STATISTICAL ANALYSIS PLAN

Protocol Number:	SGT-54-07
Study Title:	A Multi-Center, Open-Label, Long-Term Safety Study of S5G4T-1 to Evaluate the Safety of S5G4T-1 in Papulopustular Rosacea Patients
Development Phase of Study:	3
Sponsor:	Sol-Gel Technologies Ltd.
Sponsor Contact:	[redacted]
Statistical Analysis Plan based on Protocol Version:	4.0
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SAP Approval

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Sol-Gel Technologies Ltd.

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	18NOV2019	Original document	[redacted]

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	adverse event(s)
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
BPO	benzoyl peroxide
C	Celsius
cm	centimeters
CRF(s)	case report form(s)
CI	confidence interval
eCRF(s)	electronic case report form(s)
E-BPO	encapsulated benzoyl peroxide
ET	early termination
IGA	Investigator Global Assessment
IWRS	Interactive Web Response System
kg	kilograms
max	maximum
min	minimum
n	number of observations
N	number of subjects (sample size)
PI	Principal Investigator
QST	QST Consultations, Ltd.
RosaQoL	Rosacea Quality of Life Questionnaire
SAE(s)	serious adverse event(s)
SAP	Statistical Analysis Plan
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 the database is locked. 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 the database lock.

The following documents were reviewed in preparation of this SAP:

- Clinical Study Protocol SGT-54-07
    - Version 1.0 issued on 27JUN2018,
    - Version 2.0 issued on 20AUG2018,
    - Version 3.0 issued on 16SEP2018,
    - Version 4.0 issued on 27NOV2018
- Case report form (CRF) for SGT-54-07.
- 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 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 rosacea. If approved, S5G4T-1 will be the

first product containing E-BPO for the treatment of 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 [3, 5]. 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.

The first report on the treatment of rosacea with benzoyl peroxide (BPO) as a single agent was described by in Montes *et al.* in 1983 [6]. In this limited study, 5% BPO, after 5 to 8 weeks of treatment, demonstrated superiority compared to control with respect to papules, pustules and erythema but not telangiectasia. The formulation was a basic formulation with BPO dissolved and delivered in acetone. Irritation and burning was reported in both groups, most likely due to the well-known effects of BPO.

More recently, Breneman *et al.* 2004 [1] published the results of a study in collaboration with J. Leyden. This study was a double-blind, vehicle-controlled study, using a combination gel product of 5% BPO and 1% clindamycin to treat patients having moderate to severe rosacea. The most dramatic effect of the BPO/clindamycin treatment was on the reduction of papules and pustules. Side effects included the well-known effects of BPO, burning and itching.

The most prevalent AEs associated with topical BPO were related to local irritation. These included dry skin, peeling, burning and erythema. For the published studies, the percentage of subjects with dermatological AEs considered possibly related to BPO monotherapy ranged from 7% [7] to 22% [8]. In studies sponsored by Sol-Gel, the percentage of subjects with dermatological AEs associated with E-BPO 7% cream ranged from 0% (Study SGT-03B) to 37% (Study SGT-04), and the incidence of dermatological AEs associated with lower concentrations of E-BPO cream was ≤ 2%.

Several published studies reported AEs that might be associated with sensitivity of subjects to BPO. Leyden *et al.* 2001 [4] reported that 1 of 164 subjects (0.6%) receiving 5% BPO had an allergic reaction, and that allergic reactions occurred for 1.2% of subjects receiving 5% BPO plus 1% clindamycin and for 3.1% of subjects receiving 5% BPO plus 3% erythromycin. Tschen *et*

al. 2001 [8] reported a rash for l of 95 subjects (1%) that received 5% BPO monotherapy. Fyrand and Jakobsen 1986 [2] reported that 2 of 49 subjects withdrew from the study due to severe dermatitis indicating possible sensitization. Montes *et al.* 1983 [6] reported hypersensitivity to BPO in 4 of 31 subjects receiving 5% BPO acetone gel for rosacea. Weiss *et al.* 2002 [9] reported that 2 of 257 subjects receiving BPO plus clindamycin developed urticaria. In Study KGL 5782, 1 subject developed possible delayed contact hypersensitivity to both E-BPO, 2.5%, and Proactiv, 2.5%, indicating the hypersensitivity was probably due to BPO not an excipient. None of these events that might possibly indicate sensitization were confirmed by patch testing.

In 2012, Sol-Gel completed a double blind, randomized, dose-ranging Phase 2 trial for S5G4T-1 involving 92 adult patients at 10 centers in the United States (Study SGT-EBPO1-09: A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Dose-Range Study of E-BPO Gel, 1% and 5%, and Vehicle Gel in the Treatment of Rosacea). The Phase 2 study had the primary endpoints: Success in Investigator Global Assessment (IGA) and reduction in the mean inflammatory lesion count at Week 12 (End of Study). Safety was evaluated through AE reporting and cutaneous safety and local tolerability assessments. Both E-BPO cream, 1% and 5% applied once daily for 12 weeks had a positive effect on rosacea and were safe and well tolerated in this study. No deaths or other SAEs were reported during the study. Study medication was withdrawn for 1 subject who applied E-BPO cream, 5% (severe application site reaction) and for 2 subjects who applied E-BPO cream, 1% (severe cyst and moderate application site dermatitis). None of the subjects had severe dryness, scaling, or pruritus post-baseline. One subject in the E-BPO cream, 5% group experienced severe stinging and burning reported as an AE.

