STATISTICAL ANALYSIS PLAN

Protocol Number:	SGT-54-02
Study Title:	A Phase 3 Multi-Center, Double-Blind, Randomized, Vehicle-Controlled Study of S5G4T-1 in the Treatment of Papulopustular Rosacea
Development Phase of Study:	3
Sponsor:	Sol-Gel Technologies Ltd.
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Statistical Analysis Plan based on Protocol Version:	4
Statistical Analysis Plan Date:	02MAY2019
Statistical Analysis Plan Version:	V1.0

SAP Approval

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

SAP Change History

Version	Date	Summary of Changes	Author
1	02MAY2019	Original document	[redacted]

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	adverse event(s)
ANCOVA	analysis of covariance
ANOVA	analysis of variance
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
C	Celsius
cm	centimeters
CRF(s)	case report form(s)
eCRF(s)	electronic case report form(s)
E-BPO	encapsulated benzoyl peroxide
FDA	Food and Drug Administration
GCP	good clinical practice
IGA	Investigator Global Assessment
ITT	Intent-to-Treat
IWRS	Interactive Web Response System
kg	kilograms
LOCF	last observation carried forward
LSMean or LSM	least square mean
max	maximum
MCMC	Markov Chain Monte Carlo
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
min	minimum
n	number of observations
N	number of subjects (sample size)
PAPI	Patient Assessment of Papulopustular rosacea Impacts
PAPSS	Patient Assessment of Papulopustular Rosacea Signs and Symptoms
PGI-C	Patient Global Impression of Change
PGI-S	Patient Global Impression of Symptom Severity
PGI-SE	Patient Global Impression of Treatments Side Effects
PGI-TS	Patient Global Impression of Treatments Satisfaction
PP	per-protocol

PT	preferred term
QST	QST Consultations, Ltd.
RosQoL	Rosacea Quality-of-Life
SAE(s)	serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	standard deviation
SOC	system organ class
TEAE(s)	treatment-emergent adverse event(s)
WHO	World Health Organization

2. PREFACE

This Statistical Analysis Plan (SAP) describes the statistical analyses as it is foreseen before breaking the blind. The SAP will serve as a compliment to the study protocol and supersedes it in case of differences. In case of major differences between the study protocol and SAP, e.g. changes in the analysis related to the primary endpoint, a protocol amendment will be considered. The SAP may be updated during the study conduct and will be finalized before breaking the blind.

The following documents were reviewed in preparation of this SAP:

- Clinical Study Protocol SGT-54-02
    - Version 1.0 issued on 15MAR2018,
    - Version 2.0 issued on 30APR2018,
    - Version 3.0 issued on 07JUN2018,
    - Version 4.0 issued on 13NOV2018
- Case report form (CRF) for SGT-54-02.
- ICH E9 Guidance on Statistical Principles for Clinical Trials.
- ICH E3 Structure and Content of Clinical Study Reports (CSRs)

The reader of this SAP is encouraged to also read the clinical protocol for details on the conduct of this study, and the operational aspects of clinical assessments and timing for completing a patient in this study.

3. RESPONSIBILITIES

The study statistician will be responsible for the statistical analysis planning. QST Consultations, Ltd. (QST), a Contract Research Organization (CRO) selected by Sol-Gel, will be responsible for the execution of all statistical programming deliverables. The statistical programming work will be supervised by the study statistician.

4. INTRODUCTION

S5G4T-1 is an innovative topical formulation containing 5% encapsulated benzoyl peroxide (E-BPO) that Sol-Gel is developing for the treatment of papulpustular rosacea. If approved, S5G4T-1 will be the first product containing E-BPO for the treatment of papulpustular rosacea. Sol-Gel believes S5G4T-1 has the potential to be as tolerable as, and more effective than, currently marketed rosacea drugs.

Rosacea is a chronic and recurrent inflammatory dermatological disorder of unknown etiology. The disease is common, especially in fair-skinned people of Celtic and northern European heritage. The onset of the disorder is usually between the ages of 30 and 50. Early stages of the disease affect women more often than men at a ratio of 3 to 1 [1, 2]. Rosacea usually starts as flushing and subtle redness on the cheeks, nose, chin or forehead. Alcohol, hot drinks, spicy foods, stress, sunlight and extreme heat or cold can trigger the onset of this disease. If left untreated, rosacea can slowly worsen over time. As the condition progresses, patients experience inflammatory lesions (papules and pustules), vivid erythema and telangiectasia. Patients may develop furuncles, cystic nodules, granulomas and tissue hypertrophy, sometimes leading to rhinophyma.

Rosacea is treated with both systemic and topical therapies. However, topical therapies are preferable because of side effects caused by the use of systemic therapies.

According to the U.S. National Rosacea Society, approximately 16 million people in the United States are affected by rosacea. According to a study commissioned by the Sponsor, approximately 4.8 million people in the United States experience subtype II symptoms and physicians estimate that only 20% of the U.S. rosacea population is treated. The topical drugs approved by the Food and Drug Administration (FDA) to treat subtype II rosacea generated aggregate revenues of approximately $392 million in the United States for the 12 months period ending June 30, 2017.

In August 2012, Sol-Gel completed a double blind, randomized, dose-ranging Phase 2 trial for S5G4T-1 involving 92 adult patients at ten centers in the United States (SGT-EBPO1-09: A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Dose-Range Study of

Encapsulated Benzoyl Peroxide Gel, 1% and 5%, and Vehicle Gel in the Treatment of Rosacea). The Phase 2 trial had two co-primary endpoints: success in Investigator Global Assessment (IGA) namely, a two-grade reduction in IGA on a scale of 0 to 4 ("clear", "almost clear", "mild", "moderate", "severe") with clear or almost clear at Week 12; and a reduction in the mean inflammatory lesion count at Week 12 (end of trial). The second co-primary endpoint was the change from Baseline in the inflammatory lesions (papules and pustules) count at end of trial. All patients were 18 years of age or older with 12 or more inflammatory lesions at enrollment. Patients were randomly divided into three groups of 30 to 32 patients each and received a once daily dose, with one group receiving S5G4T-1 (E-BPO 5%), a second group receiving a 1% concentration of E-BPO and a third control group receiving the vehicle (placebo) alone. The evaluator rated the following signs of local skin irritation on a scale of 0 to 3 ("none", "mild", "moderate", "severe") for dryness and scaling. Information on adverse events (AEs) was also collected.

Both E-BPO 1% and S5G4T-1 demonstrated statistically significant improvement in comparison to the vehicle in reducing papulopustular lesions based on the percentage change in the inflammatory lesion count from Baseline at Week 12, $p = 0.014$ and $p = 0.02$, respectively, and S5G4T-1 also demonstrated statistically significant improvement in comparison to the vehicle in achieving the IGA success co-primary endpoint ($p = 0.0013$). All three formulations were well tolerated. A few patients had moderate local application site irritation (dryness, scaling, pruritus, stinging and burning) during treatment.

A clear trend of dose response with IGA success of 20.0% for the vehicle, 37.5% for the E-BPO 1% and 53.3% for S5G4T-1 was observed. Both S5G4T-1 and E-BPO 1% significantly reduced the number of inflammatory lesions with a trend towards dose response indicated by median reduction of 10 lesions in the vehicle group compared to 12.5 and 15 in the E-BPO 1% and S5G4T-1 groups, respectively.

5. STUDY OBJECTIVES

The primary objectives of this pivotal study are:

- To assess the efficacy and safety of S5G4T-1 compared to S5G4T-1 Vehicle when applied once daily for 12 weeks in patients with papulopustular rosacea.

5.1 Secondary Objective

The secondary objective of this pivotal study is:

- To demonstrate statistical superiority in efficacy of S5G4T-1 compared to the vehicle with regard to percent change from baseline.

5.2 Supportive Objective

The supportive objective of this pivotal study is:

- To determine the time required to observe improvement in the efficacy parameters associated with clearance of rosacea for S5G4T-1 compared to vehicle.

5.3 Safety Objective

The safety objectives of this pivotal study are:

- To determine the nature, severity and frequency of the adverse event rate, the Cutaneous Safety Assessment and the Local Tolerability Assessment of S5G4T-1 compared to the vehicle.

6. STUDY DESIGN

6.1 Overall Study Design

This study will be a randomized, double-blind, multicenter, parallel group, active- and vehicle-controlled pivotal study of the efficacy and safety of S5G4T-1 and its vehicle for the treatment of papulopustular rosacea for 12 weeks. Approximately 350 patients with moderate to severe rosacea (rated 3 or 4 on the 5-point IGA scale) will be enrolled at up to 28 sites. Patients in this randomized, double-blind, vehicle-controlled, parallel-group multi-center study will be randomly assigned in a 2:1 ratio to S5G4T-1 or vehicle, respectively. Subjects with severe rosacea who are appropriate for systemic treatment need to be counseled regarding their treatment options by the Principal Investigator.

Patients will receive once daily treatment with S5G4T-1 or vehicle cream for 12 weeks. After the screening period, qualified patients will be randomly assigned at the Baseline visit and treated or 12 weeks. Efficacy assessments will include facial inflammatory lesion counts and IGA assessment ranging from 0 (clear) to 4 (severe). Investigators will be provided with instructions for lesion counts to ensure consistency of procedure. Patient reported outcomes (PRO) will be assessed with the PAPSS (Patient Assessment of Papulopustular Rosacea Signs and Symptoms), PAPI (Patient Assessment of Papulopustular rosacea Impacts), and PGI-S (Patient Global Impression of Symptom Severity) that will be administered at Baseline, Weeks 2, 4, 8, and 12, or at early termination. In addition, the PGI-C (Patient Global Impression of Change), PGI-TS (Patient Global Impression of Treatments Satisfaction), and PGI-SE (Patient Global Impression of Treatments Side Effects) will be administered at Weeks 2, 4, 8, and 12, or at early termination [FDA Guidance 2009]. Safety will be assessed at all visits and will include monitoring local and systemic adverse events (AEs); the Investigator Cutaneous Safety Assessment rating of

erythema, dryness and scaling, and the Local Tolerability Assessments rating of itching and burning/stinging on a scale ranging from 0 (none) to 3 (severe).

Patients will return to centers for IGA, lesion counts, PRO questionnaire, Investigator Cutaneous Safety Assessment, and Local Tolerability Assessments at Weeks 2, 4, 8 and 12. AEs and concomitant medications will be assessed throughout the treatment period. A urine pregnancy test is required at Visit 1, 2, 4, 5, and 6 for all females of child-bearing potential.

Clinical Evaluations will be performed at:

- Visit 1/Screening
- Visit 2/Baseline, Day 1
- Visit 3/Week 2, Day 15 (± 3 Days)
- Visit 4/Week 4, Day 29 (± 3 Days)
- Visit 5/Week 8, Day 57 (± 3 Days)
- Visit 6/Week 12, Day 85 (± 4 Days)/End of Treatment)

6.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 13.9 of the protocol.

6.1.2 Method of Assigning Subjects to Treatment Groups

Patients who satisfy all the inclusion and none of the exclusion criteria will be randomized to one of two treatment arms. Randomization will be performed in the Interactive Web Response System (IWRS) according to a computer-generated randomization schedule. The randomization schedule will be generated by the unblinded statistician and uploaded to the IWRS. The randomization schedule will be maintained securely within the IWRS. Patients will be randomized to E-BPO 5% or vehicle cream, once daily on a 2:1 basis for twelve (12) weeks.

Once a patient is determined eligible for the study at the Baseline visit, the patient will be randomized to study product assignment by the IWRS. Each study product carton will contain four pumps of the same product; The first supplied pump in each kit is marked A (e.g. number of pump within a kit is XXXXA), at Visit 4/ Week 4 the patient will return the pump and will be dispensed with the next pump which is marked B. At Visit 5/ Week 8, the patient will be dispensed with a pump marked C. The pump marked as D is a backup pump. The patient number will be added to both parts of the kit label (open part and tear-off label and to the pump label).

6.1.3 Blinding

The staff involved in data management and statistical evaluation will remain blinded until identification of the analysis population is completed and a database lock memo is issued.

The randomization schedule and treatment code will not be revealed to the patients, study personnel, Sol-Gel or its representatives until after the database lock, except to the Medical Monitor or Principal Investigator for an emergency. Access to the randomization list will be maintained by and limited to the unblinded Biostatistician and the designated personnel directly responsible for labeling of study materials. The Medical Monitor will not have access to the randomization list, but may determine that unblinding one or all patients may be necessary in the case that the safety of study patients is at risk. In an emergency, the study blind may be broken only if:

- In the opinion of the Medical Monitor and/or the Principal Investigator, it is in the patient's best interest to do so
- Knowledge of the treatment will alter the clinical management of the patient

In the case of an emergency that requires unblinding, the Investigator can request to unblind the patient without prior contact with the Medical Monitor although follow-up between the Investigator and Medical Monitor must occur so that all parties are aware of the unblinding. Although it is recommended that the Investigator contact the Medical Monitor prior to unblinding any patient, in instances where this is not feasible or advisable the Principal Investigator may directly access the patient's treatment assignment. In all situations, the IWRS will be used to obtain treatment assignment information with limited access to only the above-designated individuals, and any unblinding will be documented as a protocol deviation.

7. EFFICACY AND SAFETY ENDPOINTS

7.1 Efficacy Endpoints

7.1.1 Primary Efficacy Endpoints

There are two co-primary efficacy endpoints:

- Proportion of patients with the primary measure of success (clear or almost clear) in IGA relative to Baseline at Week 12
- Absolute change in inflammatory lesion counts from Baseline to Week 12

7.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints are as follows:

- Percent change in inflammatory lesion count from Baseline to Week 12
- Absolute change in inflammatory lesion count from Baseline to Week 8
- Proportion of patients with the primary measure of success (clear or almost clear) in the IGA relative to Baseline at Week 8
- Absolute change in inflammatory lesion count from Baseline to Week 4
- Proportion of patients with the primary measure of success (clear or almost clear) in the IGA relative to Baseline at Week 4

7.1.3 Additional Supportive Efficacy Endpoints

The supportive efficacy endpoints include the following:

- Percent change in inflammatory lesion count at Week 8
- Percent change in inflammatory lesion count at Week 4
- Mean change comparison in PAPSS item 1 (burning) between groups from Baseline to Weeks 4, 8 and 12
- Mean change comparison in PAPSS item 2 (itching) between groups from Baseline to Weeks 4, 8 and 12
- Mean change comparison in PAPSS item 3 (redness) between groups from Baseline to Weeks 4, 8 and 12
- Mean change comparison in PAPSS item 4 (bumps) between groups from Baseline to Weeks 4, 8 and 12
- Rosacea erythema assessment at Week 12
- Telangiectasia assessment at Week 12
- The proportion of patients in treatment relative to control who report at least “minimally improved” (defined as “very much improved”, “much improved” or “minimally improved”) as measured by the PGI-C at Week 12
- Mean change in the components of the PAPI score between groups from Baseline to Week 12

- Proportion of patients in the treatment relative to control achieving a three-point improvement in the components of the PAPI score from Baseline to Week 12
- PGI-S at Week 12
- PGI-TS at Week 12
- PAPSS within-person absolute change from Baseline to Week 12 (and/or other, earlier time points if so desired)

Other supportive endpoints not outlined in the SAP will be explored by Sol-Gel as appropriate.

7.1.4 Exploratory Endpoints

The exploratory endpoint is the mean change in Rosacea Quality-of-Life (RosaQoL) subscale scores from Baseline to Week 12.

7.2 Safety Endpoints

Safety will be assessed through Cutaneous Safety Assessment, Local Tolerability Assessment, AE reporting, physical examination, vital signs, and PGI-SE.

8. STATISTICAL AND ANALYTICAL PLANS

8.1 General Methodology

All statistical processing will be performed using SAS® version 9.3 or later unless otherwise stated. Statistical significance will be based on two-tailed tests of the null hypothesis resulting in p-values of 0.05 or less. These methods are intended to analyze the results of the study.

The primary method of handling missing efficacy data will be based on estimation using the method of Markov Chain Monte Carlo (MCMC) imputation. This method provides robust estimation when the pattern of missingness is arbitrary. Additionally, the estimation will be done for each treatment group separately so that the pattern of missingness for one group does not influence the estimation of missing data for another group. Groups of complete datasets following the estimation will be concatenated to form analysis datasets for the comparative analyses and subsequent imputation result inference with SAS PROC MIANALYZE. Descriptive statistics will also be derived from the multiply imputed datasets.

Additionally, a model-based multiple imputation process will be used as a sensitivity analysis to the MCMC imputation. Finally, the absolute change in lesion count will be analyzed using a repeated measures analysis of covariance (ANCOVA) for lesion count data and a repeated measures logistic regression model (generalized estimating equations) for the dichotomized IGA.

8.1.1 Statistical Analysis

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

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

All data listings will be by subject. Additionally, all listings except the screen failure and randomization listings will be by treatment.

8.1.2 Baseline Definition

Baseline is defined as the last non-missing assessment prior to first application of study drug. If the date of first application is unknown due to the subject being lost to follow-up, the Baseline visit record will be used as Baseline if it is non-missing. Missing results will not be flagged as Baseline.

8.1.3 Visit Windowing

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

Analysis Windows for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Window (Days)
Week 2	15	8 to 21
Week 4	29	22 to 42
Week 8	57	43 to 70
Week 12	85	71 to 98

Data collected at early termination and unscheduled visits prior to study day 8 will not be analyzed, with the exception of those identified as Baseline values. Data collected at early termination and unscheduled visits after study day 98 will not be included in analyses.

