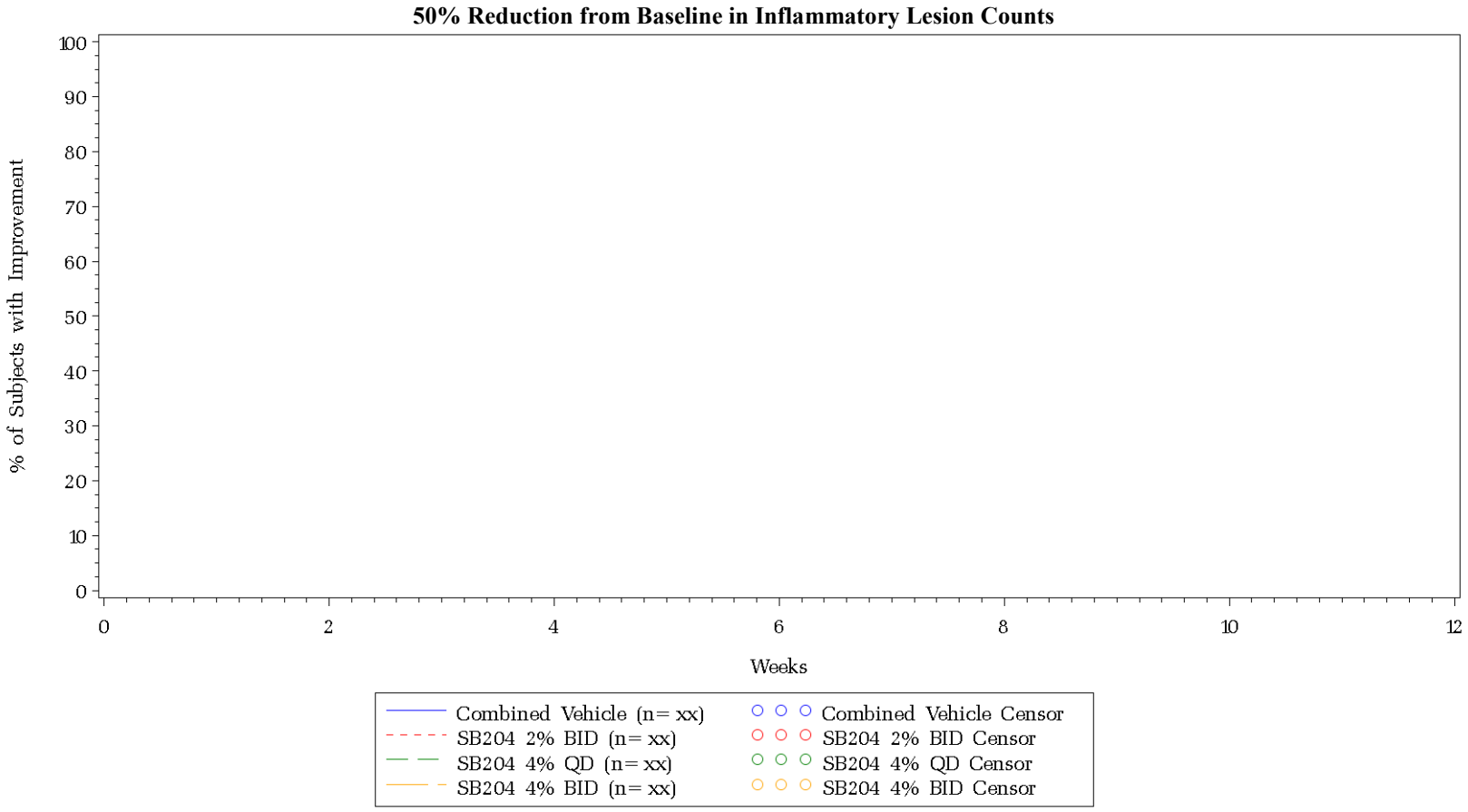
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Intent-to-Treat Population)
(Page 5 of 6)



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

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Intent-to-Treat Population)
(Page 6 of 6)



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

Table 14.2.4.2.2: Secondary Efficacy Analysis: Time to Improvement
(Per-Protocol Population)