5. STUDY OBJECTIVES

The objective of this long-term safety study is to determine the nature, severity and frequency of the AE rate and the cutaneous safety and local tolerability assessments of S5G4T-1 when applied once daily, if applicable, for up to 52 weeks.

The safety endpoints to be assessed include the following:

- The frequency of both local and systemic AEs
- Investigator cutaneous safety assessment (dryness and scaling) and the local tolerability assessment (itching and burning/stinging) at Baseline and all post-baseline study visits.

6. STUDY DESIGN

6.1 Overall Study Design

Approximately 700 patients will be enrolled at up to 56 sites. All patients in this open-label, long-term safety study will be assigned to treatment with S5G4T-1.

The objective of this study is to determine the long-term safety and tolerability of daily use of S5G4T-1 in papulopustular rosacea patients.

Patients who successfully completed the 12-week treatment period from Study SGT-54-01 or Study SGT-54-02 may be offered to continue in the long-term safety, open-label extension study (Study SGT-54-07) for up to an additional 40 weeks (sum of up to 52 weeks). The Sponsor may terminate the study once 300 patients complete a total of 28 weeks of treatment and 100 patients complete a total of 52 weeks.

Patients who completed the 12-week treatment period (± 4 days) for SGT-54-01 or SGT-54-02 and did not miss more than one visit (Visit 3, 4 or 5) in SGT-54-01 or SGT-54-02 will be admitted into the 54-07 study after the Entry Criteria have been met and an ICF has been signed. Qualified patients will receive study product at Baseline and will be treated for up to 40 weeks. At each visit, the patients will be assessed for a 5-point scale IGA of rosacea. If a patient is assessed as “clear” (0) or “almost clear” (1), the patient will not be dispensed the study product. If a patient is assessed as “mild”, “moderate” or “severe” (score of 2, 3 or 4, respectively), study product will be dispensed and the patient will use the study product daily according to patient instructions. Rosacea Quality of Life Questionnaire (RosaQoL) will be completed at Baseline, Visits 5, 8, 11, and 14 and at End of Study or at early termination. The RosaQoL data of patients who were enrolled from SGT-54-01 or SGT-54-02, will be used from the questionnaire completed at Visit 6/Week 12 of SGT-54-01 or SGT-54-02. Rosacea erythema severity and telangiectasia assessments will be completed at all study visits. At each visit, the following safety measures will be recorded: monitoring for any local and systemic AEs, cutaneous safety (dryness, and scaling) and local tolerability (itching and burning/stinging) assessments on a scale ranging from 0 (None) to 3 (Severe), vital signs and physical examinations.

A urine pregnancy test is required at all visits for all females of child-bearing potential.

Clinical Evaluations will be performed at:

1. Visit 1/Screening, only applies for new patients
2. Visit 2/Baseline, Day 1 can also be Visit 6/Week 12, Day 85 of Study SGT-54-01 or Study SGT-54-02

3. Visit 3/Week 4, Day 29 (± 10 Days)
4. Visit 4/Week 8, Day 57 (± 10 Days)
5. Visit 5/Week 12, Day 85 (± 10 Days)
6. Visit 6/Week 16, Day 113 (± 10 Days)
7. Visit 7/Week 20, Day 141 (± 10 Days)
8. Visit 8/Week 24, Day 169 (± 10 Days)
9. Visit 9/Week 28, Day 197 (± 10 Days)
10. Visit 10/Week 32, Day 225 (± 10 Days)
11. Visit 11/Week 36, Day 253 (± 10 Days)
12. Visit 12/Week 40, Day 281 (± 10 Days)/ End of Treatment/End of Study for patients who complete the study, early terminate, or if the Sponsor terminates the study prematurely.

The study product will be administered in an open-label fashion, i.e., the treatment assignment will be known to the patient, to study personnel and Sol-Gel personnel and its representatives.

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

All patients will receive S5G4T-1. The patient assignment schedule will be a stratified by investigational site. Patients will be assigned through the Interactive Web Response System (IWRS) a unique ID indicating pump number. The format of the supplied number of pump is XXXX. At each visit the patient will return the pump and will be dispensed the next pump according to the IWRS assignment.

6.1.3 Blinding

Not applicable.

7. EFFICACY AND SAFETY ENDPOINTS

7.1 Efficacy Endpoints

This study is not intended to assess efficacy.

IGA is included to determine the need for treatment and subsequent re-treatment after treatment course (in either Study SGT-54-01 or Study SGT-54-02) and any subsequent 4-week courses, if applicable. Certain efficacy data and endpoints will, however, be summarized.

The number of retreatments and the number of treatment free days until the first retreatment (relapse) will be calculated as described in Section 8.7.2.2.

RosaQoL will be completed at Baseline, Visits 5, 8, 11, 14, and End of Study. The RosaQoL data of patients who were enrolled from SGT-54-01 or SGT-54-02, will be used from the questionnaire completed at Visit 6/Week 12 of SGT-54-01 or SGT-54-02.

Erythema severity and telangiectasia assessments will be completed at each study visit.

7.2 Safety Endpoints

Safety will be evaluated by monitoring AEs, and cutaneous safety (dryness and scaling) and local tolerability (itching and burning/stinging) assessments.