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

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

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

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

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

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

8.1.4 Adjustments for Covariates

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

8.1.5 Handling of Dropouts or Missing Data

Missing data for the ITT population will be estimated by multiple imputation and subsequently analyzed. Missing lesion count and IGA data will be derived for the analysis using the method of Markov Chain Monte Carlo (MCMC) multiple imputation. The pattern of missing observations in each treatment group cannot influence the missing value estimation in the other group because the imputation will be conducted independently for each treatment group.

Last observation carried forward (LOCF) will be used to impute missing data for the efficacy analyses using the PP population.

Patients that discontinue from the study due to an AE related to study treatment or documented lack of treatment effect will be included in the PP population. Data for these subjects will not be imputed by multiple imputation or LOCF but rather their data will be imputed with values consistent with their status as treatment failures. For these subjects, values for lesion count and IGA will be imputed such that change from Baseline is zero, meaning the values will be set to the Baseline value. This imputation will be done after the data for all subjects has been through the MI process.

Incomplete start and end dates for medications will be imputed. Other safety data will not be imputed and will be summarized on an observed case basis.

8.1.5.1 Lesion Count Variable Missing Data Imputation

Multiple imputation and subsequent analysis will involve 3 distinct phases with these principal tasks:

1. Create a data set of patients, one for each treatment group, with observed values and those needing estimation by MCMC. The missing lesion count values in each data set will be filled in using the MCMC method 5 times to generate 5 data sets. The resulting data sets for each treatment arm will be combined into one complete data set for each imputation.

   Syntax:

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

2. For each complete data set, the variable of interest for Baseline minus the value for the week imputed will be computed. Each complete data set will be analyzed as specified for the particular analysis.
3. The results from these analyses will be combined into a single inference using SAS PROC MIANALYZE.

A total of 2 random seeds are needed to impute inflammatory lesion counts. These random seeds have been pre-specified by using a random number generator:

- Inflammatory Lesion Counts S5G4T-1: Seed = 1787019983
- Inflammatory Lesion Counts Vehicle: Seed = 814066626

8.1.5.2 IGA Missing Data Imputation

A similar procedure will be used for the analyses based on proportion of IGA successes wherein the ANCOVA analysis is replaced with a logistic regression analysis. Specifically, missing IGA values from which the dichotomized IGA is derived will be estimated by MCMC.

The pattern of missing observations in each treatment group cannot influence the missing value estimation in the other because the imputation is being conducted independently for each treatment group.

The missing IGA values will be derived for the analysis using the method of MCMC multiple imputation. Multiple imputation and subsequent analysis will involve 3 principal tasks:

1. Create a data set, one for each treatment group, of patients with observed values and those needing estimation by MCMC. The missing IGA values in each data set will be filled in using the MCMC method 5 times to generate 5 data sets. The resulting data sets for each treatment arm will be combined into one complete data set by imputation.

   Syntax:

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

2. For each complete data set, the dichotomous success rate (clear or almost clear) will be computed. The estimated global values will be rounded to the nearest integer value prior to evaluating the success rate. Each complete data set will be analyzed with a logistic regression with factors of treatment group and analysis center.
3. The results from these analyses will be combined into a single inference using SAS PROC MIANALYZE.

A total of 2 random seeds will be needed to impute IGA for the two treatment groups. Those 2 random seeds have been pre-specified by using a random number generator:

- IGA Week S5G4T-1: Seed = 325011659
- IGA Week Vehicle: Seed = 1440479769

8.1.5.3 Medication Date Imputation

If the medication start date is incomplete, then it will be imputed as follows for the purpose of determining concomitant use:

- If the start date is completely missing, the start date will be equal to the first dose date. However, if the stop date is not missing and is before the first dose date, then the stop date will be used instead.
- If the start day is missing, the first day of the month will be used.

- If the start day and month are missing, then the first day of the first month (January) will be used.

If the medication stop date is incomplete, then it will be imputed as follows for the purpose of determining concomitant use:

- If the stop date is completely missing and the medication is not ongoing, the stop date will be equal to the last dose date or date of completion/withdrawal, whichever is the latest.
- If the stop day is missing, the last day of the month will be used.

If the stop day and month are missing, then the last day of the last month (December) will be used.

8.1.6 Interim Analyses and Data Monitoring

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

8.1.7 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site with the intention of pooling the data for analysis. Every effort will be made to promote consistency in study execution at each investigational site. The study is intended to be conducted in a manner such that a minimum of 15 subjects will be randomized and included in the ITT population (i.e., at least ten subjects in the active treatment arm and five subjects in the vehicle treatment arm) for any investigator. In the event that there are too few subjects in a treatment arm for an investigational site, then the site's data will be combined with other site's data to achieve the desired sample size minimum per treatment arm. The combining of investigator data will be accomplished by taking the data of the investigator with the smallest enrollment and combining them with the data of the investigator with the largest enrollment, restricted to investigational sites which did not meet minimum enrollment. If there is a further need to combine data, then the data of the investigator with the second smallest enrollment will be combined with the site's data which had the second largest enrollment (restricted to investigational sites which did not meet minimum enrollment), and so on. This process will continue for all investigators who did not have a minimum of 15 subjects enrolled. The process of combining investigator data that have insufficient subjects per treatment arm will result in redefining the groups of investigators for the purposes of statistical analyses. These combined groups will be referred to as "analysis centers" in the statistical analyses.

The consistency of treatment response will be investigated across the analysis centers subsequent to combining the data as described above. Statistical tests will be conducted to identify if there are extreme analysis centers that could affect the interpretation of common statistical and clinical conclusions. An analysis center by treatment interaction will be included in the primary analyses to test for parallel treatment effect at an alpha level of 0.10. Change from Baseline in inflammatory lesions will be analyzed with an ANCOVA (unranked or ranked) with factors of treatment group, analysis center, and treatment group by analysis center interaction, and the Baseline lesion count variable as a covariate. For the purpose of testing consistency of treatment response, the dichotomized IGA will be analyzed with a logistic regression with factors of treatment group, analysis center, and the interaction term of treatment group by analysis center. Further examination will follow for any variables that have a significant ANCOVA or logistic regression interaction term.

In the event that the ANCOVA or logistic regression interaction (referred to henceforth as the "appropriate test") p-value is less than or equal to 0.10, a sensitivity analysis that excludes analysis centers with the extreme efficacy result will be performed to determine the robustness of the treatment effect. On the other hand, if all three analyses result in interaction terms with p-values greater than 0.10, then the conclusions from the pooled data will be considered to be free of the impact of extreme analysis centers.

The first step in conducting a sensitivity analysis is to identify the extreme analysis center or centers that contribute to the statistical significance of the appropriate test. The process involves submitting subsets of analysis centers to the appropriate test and observing the appropriate test p-value for the subset. Subsets with p-values greater than 0.10 for the appropriate test are considered homogeneous.

The search for an extreme analysis center begins by analyzing all subsets that can be created by excluding one analysis center. If one or more of the subsets result in an appropriate test p-value greater than or equal to 0.10, then the analysis center excluded from the subset with the largest p-values for the appropriate test is deemed to be the extreme analysis center.

If all appropriate test subset p-values are less than or equal to 0.10, then the process will analyze the appropriate test for all subsets that can be created by excluding two analysis centers. If one or more of these subsets generate appropriate test p-values larger than 0.10, then the analysis centers excluded from the subset with the largest appropriate test p-value are deemed the extreme analysis centers.

Thus, the process of identifying the extreme analysis centers will continue in a stepwise manner by first excluding one, then two, then three, etc., analysis centers until the appropriate test p-value exceeds 0.10.

Once the extreme analysis center or centers have been identified, then the treatment p-values of the remaining analysis centers will be computed. Inferences will be drawn from the p-values as well as any pertinent observations regarding the extreme analysis center or centers. Additionally, it is noted that this process excludes patients from the analysis in a non-random manner and has an unpredictable impact on the power of the treatment effect test. In the event that the treatment effect of the remaining subset is not statistically significant, due consideration of the post-hoc aspects of the process will be given when the results are interpreted. Conclusions will be presented by the Sponsor as appropriate to the findings of the sensitivity analysis.

Prior to investigating the treatment effect within the analysis centers, the treatment effect within investigational site will be investigated to determine if the site-to-site variability is such that it could mask the analysis center effects. Thus, prior to pooling, change from Baseline in inflammatory lesions will be analyzed with an ANCOVA (unranked or ranked) with factors of treatment group, investigational site, and treatment group by investigational site interaction, and the Baseline lesion count variable as a covariate. The dichotomized primary endpoint will be analyzed with a logistic regression with factors of treatment group, investigational site, and the interaction term of treatment group by investigational site. If any of the analyses are not computationally feasible due to some investigational sites having very few subjects enrolled, the low-enrolling investigational sites will be excluded from the analysis.

8.1.8 Multiple Comparisons/Multiplicity

In testing the secondary efficacy endpoints the overall Type I error will be controlled by requiring the two co-primary efficacy endpoints to be statistically significant. Specifically, failure of either one of the primary efficacy endpoints will invalidate the statistical significance of the secondary efficacy endpoints.

A stepwise process will be conducted for testing the secondary efficacy endpoints in order to control for multiplicity. These tests will be performed for only the ITT population. The testing process will terminate whenever a statistical test for a step is not significant. All subsequent tests for the remaining steps will be considered not significant. The order of testing is provided below.

Step Number	Secondary Endpoint
1	Percent change in inflammatory lesion count from Baseline to Week 12
2	Absolute change in inflammatory lesion count from Baseline to Week 8
3	Proportion of patients with the primary measure of success "Clear" (0) or "Almost clear" (1) in the IGA relative to Baseline at Week 8
4	Absolute change in inflammatory lesion count from Baseline to Week 4
5	Proportion of patients with the primary measure of success "Clear" (0) or "Almost clear" (1) in the IGA relative to Baseline at Week 4

In testing the supportive efficacy endpoints, the overall Type I error will be controlled by the Benjamini-Hochberg method. The Hochberg and Bejamini adaptive step-down Bonferoni method will be used within PROC MULTTEST in SAS (AHOLM option in PROC MULTTEST).

8.1.9 Use of an Efficacy Subset of Subjects

Subjects randomized to study drug who were dispensed study product and do not have major protocol deviations will form the Per Protocol (PP) Population. The requirements for the PP Population are outlined in Section 8.4.4. Any additional major protocol deviations will be defined at the time of evaluability evaluation, the time between the database soft lock and hard lock before unblinding.

Excluding subjects who have major protocol deviations will decrease the variability in treatment response and will allow for a better determination of dose-response relationship of S5G4T-1, E-BPO Cream, 5%.

8.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

8.1.11 Examination of Subgroups

Subset analyses will be conducted for the ITT populations for the subgroups based on at least the following:

- Baseline Global Severity;

  - Categorized as Baseline IGA = 3 (moderate) and Baseline IGA = 4 (severe); due to the inclusion criteria requiring subjects to have either a 3 or 4 IGA score at study entry other IGA response categories will not be presented

- Sex;
  - Male versus female subjects
- Age;
  - Dichotomized to less than the median age of ITT subjects and greater than or equal to the median age of ITT subjects
- Ethnicity;
  - Categorized as Hispanic or Latino and Not Hispanic or Latino; ethnicities of Not Reported and Unknown will not be included
- Race
  - Categorized as White and Non-White; subjects indicating more than one race category which includes both white and a non-white race will be summarized under the Non-White subgroup.

Subset analyses will be conducted on the variables absolute change from Baseline in inflammatory lesions at Week 12 as well as the dichotomized global severity score at Week 12. These analyses will contain only descriptive statistics.

8.2 Disposition of Subjects

The number of subjects included in each analysis population (randomized, ITT, Safety, and PP) will be summarized by treatment group and overall. The number of subjects completed and discontinued (including the reasons for discontinuation) will be summarized for each treatment group as well as by overall. The percentages will be calculated based on the number of randomized patients, unless otherwise specified.

8.3 Protocol Deviations

In order to define the PP Population, protocol deviations potentially influencing the evaluation of the primary efficacy endpoint will be defined as major deviations. The protocol deviations that will exclude a subject from PP are given in Section 8.4.4.

In case other deviations detected during the study conduct are considered to potentially influence the evaluation of the primary efficacy endpoint, these deviations will be documented prior to the database lock and the patients having these deviations will be excluded from the PP Population.

All protocol deviations will be reported to the sponsor and recorded throughout the study. Protocol deviations will not be entered into the database. SolGel will provide a list of protocol deviations to QST. A tabulation of protocol deviations will be presented in a data listing.

8.4 Data Sets Analyzed

Subjects will be presented/summarized based on the primary reason for exclusion. Below is the order to be used in summaries:

8.4.1 Randomized Population

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

8.4.2 Intent-to-Treat (ITT) Population

All subjects in the randomized population who are dispensed study product will be included in the ITT population and will be analyzed according to the treatment group they were randomized. All efficacy analyses will be presented using the ITT population.

8.4.3 Safety Population

All subjects in the randomized population who are presumed to have used the study product at least once and who provide at least one post-baseline safety evaluation will be included in the Safety population and will be analyzed according to the treatment they received. Presumed to have used study product will be defined as having at least one confirmed application of study medication. All safety analyses will be performed using the Safety population.

8.4.4 Per-Protocol (PP) Population

All subjects in the ITT population who complete the Week 12 evaluation without noteworthy study protocol violations (i.e., any patient or investigator activity that could have possibly interfered with the therapeutic administration of the treatment or the precise evaluation of treatment efficacy) will be included in the PP population and analyzed according to the treatment group they received. The PP population will include subjects in the ITT population who do not meet any of the following criteria:

- Failed any of the inclusion/exclusion criteria;
- Have taken any interfering concomitant medications;
- Did not attend the Week 12 Visit;
- Missed more than 1 post-baseline study visit prior to Week 12;
- Have not been compliant with the dosing regimen (i.e., Patients may not miss more than five consecutive days of dosing and must take 80 to 120% of expected applications. The number of expected applications will be determined for each patient based on the length of their participation in the study);
- Out of visit window (± 4 days) at the 12-week Visit.

Subjects that discontinue from the study due to an AE related to study treatment or documented lack of treatment effect will be included in the PP population. Data for these subjects will not be imputed by multiple imputation but rather their data will be imputed with values consistent with their status as treatment failures. See Section 8.1.5 for additional detail. Prior to breaking the blind, other additional criteria may be added to the list to accommodate for unforeseen events that may occur during the conduct of the trial and result in noteworthy study protocol violations.

All efficacy analyses performed on the PP population will be according to the treatment they received.

8.5 Demographic and Other Baseline Characteristics

All Baseline summaries will be done on the ITT, PP, and Safety populations by treatment group and overall.

Sex (categorical), race (categorical), and ethnicity (categorical) will be summarized by counts and percentages. Age (continuous), height (cm) (continuous), and weight (kg) (continuous), and body mass index (BMI) (continuous) will be summarized with descriptive statistics.

Age will be calculated as the difference in days between the date of birth and the date of informed consent and converted to years by dividing the number of days by 365.25 and using a floor function to drop the decimal portion. In case the exact birth day is missing, day 15 will be used. The BMI will be calculated as weight (kg) divided by squared height (m^2).

Medical histories will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary and presented in a by-subject listing.

The medical history data will be summarized with frequencies and percentages of patients with at least one medical history term reported, and patient frequencies and percentages on the System Organ Class (SOC) and Preferred Term (PT) levels. The number of events will also be summarized. The table will be sorted by overall descending frequency of SOC and then, within a SOC, by overall descending frequency of PT.

8.6 Prior and Concomitant Medications

Concomitant medications will be coded to preferred name and Anatomical Therapeutic Chemical (ATC) classification of ingredients using the World Health Organization (WHO) Drug Global Dictionary, Format B3, Version March 1, 2018.

Medications which start prior to first application will be considered prior medications. Ongoing medications and medications ending after the date of first application will be considered concomitant medications. If the date of first application is unknown and the medication is not listed as ongoing the interval will be considered "unknown". If the date of first application is unknown and the medication is listed as ongoing the interval will be considered concomitant.

Incomplete medication start and end dates will be imputed as described in Section 8.1.5.3

A summary of prior and concomitant medications will be provided.

A by-subject listing of all prior and concomitant medications will be presented for the Safety population.

8.7 Analysis of Efficacy

Inflammatory 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 using descriptive statistics. The dichotomized IGA scores will be summarized at Weeks 2, 4, 8, and 12 using descriptive statistics.

All efficacy results will be presented in by-subject listings.

8.7.1 Primary Efficacy Analysis

The primary efficacy analysis will be presented on both the ITT and PP populations.

8.7.1.1 Lesion Counts

Tests of superiority for the absolute change from Baseline in inflammatory lesions will be based on either parametric or non-parametric methods consistent with the statistical assumptions required to support the analyses. Specifically, the tests of superiority will be based on an ANCOVA with factors of treatment and analysis center and the respective Baseline lesion count as a covariate or on ranked data submitted to an ANCOVA with factors of treatment and analysis center and the respective Baseline lesion count as a covariate. If the treatment-by-analysis center interaction effect is significant at an alpha less than 0.10, then the effect will be included in the model; otherwise it will be removed.

A skewness test, based on the methods presented by J.H. Zar [4], will be applied to the residuals resulting from an ANCOVA. A two-sided p-value for the skewness test significant at 0.01 will imply the use of the non-parametric method. If a parametric analysis is indicated, the results of the parametric analysis will be considered the primary analysis. Should a non-parametric analysis be indicated, the absolute or percent changes in inflammatory lesions will be rank transformed prior to submitting them to the ANCOVA. Results of the rank-transformed analyses then will be considered the primary analysis; however, results of the non-ranked transformed analyses will also be presented.