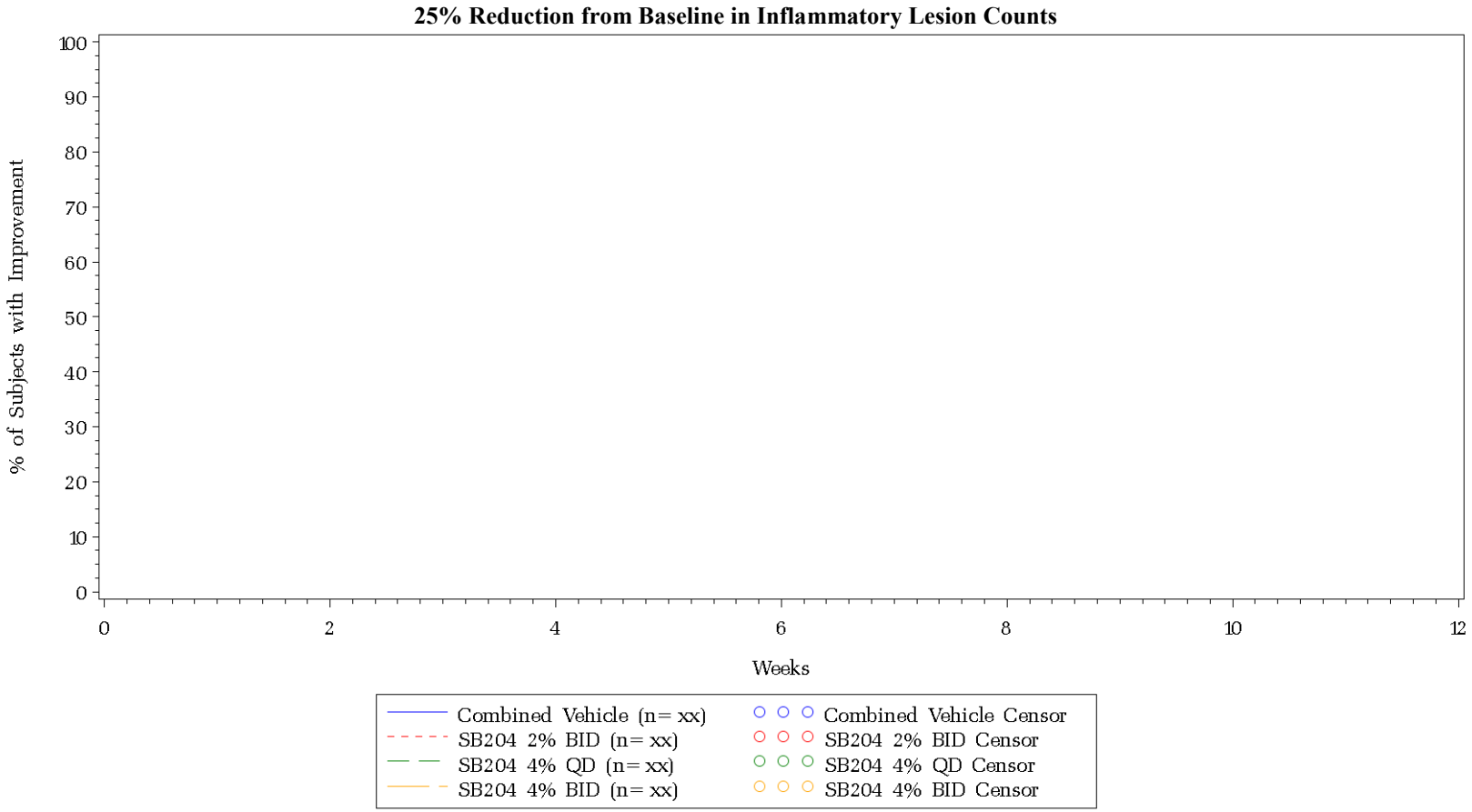
Time to Improvement	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
25% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
30% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
35% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
40% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
45% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx
50% Reduction from Baseline in Inflammatory Lesion Counts				
Median[a] (Weeks)	x.x	x.x	x.x	x.x
P-Value[b]		x.xxx	x.xxx	x.xxx

[a] Median based on Kaplan-Meier method.
[b] P-value from a log-rank test comparing SB204 treatment group with Combined Vehicle treatment group.

Note: Subjects censored if improvement is not achieved by time of completion/discontinuation.