8. STATISTICAL AND ANALYTICAL PLANS

8.1 General Methodology

All statistical processing will be performed using SAS® version 9.4 or later unless otherwise stated.

Descriptive statistics will be used to provide an overview of the efficacy and safety results. For categorical parameters, the number and percentage of subjects in each category will be presented. For continuous parameters, descriptive statistics will include n (number of subjects), mean, standard deviation (SD), median, minimum (min) and maximum (max).

No inferential testing or imputations for missing data will be performed. No interim analyses are planned.

All analyses will be performed using the Safety Population of the study.

Where applicable the analysis will be presented by overall treatment group in 54-07 as well as by treatment group assignment in 54-01/54-02.

8.1.1 Statistical Analysis

All analyses will be performed by QST using SAS® Version 9.4 or later. All summary tables and data listings will be prepared utilizing SAS® software.

The standard operating procedures (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 in 54-01/02. For all subjects enrolled in 54-01/54-02, the baseline values from 54-01/54-02 will be considered the baseline values for calculations in 54-07. Missing results will not be flagged as baseline.

8.1.3 Visit Windowing

For subjects receiving S5G4T-1 in 54-01/54-02, data from 54-01/54-02 will be included in summaries of 54-07. For subjects receiving vehicle in 54-01/54-02, baseline values will be sourced from 54-01/54-02 and data from follow-up visits of 54-07 will be used in summaries. The table below details the analysis visits to be summarized and the associated visits from 54-01/54-02 or 54-07 which will be sourced for each type of subject.

Analysis Visits for Efficacy and Safety Assessments

Analysis Visit	Subjects Receiving S5G4T-1 in 54-01/54-02	Subjects Receiving vehicle in 54-01/54-02
Week 4	54-01/02 - Week 4	54-07 - Week 4
Week 8	54-01/02 - Week 8	54-07 - Week 8
Week 12	54-01/02 - Week 12	54-07 - Week 12
Week 16	54-07 - Week 4	54-07 - Week 16
Week 20	54-07 - Week 8	54-07 - Week 20
Week 24	54-07 - Week 12	54-07 - Week 24
Week 28	54-07 - Week 16	54-07 - Week 28
Week 32	54-07 - Week 20	54-07 - Week 32
Week 36	54-07 - Week 24	54-07 - Week 36
Week 40	54-07 - Week 28	54-07 - Week 40
Week 44	54-07 - Week 32	Not available
Week 48	54-07 - Week 36	Not available
Week 52	54-07 - Week 40	Not available

Data from 54-07 will be mapped to the appropriate analysis visit described above based on nominal visit indications. Data from Early Termination (ET) and unscheduled visits will be determined using analysis visit windows. The analysis visit windows for ET and unscheduled visits are presented in the following table.

SGT-54-07 Analysis Visit Windows for Efficacy and Safety Assessments

Nominal Visit	Target Study Day[1]	Window (Days)
Week 4	29	22 to 42
Week 8	57	43 to 70
Week 12	85	71 to 98
Week 16	113	99 to 126
Week 20	141	127 to 154
Week 24	169	155 to 182
Week 28	197	183 to 210
Week 32	225	211 to 238
Week 36	253	239 to 266
Week 40	281	267 to 294
Week 44	309	295 to 322
Week 48	337	323 to 350
Week 52	365	351 to 378

[1] Number of days since nominal Baseline visit of 54-07

Data collected at ET and unscheduled visits prior to study day 22 will not be analyzed. Data collected at ET and unscheduled visits after study day 378 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 nominal 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 nominal visit, the data collected at the ET or unscheduled visit will not be included in analyses.

In the event of multiple values from unscheduled or ET assessments within an analysis visit window, the value closest to the scheduled visit target study day will be used for analyses. If 2 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 the 54-07 analysis visit presented.

8.1.4 Adjustments for Covariates

Not applicable to this study.

8.1.5 Handling of Dropouts or Missing Data

Incomplete start and end dates for medications will be imputed. Incomplete start dates for adverse events (AEs) will be imputed. Other data will not be imputed and will be summarized on an observed case basis.

8.1.5.1 Medication Date Imputation

If the medication or procedure/therapy 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 or procedure/therapy 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.

8.1.5.2 Adverse Event Start Date Imputation

If the AE start date is incomplete, then it will be imputed as follows for the purpose of determining study day for the AE period breakdown described in Section 8.8.2:

- 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.

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 all the data for analysis. Every effort will be made to promote consistency in study execution at each study site.

8.1.8 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons or multiplicity will be made.

8.1.9 Use of an Efficacy Subset of Subjects

Not applicable to this study.

8.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

8.1.11 Examination of Subgroups

Not applicable to this study.

8.2 Disposition of Subjects

The number of subjects included in the Safety population will be summarized for all subjects, for subjects that received S5G4T-1 in 54-01/54-02, and for subjects that received vehicle in 54-01/54-02. The number of subjects enrolled, completed, and discontinued (including the reasons for discontinuation) will be summarized similarly.

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

8.3 Protocol Deviations

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.

8.4.1 Safety Population

All analyses will be performed using the Safety Population of the study. All patients who receive at least one confirmed dose of S5G4T-1 and have at least one assessment will be included in the Safety Population.

8.5 Demographic and Other Baseline Characteristics

All baseline summaries will be done on the Safety population.