The following steps provide a brief synopsis of the process that will be followed.

1. Missing data will be imputed using multiple imputation. Refer to Section 8.1.5.1.
2. The pooling analysis will be conducted. Refer to Section 8.1.7.
    a. The treatment-by-analysis center interaction p-values from both parametric and non-parametric (unranked and ranked) analyses will be presented, along with the skewness p-value calculated from the residuals from the unranked ANCOVA. The skewness p-value will determine which analysis results to report:
        i. Skewness p-value > 0.01: Report results based on the parametric (unranked) approach.
        ii. Skewness p-value ≤ 0.01: Report results based on the non-parametric (ranked) approach.
3. For the primary efficacy analysis
    a. Results of both parametric and non-parametric (unranked and ranked) analyses will be presented. For each, data will be submitted to an ANCOVA with factors of treatment and analysis center and Baseline lesion count as a covariate (if the

treatment-by-analysis center interaction p-value is ≤ 0.10, the interaction will also be included in the model). The residuals from the unranked analysis will be used to calculate the skewness p-value. The skewness p-value will determine which analysis results to report:

i. Skewness p-value > 0.01: Report results from the parametric (unranked) ANCOVA.

ii. Skewness p-value ≤ 0.01: Report results from the non-parametric (ranked) ANCOVA.

4. If there was a significant treatment by analysis center interaction (as determined in step 1 – the pooling analysis), a sensitivity analysis will be performed as described in Section 8.1.7 to find the extreme analysis center(s). Then step 3 above will be repeated the extreme analysis center(s) removed, to confirm the treatment response.

8.7.1.2 Investigator Global Assessment (IGA)

The IGA will be dichotomized into "success" and "failure" with a patient considered a success for those visits if the IGA is "clear" or "almost clear". The analysis of the dichotomized IGA will be based on a logistic regression test with factors of treatment group and analysis center.

8.7.2 Sensitivity Efficacy Analysis

8.7.2.1 Sensitivity Analyses for Absolute Change in Lesion Count

The first sensitivity analysis for absolute change in lesion count will use a repeated measures ANCOVA, with treatment, analysis center, visit (i.e., Weeks 2, 4 and 8), and treatment group by visit interaction as independent factors and a covariate of Baseline lesion count. In this analysis, data from all post-baseline visits will be included with no imputation for missing data.

The second sensitivity analysis will use the model based multiple imputation method to impute missing data for the absolute change in lesion counts at Week 12. The multiple imputation will involve 3 principal tasks:

1. Missing values will be filled in 5 times to generate 5 complete data sets. The imputation model used will be an ANCOVA with factors of treatment group and analysis center, and a covariate of Baseline lesion count (i.e., the imputation model will be the same as the analysis model).

   Syntax:

```
proc mi data=datain out=dataout seed=&seed. nimpute=5 <options>;
  class trtpn sitegr1;
  var trtpn baseline sitegr1 week12;
  monotone logistic (sitegr1=trtpn baseline);
  monotone reg (week12=trtpn baseline sitegr1);
run;
```

2. Each complete data set will be analyzed with an ANCOVA with factors of treatment group, and analysis center, and a covariate of Baseline lesion count. Appropriate modifications will be made should the analysis be based on a non-parametric method.

3. Results from these analyses will be combined into a single inference.

One random seed will be needed to impute the inflammatory lesion counts. The following random seed has been pre-specified by using a random number generator:

Inflammatory Lesion Count Seed=1827396453

8.7.2.2 Sensitivity Analyses for IGA

The first sensitivity analysis for the dichotomized IGA success will use a repeated measures logistic regression model (generalized estimating equations), with dichotomized IGA success as the dependent variable and treatment, analysis center, visit (i.e., Weeks 2, 4 and 8), and treatment group by visit interaction as independent factors. In this analysis, data from all post-baseline visits will be included with no imputation for missing data.

The second sensitivity analysis will use the model based multiple imputation method to impute missing data for the dichotomized IGA data. The multiple imputation will involve 3 principal tasks:

1. Missing values will be filled in 5 times to generate 5 complete data sets. The imputation model used logistic regression with factors of treatment group and analysis center (i.e., the imputation model will be the same as the analysis model).

   Syntax:

```
proc mi data=datain out=dataout seed=&seed. nimpute=5 <options>;
  class trtpn sitegr1 diiga;
  var trtpn sitegr1 diiga;
  monotone logistic (sitegr1=trtpn);
  monotone logistic (diiga=trtpn sitegr1);
run;
```

2. Each complete data set will be analyzed with a logistic regression a factors of treatment group and analysis center.

3. Results from these analyses will be combined into a single inference.

One random seed will be needed to impute IGA. The following random seed has been pre-specified by using a random number generator:

IGA Seed= 65762814

8.7.3 Secondary Efficacy Analysis

Appropriate descriptive statistics will be computed for all secondary efficacy parameters.

The percent change from Baseline to Week 12 in inflammatory lesion counts and the absolute change from Baseline in inflammatory lesion counts at Week 8 and Week 4 will be analyzed using the same ANCOVA method described for the primary endpoint.

The proportion of subjects who are dichotomized to success ("clear" or "almost clear") at Week 8 and Week 4 will be analyzed using the same logistic analysis method described for the co-primary endpoint.

A stepwise process will be conducted for testing the secondary efficacy endpoints in order to control for multiplicity, refer to Section 8.1.8.

The secondary efficacy analysis will be presented on only the ITT population.

8.7.4 Supportive Efficacy Analysis

Appropriate descriptive statistics will be computed for all supportive efficacy parameters.

In addition, the mean change comparison in PAPSS item 1 (burning), item 2 (itching), item 3 (redness) and item 4 (bumps) from Baseline to Week 12 will be analyzed using an analysis of variance (ANOVA) with factors of treatment, analysis center, and the respective Baseline score. Missing values will not be imputed.

A set of cumulative distribution function curves will be generated to allow for the evaluation of within-person change by treatment group. Specifically, 5 plots will be generated showing the change from Baseline to Week 12 (and/or other, earlier time points if so desired) by the cumulative percent of subjects for each of the treatment arms (change on the x-axis will be expressed as absolute change) on:

- PAPSS total scale scores

- The total scale score is the sum of PAPSS items 1 through 4.

- PAPSS item 1 (burning) scores
- PAPSS item 2 (itching) scores
- PAPSS item 3 (redness) scores
- PAPSS item 4 (bumps) scores

8.7.5 Exploratory Endpoint Analysis

The mean change in RosaQoL subscale scores from Baseline to Week 12 will be summarized using descriptive statistics.

The subscores for the RosaQoL are computed as follows:

Total Score: the unweighted mean of all RosaQoL questions

Symptom subscale score: the unweighted mean of the following symptom questions

My rosacea burns or stings (item #2)

My rosacea is irritated (item #6)

My rosacea makes my skin sensitive (item #9)

My skin feels bumpy (uneven, not smooth, irregular) (item #16)

My skin flushes (item #17)

My skin gets irritated easily (cosmetics, aftershaves, cleansers) (item #18)

My eyes bother me (feels dry or gritty) (item #19)

Functional subscale score: the unweighted mean of the following functional questions

I try to cover up my rosacea (with make-up) (item #13)

I avoid certain foods or drinks because of my rosacea (item #15)

I avoid certain environments (heat, humidity, cold) because of my rosacea (item #21)

Emotion subscale score: the unweighted mean of the following emotion questions

I worry that my rosacea may be serious (item #1)

I worry about getting scars from my rosacea (item #3)

I worry that my rosacea may get worse (item #4)

I worry about side effects from rosacea medications (item #5)

I am embarrassed by my rosacea (item #7)

I am frustrated by my rosacea (item #8)

I am annoyed by my rosacea (item #10)

I am bothered by the appearance of my skin (redness, blotchiness) (item #11)

My rosacea makes me feel self-conscious (item #12)

I am bothered by persistence/reoccurrence of my rosacea (item #14)

I think about my rosacea (item #20)

Each individual item should be scored as follows: 1=Never, 2=Rarely, 3=Sometimes, 4=Often, and 5=All the time. Missing data values will not be used. If a subscale has items with missing results, the subscore and the total will not be calculated.

8.8 Safety Evaluation

8.8.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of days of exposure, total number of applications, number of missed applications and number and percentage of subjects who are compliant. A subject will be considered compliant with the dosing regimen if the subject applied 80% to 120% of the expected number of applications and did not miss more than 5 consecutive applications while enrolled in the study.

Days of exposure = Date of last study application – Date of first study application + 1

The total number of applications taken is as follows:

(Date of Last Application – Date of First Application + 1) – (Number of Days marked as missed applications on the CRF) + (Number of extra applications marked on the CRF)

If a subject did apply medication on the last day, the total number of applications expected is as follows:

Date Subject End Participation – Date of Baseline +1.

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

If a subject did not apply medication on the last day, the total number of applications expected is as follows:

Date Subject End Participation - Date of Baseline

If the total number of applications exceeds 88 then it will be set to 88.

Compliance will be calculated as a percentage as 100 times the total number of applications taken from the first application until Week 12 divided by the total number of applications expected from first application until Week 12. Subjects who discontinue study medication before Week 12 will be considered to be 0% compliant for the number of days from discontinuing study medication until Week 12.

Compliance will not be calculated for subjects who are lost to follow-up or subjects who have unknown first or last application dates.

8.8.2 Adverse Events (AEs)

All AEs occurring during the study will be recorded and classified on the basis of MedDRA terminology. Descriptions of AEs will include the date of onset, the date the AE ended, the severity of the AE, the relationship to study product, the action taken regarding study product usage, the action taken to treat the AE, and the outcome. All reported treatment-emergent AEs (TEAEs) will be summarized by the number of patients reporting AEs, system organ class, severity, seriousness, and relationship to study product. TEAEs are those AEs with an onset on or after the date of the first study product application; if the AE is not indicated as prior to first application on the CRF then it will be considered a TEAE.

AEs will be summarized by treatment group and severity. Each patient will be counted only once within a system organ class or a preferred term by using the AEs with the highest severity within each category.

AEs will be summarized by treatment group and relationship to study product. Each patient will be counted only once within a system organ class or a preferred term by using the AEs with the greatest relationship within each category.

If relationship to study drug is reported as definitely, probably, or possible, then this is defined as related. If relationship to study drug is reported as unlikely or not related, then this is defined as unrelated.

Comparisons among treatment groups will be made by tabulating the frequency of patients with one or more AEs (classified into MedDRA terms) during the study. The Fisher's Exact test will be used to compare the proportion of patients in each treatment group who report any AE at a

significance level of 0.05. The specific system organ classes and preferred terms analyzed will be those that are reported by at least one percent of the patients in any treatment group.

All information pertaining to AEs noted during the study will be listed by patient, detailing verbatim given by the investigator, preferred term, system organ class, start date, stop date, severity, actions taken, and drug relatedness. The AE onset will also be shown relative (in number of days) to the day of initial application of the randomized study product.

Serious adverse events (SAEs) will be tabulated by patient within treatment groups.

In addition, a list of patients who discontinued from the study and a list of patients who experienced SAEs will also be provided.

8.8.3 Clinical Laboratory Evaluation

Urine pregnancy test results will be presented in a by-subject listing.

8.8.4 Other Observations Related to Safety

8.8.4.1 Cutaneous Safety Assessments

Descriptive statistics by treatment group and visit will be provided for dryness and scaling.

8.8.4.2 Local Tolerability Assessments

Descriptive statistics by treatment group and visit will be provided for itching and burning/stinging.

8.8.4.3 Vital Signs

Vital sign measurements include heart rate (HR), sitting blood pressure (BP) (both systolic and diastolic), body temperature, and weight. The data will be summarized with descriptive statistics by visit and treatment group. In addition, the changes from baseline will be summarized with descriptive statistics.

Furthermore, to identify potentially clinically significant vital signs, the following criteria will be used and tabulated as a shift table by visit:

- Systolic Blood Pressure: <90 mmHg (low), 90-140 mmHg (normal), >140 mmHg (high)
- Diastolic Blood Pressure: <90 mm Hg (low), 90-100 mmHg (normal), >100 mmHg (high)

- Heart Rate: <60 beats per minute (low), 60-100 beats per minute (normal), >100 beats per minute (high).

8.8.4.4 Physical Examination

Abnormal physical examination findings will be summarized by body system, visit, and treatment group. In addition to the summary, all physical examination findings will be listed.

8.8.4.5 Patient Global Impression of Treatment Side-Effects (PGI-SE)

Descriptive statistics by treatment group and visit will be provided for PGI-SE.

9. DETERMINATION OF SAMPLE SIZE

The following power calculations are based on the observed Week 12 results of the Phase 2 study, SGT-EBP01-09. This study was a three-arm trial including E-BPO cream, 1% and 5%, and vehicle in the treatment of rosacea. Estimates from the E-BPO cream, 5% arm were used in the power assessments. The anticipated randomization ratio is 2:1 for E-BPO cream, 5% and vehicle, respectively. The computations were performed with nQuery Advisor Version 7.0 using a two-sided test with a statistical significance value of 0.05.

A sample size of 86 in the E-BPO cream, 5% and 43 in the vehicle group has 95% power to detect a statistically significant difference in the proportion of patients who have at least a 2-grade reduction at Week 12 from Baseline in IGA and are clear or almost clear. The estimated percentages with a 2-grade reduction at Week 12 from Baseline in the IGA and clear or almost clear are 53.3% and 20.0% for the E-BPO cream and vehicle, respectively.

A sample size of 200 in the E-BPO cream, 5% and 100 in the vehicle group has 95% power to detect a statistically significant difference in inflammatory lesions. The estimated absolute change from Baseline in treatment means were -14.1 and -7.4 for E-BPO cream and vehicle, respectively, with a standard deviation (SD) of 6.70 and 17.24, respectively.

The sample sizes above will be increased to give a planned enrollment of 234 in the E-BPO cream, 5% group and 117 in the vehicle group since the Phase 3 trial is expected to enroll patients who are as a group more severe than those of the Phase 2 trial. This is a consequence of some changes in the inclusion criteria.

10. CHANGES IN THE PLANNED ANALYSES

There are no changes in the conduct of the study, but there are minor changes to the planned analyses.

Due to feedback received, the primary efficacy analysis was adjusted back to the original analysis. The modification to only use the non-parametric version as described in v4 of the protocol was not accepted by the agency. The original approach uses an ANCOVA analysis with the terms for treatment, analysis center, and Baseline count (and treatment-by-center interaction if the term is significant at 0.10). If the two-sided p-value for the skewness test is significant at 0.01, then the rank-transformed data will be used instead of nominal values. The original approach was accepted by the agency.

The pooling analysis described in the protocol is updated in the statistical analysis plan (SAP) to reflect the intended analysis. The protocol discusses pooling sites with five or fewer subjects enrolled in each treatment arm. Taking into consideration the randomization ratio, the SAP requires ten subjects in the active treatment arm and five subjects in the vehicle group.

As part of the pooling analysis, the treatment effect within investigational site must be investigated. The protocol states the site main effect will be examined by using a one-way analysis of variance (for lesion count variables) or a logistic regression analysis (for dichotomized IGA) with a factor of site. The SAP instead explains site will be incorporated into the primary analysis models. Change from Baseline in lesion counts will be analyzed with an ANCOVA (unranked or ranked) with factors of treatment group, investigational site and treatment group by investigational site interaction, and the respective Baseline lesion count variable as a covariate. The dichotomized primary endpoint will be analyzed with a logistic regression with factors of treatment group, investigational site and the interaction term of treatment group by investigational site.

The protocol describes repeated measures sensitivity analyses for the primary efficacy endpoints. Treatment group, analysis center and visit are listed as factors for the repeated measures analyses. In addition to these factors, the SAP includes a factor of treatment group by visit interaction.

The protocol describes imputing only Week 12 data with MCMC imputation, but all missing post-baseline data will be imputed. Only 2 seeds are needed for the MCMC imputation for inflammatory lesions (one seed for S5G4T-1 and one seed for vehicle) instead of the 6 seeds that are given in the proctol. Only 2 seeds are needed for the MCMC imputation for IGA (one seed for S5G4T-1 and one seed for vehicle) so only one seed was given in the SAP. Using only the Week 12 seed addresses concern from the FDA with regard to imputing data at each visit as the multiple seeds in the protocol suggests. Only one seed is needed for treatment group as PROC MI will impute data across the visits.

All seeds given the in SAP were produced in SAS as seeds given in the 54-02 protocol were identical to the 54-01 study protocol.

Geographic region was removed from the examination of subgroups as all sites in the study are in the United States.