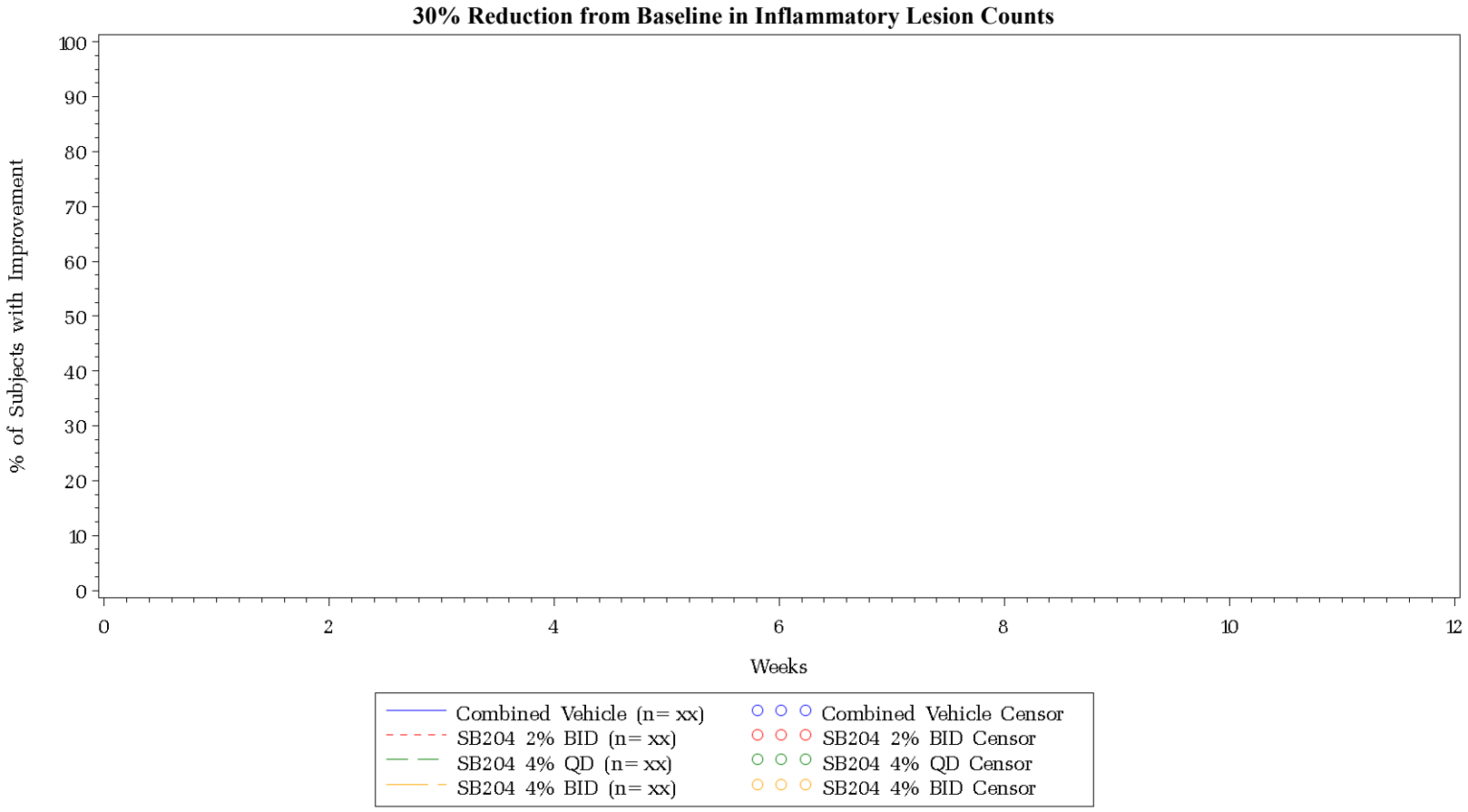
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.2: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Per-Protocol Population)
(Page 1 of 6)



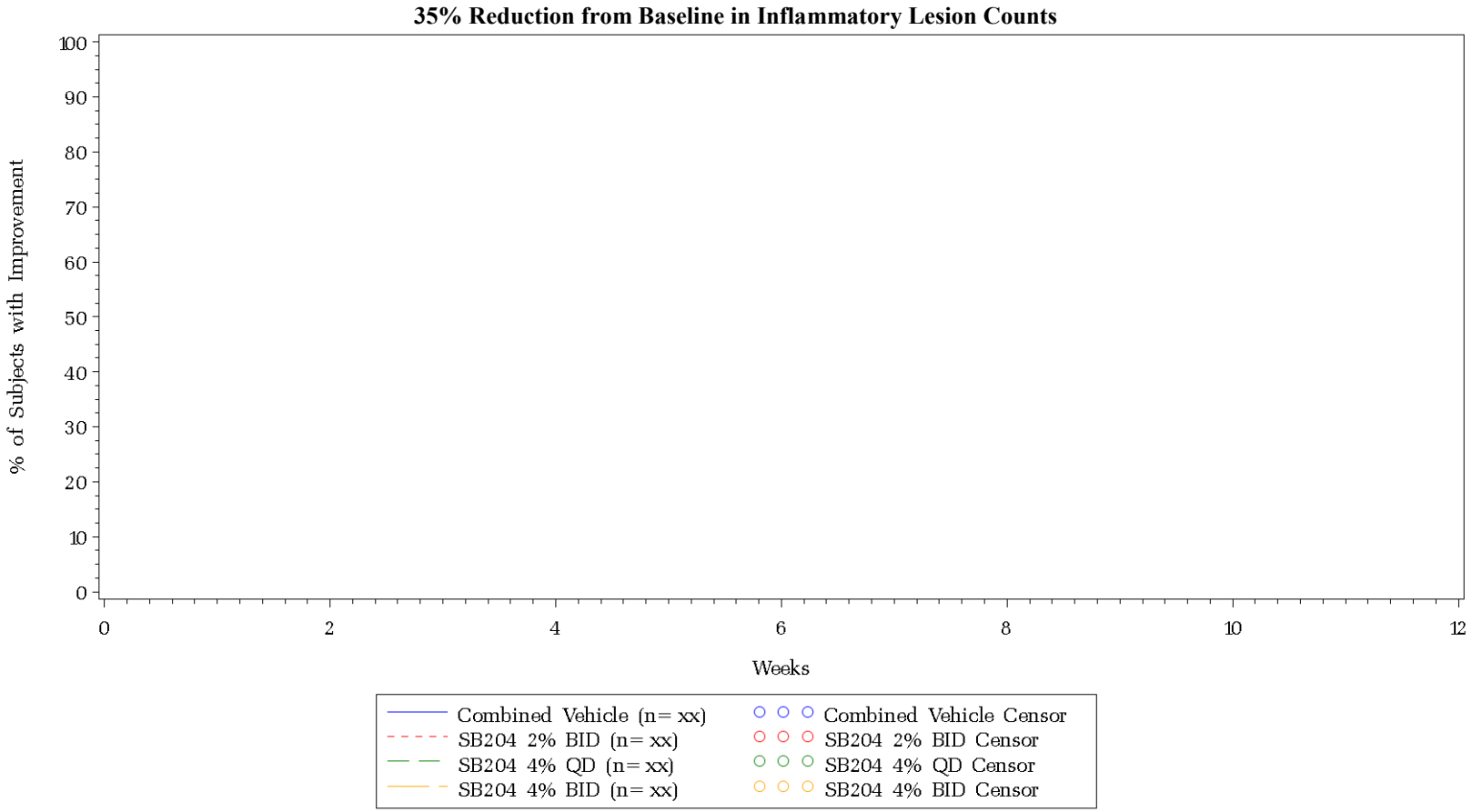
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.2: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Per-Protocol Population)
(Page 2 of 6)