Sex (categorical), race (categorical), and ethnicity (categorical) will be summarized by counts and percentages. Age (continuous), height (cm) (continuous), and weight (kilograms (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. All medical history for rollover subjects will be entered into 54-07 database and therefore medical history data will not be pulled from the 54-01 or 54-02 studies. The date of rosacea diagnosis for rollover subjects will be pulled from the 54-01 or 54-02 study.

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 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 Preferred Term.

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. Ongoing medications for rollover subjects will be entered into 54-07. Only medications that are not ongoing in 54-01 or 54-02 will be pulled forward for subjects who received S5G4T-1 in 54-01 or 54-02.

Medications which start prior to first application of S5G4T-1 (from 54-01/02 or 54-07) will be considered prior medications. Ongoing medications and medications ending after the date of first application (in 54-01/02 or 54-07) 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 8.1.5.1.

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

8.7 Prior and Concomitant Procedures/Therapies

Procedures/therapies will be coded using the MedDRA dictionary. Ongoing procedures/therapies for rollover subjects will be entered into 54-07. Only procedures/therapies that are not ongoing in 54-01 or 54-02 will be pulled forward for subjects who received S5G4T-1 in 54-01 or 54-02.

Procedures/therapies which start prior to first application of S5G4T-1 (from 54-01/02 or 54-07) will be considered prior procedures/therapies. Ongoing procedures/therapies and procedures/therapies ending after the date of first application (in 54-01/02 or 54-07) will be considered concomitant procedures/therapies. If the date of first application is unknown and the procedures/therapies is not listed as ongoing the interval will be considered "unknown". If the date of first application is unknown and the procedures/therapies is listed as ongoing the interval will be considered concomitant.

Incomplete procedures/therapies start and end dates will be imputed as described in Section 8.1.5.1.

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

8.8 Analysis of Efficacy

All efficacy analysis will be conducted on the Safety population.

8.8.1 IGA

Descriptive statistics will be used to summarize the assessment of efficacy. IGA scores will be summarized at Baseline (see definition of baseline in Section 8.1.2) and every 4 weeks through end of the study. The number and percentage of patients who achieve treatment success at the scheduled study visits will be tabulated. A patient will be considered a success if their IGA score is clear or almost clear.

In addition to the above summary a by-subject listing of all IGA results will be presented.

8.8.2 Retreatments

The number of retreatments is defined as the number of clinical confirmations of the condition for which the subject was initially treated after the first treatment period with S5G4T-1. For rollover subjects previously treated with vehicle, this is the number of treatments after the initial treatment in 54-07. For rollover subjects previously treated with S5G4T-1, this is the number of treatments in 54-07 following the cessation of the treatment which began in 54-01 or 54-02. A clinical confirmation of the condition will be defined as IGA no longer being clear or almost clear after a previous IGA of clear or almost clear. When a subject has a clear or almost clear IGA in 54-07, it is expected they were instructed not to dose until the IGA reached mild, moderate or severe.

The number of treatment free days until the first retreatment (relapse) will be calculated and summarized. Relapse will be defined as a subject no longer having an IGA of clear or almost clear after a previous visit IGA of clear or almost clear. When a subject has a clear or almost clear IGA in 54-07, it is expected they were instructed not to dose until the IGA reached mild, moderate or severe. Number of treatment free days until first retreatment is defined as the number of days between an initial IGA assessment of clear or almost clear while the subject was receiving S5G4T-1 until an IGA of mild, moderate or severe.

For rollover subjects previously treated with vehicle, the number of treatment free days will be the number of days between the end of their first treatment of S5G4T-1 in 54-07 (when the subject has an IGA of clear or almost clear) and the start of the next treatment in 54-07 (when the

subject has an IGA indicating they should dose) if they treated with S5G4T-1 again or the end of the subject's participation in 54-07. For rollover subjects previously treated with S5G4T-1, the number of treatment free days will be the number of days between the end of the treatment that began in 54-01 or 54-02 (when the subject has an IGA of clear or almost clear) and the start of the next treatment in 54-07 (when the subject has an IGA indicating they should dose) if they treated with S5G4T-1 again or the end of the subject's participation in the 54-07.

Descriptive statistics for time to relapse (number of treatment free days until retreatment) and number of retreatments will be presented. A confidence interval (CI) for the median time to relapse will be presented using the Kaplan–Meier method. Patients who discontinue in 54-07 while not being treated and had not yet previously relapsed will be considered censored in the Kaplan–Meier analysis.

8.8.2.1 RosaQoL

The mean change in RosaQoL subscale scores from Baseline to Weeks 12, 24, 36, 48 and 52 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.

8.8.2.2 Rosacea Erythema and Telangiectasia Assessments

Rosacea erythema and telangiectasia assessments will be summarized at Baseline and every 4 weeks by counts and percentages. A by-subject listing will also be presented.

8.9 Safety Evaluation

8.9.1 Extent of Exposure

The extent of exposure to study product in each treatment group will be summarized by total number of days of exposure to S5G4T-1, total number of applications, number of missed applications, and number of applications the subject did not take because they were instructed not to dose. If the CRF reason for not dosing is anything but “Per Principal Investigator (PI) Instruction” it will be counted as a non-instructed missed dose. If the CRF reason for not dosing is “Per PI Instruction” it will be counted as an instructed missed dose.