11. REFERENCES

1. Jansen T. and Plewig G. Rosacea: classification and treatment. JR Soc Med. 1997; 90(3):144-150.
2. McDonnell JK and Tomecki KJ. Rosacea: an update. Clev Clinic J Med. 2000; 67(8):587-590.
3. Zar, JH. Bio-statistical analysis, 1984 2nd ed. Englewood Cliffs (NJ) Prentice-Hall. (*Available upon request).*

12. INDEX OF PLANNED TABLES

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

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Total (N=xxx)
Completed Study			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation			
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Worsening of Condition	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.0.2.1: Summary of Subject Enrollment and Evaluability
(All Randomized Subjects)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Total (N=xxx)
Number of Randomized Subjects	xx	xx	xx
Number of Subjects Included in the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason Excluded from the ITT Population			
Not Dispensed Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reasons Excluded from the Safety Population[a]			
No Documented use of Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Post Baseline Safety Assessment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reasons Excluded from the PP Population[a]			
Not Included in ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Violated Inclusion/Exclusion Criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Used Interfering Concomitant Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Did not Attend Week 12/ET Visit	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missed More Than 1 Post-Baseline Visit Prior to Week 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Compliant with Dosing Regimen[b]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12/ET Visit Out of Window (+/-4 days)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Table includes primary reason (assigned in order presented in table) for reason subject was excluded.
[b] Subjects lost to follow-up not included. A subject was considered compliant with the dosing regimen if the subject applied 80-120% of the expected number of applications and did not miss more than 5 consecutive applications while enrolled in the study.

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

Table 14.0.2.2: Summary of Subject Evaluability by Analysis Center and Investigational Site
(All Randomized Subjects)
(Page 1 of xx)

Analysis Center	Investigational Site	Number Randomized	E-BPO 5% Cream			Vehicle Cream		
			ITT	PP	Safety	ITT	PP	Safety
xx	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx

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

Table 14.1.1.1: Summary of Subject Demographic Characteristics
(Intent-to-Treat Population)
(Page 1 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Total (N=xxx)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
< Median (xx years)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
≥ Median (xx years)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Sex			
n	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Reported/Unknown	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of other races.

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

Table 14.1.1.1: Summary of Subject Demographics
(Intent-to-Treat Population)
(Page 2 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Total (N=xxx)
Race			
n	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of other races.

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

Repeat Table 14.1.1.1 for the following tables:

Table 14.1.1.2: Summary of Subject Demographics (Per-Protocol Population)
Table 14.1.1.3: Summary of Subject Demographics (Safety Population)

Table 14.1.2.1: Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 1 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Total (N=xxx)
Height (cm)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Weight (kg)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
BMI (kg/m^2)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.1.2.1: Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 2 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Total (N=xxx)
Inflammatory Lesion Count			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Investigator Global Assessment			
n	xx	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Repeat Table 14.1.2.1 for the following table:

Table 14.1.2.2: Subject Baseline Characteristics (Per-Protocol Population)
Table 14.1.2.3: Subject Baseline Characteristics (Safety Population)

Table 14.1.3.1: Summary of Medical History by System Organ Class and Preferred Term
(Intent-to-Treat Population)
(Page 1 of xx)

System Organ Class Preferred Term	E-BPO 5% Cream (N=xxx)		Vehicle Cream (N=xxx)		Total (N=xxx)	
	By Subject[a]	By Event[b]	By Subject[a]	By Event[b]	By Subject[a]	By Event[b]
Number (%) of Subjects Reporting at Least One Medical History Term	xx (xx.x%)		xx (xx.x%)		xx (xx.x%)	
System Organ Class	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx
Preferred Term	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx

[a] Counts reflect number of subjects reporting one or more medical history terms that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once. Percentages are based on the number of subjects in the safety population.
[b] Counts reflect number of medical history terms that map to MedDRA.

Note: MedDRA Version 21.0

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

{NOTE TO PROGRAMMER: The table will be sorted by overall descending frequency of SOC and then, within a SOC, by overall descending frequency of PT}

Repeat Table 14.1.3.1 for the following table:

Table 14.1.3.2: Summary of Medical History by System Organ Class and Preferred Term (Per-Protocol Population)
Table 14.1.3.3: Summary of Medical History by System Organ Class and Preferred Term (Safety Population)

Table 14.1.4.1: Summary of Prior Medications by ATC Level 2 and Preferred Name
(Safety Population)
(Page 1 of xx)

ATC Level 2 Term[a] Preferred Name	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Number (%) of Subjects Reporting at Least One Prior Medication	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more medications that map to the WHO term. At each level of summarization (ATC Level 2 Term or Preferred Name) subjects are counted once. Percentages are based on the number of subjects in the safety population.

Note: WHO Drug Global Dictionary, Format B3, Version March 1, 2018
Prior medications are those used before the date of first study drug application.

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

Table 14.1.4.2: Summary of Concomitant Medications by ATC Level 2 and Preferred Name
(Safety Population)
(Page 1 of xx)

ATC Level 2 Term[a] Preferred Name	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Number (%) of Subjects Reporting at Least One Concomitant Medication	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more medications that map to the WHO term. At each level of summarization (ATC Level 2 Term or Preferred Name) subjects are counted once. Percentages are based on the number of subjects in the safety population.

Note: WHO Drug Global Dictionary, Format B3, Version March 1, 2018
Concomitant medications are those used on/after the date of first study drug application.

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

Table 14.2.1.1: Pooling Analysis for Primacy Efficacy Endpoints
(Intent-to-Treat Population)

	Investigational Site Pooling Analysis		Analysis Center Pooling Analysis	
Endpoint	Skewness P-Value	Investigational Site by Tretment Group P-Value	Skewness P-Value	Analysis Center Tretment Group P-Value
Absolute Change from Baseline in Inflammatory Lesion Counts at Week 12	x.xxx[c]			
Ranked Analysis		x.xxx[a]		x.xxx[e]
Unranked Analysis		x.xxx[b]		x.xxx[f]
Achieving Clear or Almost Clear at Week 12	NA	x.xxx[d]	NA	x.xxx[g]

[a] P-value for the interaction term from a ranked analysis of covariance with factors of treatment, investigational site, treatment by investigational site interaction and Baseline lesion count as a covariate.
[b] P-value for the interaction term from an unranked analysis of covariance with factors of treatment, investigational site, treatment by investigational site interaction and Baseline lesion count as a covariate.
[c] Skewness test, based on methods presented by J.H. Zar (1984), assessed for each imputed dataset. The average p-value is presented.
[d] P-value for the interaction term from a logistic regression with factors of treatment, investigational site, treatment by investigational site interaction.
[e] P-value for the interaction term from a ranked analysis of covariance with factors of treatment, analysis center, treatment by analysis center interaction and Baseline lesion count as a covariate.
[g] P-value for the interaction term from an unranked analysis of covariance with factors of treatment, analysis center, treatment by analysis center interaction and Baseline lesion count as a covariate.
[g] P-value for the interaction term from a logistic regression with factors of treatment, analysis center, treatment by analysis center interaction.

Note: Multiple imputation (MCMC) used to impute missing values.

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

{NOTE TO PROGRAMMER: ADJUST FOOTNOTE "d" AND/OR "g" IF FIRTH'S PENALIZED LIKELIHOOD IS NEEDED}

Table 14.2.1.2: Primary Efficacy Analysis: Absolute Change from Baseline in Inflammatory Lesion Count and Dichotomized IGA Success at Week 12 (Intent-to-Treat Population)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Skewness P-Value	Treatment P-Value
Inflammatory Lesion Count – Absolute Change from Baseline				
LSMean[a]	xx.x	xx.x	x.xxx[b]	x.xxx[a]
LSSD[a]	xx.xx	xx.xx		x.xxx[c]
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	N/A	x.xxx[d]
Failure	xx.x%	xx.x%		

[a] Least squares means, standard deviations and treatment p-value from an analysis of covariance with factors of treatment group and analysis center and Baseline lesion count as a covariate. Negative least squares means values represent decrease from Baseline.
[b] Skewness test, based on methods presented by J.H. Zar (1984), assessed for each imputed dataset. The average p-value is presented.
[c] P-value from a ranked analysis of covariance with factors of treatment group and analysis center and Baseline lesion count as a covariate.
[d] P-value from a logistic regression with factors of treatment group and analysis center.

Note: Multiple imputation (MCMC) used to impute missing values.

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

{NOTE TO PROGRAMMER: ADJUST FOOTNOTE "d" IF FIRTH'S PENALIZED LIKELIHOOD IS NEEDED}

Repeat Table 14.2.1.2 for the following table:

Table 14.2.1.3: Primary Efficacy Analysis: Absolute Change from Baseline in Inflammatory Lesion Count and Dichotomized IGA Success at Week 12 (Per-Protocol Population)

Update footnote to “Note: Missing values imputed using last observation carried forward.”

Table 14.2.2.1.1: Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 4)

Inflammatory Lesion Counts	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Percent Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.1: Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 4)

Inflammatory Lesion Counts	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Percent Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.1: Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 4)

Inflammatory Lesion Counts	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Percent Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.1: Summary of Inflammatory Lesion Counts at Each Evaluation
(Intent-to-Treat Population)
(Page 4 of 4)

Inflammatory Lesion Counts	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Percent Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative values represent decrease from Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.1.1 for the following table:

Table 14.2.2.1.2: Summary of Inflammatory Lesion Counts at Each Evaluation (Per-Protocol Population)

Change footnote to “Note: Missing values imputed using last observation carried forward. Negative values represent decrease from Baseline.”

Table 14.2.2.2: Summary of Absolute Change in Inflammatory Lesion Counts at Week 12 by Analysis Center
(Intent-to-Treat Population)

	E-BPO 5% Cream (N=xxx)			Vehicle Cream (N=xxx)		
Analysis Center (Investigational Sites)	n	Mean	SD	n	Mean	SD
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx
xx (y, z)	xx	xx.x	xx.xx	xx	xx.x	xx.xx

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative values represent decrease from Baseline.

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

Table 14.2.3.1.1: Summary of Investigator Global Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 4)

Investigator Global Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
0 - Clear	xx.x%	xx.x%
1 - Almost Clear	xx.x%	xx.x%
2 - Mild	xx.x%	xx.x%
3 - Moderate	xx.x%	xx.x%
4 - Severe	xx.x%	xx.x%
Achieving Clear or Almost Clear		
Success	xx.x%	xx.x%
Failure	xx.x%	xx.x%

Note: Multiple imputation (MCMC) used to impute missing values. Percentages for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.

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

Table 14.2.3.1.1: Summary of Investigator Global Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 4)

Investigator Global Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
0 - Clear	xx.x%	xx.x%
1 - Almost Clear	xx.x%	xx.x%
2 - Mild	xx.x%	xx.x%
3 - Moderate	xx.x%	xx.x%
4 - Severe	xx.x%	xx.x%
Achieving Clear or Almost Clear		
Success	xx.x%	xx.x%
Failure	xx.x%	xx.x%

Note: Multiple imputation (MCMC) used to impute missing values. Percentages for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.

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

Table 14.2.3.1.1: Summary of Investigator Global Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 3 of 4)

Investigator Global Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
0 - Clear	xx.x%	xx.x%
1 - Almost Clear	xx.x%	xx.x%
2 - Mild	xx.x%	xx.x%
3 - Moderate	xx.x%	xx.x%
4 - Severe	xx.x%	xx.x%
Achieving Clear or Almost Clear		
Success	xx.x%	xx.x%
Failure	xx.x%	xx.x%

Note: Multiple imputation (MCMC) used to impute missing values. Percentages for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.

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

Table 14.2.3.1.1: Summary of Investigator Global Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 4 of 4)

Investigator Global Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
0 - Clear	xx.x%	xx.x%
1 - Almost Clear	xx.x%	xx.x%
2 - Mild	xx.x%	xx.x%
3 - Moderate	xx.x%	xx.x%
4 - Severe	xx.x%	xx.x%
Achieving Clear or Almost Clear		
Success	xx.x%	xx.x%
Failure	xx.x%	xx.x%

Note: Multiple imputation (MCMC) used to impute missing values. Percentages for Weeks 2, 4, 8, and 12 represent average values, obtained from averaging the summary statistics generated from each imputed dataset.

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

Repeat Table 14.2.3.1.1 for the following table:

Table 14.2.3.1.2: Summary of Investigator Global Assessment at Each Evaluation (Per-Protocol Population)

Change footnote to “Note: Missing values imputed using last observation carried forward.”

Table 14.2.3.2: Summary of Investigator Global Assessment (Achieving Clear or Almost Clear) at Week 12 by Analysis Center
(Intent-to-Treat Population)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Analysis Center (Investigational Sites)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%
xx (y, z)	xx.x%	xx.x%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset.

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

Table 14.2.4.1: Subgroup Summaries of Primary Endpoints
(Intent-to-Treat Population)
(Page 1 of 5)

Age	Age < Median Age (xx)		Age >= Median Age (xx)	
	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Inflammatory Lesion Count – Absolute Change from Baseline				
n	xxx	xxx	xxx	xxx
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
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%

[a] Ethnicities of Not Reported and Unknown are not included.

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative absolute change values represent decrease from Baseline.

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

Table 14.2.4.1: Subgroup Summaries of Primary Endpoints
(Intent-to-Treat Population)
(Page 2 of 5)

Sex	Male		Female	
	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Inflammatory Lesion Count – Absolute Change from Baseline				
n	xxx	xxx	xxx	xxx
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
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%

[a] Ethnicities of Not Reported and Unknown are not included.

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative absolute change values represent decrease from Baseline.

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

Table 14.2.4.1: Subgroup Summaries of Primary Endpoints
(Intent-to-Treat Population)
(Page 3 of 5)

Ethnicity[a]	Hispanic or Latino		Not Hispanic or Latino	
	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Inflammatory Lesion Count – Absolute Change from Baseline				
n	xxx	xxx	xxx	xxx
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
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%

[a] Ethnicities of Not Reported and Unknown are not included.

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative absolute change values represent decrease from Baseline.

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

Table 14.2.4.1: Subgroup Summaries of Primary Endpoints
(Intent-to-Treat Population)
(Page 4 of 5)

Race	White		Non-White	
	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Inflammatory Lesion Count – Absolute Change from Baseline				
n	xxx	xxx	xxx	xxx
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
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%

[a] Ethnicities of Not Reported and Unknown are not included.

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative absolute change values represent decrease from Baseline.

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

Table 14.2.4.1: Subgroup Summaries of Primary Endpoints
(Intent-to-Treat Population)
(Page 5 of 5)

Baseline IGA	Moderate		Severe	
	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Inflammatory Lesion Count – Absolute Change from Baseline				
n	xxx	xxx	xxx	xxx
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
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%	xx.x%

[a] Ethnicities of Not Reported and Unknown are not included.

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained from averaging the summary statistics generated from each imputed dataset. Negative absolute change values represent decrease from Baseline.

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

Table 14.2.5.1: Sensitivity Analysis of Primary Endpoints: Absolute Change from Baseline in Inflammatory Lesion Count and Dichotomized IGA Success at Week 12
(Intent-to-Treat Population)
(Page 1 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Skewness P-Value	Treatment P-Value
Inflammatory Lesion Count – Absolute Change from Baseline				
LSMean[a]	xx.x	xx.x	x.xxx[b]	x.xxx[a]
LSSD[a]	xx.xx	xx.xx		x.xxx[c]
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	N/A	x.xxx[d]
Failure	xx.x%	xx.x%		

[a] Least squares means, standard deviations and treatment p-value from a repeated measures analysis of covariance with factors of treatment group, analysis center, visit and treatment group by visit interaction, and Baseline lesion count as a covariate. Negative least squares means values represent decrease from Baseline.
[b] Skewness test based on methods presented by J.H. Zar (1984).
[c] P-value from a ranked repeated measures analysis of covariance with factors of treatment group, analysis center, visit and treatment group by visit interaction, and Baseline lesion count as a covariate.
[d] P-value from a repeated measures logistic regression with factors of treatment group, analysis center, visit and treatment group by visit interaction.

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

Table 14.2.5.1: Sensitivity Analysis of Primary Endpoints: Absolute Change from Baseline in Inflammatory Lesion Count and Dichotomized IGA Success at Week 12
(Intent-to-Treat Population)
(Page 2 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Skewness P-Value	Treatment P-Value
Inflammatory Lesion Count – Absolute Change from Baseline				
LSMean[a]	xx.x	xx.x	x.xxx[b]	x.xxx[a]
LSSD[a]	xx.xx	xx.xx		x.xxx[c]
Achieving Clear or Almost Clear				
Success	xx.x%	xx.x%	N/A	x.xxx[d]
Failure	xx.x%	xx.x%		

[a] Least squares means, standard deviations and treatment p-value from an analysis of covariance with factors of treatment group and analysis center and Baseline lesion count as a covariate. Negative least squares means values represent decrease from Baseline.
[b] Skewness test, based on methods presented by J.H. Zar (1984), assessed for each imputed dataset. The average p-value is presented.
[c] P-value from a ranked analysis of covariance with factors of treatment group and analysis center and Baseline lesion count as a covariate.
[d] P-value from a logistic regression with factors of treatment group and analysis center.

Note: Multiple imputation (regression model) used to impute missing values.

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

Table 14.2.6.1: Secondary Efficacy Analyses
(Intent-to-Treat Population)
(Page 1 of 3)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Skewness P-Value	Treatment P-Value
Inflammatory Lesion Count – Percent Change from Baseline to Week 12				
LSMean[a]	xx.x	xx.x	x.xxx[b]	x.xxx[a]
LSSD[a]	xx.xx	xx.xx		x.xxx[c]

[a] Least squares means, standard deviations and treatment p-value from an analysis of covariance with factors of treatment and analysis center and the Baseline lesion count as a covariate. Negative least squares means values represent decrease from Baseline.
[b] Skewness test, based on methods presented by J.H. Zar (1984), assessed for each imputed dataset. The average p-value is presented.
[c] P-value from a ranked analysis of covariance with factors of treatment and analysis center and the Baseline lesion count as a covariate.
[d] P-value from a logistic regression with factors of treatment group and analysis center.

Note: Multiple imputation (MCMC) used to impute missing values.