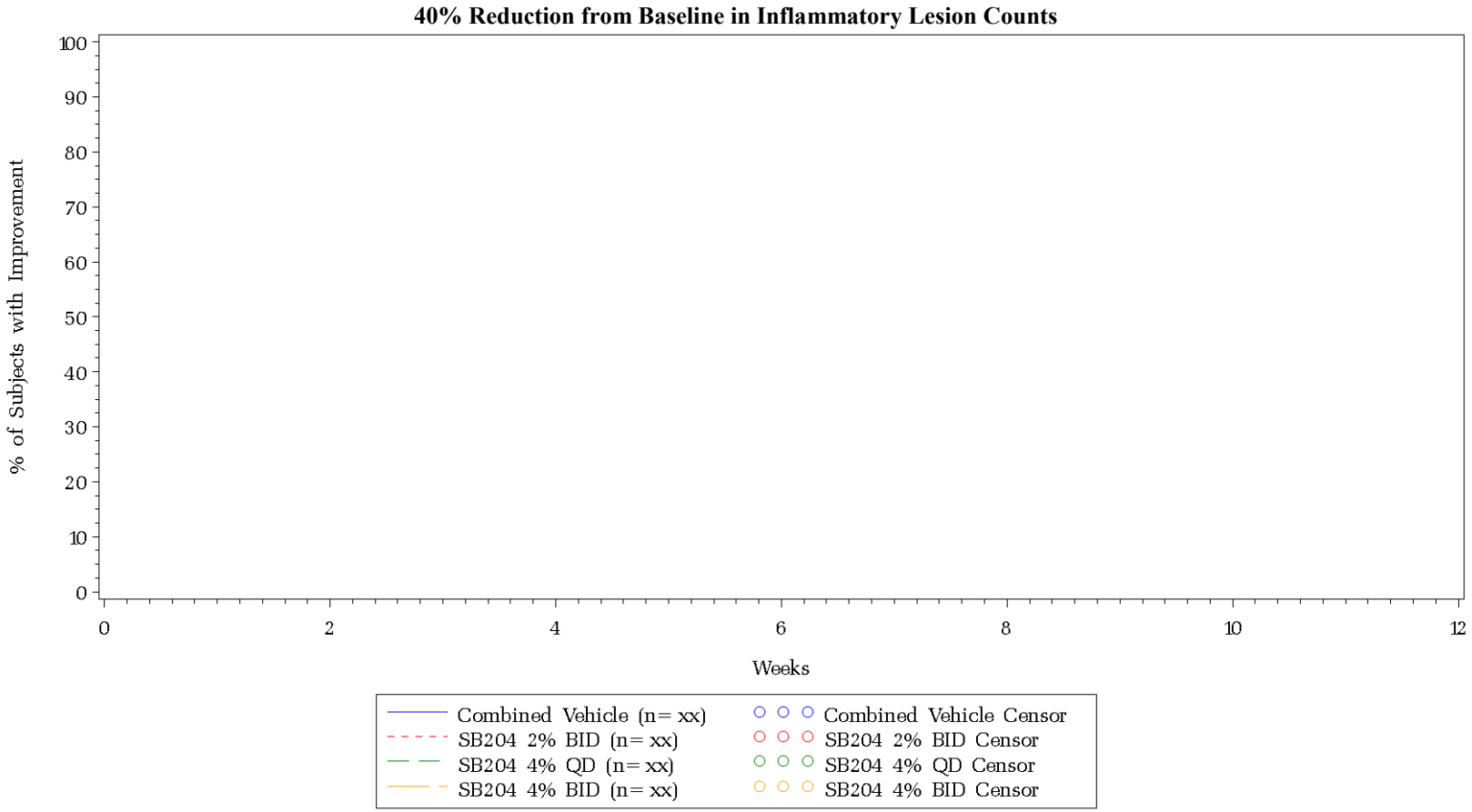
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.1: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Per-Protocol Population)
(Page 3 of 6)