The total number of days of exposure to S5G4T-1 is as follows:

Date of last documented dose of S5G4T-1 - Date of first documented dose of S5G4T-1 +1

The total number of applications taken is as follows:

Sum of: [(End date of dosing interval from the CRF – Start date of dosing interval from the CRF + 1)*Number of doses taking in dosing interval on CRF] for all dosing intervals on the CRF

The total number of non-instructed missed applications taken is as follows:

Sum of: (End date of dosing interval from the CRF with reason of "Other, specify reason" – Start date of dosing interval from the CRF + 1) for all dosing intervals on the CRF marked with a dose of 0 and with reason of "Other, specify reason".

The total number of instructed missed applications is as follows:

Sum of: (End date of dosing interval from the CRF with reason of "Per PI Instruction" – Start date of dosing interval from the CRF + 1) for all dosing intervals on the CRF marked with a dose of 0 and with reason of "Per PI Instruction".

Subjects who are lost to follow-up or have a dosing record with an unknown number of doses or unknown dates of the dosing intervals will not have extent of exposure variables calculated.

8.9.2 Adverse Events

AEs from 54-01/02 will be included in the analysis for 54-07. All AEs that were reported as ongoing in 54-01/02 will be added into the CRF for 54-07, while AEs reported as recovered/resolved will be pulled forward programmatically into 54-07.

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. For AEs recorded in the 54-07 study if the AE is not indicated as prior to first application on the CRF then it will be considered a TEAE. AEs from 54-01/02 for subjects who received S5G4T-1 in 54-01 or 54-02 will be considered a TEAE if they were considered at TEAE in the 54-01/02 study. AEs (including ongoing) from 54-01/02 study for subjects who received vehicle in 54-01 or 54-02 will be considered pre-treatment.

AEs will be summarized by period (and total) and by severity. Each patient will be counted only once within a SOC or a Preferred Term by using the AEs with the highest severity within each category.

AEs will be summarized by period (and total) and by 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.

TEAEs will be summarized in total as well as by the following periods based on time of onset in relation to date of first application of S5G4T-1, based on the definitions below. Start dates will be imputed as described in Section 8.1.5.2.

- 0-12 Weeks $0 \leq$ onset day ≤ 85
- >12-28 Weeks $86 \leq$ onset day ≤ 197
- >28-52 Weeks $198 \leq$ onset day ≤ 365
- >52 Weeks onset day ≥ 366

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 study product.

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

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

8.9.3 Clinical Laboratory Evaluation

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

8.9.4 Other Observations Related to Safety

8.9.4.1 Cutaneous Safety Assessments

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

Cutaneous Safety Assessments will be presented in a by-subject listing.

8.9.4.2 Local Tolerability Assessments

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

Local tolerability data will be presented in a by-subject listing.

8.9.4.3 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. In addition, the changes from Baseline will be summarized with descriptive statistics.

Vital sign data will be presented in a by-subject listing.

8.9.4.4 Physical Examination

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

9. DETERMINATION OF SAMPLE SIZE

The sample size for this study was based on the minimum requirement for a long-term safety study.

10. CHANGES IN THE PLANNED ANALYSES

The protocol was written in a way that subjects who did not participate in 54-01 or 54-02 could be enrolled into 54-07. When the SAP was created, 54-07 was fully enrolled, and no subject was enrolled who did not complete the 54-01 or 54-02 study. The SAP was written such that any text from the protocol that discusses the new subjects was excluded.

11. REFERENCES

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7. Thiboutot DM, Weiss J, Bucko A, Eichenfield L, Jones T, Clark S, Liu Y, Graeber M, Kang S. Adapalen-BPO Study Group. Adapalene-benzoyl peroxide, a fixed-dose combination for the treatment of acne vulgaris: results of a multicenter, randomized double-blind, controlled study. *J Am Acad Dermatol*. 2007. 57:791-799.

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12. INDEX OF PLANNED TABLES

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

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (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 Enrolled Subjects)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
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%)

[a] Table includes primary reason (assigned in order presented in table) for reason subject was excluded.

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

Table 14.1.1.1: Summary of Subject Demographic Characteristics
(Safety Population)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (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
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%)
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)

Table 14.1.2.1: Subject Baseline Characteristics
(Safety Population)
(Page 1 of 2)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (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
(Safety Population)
(Page 2 of 2)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (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)

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

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

Table 14.1.4.1: 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)
Number (%) of Subjects Reporting at Least One Concomitant Medication	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)
Preferred Name	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 application of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07).

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

Table 14.2.1.1: Summary of Investigator Global Assessment at Baseline and Week 40
(Safety Population)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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%)
Week 40/ET[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based on nominal visit Week 40/ET from SGT-54-07.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 1 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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%)
Week 4[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 2 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 8[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 3 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 16[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 20[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 4 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 24[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 28[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 5 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 32[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 36[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 6 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 40[b]			
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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 44[b]			
n	xx	NA	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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)		xx (xx.x%)
Failure	xx (xx.x%)		xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.1.2: Summary of Investigator Global Assessment at Each Evaluation
(Safety Population)
(Page 7 of 7)

Investigator Global Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 48[b]			
n	xx	NA	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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)		xx (xx.x%)
Failure	xx (xx.x%)		xx (xx.x%)
Week 52[b]			
n	xx	NA	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%)
Achieving Clear or Almost Clear			
Success	xx (xx.x%)		xx (xx.x%)
Failure	xx (xx.x%)		xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.2.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 40
(Safety Population)
(Page 1 of 4)