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

{NOTE TO PROGRAMMER: ADJUST FOOTNOTE "d" IF FIRTH'S PENALIZED LIKELIHOOD IS NEEDED}

Table 14.2.6.1: Secondary Efficacy Analyses
(Intent-to-Treat Population)
(Page 2 of 3)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Skewness P-Value	Treatment P-Value
Inflammatory Lesion Count –Absolute Change from Baseline to Week 8				
LSMean[a]	xx.x	xx.x	x.xxx[b]	x.xxx[a]
LSSD[a]	xx.xx	xx.xx		x.xxx[c]
Achieving Clear or Almost Clear at Week 8				
Success	xx.x%	xx.x%	N/A	x.xxx[d]
Failure	xx.x%	xx.x%		

[a] Least squares means, standard deviations and treatment p-value from an analysis of covariance with factors of treatment and analysis center and the Baseline lesion count as a covariate. Negative least squares means values represent decrease from Baseline.
[b] Skewness test, based on methods presented by J.H. Zar (1984), assessed for each imputed dataset. The average p-value is presented.
[c] P-value from a ranked analysis of covariance with factors of treatment and analysis center and the Baseline lesion count as a covariate.
[d] P-value from a logistic regression with factors of treatment group and analysis center.

Note: Multiple imputation (MCMC) used to impute missing values.

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

Table 14.2.6.1: Secondary Efficacy Analyses
(Intent-to-Treat Population)
(Page 3 of 3)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Skewness P-Value	Treatment P-Value
Inflammatory Lesion Count – Absolute Change from Baseline to Week 4				
LSMean[a]	xx.x	xx.x	x.xxx[b]	x.xxx[a]
LSSD[a]	xx.xx	xx.xx		x.xxx[c]
Achieving Clear or Almost Clear at Week 4				
Success	xx.x%	xx.x%	N/A	x.xxx[d]
Failure	xx.x%	xx.x%		

[a] Least squares means, standard deviations and treatment p-value from an analysis of covariance with factors of treatment and analysis center and the Baseline lesion count as a covariate. Negative least squares means values represent decrease from Baseline.
[b] Skewness test, based on methods presented by J.H. Zar (1984), assessed for each imputed dataset. The average p-value is presented.
[c] P-value from a ranked analysis of covariance with factors of treatment and analysis center and the Baseline lesion count as a covariate.
[d] P-value from a logistic regression with factors of treatment group and analysis center.

Note: Multiple imputation (MCMC) used to impute missing values.

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

Table 14.2.7.1: Patient Assessment of Papulopustular rosacea Signs and Symptoms (PAPSS) Analyses at Week 12
(Intent-to-Treat Population)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	Treatment P-Value
PAPSS Total Scale Score – Absolute Change from Baseline to Week 12			
LSMean[a]	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	
PAPSS Burning – Absolute Change from Baseline to Week 12			
LSMean[a]	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	
PAPSS Itching – Absolute Change from Baseline to Week 12			
LSMean[a]	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	
PAPSS Redness – Absolute Change from Baseline to Week 12			
LSMean[a]	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	
PAPSS Bumps – Absolute Change from Baseline to Week 12			
LSMean[a]	xx.x	xx.x	x.xxx[a]
LSSD[a]	xx.xx	xx.xx	

[a] Least squares means, standard deviations and treatment p-value from an analysis of variance with factors of treatment, analysis center, and the respective Baseline score. Negative least squares means values represent decrease from Baseline.

Note: No imputation of missing values. To control family-wise type I error rate at 5%, the Benjamini-Hochberg procedure (Hochberg and Bejamini adaptive step-down Bonferroni method) was utilized, and each p-value with an (*) is to be considered statistically significant.

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

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 15)

Total Scale Scores	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
Total scale score is the sum of all PAPSS items.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 15)

Total Scale Scores	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
Total scale score is the sum of all PAPSS items.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 3 of 15)

Total Scale Scores	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
Total scale score is the sum of all PAPSS items.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 4 of 15)

Over the past 24 hours, what was the worst burning you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No burning at all, 10 = Worst possible burning
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 5 of 15)

Over the past 24 hours, what was the worst burning you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No burning at all, 10 = Worst possible burning
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 6 of 15)

Over the past 24 hours, what was the worst burning you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No burning at all, 10 = Worst possible burning
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 7 of 15)

Over the past 24 hours, what was the worst itching you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No itching at all, 10 = Worst possible itching
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 8 of 15)

Over the past 24 hours, what was the worst itching you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No itching at all, 10 = Worst possible itching
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 9 of 15)

Over the past 24 hours, what was the worst itching you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No itching at all, 10 = Worst possible itching
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 10 of 15)

Over the past 24 hours, what was the worst redness you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No redness at all, 10 = Worst possible redness
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 11 of 15)

Over the past 24 hours, what was the worst redness you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No redness at all, 10 = Worst possible redness
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 12 of 15)

Over the past 24 hours, what was the worst redness you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No redness at all, 10 = Worst possible redness
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 13 of 15)

Over the past 24 hours, what were the worst bumps you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No bumps at all, 10 = Worst possible bumps
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 14 of 15)

Over the past 24 hours, what were the worst bumps you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No bumps at all, 10 = Worst possible bumps
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation
(Intent-to-Treat Population)
(Page 15 of 15)

Over the past 24 hours, what were the worst bumps you experienced because of your rosacea?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
0 = No bumps at all, 10 = Worst possible bumps
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.8.1 for the following table:

Table 14.2.8.2: Summary of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Each Evaluation (Per-Protocol Population)

Table 14.2.9.1: Summary of Erythema Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Rosacea Erythema Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.2.9.1: Summary of Erythema Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Rosacea Erythema Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Repeat Table 14.2.9.1 for the following table:

Table 14.2.9.2: Summary of Erythema Assessment at Each Evaluation (Per-Protocol Population)

Table 14.2.10.1: Summary of Telangiectasia Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Telangiectasia Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.2.10.1: Summary of Telangiectasia Assessment at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Telangiectasia Assessment	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Repeat Table 14.2.10.1 for the following table:

Table 14.2.10.2: Summary of Telangiectasia Assessment at Each Evaluation (Per-Protocol Population)

Table 14.2.11.1: Summary of Patient Global Impression of Change (PGI-C) at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Since the start of the study, how have your rosacea symptoms changed?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 2		
n	xx	xx
0 - Very much improved	xx (xx.x%)	xx (xx.x%)
1 - Much improved	xx (xx.x%)	xx (xx.x%)
2 - Minimally improved	xx (xx.x%)	xx (xx.x%)
3 - No Change	xx (xx.x%)	xx (xx.x%)
4 - Minimally worse	xx (xx.x%)	xx (xx.x%)
5 - Much worse	xx (xx.x%)	xx (xx.x%)
6 - Very much worse	xx (xx.x%)	xx (xx.x%)
At least minimally improved	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 - Very much improved	xx (xx.x%)	xx (xx.x%)
1 - Much improved	xx (xx.x%)	xx (xx.x%)
2 - Minimally improved	xx (xx.x%)	xx (xx.x%)
3 - No Change	xx (xx.x%)	xx (xx.x%)
4 - Minimally worse	xx (xx.x%)	xx (xx.x%)
5 - Much worse	xx (xx.x%)	xx (xx.x%)
6 - Very much worse	xx (xx.x%)	xx (xx.x%)
At least minimally improved	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. At least minimally improved defined as “very much improved”, “much improved”, or “minimally improved”.

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

Table 14.2.11.1: Summary of Patient Global Impression of Change (PGI-C) at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Since the start of the study, how have your rosacea symptoms changed?	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 - Very much improved	xx (xx.x%)	xx (xx.x%)
1 - Much improved	xx (xx.x%)	xx (xx.x%)
2 - Minimally improved	xx (xx.x%)	xx (xx.x%)
3 - No Change	xx (xx.x%)	xx (xx.x%)
4 - Minimally worse	xx (xx.x%)	xx (xx.x%)
5 - Much worse	xx (xx.x%)	xx (xx.x%)
6 - Very much worse	xx (xx.x%)	xx (xx.x%)
At least minimally improved	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 - Very much improved	xx (xx.x%)	xx (xx.x%)
1 - Much improved	xx (xx.x%)	xx (xx.x%)
2 - Minimally improved	xx (xx.x%)	xx (xx.x%)
3 - No Change	xx (xx.x%)	xx (xx.x%)
4 - Minimally worse	xx (xx.x%)	xx (xx.x%)
5 - Much worse	xx (xx.x%)	xx (xx.x%)
6 - Very much worse	xx (xx.x%)	xx (xx.x%)
At least minimally improved	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. At least minimally improved defined as “very much improved”, “much improved”, or “minimally improved”.

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

Repeat Table 14.2.11.1 for the following table:

Table 14.2.11.2: Summary of Patient Global Impression of Change (PGI-C) at Each Evaluation (Per-Protocol Population)

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 12)

Over the past seven days, rate how embarrassed you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not embarrassed at all, 10 = Extremely embarassed

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 12)

Over the past seven days, rate how embarrassed you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not embarrassed at all, 10 = Extremely embarassed

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 3 of 12)

Over the past seven days, rate how embarrassed you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not embarrassed at all, 10 = Extremely embarassed

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 4 of 12)

Over the past seven days, rate how embarrassed you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not embarrassed at all, 10 = Extremely embarassed

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 5 of 12)

Over the past seven days, rate how self-conscious you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not self-conscious at all, 10 = Extremely self-conscious

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 6 of 12)

Over the past seven days, rate how self-conscious you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not self-conscious at all, 10 = Extremely self-conscious

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 7 of 12)

Over the past seven days, rate how self-conscious you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not self-conscious at all, 10 = Extremely self-conscious

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 8 of 12)

Over the past seven days, rate how self-conscious you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not self-conscious at all, 10 = Extremely self-conscious

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 9 of 12)

Over the past seven days, rate how frustrated you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not frustrated at all, 10 = Extremely frustrated

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 10 of 12)

Over the past seven days, rate how frustrated you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not frustrated at all, 10 = Extremely frustrated

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 11 of 12)

Over the past seven days, rate how frustrated you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values.
0 = Not frustrated at all, 10 = Extremely frustrated

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

Table 14.2.12.1: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation
(Intent-to-Treat Population)
(Page 12 of 12)

Over the past seven days, rate how frustrated you felt because of your rosacea.	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Three-Point Improvement from Baseline	xx (xx.xx%)	xx (xx.xx%)

Note: No imputation of missing values. Absolute Change calculated as Post-Baseline Visit – Baseline. Negative values represent decrease from Baseline.
0 = Not frustrated at all, 10 = Extremely frustrated

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

Repeat Table 14.2.12.1 for the following table:

Table 14.2.12.2: Summary of Patient Assessment of Papulopustular rosacea Impacts (PAPI) at Each Evaluation (Per-Protocol Population)

Table 14.2.13.1: Summary of Patient Global Impression of Symptom Severity (PGI-S) at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Right now, my rosacea symptoms are:	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.2.13.1: Summary of Patient Global Impression of Symptom Severity (PGI-S) at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Right now, my rosacea symptoms are:	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Repeat Table 14.2.13.1 for the following table:

Table 14.2.13.2: Summary of Patient Global Impression of Symptom Severity (PGI-S) at Each Evaluation (Per-Protocol Population)

Table 14.2.14.1: Summary of Patient Global Impression of Treatments Satisfaction (PGI-TS) at Each Evaluation
(Intent-to-Treat Population)
(Page 1 of 2)

Right now, how satisfied are you with your rosacea treatment:	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 2		
n	xx	xx
0 – I am very satisfied	xx (xx.x%)	xx (xx.x%)
1 – I am satisfied	xx (xx.x%)	xx (xx.x%)
2 – I am neither satisfied not dissatisfied	xx (xx.x%)	xx (xx.x%)
3 – I am dissatisfied	xx (xx.x%)	xx (xx.x%)
4 – I am very dissatisfied	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 – I am very satisfied	xx (xx.x%)	xx (xx.x%)
1 – I am satisfied	xx (xx.x%)	xx (xx.x%)
2 – I am neither satisfied not dissatisfied	xx (xx.x%)	xx (xx.x%)
3 – I am dissatisfied	xx (xx.x%)	xx (xx.x%)
4 – I am very dissatisfied	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.2.14.1: Summary of Patient Global Impression of Treatments Satisfaction (PGI-TS) at Each Evaluation
(Intent-to-Treat Population)
(Page 2 of 2)

Right now, how satisfied are you with your rosacea treatment:	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 – I am very satisfied	xx (xx.x%)	xx (xx.x%)
1 – I am satisfied	xx (xx.x%)	xx (xx.x%)
2 – I am neither satisfied not dissatisfied	xx (xx.x%)	xx (xx.x%)
3 – I am dissatisfied	xx (xx.x%)	xx (xx.x%)
4 – I am very dissatisfied	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 – I am very satisfied	xx (xx.x%)	xx (xx.x%)
1 – I am satisfied	xx (xx.x%)	xx (xx.x%)
2 – I am neither satisfied not dissatisfied	xx (xx.x%)	xx (xx.x%)
3 – I am dissatisfied	xx (xx.x%)	xx (xx.x%)
4 – I am very dissatisfied	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Repeat Table 14.2.14.1 for the following table:

Table 14.2.14.2: Summary of Patient Global Impression of Treatments Satisfaction (PGI-TS) at Each Evaluation (Per-Protocol Population)

Table 14.2.15.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 12
(Intent-to-Treat Population)
(Page 1 of 4)

Total Score	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.
Total Score calculated from the unweighted mean of all RosaQoL questions.
Symptom Subscale Score calculated from items 2, 6, 9, 16, 17, 18, and 19.
Functional Subscale Score calculated from items 13, 15, and 21.
Emotional Subscale Score calculated from items 1, 3, 4, 5, 7, 8, 10, 11, 12, 14, and 20.

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

Table 14.2.15.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 12
(Intent-to-Treat Population)
(Page 2 of 4)

Symptom Subscale Score	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.
Total Score calculated from the unweighted mean of all RosaQoL questions.
Symptom Subscale Score calculated from items 2, 6, 9, 16, 17, 18, and 19.
Functional Subscale Score calculated from items 13, 15, and 21.
Emotional Subscale Score calculated from items 1, 3, 4, 5, 7, 8, 10, 11, 12, 14, and 20.

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

Table 14.2.15.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 12
(Intent-to-Treat Population)
(Page 3 of 4)

Functional Subscale Score	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.
Total Score calculated from the unweighted mean of all RosaQoL questions.
Symptom Subscale Score calculated from items 2, 6, 9, 16, 17, 18, and 19.
Functional Subscale Score calculated from items 13, 15, and 21.
Emotional Subscale Score calculated from items 1, 3, 4, 5, 7, 8, 10, 11, 12, 14, and 20.

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

Table 14.2.15.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 12
(Intent-to-Treat Population)
(Page 4 of 4)

Emotional Subscale Score	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.
Total Score calculated from the unweighted mean of all RosaQoL questions.
Symptom Subscale Score calculated from items 2, 6, 9, 16, 17, 18, and 19.
Functional Subscale Score calculated from items 13, 15, and 21.
Emotional Subscale Score calculated from items 1, 3, 4, 5, 7, 8, 10, 11, 12, 14, and 20.

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

Repeat Table 14.2.15.1 for the following table:

Table 14.2.15.2: Summary of RosaQoL Questionnaire Responses at Baseline and Week 12 (Per-Protocol Population)

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

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Total Number of Days of Exposure		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Total Number of Applications		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Total Number of Missed Applications		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Compliant[a]		
n	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)
Noe	xx (xx.x%)	xx (xx.x%)

[a] A subject was considered compliant with the dosing regimen if the subject applied 80-120% of the expected number of applications and did not miss more than 5 consecutive applications while enrolled in the study.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 1 of 8)

Dryness	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 2 of 8)

Dryness	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 3 of 8)

Scaling	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 4 of 8)

Scaling	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 5 of 8)

Itching	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 6 of 8)

Itching	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 7 of 8)

Burning/Stinging	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 8 of 8)

Burning/Stinging	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing data.

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

Table 14.3.1.2.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 1 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Subjects Reporting Any Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events	xx	xx
Subjects Reporting Any Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events	xx	xx
Subjects Reporting Treatment-Emergent Adverse Event with Outcome of Fatal	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events with Outcome of Fatal	xx	xx
Subjects Who Discontinued Study Drug Due to a Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug	xx	xx
Subjects Who Discontinued from the Study Due to a Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events Leading to Discontinuation of Study	xx	xx

Note: Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.2.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 2 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
By Maximum Severity		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
By Strongest Relationship to Study Drug		
Related	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)
Maximum Severity within Relationship to Study Drug		
Related		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Not Related		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.2.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of x)

System Organ Class[a] Preferred Term	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	P-Value[b]
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	x.xxx
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	x.xxx

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
[b] P-value for the difference between treatment groups from a Fisher's Exact test. The specific system organ classes and preferred terms analyzed will be those that are reported by at least one percent of the patients in any treatment group.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.

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

Table 14.3.1.2.3: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)
(Page 1 of x)

System Organ Class[a] Preferred Term	Severity	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)

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

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.