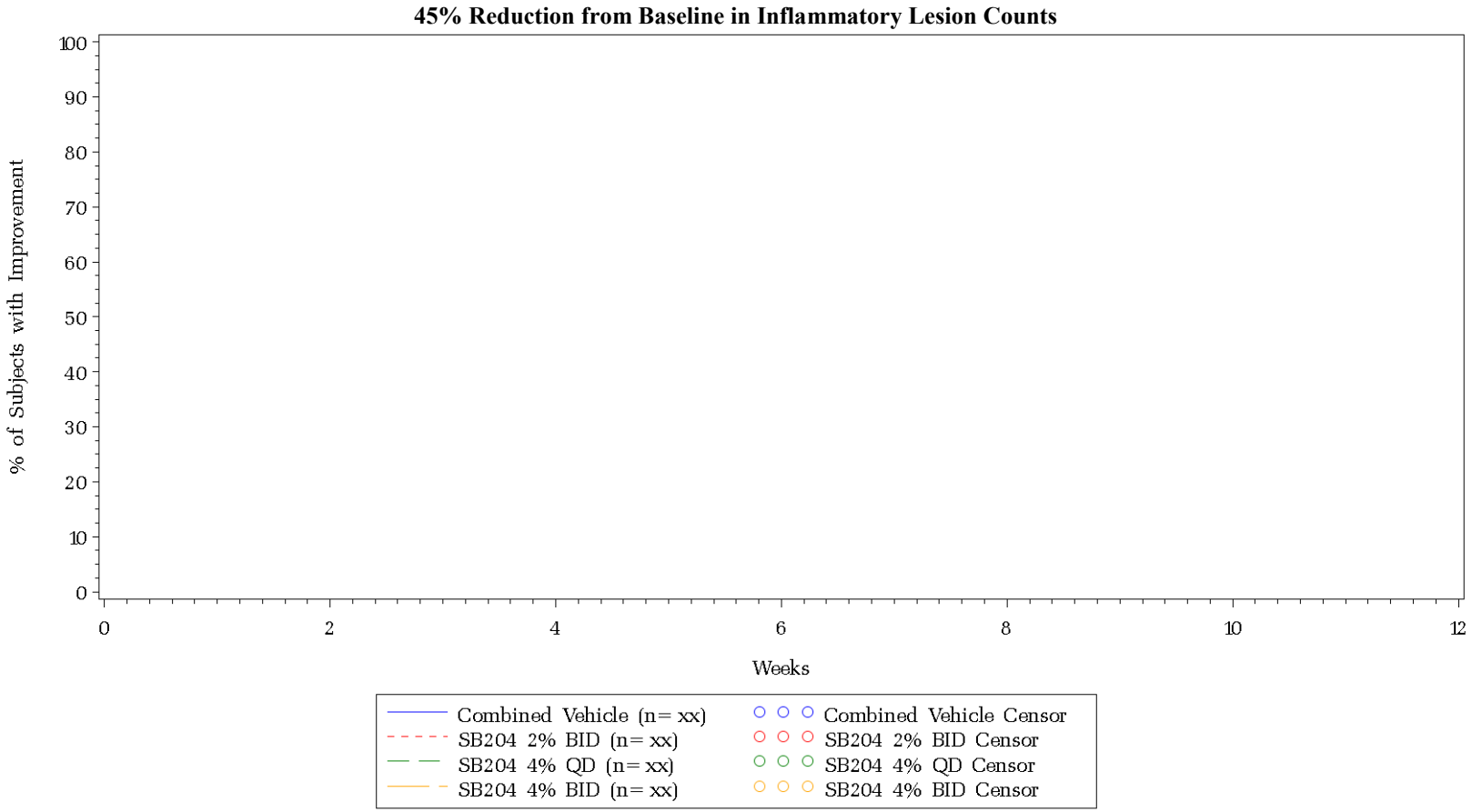
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.2: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Per-Protocol Population)
(Page 4 of 6)