Total Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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
Week 40/ET[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based on nominal visit Week 40/ET from SGT-54-07.
Note: Change calculated as Week 40/ET – 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 14.2.2.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 40
(Safety Population)
(Page 2 of 4)

Symptom Subscale Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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
Week 40/ET[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based on nominal visit Week 40/ET from SGT-54-07.
Note: Change calculated as Week 40/ET – 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 14.2.2.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 40
(Safety Population)
(Page 3 of 4)

Functional Subscale Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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
Week 40/ET[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based on nominal visit Week 40/ET from SGT-54-07.
Note: Change calculated as Week 40/ET – 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 14.2.2.1: Summary of RosaQoL Questionnaire Responses at Baseline and Week 40
(Safety Population)
(Page 4 of 4)

Emotional Subscale Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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
Week 40/ET[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based on nominal visit Week 40/ET from SGT-54-07.
Note: Change calculated as Week 40/ET – 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 14.2.2.2: Summary of RosaQoL Questionnaire Responses at Each Evaluation
(Safety Population)
(Page 1 of 24)

Total Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
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
Week 12[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.
Note: Change calculated as post-Baseline – 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 14.2.2.2: Summary of RosaQoL Questionnaire Responses at Each Evaluation
(Safety Population)

Total Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 24[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.
Note: Change calculated as post-Baseline – 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 14.2.2.2: Summary of RosaQoL Questionnaire Responses at Each Evaluation
(Safety Population)
(Page 3 of 24)

Total Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 36[b]			
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
Absolute Change from Baseline			
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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.
Note: Change calculated as post-Baseline – 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 14.2.2.2: Summary of RosaQoL Questionnaire Responses at Each Evaluation
(Safety Population)

Total Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 40[b]			
n	NA	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	NA	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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.
Note: Change calculated as post-Baseline – 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 14.2.2.2: Summary of RosaQoL Questionnaire Responses at Each Evaluation
(Safety Population)
(Page 5 of 24)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Total Score			
Week 48[b]			
n	xx	NA	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	NA	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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.
Note: Change calculated as post-Baseline – 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 14.2.2.2: Summary of RosaQoL Questionnaire Responses at Each Evaluation
(Safety Population)
(Page 6 of 24)

Total Score	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 52[b]			
n	xx	NA	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	NA	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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.
Note: Change calculated as post-Baseline – 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 these pages for [**Symptom Subscale Score**, **Functional Subscale Score** and **Emotional Subscale Score**].

Table 14.2.3: Summary of Erythema Assessment at Each Evaluation
(Safety Population)
(Page 1 of 5)

Rosacea Erythema Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.3: Summary of Erythema Assessment at Each Evaluation
(Safety Population)
(Page 2 of 5)

Rosacea Erythema Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 12[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 20[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.3: Summary of Erythema Assessment at Each Evaluation
(Safety Population)
(Page 3 of 5)

Rosacea Erythema Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 24[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 28[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 32[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.3: Summary of Erythema Assessment at Each Evaluation
(Safety Population)
(Page 4 of 5)

Rosacea Erythema Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 36[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 40[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 44[b]			
n	xx	NA	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%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.3: Summary of Erythema Assessment at Each Evaluation
(Safety Population)
(Page 5 of 5)

Rosacea Erythema Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 48[b]			
n	xx	NA	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 52[b]			
n	xx	NA	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%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.4: Summary of Telangiectasia Assessment at Each Evaluation
(Safety Population)
(Page 1 of 5)

Telangiectasia Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.4: Summary of Telangiectasia Assessment at Each Evaluation
(Safety Population)
(Page 2 of 5)

Telangiectasia Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 12[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 20[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.4: Summary of Telangiectasia Assessment at Each Evaluation
(Safety Population)
(Page 3 of 5)

Telangiectasia Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 24[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 28[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 32[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.4: Summary of Telangiectasia Assessment at Each Evaluation
(Safety Population)
(Page 4 of 5)

Telangiectasia Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 36[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 40[b]			
n	xx	xx	xx
0 - None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 44[b]			
n	xx	NA	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%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.4: Summary of Telangiectasia Assessment at Each Evaluation
(Safety Population)
(Page 5 of 5)

Telangiectasia Assessment	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 48[b]			
n	xx	NA	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 52[b]			
n	xx	NA	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%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.2.5: Summary of Reoccurrence
(Safety Population)

	E-BPO 5% Cream (N=xxx)
Number of Retreatments	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Number of Treatment Free Days Until First Retreatment	
n	xx
Median[c] (days)	xx.x
95% Confidence Interval[c]	(xx.x, xx.x)

[a] Number of retreatments is defined as the number of times a subject's IGA goes from clear or almost clear to mild, moderate or severe after the subject was clear or almost clear while receiving E-BPO 5% Cream.
[b] Number of treatment free days until first retreatment is defined as the number of days between an initial IGA assessment of clear or almost clear while the subject was receiving E-BPO 5% Cream until an IGA of mild, moderate or severe.
[c] Median and 95% confidence intervals based on Kaplan-Meier method.

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

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

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Total Number of Days of Exposure			
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
Total Number of Applications			
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
Total Number of Non-Instructed Missed Applications[a]			
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

[a] Non-Instructed missed applications are missed doses on the CRF with reason of "Other, specify reason".
[b] Instructed missed applications are missed doses on the CRF with reason of "Per PI Instruction".