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

Table 14.3.1.2.4: Summary of Treatment-Emergent Adverse Events by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)

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

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 1 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Subjects Reporting Any Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events	xx	xx
Subjects Reporting Serious Treatment-Emergent Adverse Event with Outcome of Fatal	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events with Outcome of Fatal	xx	xx
Subjects Who Discontinued Study Drug Due to a Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug	xx	xx
Subjects Who Discontinued from the Study Due to a Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events Leading to Discontinuation of Study	xx	xx

Note: Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 2 of 2)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
By Maximum Severity		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
By Strongest Relationship to Study Drug		
Related	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)
Maximum Severity within Relationship to Study Drug		
Related		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Not Related		
Severe	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.3.2: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of x)

System Organ Class[a] Preferred Term	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)	P-Value[b]
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	x.xxx
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	x.xxx

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
[b] P-value for the difference between treatment groups from a Fisher's Exact test. The specific system organ classes and preferred terms analyzed will be those that are reported by at least one percent of the patients in any treatment group.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.

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

Table 14.3.1.3.3: Summary of Serious Treatment-Emergent Adverse Events by Severity
(Safety Population)
(Page 1 of x)

System Organ Class[a] Preferred Term	Severity	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)

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

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.

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

Table 14.3.1.3.4: Summary of Treatment-Emergent Serious Adverse Events by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)

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

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events that were not indicated as occuring prior to first application.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.4.1: Summary of Vital Signs
(Safety Population)
(Page 1 of 5)

Temperature (°C)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Negative change values represent decrease from Baseline.

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

Table 14.3.1.4.1: Summary of Vital Signs
(Safety Population)
(Page 2 of 5)

Respiratory Rate (breaths/min)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Negative change values represent decrease from Baseline.

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

Table 14.3.1.4.1: Summary of Vital Signs
(Safety Population)
(Page 3 of 5)

Systolic Blood Pressure (mmHg)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Negative change values represent decrease from Baseline.

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

Table 14.3.1.4.1: Summary of Vital Signs
(Safety Population)
(Page 4 of 5)

Diastolic Blood Pressure (mmHg)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Negative change values represent decrease from Baseline.

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

Table 14.3.1.4.1: Summary of Vital Signs
(Safety Population)
(Page 5 of 5)

Heart Rate (beats/min)	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 12		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Change from Baseline		
n	xxx	xxx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Negative change values represent decrease from Baseline.

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

Table 14.3.1.4.2: Shift Table of Vital Signs
(Safety Population)

	E-BPO 5% Cream (N=xxx)			Vehicle Cream (N=xxx)		
Systolic Blood Pressure (mmHg)	Week 12			Week 12		
Baseline	<90 mmHg	90-140 mmHg	>140 mmHg	<90 mmHg	90-140 mmHg	>140 mmHg
<90 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90-140 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
>140 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Diastolic Blood Pressure (mmHg)	Week 12			Week 12		
Baseline	<90 mmHg	90-100 mmHg	>100 mmHg	<90 mmHg	90-100 mmHg	>100 mmHg
<90 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90-100 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
>100 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heart Rate (beats/min)	Week 12			Week 12		
Baseline	<60 bpm	60-100 bpm	>100 bpm	<60 bpm	60-100 bpm	>100 bpm
<60 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
60-100 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
>100 mmHg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.3.1.5: Summary of Abnormal Physical Examination Findings by Visit
(Safety Population)

	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Heart		
Baseline		
n	xx	xx
Abnormal	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
Abnormal	xx (xx.x%)	xx (xx.x%)
Lung		
Baseline		
n	xx	xx
Abnormal	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
Abnormal	xx (xx.x%)	xx (xx.x%)
Abdomen		
Baseline		
n	xx	xx
Abnormal	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
Abnormal	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.3.1.6: Summary of Patient Global Impression of Treatment Side-Effects (PGI-SE) at Each Evaluation
(Safety Population)
(Page 1 of 2)

Right now, how bothered are you by the side effects of your rosacea treatment:	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 2		
n	xx	xx
0 - I am not bothered	xx (xx.x%)	xx (xx.x%)
1 - I am somewhat bothered	xx (xx.x%)	xx (xx.x%)
2 - I am moderately bothered	xx (xx.x%)	xx (xx.x%)
3 - I am very bothered	xx (xx.x%)	xx (xx.x%)
4 - I am extremely bothered	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
0 - I am not bothered	xx (xx.x%)	xx (xx.x%)
1 - I am somewhat bothered	xx (xx.x%)	xx (xx.x%)
2 - I am moderately bothered	xx (xx.x%)	xx (xx.x%)
3 - I am very bothered	xx (xx.x%)	xx (xx.x%)
4 - I am extremely bothered	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

Table 14.3.1.6: Summary of Patient Global Impression of Treatment Side-Effects (PGI-SE) at Each Evaluation
(Safety Population)
(Page 2 of 2)

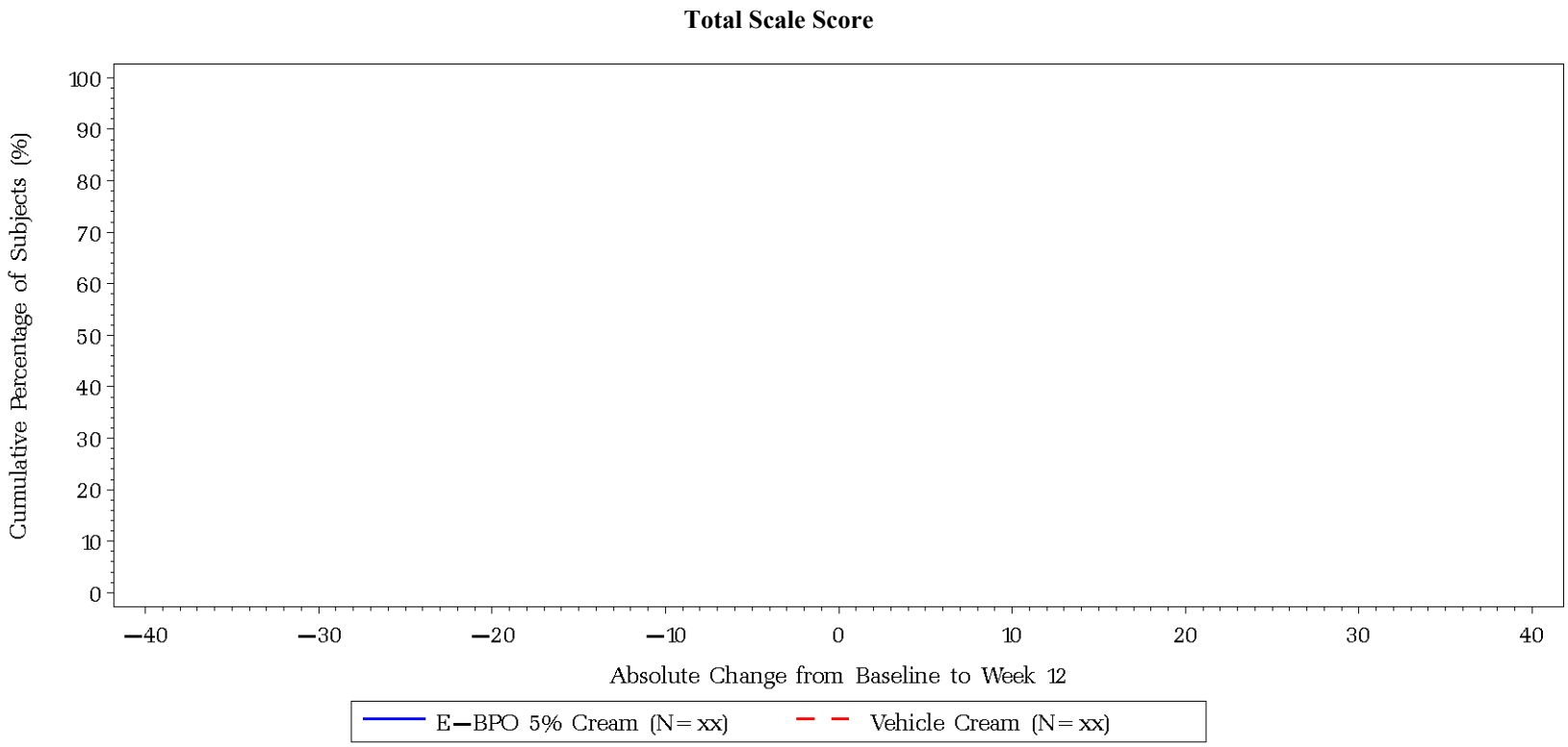
Right now, how bothered are you by the side effects of your rosacea treatment:	E-BPO 5% Cream (N=xxx)	Vehicle Cream (N=xxx)
Week 8		
n	xx	xx
0 - I am not bothered	xx (xx.x%)	xx (xx.x%)
1 - I am somewhat bothered	xx (xx.x%)	xx (xx.x%)
2 - I am moderately bothered	xx (xx.x%)	xx (xx.x%)
3 - I am very bothered	xx (xx.x%)	xx (xx.x%)
4 - I am extremely bothered	xx (xx.x%)	xx (xx.x%)
Week 12		
n	xx	xx
0 - I am not bothered	xx (xx.x%)	xx (xx.x%)
1 - I am somewhat bothered	xx (xx.x%)	xx (xx.x%)
2 - I am moderately bothered	xx (xx.x%)	xx (xx.x%)
3 - I am very bothered	xx (xx.x%)	xx (xx.x%)
4 - I am extremely bothered	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.

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

13. INDEX OF PLANNED FIGURES

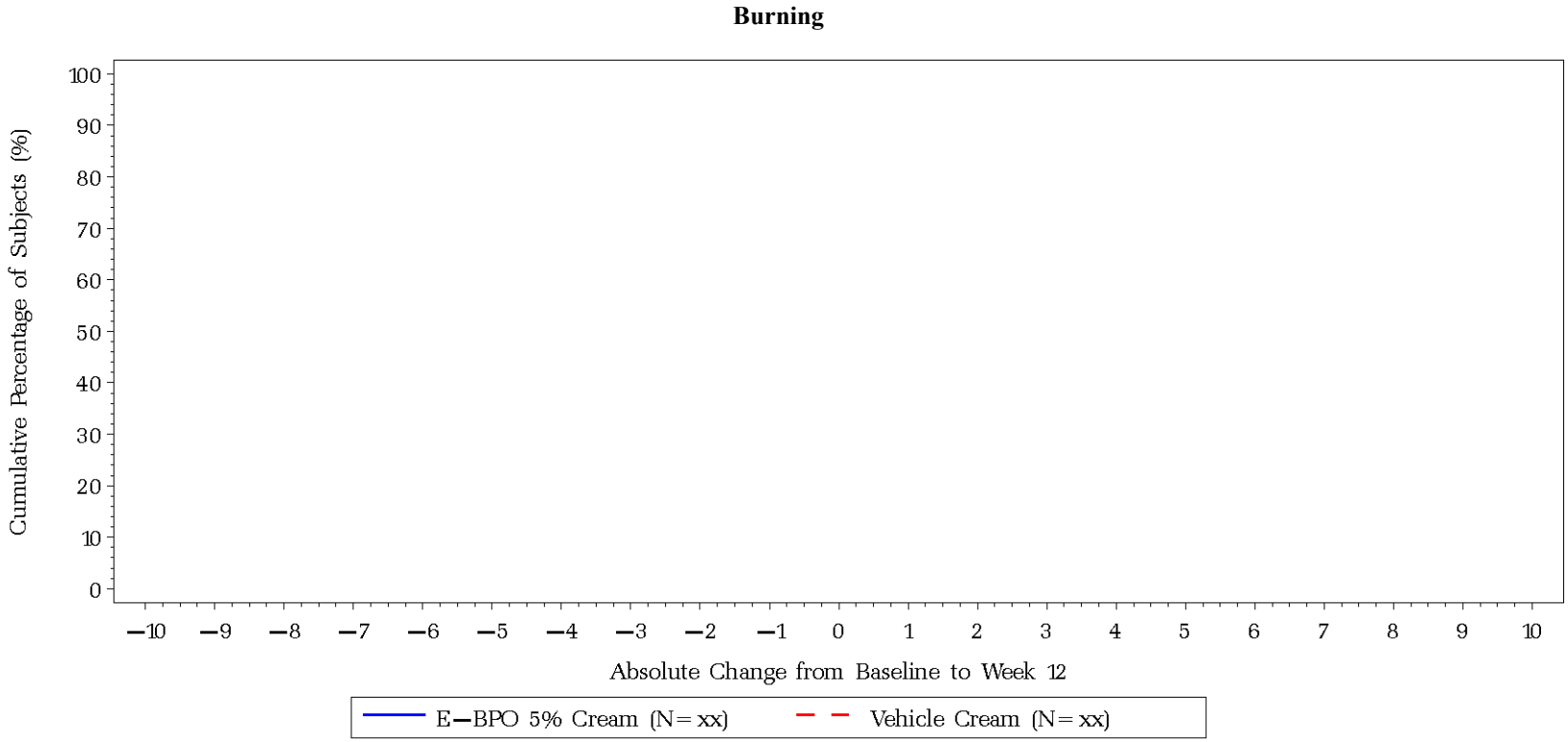
Figure 14.2.3.1: Cumulative Distribution Function of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Week 12
(Intent-to-Treat Population)
(Page 1 of 5)



Note: No imputation of missing values. Absolute Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.

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

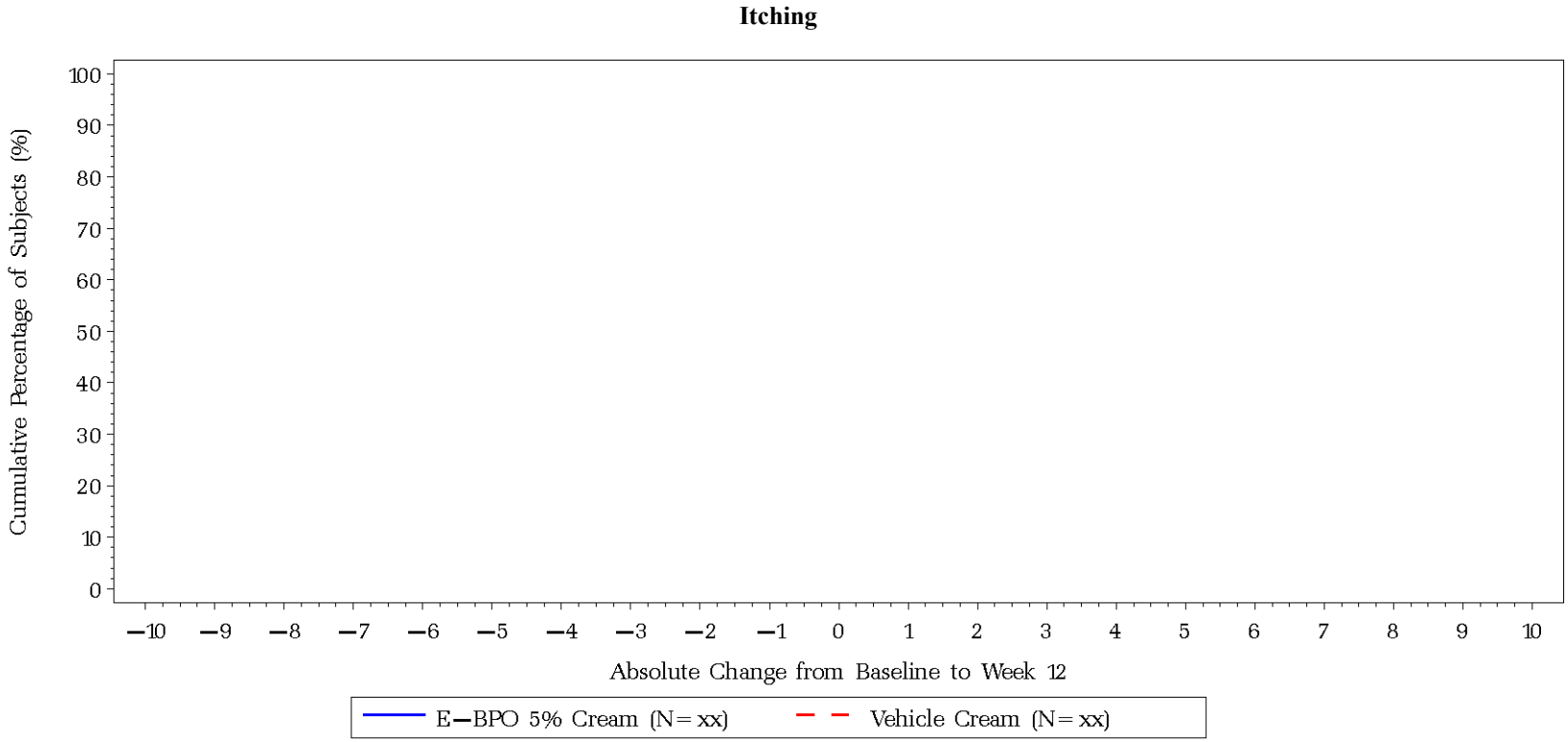
Figure 14.2.3.1: Cumulative Distribution Function of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Week 12
(Intent-to-Treat Population)
(Page 2 of 5)



Note: No imputation of missing values. Absolute Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.