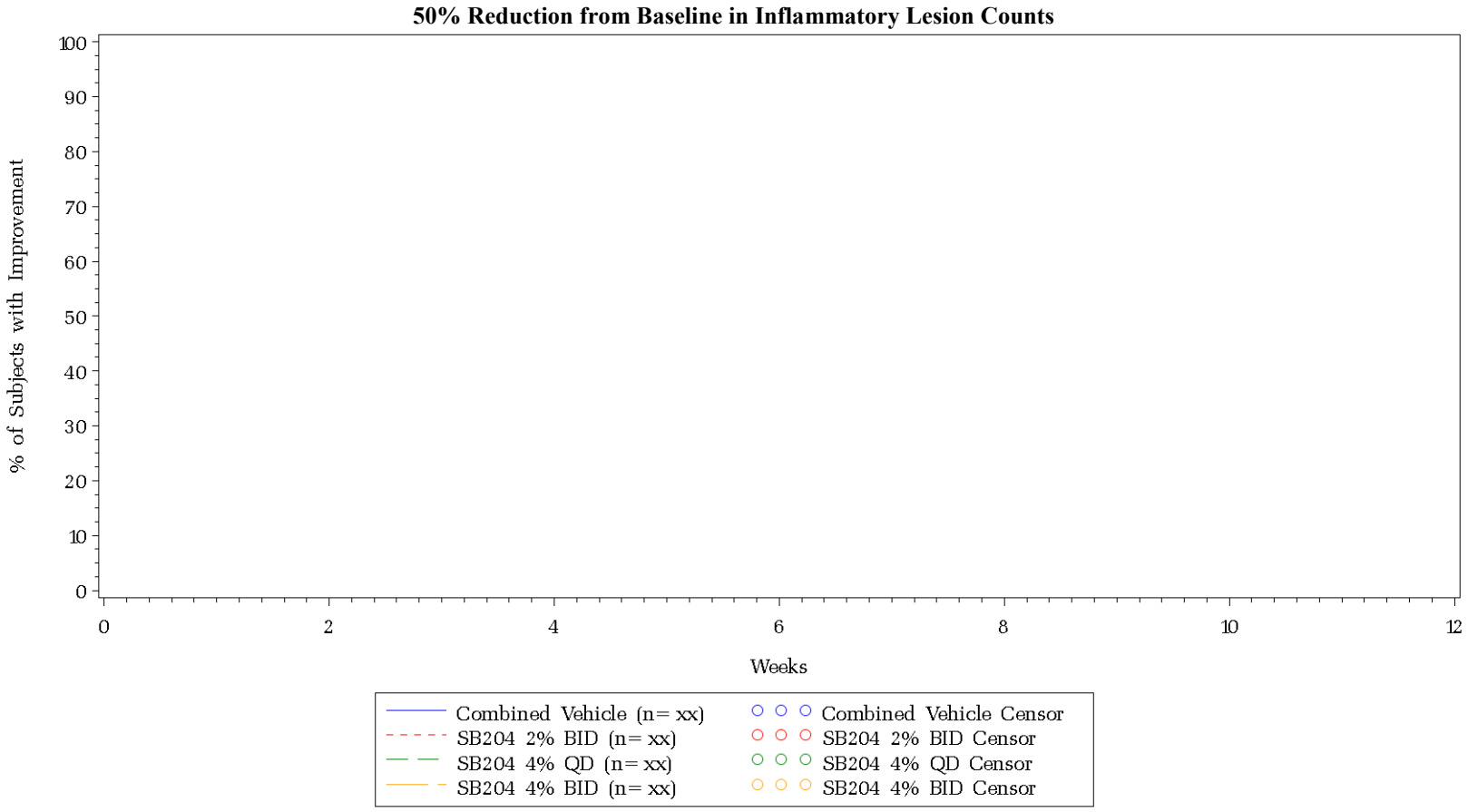
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.4.2.2: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Per-Protocol Population)
(Page 5 of 6)



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

Figure 14.2.4.2.2: Secondary Efficacy Analysis: Kaplan-Meier Curves for Time to Improvement
(Per-Protocol Population)
(Page 6 of 6)



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

Table 14.2.5.1.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)
(Page 1 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.2: Subgroup Summary of Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.5.1.3: Subgroup Summary of Percent Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Percent Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.5.1.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)
(Page 1 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)
(Page 2 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.5: Subgroup Summary of Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.5.1.6: Subgroup Summary of Percent Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.5.1.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 8						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.1.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Male)

Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)
(Page 1 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)
(Page 2 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.2: Subgroup Summary of Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.5.2.3: Subgroup Summary of Percent Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Percent Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.5.2.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)
(Page 1 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)
(Page 2 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.5: Subgroup Summary of Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.5.2.6: Subgroup Summary of Percent Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.5.2.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 8						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.5.2.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Sex = Female)

Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})
(Page 1 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.2: Subgroup Summary of Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.6.1.3: Subgroup Summary of Percent Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Percent Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.6.1.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.5: Subgroup Summary of Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.6.1.6: Subgroup Summary of Percent Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.6.1.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 8						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})
(Page 1 of 2)

Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.1.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age >= {median age})

Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})
(Page 1 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.1: Subgroup Summary of Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})
(Page 2 of 2)

Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.2: Subgroup Summary of Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.6.2.3: Subgroup Summary of Percent Change from Baseline in Non-Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Percent Change from Baseline in Non-Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.6.2.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})
(Page 1 of 2)

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.4: Subgroup Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.5: Subgroup Summary of Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Change from Baseline calculated as follow-up minus Baseline.