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

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

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Total Number of Instructed Missed Applications[b]			
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

[a] Non-Instructed missed applications are missed doses on the CRF with reason of "Other, specify reason".
[b] Instructed missed applications are missed doses on the CRF with reason of "Per PI Instruction".

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 1 of 20)

Dryness	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Baseline[a]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 2 of 20)

Dryness	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 12[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 20[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 3 of 20)

Dryness	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Week 24[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 28[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 32[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 4 of 20)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Dryness			
Week 36[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 40[b]			
n	xx	xx	xx
0 – None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 44[b]			
n	xx	NA	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%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Table 14.3.1.1: Summary of Cutaneous Safety and Tolerability Evaluations
(Safety Population)
(Page 5 of 20)

	SGT-54-01/SGT-54-02 Vehicle Cream (N=xxx)	SGT-54-01/SG-54-02 E-BPO 5% Cream (N=xxx)	SGT-54-07 E-BPO 5% Cream (N=xxx)
Dryness			
Week 48[b]			
n	xx	NA	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 52[b]			
n	xx	NA	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%)

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

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

Repeat these pages for [**Scaling**, **Itching** and **Burning/Stinging**]

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

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
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)	
By Maximum Severity		
Severe	xx	(xx.x%)
Moderate	xx	(xx.x%)
Mild	xx	(xx.x%)
By Strongest Relationship to Study Drug		
Related	xx	(xx.x%)
Not Related	xx	(xx.x%)
Maximum Severity within Relationship to Study Drug		
Related		
Severe	xx	(xx.x%)
Moderate	xx	(xx.x%)
Mild	xx	(xx.x%)
Not Related		
Severe	xx	(xx.x%)
Moderate	xx	(xx.x%)
Mild	xx	(xx.x%)

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
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)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	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.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.

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)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)
	Moderate	xx (xx.x%)
	Mild	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)
	Moderate	xx (xx.x%)
	Mild	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 severity.

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.

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)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)
	Not Related	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)
	Not Related	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 with an onset after the first application of E-BPO 5% Cream.
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 Adverse Event Characteristics - By Period
(Safety Population)
(Page 1 of 2)

	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
Subjects Reporting Any Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events	xx	xx	xx	xx
Subjects Reporting Any Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events	xx	xx	xx	xx
Subjects Reporting Treatment-Emergent Adverse Event with Outcome of Fatal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events with Outcome of Fatal	xx	xx	xx	xx
Subjects Who Discontinued Study Drug Due to a Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug	xx	xx	xx	xx
Subjects Who Discontinued from the Study Due to a Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Treatment-Emergent Adverse Events Leading to Discontinuation of Study	xx	xx	xx	xx

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.
By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

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

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

	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
By Maximum Severity				
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
By Strongest Relationship to Study Drug				
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity within Relationship to Study Drug				
Related				
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related				
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.
By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

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

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

System Organ Class[a] Preferred Term	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	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. By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.

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

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

System Organ Class[a] Preferred Term	Severity	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)	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. By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.

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

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

System Organ Class[a] Preferred Term	Relationship	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[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. By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.

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

Table 14.3.1.4.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 1 of 2)

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

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
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 Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 2 of 2)

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

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.4.2: 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)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	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.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.

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

Table 14.3.1.4.3: 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)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)
	Moderate	xx (xx.x%)
	Mild	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)
	Moderate	xx (xx.x%)
	Mild	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 severity.

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.

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

Table 14.3.1.4.4: 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)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)
	Not Related	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)
	Not Related	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 with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.

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

Table 14.3.1.5.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics – By Period
(Safety Population)
(Page 1 of 2)

	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
Subjects Reporting Any Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events	xx	xx	xx	xx
Subjects Reporting Serious Treatment-Emergent Adverse Event with Outcome of Fatal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events with Outcome of Fatal	xx	xx	xx	xx
Subjects Who Discontinued Study Drug Due to a Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug	xx	xx	xx	xx
Subjects Who Discontinued from the Study Due to a Serious Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Treatment-Emergent Adverse Events Leading to Discontinuation of Study	xx	xx	xx	xx

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.
By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

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

Table 14.3.1.5.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics – By Period
(Safety Population)
(Page 2 of 2)

	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
By Maximum Severity				
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
By Strongest Relationship to Study Drug				
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity within Relationship to Study Drug				
Related				
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related				
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.
By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

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

Table 14.3.1.5.2: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term – By Period
(Safety Population)
(Page 1 of x)

System Organ Class[a] Preferred Term	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	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. By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.

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

Table 14.3.1.5.3: Summary of Treatment-Emergent Serious Adverse Events by Severity – By Period
(Safety Population)
(Page 1 of x)

System Organ Class[a] Preferred Term	Severity	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mild	xx (xx.x%)	xx (xx.x%)	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. By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

Note: MedDRA Version 21.0
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.

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

Table 14.3.1.5.4: Summary of Treatment-Emergent Serious Adverse Events by Relationship to Study Drug – By Period
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	0-12 Weeks (N=xxx)	>12-28 Weeks (N=xxx)	>28-52 Weeks (N=xxx)	>52 Weeks (N=xxx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[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. By subject denominator for each period includes the number of subjects in the safety population completing the period or experiencing an adverse event during the period.