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

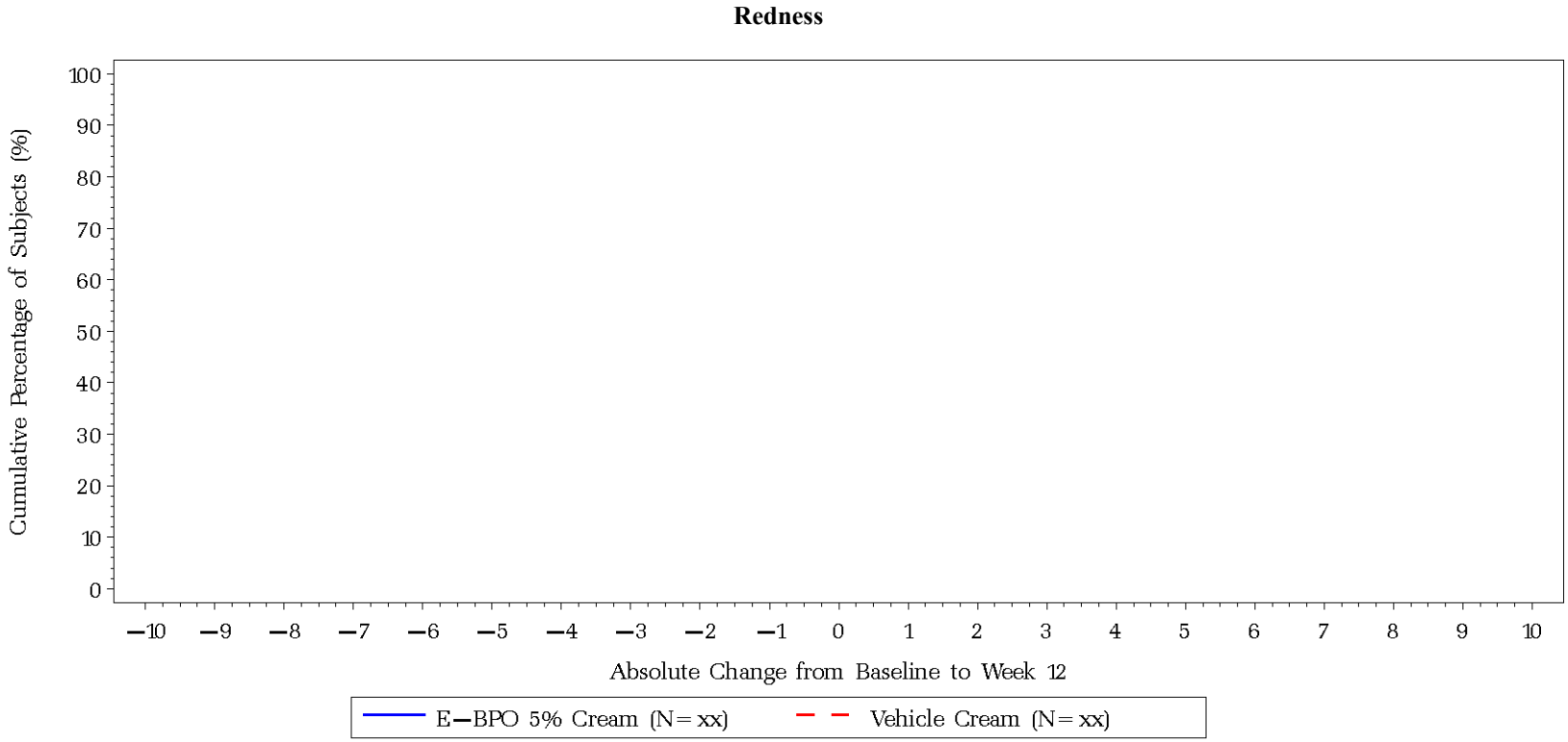
Figure 14.2.3.1: Cumulative Distribution Function of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Week 12
(Intent-to-Treat Population)
(Page 3 of 5)



Note: No imputation of missing values. Absolute Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.

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

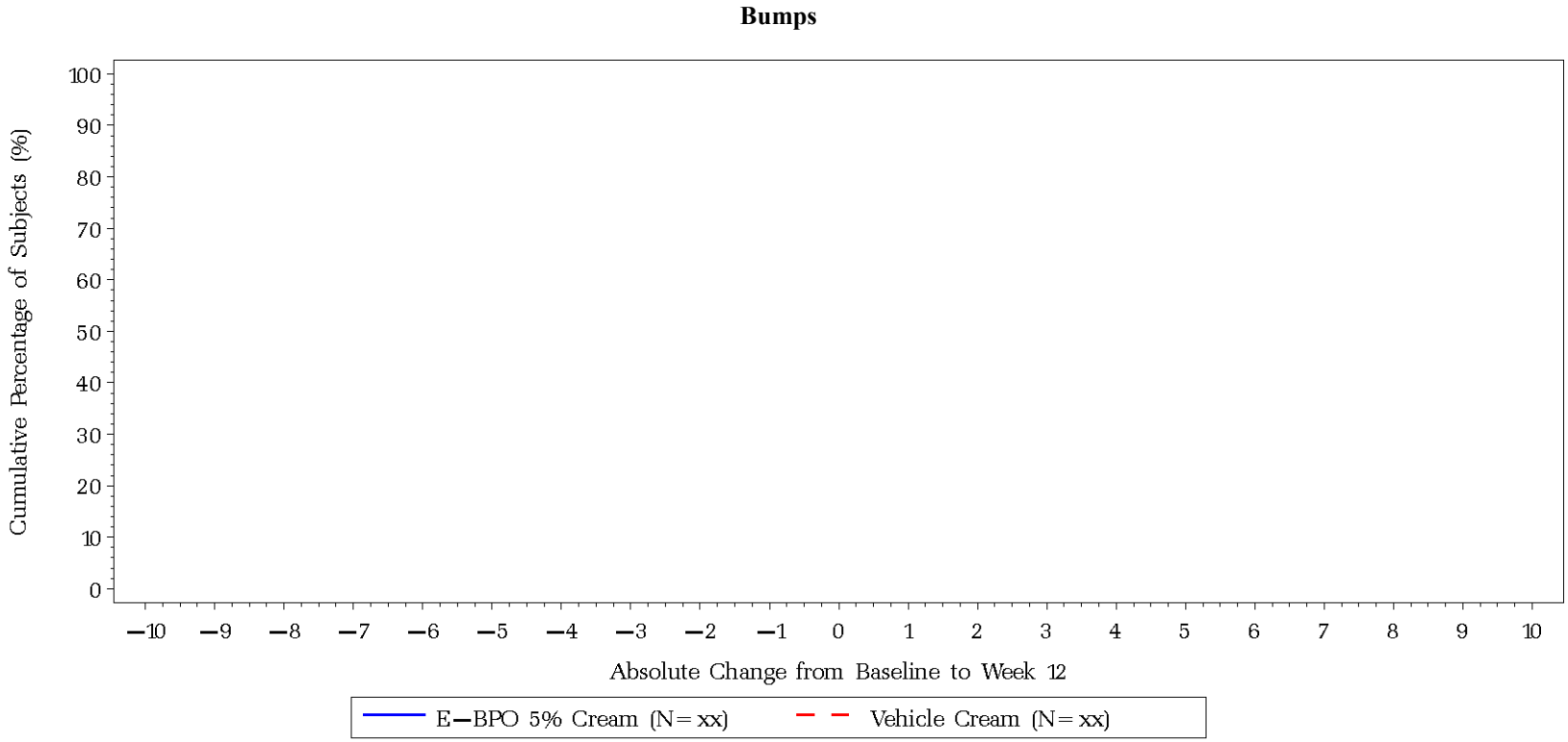
Figure 14.2.3.1: Cumulative Distribution Function of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Week 12
(Intent-to-Treat Population)
(Page 4 of 5)



Note: No imputation of missing values. Absolute Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.

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

Figure 14.2.3.1: Cumulative Distribution Function of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Week 12
(Intent-to-Treat Population)
(Page 5 of 5)



Note: No imputation of missing values. Absolute Change calculated as Week 12 – Baseline. Negative values represent decrease from Baseline.

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

Repeat Figure 14.2.3.1 for the following tables:

Figure 14.2.3.2: Cumulative Distribution Function of Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) at Week 12 (Per-Protocol Population)

14. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Randomization Scheme
(Page xx of yy)

Subject	Age/Sex	Eval	Randomization Date	Kit Number	Assigned Arm
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxx xx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxx xx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxx xx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxx xx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxx xx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxx	xxxx	xxxxxxx xxxxx

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

Listing sorted by Subject.

Listing 16.2.1.1: End of Study Information
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Application	Date of Last Application	Date of Study Completion/ Discontinuation (Day)[1]	Did Subject Complete the Study	Primary Reason for Study Discontinuation	Continue to the the Long Term Safety Study
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxxxx	xxx		xxx x xxx xxxxxx xxxx xxxxxxxx xxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxxxx	xx	xxxxxxx xxxxx	xx x xxx xxxxxxx xxxx xxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxxxx	xx	xxxx xx xxxxxxxxxx xxxxxxx xx xxxx xx xxxxxxxxxxx xxxxx xxxxx xxxxx xxx xxxx	xx x xxx xxxxxxx xxxx xxx xxxxxxxx

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

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

Listing sorted by Subject.
If Primary Reason for Study Discontinuation is Lost to Follow-Up, Protocol Violation, Withdrawal by Subject, or Other, the reason specification will be included following a colon (for example, WITHDRAWAL BY SUBJECT: xxxxx)
If subject will not continue to the LTS, the reason specification will be included in the final column following a colon.

Listing 16.2.2.1: Inclusion/Exclusion Criteria
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Criterion Failed	Description
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxx xxx

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

Listing sorted by Subject and Criterion Failed.

Listing 16.2.2.2: Screen Failure
(Page xx of yy)

Subject	Age/Sex	Eval	Date of Screen Failure	Reason for Screen Failure
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxxxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxxxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxxx xxx

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

Listing sorted by Subject.

Listing 16.2.2.3: Protocol Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Deviation	Date (Day[1])
xxxxxx	xxxx	xxxxxxxxx	xxxxxx x xxxxxxxx xxx xx xxxxxx xxxxxx xxx xxx xx xxxxxxxxxxxx	xxxxxxxxxxxxxx
			xxxxxx xxx xx xxxxxx xxxxxx xxx xxx xx	xxxxxxxxxxxxxx
			xxxxxx x xxxxxxxx	
xxxxxx	xxxx	xxxxxxxxx	xxxxxx xxx xx xxxxxx xxxxxx xxx xxx xx	xxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxx xxx xx xxxxxx xxxxxx xxx xxx xx	xxxxxxxxxxxxxx

[1] Day is calculated as date - Baseline date for dates prior to Baseline visit. Otherwise, day is calculated as date - Baseline date + 1 for dates on or after Baseline visit.

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

Listing sorted by Subject and Date.

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

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

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

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

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

Subject	Eval	B: Date of Birth A: Age S: Sex	R: Race E: Ethnicity	C: Childbearing Potential M: Method of Birth Control	I: Informed Consent Date P: Photography Consent Signed
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxxx xxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxx xxxx x xxxxxxxxxx xx xxxxxxxxx xxxxxxxxxx xxxx xxxxxxx	I: xxxx-xx-xx P: xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xx M:	I: xxxx-xx-xx P: xx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxx xxxxxxxxxxxx	I: xxxx-xx-xx P: xx xxxx x xxxxxxxxxx xxxxx

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

Listing sorted by Subject.

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

MedDRA System Organ Class	MedDRA Preferred Term	Medical/Surgical History Verbatim Term
xxxx xxx xxxxxxxxx xxxxxx xxxxxxxxx	xxxxxxx	xxxxxx
	xxxx xxxxxxxxx xxxxxxxx	xxxx xxxxxxxxxx xxxxxx
xxxxxxxxxx xxx xxxxxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxxx
	xxxxxxxxxxxxx	xxxxxxxxxxxxx x xxxx xxx xxx
		xxxxxxxxxxxxx xx xxxxx xx xxxx xxxxx xxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

Listing sorted by System Organ Class, Preferred Term, and Verbatim Term.

Listing 16.2.4.2.2: Medical/Surgical History
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Medical/Surgical History Verbatim Term	S: MedDRA System Organ Class P: MedDRA Preferred Term	S: Onset Date E: End Date
xxxxxx	xxxx	xxxxxxxxx	xxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx P: xxxxxxx	S: xxxx E:
			xxxxxxx xx xxxxxxxxxxx xxxxxxxxx	S: xxxxxx xxxxxx xxxxxxxxx P: xxxxxxxx xxxxx xxxxxxx	S: xxxx E: xxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx P: xxxxxxx	S: xxxx E:
xxxxxx	xxxx	xxxxxxxxx	xxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx P: xxxxxxx	S: xxxx E:
xxxxxx	xxxx	xxxxxxxxx	xxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx P: xxxxxxx	S: xxxx E:
			xxxxxxxxxxxxxxxx	S: xxxxxx xxxxxx xxxx P: xxxx xxxxxxxxxxx	S: xxxxxxxxxx E: xxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

Listing sorted by Subject, Rosacea Diagnosis (all Rosacea MH will appear first), Onset Date, End Date, Verbatim Term

Listing 16.2.4.3.1: Unique Medication Names Coded to WHO Drug Global Dictionary ATC Level 2 Terms and Preferred Names
(Page xx of yy)

WHO ATC Level 2 Term	WHO Preferred Name	Medication Verbatim Term	I: Indication T: Route
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx

Note: ATC Level 2 Term and Preferred Name map to WHO Drug Global Dictionary, Format B3, Version March 1, 2018.

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

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

Listing 16.2.4.3.2: Prior and Concomitant Medications
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	A: ATC Level 2 Term P: Preferred Name M: Medication Name	S: Start Date (Day)[1] E: End Date (Day)[1] P: Prior/Concomitant	I: Indication D: Dose U: Units	F: Frequency T: Route
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxx xxx xxxxxxxxxx P: xxxxxxxxxxx xxxxxxx xxxxxxxxxxx xxx xxxxxxx xxx M: xxxxxx xxxxx xxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxxx	I: xxxxxxx D: xx U: xxxxxxxxxxx	F: xxx T: xxxxxxxxxxxxxx
	A: xxxxxxxx xx xxxxxxxx P: xxxxxxxxxxx xxxxxxx xxx M: xxxxxx xxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx P: xxxxx	I: xxxxxxx D: xx U: xxxxxxxx	F: xx T: xxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxx xxx xxxxxxxxxx P: xxxxxxxxxxx xxxxxxx xxxxxxxxxxx xxx xxxxxxx xxx M: xxxxxx xxxxx xxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxxx	I: xxxxxxx D: xx U: xxxxxxxxxxx	F: xxx T: xxxxxxxxxxxxxx
	A: xxxxxxxx xx xxxxxxxx P: xxxxxxxxxxx xxxxxxx xxx M: xxxxxx xxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx P: xxxxx	I: xxxxxxx D: xx U: xxxxxxxx	F: xx T: xxxxx

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

Note: ATC Level 2 Term and Preferred Name map to WHO Drug Global Dictionary, Format B3, Version March 1, 2018.

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

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, Route, Frequency. If the Route is Topical, then the area treated is presented within parenthesis (T: Topical (specify area)).

Listing 16.2.4.4.1: Unique Procedure/Therapy Names Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Procedure/Therapy Verbatim Term	Indication
xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxx xx xxxxx	xxxxxxxxxxx
		xxxxxxxxx	xxxxx xx xxxx
xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx
			xxxxxxxxxxx
		xxxxxxxxx	xxxxxxxxxxx
xxxxx xxx xx xxxxxxx	xxxxxxx xxxxxxx xxxx	xxxxxxxx xxxxxx	xxxxxxxx xxxxxxxx xx xx xxxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

Listing sorted by System Organ Class, Preferred Term, Verbatim Term, and Indication.

Listing 16.2.4.4.2: Prior and Concomitant Procedures/Therapies
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	S: MedDRA System Organ Class P: MedDRA Preferred Term M: Procedure/Therapy Name	S: Start Date (Day)[1] E: End Date (Day)[1] P: Prior/Concomitant	I: Indication A: Anatomical Area Treated
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxx xxx xxxxxxxx xxxxxxxxx P: xxxxxxxxxxxx xxxxxxxxxx xxxxxxxx M: xxxxxxx xxxxx xxxxxxx xxxxxxx	S: xxxxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxx	I: xxxxx xxxxxxx A:
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxx xxx xxxxxxxx xxxxxxxxx P: xxxxxxxxxxxx xxxxxxxxxx xxxxxxxx M: xxxxxxx xxxxx xxxxxxx xxxxxxx	S: xxxxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxx	I: xxxxx xxxxxxx A:
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxx xxx xxxxxxxx xxxxxxxxx P: xxxxxxxxxxxx xxxxxxxxxx xxxxxxxx M: xxxxxxx xxxxx xxxxxxx xxxxxxx	S: xxxxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxx	I: xxxxx xxxxxxx A:
			S: xxxxxxx xxxxxxxx xxxx P: xxx xxxxxxxxxx xxxxxxxx M: xxxxxxx xxxxxxx	S: xxxxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxx	I: xxxxxxxxx xxxxx xx xx A: xxxxxxxxxx
			S: xxxxxxx xxxxxxxx xxxx P: xxx xxxxxxxxxx xxxxxxxx M: xxxxxxx xxxxxxx	S: xxxxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxx	I: xxxxxxxxx xxxxx xx xx A: xxxxxxxxxx

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

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

Listing sorted by Subject, Start Date, End Date, Procedure/Therapy Name, and Indication.