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

Table 14.2.6.2.6: Subgroup Summary of Percent Change from Baseline in Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Percent Change from Baseline in Inflammatory Lesion Counts	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12						
N	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: Missing values imputed using last observation carried forward. Percent change from Baseline calculated as 100* (follow-up minus Baseline)/Baseline.

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

Table 14.2.6.2.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age < {median age})
(Page 1 of 2)

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Baseline						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.7: Subgroup Summary of Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Investigator's Global Assessment[a]	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 8						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
0 Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] 0 = Clear: Clear skin with no inflammatory or non-inflammatory lesions
1 = Almost clear: Few non-inflammatory lesions with no more than rare papules (papules may be resolving and hyperpigmented, though not pink-red)
2 = Mild: Some non-inflammatory lesions with no more than a few inflammatory lesions
3 = Moderate: Up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one nodular lesion
4 = Severe: Up to many non-inflammatory and inflammatory lesions, including nodular lesions

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Dichotomized Investigator's Global Assessment - Clear or Almost Clear and at Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.2.6.2.8: Summary of Dichotomized Investigator's Global Assessment at Each Evaluation
(Intent-to-Treat Population; Age < {median age})

Dichotomized Investigator's Global Assessment - At Least 2 Grades Less than Baseline	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Week 2						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12						
N	xx	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing values imputed using last observation carried forward.

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

Table 14.3.0.1: Summary of Extent of Exposure
(Page 1 of 3)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Intent-to-Treat Subjects					
Number of Applications					
N	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Compliant[a]					
N	xx	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of expected applications.

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

Table 14.3.0.1: Summary of Extent of Exposure
(Page 2 of 3)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Per-Protocol Subjects					
Number of Applications					
N	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Compliant[a]					
N	xx	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of expected applications.

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

Table 14.3.0.1: Summary of Extent of Exposure
(Page 3 of 3)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)
Safety Subjects					
Number of Applications					
N	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Compliant[a]					
N	xx	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of expected applications.

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

Table 14.3.0.2: Summary of Cutaneous Tolerability Assessments
(Safety Population)
(Page 1 of 5)

Erythema	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.0.2: Summary of Cutaneous Tolerability Assessments
(Safety Population)
(Page 2 of 5)

Scaling	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.0.2: Summary of Cutaneous Tolerability Assessments
(Safety Population)
(Page 3 of 5)

Dryness	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.0.2: Summary of Cutaneous Tolerability Assessments
(Safety Population)
(Page 4 of 5)

Pruritus	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.0.2: Summary of Cutaneous Tolerability Assessments
(Safety Population)
(Page 5 of 5)

Burning/Stinging	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.1.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Number (%) of Subjects Reporting At Least One Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
By Subject							
Maximum Severity							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongest Relationship to Study Drug							
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related							
Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
By Subject							
Maximum Severity within Relationship to Study Drug							
Unrelated							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possible							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Number of Events Reported	xx	xx	xx	xx	xx	xx	xx
By Event							
Serious							
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death							
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severity							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Relationship to Study Drug							
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related							
Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 4 of 4)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
By Event							
Severity within Relationship to Study Drug							
Unrelated							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possible							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.1.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population - By Subject)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary term. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.1.3: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population - By Event)
(Page 1 of xx)

System Organ Class Preferred Term	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.1.4: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)

System Organ Class[a] Preferred Term	Severity	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary term. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.1.5: Summary of Treatment-Emergent Adverse Events by Relationship to Study Drug
(Safety Population)

System Organ Class[a] Preferred Term	Relationship	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary term. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 1 of 4)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
By Subject							
Maximum Severity							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongest Relationship to Study Drug							
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related							
Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.2.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
By Subject							
Maximum Severity within Relationship to Study Drug							
Unrelated							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possible							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.2.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 3 of 4)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Number of Serious Events Reported	xx	xx	xx	xx	xx	xx	xx
By Event							
Death							
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severity							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Relationship to Study Drug							
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related							
Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.2.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)

	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
By Event							
Severity within Relationship to Study Drug							
Unrelated							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possible							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite							
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.2.2: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population - By Subject)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary term. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2.3: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population - By Event)
(Page 1 of xx)

System Organ Class Preferred Term	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.