Listing 16.2.5.1: Study Visit Compliance
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Visit Date	Study Day[1]	Within Visit Window[2]	Reason Screening And Baseline Occurred on Different Days	Reason for Unscheduled Visit
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx		
			xxxxxxxx	xxxxxxxxxx	xx	xxx	xxxxxxx xxx xx xxxxxxxxxx	
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xxxxx	xxxxxxxxxx	xx	xxx		
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx		
			xxxxxxxx	xxxxxxxxxx	xx	xxx		
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxxxxxxxxx xxxxx xxx	xxxxxxxxxx	xx			xxxxxxxxxxxxx
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xxxxx	xxxxxxxxxx	xx	xxx		
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx		
			xxxxxxxx	xxxxxxxxxx	xx	xxx		
			xxxx x	xxx xxxx	xx	xxx		xxx xxxx
			xxxx x	xxx xxxx	xx	xxx		xxx xxxx
			xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xxxxx	xxxxxxxxxx	xx	xxx		

[1] Day is calculated as date – Baseline date for dates prior to Baseline visit. Otherwise, day is calculated as date – Baseline date + 1 for dates on or after Baseline visit.
[2] Determined by protocol-specified visit window for scheduled visits after Baseline.

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

Listing sorted by Subject and Visit Number.

Listing 16.2.5.2: Subject Dosing Compliance
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Application	Date of Last Application	Number of Days of Exposure	Calculated[1] Number of Applications	Amount of Study Drug Used (g)	Maximum Number of Consecutive Missed Applications	Percent Compliant	Compliant[2]
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xxxx	xx	xxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xxxx	xx	xxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xxxx	xx	xxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xxxx	xx	xxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xxxx	xx	xxxxx	xxx

[1] The total number of applicationss was calculated using the date of first application, date of last application, and number of applied applications at a deviation.
[2] A subject was considered compliant with the dosing regimen if the subject did not miss more than 5 consecutive days applying and applied 80-120% of expected applications based on the length of their participation in the study.

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

Listing sorted by Subject.

Listing 16.2.5.3: Subject Dosing Deviations
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of Dosing Deviation (Day)[1]	Number of Applications Applied
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxxx	x
			xxxxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxxx	x

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

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

Listing sorted by Subject and Date of Dosing Deviation.

Listing 16.2.5.4: Study Medication Accountability Log
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Kit Number	Kit Contents	Pump Identifier	Dispensing Date	Dispensing Weight (g)	Return Date	Return Weight (g)	Amount Used (g)
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxx xxxx		
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxx xxxx				
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxx xxxx	xxxxxxxxxx	xxxx	
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxx xxxx	
				xxxx	x	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx

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

Note to progammers: Kit Contents is the treatment the kit contained.

Listing 16.2.5.5: Photography
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Were Photographs Taken	Date Taken
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xx	
			xxxx x	xxx	xxxxxxxxxx
			xxxx xxxxx	xxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxxxxxxxxx xxxxx xxx	xxx	xxxxxxxxxx
			xxxx xxxxx	xx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx xxxxx	xxx	xxxxxxxxxx

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

Listing sorted by Subject and Visit Number

Listing 16.2.6.1: Investigator Global Assessment
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Evaluator Initials	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx

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

Listing sorted by Subject and Visit Number

Listing 16.2.6.2: Inflammatory Lesion Counts
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Evaluator Initials	Papules	Pustules	Total Inflammatory Lesion Count	Nodules/Cysts
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x

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

Listing sorted by Subject and Visit Number

Listing 16.2.6.3.1: RosaQoL Descriptions
(Page xx of yy)

Number	RosaQoL Question
1	I worry that my rosacea may be serious
2	My rosacea burns or stings
3	I worry about getting scars from my rosacea
4	I worry that my rosacea may get worse
5	I worry about side effects from rosacea medications
6	My rosacea is irritated
7	I am embarrassed by my rosacea
8	I am frustrated by my rosacea
9	My rosacea makes my skin sensitive
10	I am annoyed by my rosacea
11	I am bothered by the appearance of my skin (redness, blotchiness)
12	My rosacea makes me feel self-conscious
13	I try to cover up my rosacea (with make-up)
14	I am bothered by persistence/reoccurrence of my rosacea
15	I avoid certain foods or drinks because of my rosacea
16	My skin feels bumpy (uneven, not smooth, irregular)

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

Listing 16.2.6.3.1: RosaQoL Descriptions
(Page xx of yy)

Number	RosaQoL Question
17	My skin flushes
18	My skin gets irritated easily (cosmetics, aftershaves, cleansers)
19	My eyes bother me (feels dry or gritty)
20	I think about my rosacea
21	I avoid certain environments (heat, humidity, cold) because of my rosacea

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

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Listing 16.2.6.3.2: RosaQoL
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

1 = Never; 2 = Rarely; 3 = Sometimes; 4 = Often; 5 = All the time; ND = Not Done

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

Listing sorted by Subject and Visit Number

Listing 16.2.6.3.3: RosaQoL Subscales Scores
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Total Score	Symptom	Functional	Emotion
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx

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

Listing sorted by Subject and Visit Number

Listing 16.2.6.4: Erythema Severity/Telangiectasia Assessments
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Evaluator Initials	Assessment	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx xxxxx	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx
			xxxx xxxxx	xxxxxxxxxx	xxx	Rosacea Erythema Telangiectasia	xxxxxxxxxx xxxxxxxxxx

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

Listing sorted by Subject and Visit Number, and Assessment (in order presented on eCRF).

Listing 16.2.6.5: PRO – PAPSS, PAPI, PGI-S
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	PRO Category	Object of Assessment	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	PAPSS	BURNING	xxxxxxxxxx
						ITCHING	xxxxxxxxxx
						REDNESS	xxxxxxxxxx
						BUMPS	xxxxxxxxxx
					PAPI	EMBARRASSED	xxxxxxxxxx
						SELF-CONSCIOUS	xxxxxxxxxx
						FRUSTRATED	xxxxxxxxxx
					PGI-S	ROSACEA	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	PAPSS	BURNING	xxxxxxxxxx
						ITCHING	xxxxxxxxxx
						REDNESS	xxxxxxxxxx
						BUMPS	xxxxxxxxxx
					PAPI	EMBARRASSED	xxxxxxxxxx
						SELF-CONSCIOUS	xxxxxxxxxx
						FRUSTRATED	xxxxxxxxxx
					PGI-S	ROSACEA	xxxxxxxxxx

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

Listing sorted by Subject and Visit Number, PRO Category, and Assessment (in order presented on eCRF).

Listing 16.2.6.6: PRO – PGI-C, PGI-TS, PGI-SE
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	PRO Category	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	PGI-C	xxxxxxxxxxxxxx
					PGI-TS	xxxxxx xxx xxxx
					PGI-SE	xxxxxxxxxxxxxx
			xxxxxxxxx	xxxxxxxxxx	PGI-C	xxxxxxxxxxxxxx
					PGI-TS	xxxxxx xxx xxxx
					PGI-SE	xxxxxxxxxxxxxx
			xxxxxxxxx	xxxxxxxxxx	PGI-C	xxxxxxxxxxxxxx
					PGI-TS	xxxxxx xxx xxxx
					PGI-SE	xxxxxxxxxxxxxx
			xxxxxxxxx	xxxxxxxxxx	PGI-C	xxxxxxxxxxxxxx
					PGI-TS	xxxxxx xxx xxxx
					PGI-SE	xxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxx	xxxxxxxxx	xxxxxxxxxx	PGI-C	xxxxxxxxxxxxxx
					PGI-TS	xxxxxx xxx xxxx
					PGI-SE	xxxxxxxxxxxxxx
			xxxxxxxxx	xxxxxxxxxx	PGI-C	xxxxxxxxxxxxxx
					PGI-TS	xxxxxx xxx xxxx
					PGI-SE	xxxxxxxxxxxxxx

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

Listing sorted by Subject, Visit Number, and PRO Assessment (in order presented on eCRF).

Listing 16.2.7.1: Cutaneous Safety and Tolerability Assessments
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Evaluator Initials	Test	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
						Scaling	xxx xxxx
						Itching	xxxxxxxxxxx
						Burning/Stinging	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
						Scaling	xxx xxxx
						Itching	xxxxxxxxxxx
						Burning/Stinging	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
						Scaling	xxx xxxx
						Itching	xxxxxxxxxxx
						Burning/Stinging	xxxxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
						Scaling	xxx xxxx
						Itching	xxxxxxxxxxx
						Burning/Stinging	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
						Scaling	xxx xxxx
						Itching	xxxxxxxxxxx
						Burning/Stinging	xxxxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
						Scaling	xxx xxxx
						Itching	xxxxxxxxxxx
						Burning/Stinging	xxxxxxxxxx

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

Listing sorted by Subject, Visit Number, and Test (in order presented on eCRF).

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

MedDRA System Organ Class	MedDRA Preferred Term	Application Area	Adverse Event
xxxxxxx xxxxxxxxx xxx xxxxxxxxxxxxxxx	xxxxxxxxxx xxx xxxxxxxxxxxxxxxx	xxx	xxxxxxxxxxxx xxxxxxxx xx xx xxxxxx
		xx	xxxxxxxx
		xx	xxxxx xxxxxxxx
	xxxxxxxxx	xx	xxxxxxxx
xxxxxx xxxxxx xxxxxxxxx	xxxxxxxx	xx	xxxxxxx
xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx	xxxxxxx	xxx	xxxxxxxxx xx xxxxxxx
	xxxx xxxxxxxxxxx	xx	xxxxxxx xxxx xxxxxxxxx xxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

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

Listing 16.2.7.2.2: Pre-Treatment Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	S: MedDRA System Organ Class P: MedDRA Preferred Term A: Adverse Event	A: In the Application Area G: Severity R: Relationship to Study Drug S: Serious Event	A: Action Taken with Study Drug T: Action Taken to Treat Event O: Outcome	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxx xxxxxxxxxxx xxxxxx P: xxx xxxxxxxxxxx A: xxxxxxx xxxx xxxxxxxxx xxxxx	A: xx G: xxxx R: xxx xxxxxxx S: xx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
	S: xxxxxxx xxxxxxxxx xxx xxxxxxxxx P: xxxxxxxxxx A: xxxxxxxx xxxxx xxxxxxxx xxxx	A: xxx G: xxxx R: xxx xxxxxxx S: xx	A: xxx xxxxxxxxx T: xxxxxxxxxxx xxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxxxxxxxx xxxxxx P: xxxxxxxxx A: xxxxxxxxx xxxxx	A: xx G: xxxxxxxx R: xxx xxxxxxx S: xx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxxxxxxxx xxxxxx P: xxxxxxxxx A: xxxxxxxxx xxxxx	A: xx G: xxxxxxxx R: xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
	S: xxxxxxx xxxxxxxxx xxx xxxxxxxxx P: xxxxxxxxxx A: xxxxxxxx xxxxx xxxxxxxx xxxx	A: xxx G: xxxx R: xxx xxxxxxx S: xx	A: xxx xxxxxxxxx T: xxxxxxxxxxx xxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx

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

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

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

Listing 16.2.7.2.3: Treatment-Emergent Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	S: MedDRA System Organ Class P: MedDRA Preferred Term A: Adverse Event	A: In the Application Area G: Severity R: Relationship to Study Drug S: Serious Event	A: Action Taken with Study Drug T: Action Taken to Treat Event O: Outcome	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxx xxxxxxxxxxx xxxxxx P: xxx xxxxxxxxxxx A: xxxxxxx xxxx xxxxxxxxx xxxxx	A: xx G: xxxx R: xxx xxxxxxx S: xx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
	S: xxxxxxx xxxxxxxxx xxx xxxxxxxxx P: xxxxxxxxxx A: xxxxxxxx xxxxx xxxxxxxx xxxx	A: xxx G: xxxx R: xxx xxxxxxx S: xx	A: xxx xxxxxxxxxx T: xxxxxxxxxxx xxxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxxxxxxxx xxxxxx P: xxxxxxxxx A: xxxxxxxxx xxxxx	A: xx G: xxxxxxxx R: xxx xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxxxxxxxx xxxxxx P: xxxxxxxxx A: xxxxxxxxx xxxxx	A: xx G: xxxxxxxx R: xxx xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
	S: xxxxxxx xxxxxxxxx xxx xxxxxxxxx P: xxxxxxxxxx A: xxxxxxxx xxxxx xxxxxxxx xxxx	A: xxx G: xxxx R: xxxxxxx S: xx	A: xxx xxxxxxxxxx T: xxxxxxxxxxx xxxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx

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

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

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

Listing 16.2.7.2.4: Serious Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	S: MedDRA System Organ Class P: MedDRA Preferred Term A: Adverse Event O: Occurred Prior to First Application	A: In the Application Area G: Severity R: Relationship to Study Drug S: Serious Event	A: Action Taken with Study Drug T: Action Taken to Treat Event O: Outcome	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx P: xxx xxxxxxxxxxx A: xxxxxxx xxxx xxxxxxxxx xxxxx O: xx	A: xx G: xxxx R: xxx xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
	S: xxxxxxx xxxxxxxxx xxx xxxxxxxxx P: xxxxxxxxxx A: xxxxxxxx xxxxx xxxxxxxx xxxx O: xx	A: xxx G: xxxx R: xxx xxxxxxx S: xxx	A: xxx xxxxxxxxx T: xxxxxxxxxxx xxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxxxxxxxx xxxxxx P: xxxxxxxxx A: xxxxxxxxx xxxxx O: xx	A: xx G: xxxxxxxx R: xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx

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

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

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

Listing 16.2.7.2.5: Subjects Who Prematurely Discontinued Study and/or Discontinued Study Drug Due to Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	S: MedDRA System Organ Class P: MedDRA Preferred Term A: Adverse Event O: Occurred Prior to First Application	A: In the Application Area G: Severity R: Relationship to Study Drug S: Serious Event	A: Action Taken with Study Drug T: Action Taken to Treat Event O: Outcome	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx P: xxx xxxxxxxxxxx A: xxxxxxx xxxx xxxxxxxxx xxxxx O: xx	A: xx G: xxxx R: xxx xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
	S: xxxxxxx xxxxxxxxx xxx xxxxxxxxx P: xxxxxxxxxx A: xxxxxxxx xxxxx xxxxxxxx xxxx O: xx	A: xxx G: xxxx R: xxx xxxxxxx S: xxx	A: xxx xxxxxxxxx T: xxxxxxxxxxx xxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx xxxxxxxxx xxxxxx P: xxxxxxxxx A: xxxxxxxxx xxxxx O: xx	A: xx G: xxxxxxxx R: xxxxxxx S: xxx	A: xxx xx xxxxxxx T: xxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx

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

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.0).

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

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

Listing 16.2.8.1: Urine Pregnancy Tests
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Results	Reason Test Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx	
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx	
			xxxx x			xxx xxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxxxxxx	
xxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx	
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxxxxxx	
xxx	xxxx	xxxxxxxx	xxxxxxxxx			xxx xxxxxxxxx
			xxxxxxxxx			xxx xxxxxxxxx
			xxxx x			xxx xxxxxxxxx
			xxxx x			xxx xxxxxxxxx
			xxxx x			xxx xxxxxxxxx

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

Listing sorted by Subject and Visit Number.

Listing 16.2.8.2: Physical Examination
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Body System	Exam Finding	Reason Exam Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxx	xxxxxx	
					xxxx	xxxxxx	
					xxxxxxx	xxxxxx	
					xxxxxxxxxxxxx	xxxxxxxxx xxxxxxxxx xxxx	
					xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx xxxxx xxxx xxx	
					xxxxxxxxx	xxxxxxxxx xx xxxx xxxxxx	
			xxxx xxxxx	xxxxxxxxxx	xxxxx		
					xxxx		
					xxxxxxxx		
					xxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxx	xxxxxx	
					xxxx	xxxxxx	
					xxxxxxx	xxxxxx	
					xxxxxxxxxxxxx	xxxxxxxxx xxxxxxxxx xxxx	
					xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx xxxxx xxxx xxx	
					xxxxxxxxx	xxxxxxxxx xx xxxx xxxxxx	
			xxxx xxxxx	xxxxxxxxxx	xxxxx		
					xxxx		
					xxxxxxxx		
					xxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx

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

Listing sorted by Subject, Visit Number, and Body System (in order presented on eCRF).

Listing 16.2.8.3: Vital Signs
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Vital Sign	Result	Units
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxx xxxxx xxxxxxxx	xx	xxxx
					xxxxx xxxx	xx	xxxxxxxxx
					xxxxxx	xxxxx	xx
					xxxxxxxxxxx xxxx	xx	xxxxxxxxxxx
					xxxxxxxx xxxxx xxxxxxxx	xxx	xxxx
					xxxxxxxxxxx	xxxx	x
					xxxxxx	xxx	xx
			xxxx xxxxx	xxxxxxxxxx	xxxxxxxxx xxxxx xxxxxxxx	xx	xxxx
					xxxxx xxxx	xxx xxxx	
					xxxxxxxxxxx xxxx	xxx	xxxxxxxxxxx
					xxxxxxxx xxxxx xxxxxxxx	xxx	xxxx
					xxxxxxxxxxx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxx xxxxx xxxxxxxx	xx	xxxx
					xxxxx xxxx	xx	xxxxxxxxx
					xxxxxx	xxx	xx
					xxxxxxxxxxx xxxx	xx	xxxxxxxxxxx
					xxxxxxxx xxxxx xxxxxxxx	xx	xxxx
					xxxxxxxxxxx	xx	x
					xxxxxx	xxx	xx
			xxxx xxxxx	xxxxxxxxxx	xxxxxxxxx xxxxx xxxxxxxx	xxx xxxx	
					xxxxx xxxx	xxx xxxx	
					xxxxxxxxxxx xxxx	xxx xxxx	
					xxxxxxxx xxxxx xxxxxxxx	xxx xxxx	
					xxxxxxxxxxx	xxx xxxx	

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

Listing sorted by Subject, Visit Number, and Vital Sign (in alphabetical order).