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

Table 14.3.1.1.2.4: Summary of Treatment-Emergent Serious Adverse Events by Severity
(Safety Population)

System Organ Class[a] Preferred Term	Severity	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary term. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2.5: Summary of Treatment-Emergent Serious Adverse Events by Relationship to Study Drug
(Safety Population)

System Organ Class[a] Preferred Term	Relationship	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
System Organ Class	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Definite	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary term. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: MedDRA Version 17.0
Treatment-emergent adverse events are those with an onset after application of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 1 of 9)

Systolic Blood Pressure (mmHg)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 2 of 9)

Systolic Blood Pressure (mmHg)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 3 of 9)

Systolic Blood Pressure (mmHg)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 4 of 9)

Diastolic Blood Pressure (mmHg)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 5 of 9)

Diastolic Blood Pressure (mmHg)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 6 of 9)

Diastolic Blood Pressure (mmHg)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 7 of 9)

Pulse Rate (beats/min)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 8 of 9)

Pulse Rate (beats/min)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 4							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 8							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Vital Signs
(Safety Population)
(Page 9 of 9)

Pulse Rate (beats/min)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.1.1: Summary of Chemistry Results
(Safety Population)
(Page 1 of xx)

Test Name (Units)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.

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

Table 14.3.1.3.1.2: Summary of Hematology Results
(Safety Population)
(Page 1 of xx)

Test Name (Units)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.

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

Table 14.3.1.3.1.3: Summary of PT/PTT Results
(Safety Population)
(Page 1 of xx)

Test Name (Units)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.

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

Table 14.3.1.3.2.1: Shift Table for Chemistry Results
(Safety Population)
(Page 1 of xx)

Test Name (Units)

Vehicle QD (N=xx)

	Week 12 (N=xx)		
Baseline	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)

	Week 12 (N=xx)		
Baseline	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%)

Combined Vehicle (N=xx)

	Week 12 (N=xx)		
Baseline	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%)

Note: No imputations were made for missing data
BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit

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

Table 14.3.1.3.2.1: Shift Table for Chemistry Results
(Safety Population)
(Page 2 of xx)

Test Name (Units)

SB204 2% BID (N=xx)

	Week 12 (N=xx)		
Baseline	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%)

SB204 4% QD (N=xx)

	Week 12 (N=xx)		
Baseline	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%)

SB204 4% BID (N=xx)

	Week 12 (N=xx)		
Baseline	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%)

Combined SB204 (N=xx)

	Week 12 (N=xx)		
Baseline	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%)

Note: No imputations were made for missing data
BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit

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

Table 14.3.1.3.2.2: Shift Table for Hematology Results
(Safety Population)
(Page 1 of xx)

Test Name (Units)

Vehicle QD (N=xx)		Week 12 (N=xx)		
	Baseline	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)		Week 12 (N=xx)		
	Baseline	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%)
Combined Vehicle (N=xx)		Week 12 (N=xx)		
	Baseline	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%)

Note: No imputations were made for missing data
BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit

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

Table 14.3.1.3.2.2: Shift Table for Hematology Results
(Safety Population)
(Page 2 of xx)

Test Name (Units)

		Week 12 (N=xx)		
SB204 2% BID (N=xx)	Baseline	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%)
		Week 12 (N=xx)		
SB204 4% QD (N=xx)	Baseline	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%)
		Week 12 (N=xx)		
SB204 4% BID (N=xx)	Baseline	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%)
		Week 12 (N=xx)		
Combined SB204 (N=xx)	Baseline	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%)

Note: No imputations were made for missing data
BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit

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

Table 14.3.1.3.2.3: Shift Table for PT/PTT Results
(Safety Population)
(Page 1 of xx)

Test Name (Units)

Vehicle QD (N=xx)

	Week 12 (N=xx)		
Baseline	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)

	Week 12 (N=xx)		
Baseline	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%)

Combined Vehicle (N=xx)

	Week 12 (N=xx)		
Baseline	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%)

Note: No imputations were made for missing data
BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit

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

Table 14.3.1.3.2.3: Shift Table for PT/PTT Results
(Safety Population)
(Page 2 of xx)

Test Name (Units)

		Week 12 (N=xx)		
SB204 2% BID (N=xx)	Baseline	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%)
		Week 12 (N=xx)		
SB204 4% QD (N=xx)	Baseline	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%)
		Week 12 (N=xx)		
SB204 4% BID (N=xx)	Baseline	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%)
		Week 12 (N=xx)		
Combined SB204 (N=xx)	Baseline	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%)

Note: No imputations were made for missing data
BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit

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

Table 14.3.1.4: Summary of Methemoglobin Level
(Safety Population)
(Page 1 of 2)

Methemoglobin Level (%)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Baseline							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 2							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.

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

Table 14.3.1.4: Summary of Methemoglobin Level
(Safety Population)
(Page 2 of 2)

Methemoglobin Level (%)	Vehicle QD (N=xx)	Vehicle BID (N=xx)	Combined Vehicle (N=xx)	SB204 2% BID (N=xx)	SB204 4% QD (N=xx)	SB204 4% BID (N=xx)	Combined SB204 (N=xx)
Week 12							
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
	Change from Baseline						
N	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: No imputations were made for missing data. Change from Baseline values calculated as post-Baseline – Baseline.

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

7. INDEX OF LISTINGS