Note: MedDRA Version 21.0.
Treatment-emergent adverse events are those events with an onset after the first application of E-BPO 5% Cream.
Related defined as “Definitely”, “Probably”, or “Possible”. Not Related defined as “Unlikely” or “Not related”.
Periods defined from date of first dose of E-BPO 5% Cream. Period >52 Weeks includes all adverse events reported after week 52 through the end of study participation.

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

Table 14.3.1.4.1: Summary of Vital Signs
(Safety Population)
(Page 1 of 20)

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

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

Note: 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 20)

	E-BPO 5% Cream (N=xxx)
Temperature (°C)	
Week 24[b]	
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

Note: 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 20)

	E-BPO 5% Cream (N=xxx)
Temperature (°C)	
Week 36[b]	
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

Note: 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 20)

Temperature (°C)	E-BPO 5% Cream (N=xxx)
Week 48[b]	
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] Baseline is defined as the baseline value from SGT-54-01/SGT-54-02.
[b] Table summaries based analysis visits, representing time from first dose of E-BPO 5% Cream.

Note: Negative change values represent decrease from Baseline.

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

Repeat these pages for [**Respiratory Rate (breaths/min), Systolic Blood Pressure (mmHg), Diastolic Blood Pressure (mmHg)** and **Heart Rate (beats/min)**]

13. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Enrollment
(Page xx of yy)

Subject	Age/Sex	Eval	Enrollment Date	Date of Last Application From SGT-54-01/02 Study	Prior Treatment From SGT-54-01/02 Study
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxx

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

Listing sorted by Subject.

Listing 16.2.1.1: End of Study Information
(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
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxxxx	xx	xxxxxxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxxxx	xx	xxxx xx xxxxxxxxxx xxxxxxxxx xxxx xx xxxxxxxxxx xxxxx xxxxx xxxxx xxx xxxx

[1] Day is calculated as date – date of first application of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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)

Listing 16.2.2.1: Inclusion/Exclusion Criteria
(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 xxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxx xxx

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

Listing sorted by Subject.

Listing 16.2.2.3: Protocol Deviations
(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 visit date from SGT-54-07 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
(Page xx of yy)

Subject	Age/Sex	Population	Included	Reason(s) Excluded
xxxxxx	xxxx	Safety	xxx	
xxxxxx	xxxx	Safety	xxx	
xxxxxx	xxxx	Safety	xx	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
(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	Informed Consent Date
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	xxxx-xx-xx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xx M:	xxxx-xx-xx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxx xxxxxxxxxxxx	xxxx-xx-xx

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	xxxxxxxxxx
	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
(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	xxxxxxxx	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	xxxxxxxx	xxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx P: xxxxxxx	S: xxxx E:
xxxxxx	xxxx	xxxxxxxx	xxxxxxx	S: xxxx xxx xxxxxxxxxxxx xxxxxx xxxxxxxxx P: xxxxxxx	S: xxxx E:
xxxxxx	xxxx	xxxxxxxx	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
(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 xxxxxxxxxxx P: xxxxxxxxxxx xxxxxxx xxxxxxxxxxx xxx xxxxxxx xxx M: xxxxxx xxxxx xxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxx	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 xxxxxxxxxxx P: xxxxxxxxxxx xxxxxxx xxxxxxxxxxx xxx xxxxxxx xxx M: xxxxxx xxxxx xxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxx	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 of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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
(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 of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	SGT-54-07 Analysis Visit	Visit Date	Day[1]	Within Study Window[2]	Reason Screening And Baseline Visit Occurred on Different Days	Reason for Unscheduled Visit
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx				
			xxxxxxxxx	xxxx x	xxxxxxxxxx			xxxxxxx xxx xx	
			xxxx x	xxxx x	xxxxxxxxxx				
			xxxx x	xxxx x	xxxxxxxxxx				
			xxxx xx	xxxx x	xxxxxxxxxx				
			xxxx xx	xxxx x	xxxxxxxxxx				
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xxxxx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		xxxxxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		xxxxxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		xxxxxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		
			xxxx xx	xxxx x	xxxxxxxxxx	xx	xxx		

[1] Day is calculated as date – Baseline date from SGT-54-07 for dates prior to Baseline visit. Otherwise, day is calculated as date - Baseline date + 1 for dates on or after Baseline visit. Day is only calculated for visits occurring in SGT-54-07.
[2] Determined by protocol-specified visit window for scheduled visits after Baseline. Only assessed for visits occurring in SGT-54-07.

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

Listing sorted by Subject and Visit Number.

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

Subject	Age/Sex	Eval	Date of First Application	Date of Last Application	Number of Days of Exposure	Total Number of Applications	Number of Instructed Missed Applications[1]	Number of Non-Instructed Missed Applications[2]
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xxx	xx	xx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xxx	xx	xx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xxx	xx	xx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xxx	xx	xx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xxx	xx	xx

[1] The number instructed missed applications is the total number of missed doses on the CRF with reason "Per PI Instruction".
[2] The number of non-instructed missed applications is the total number of missed doses on the CRF with reason of "Other, specify reason".

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

Listing sorted by Subject.

Listing 16.2.5.3: Subject Dosing
(Page xx of yy)

Subject	Age/Sex	Eval	Study Interval	Start Date	End Date	Number of Doses Applied[1] or Number Of Doses Applied Each Day of the Date Span[2]	Reason Subject Did Not Dose or Dosed More Than Once Per Day[2]
xxxxxx	xxxx	xxxxxxxx	54-01 First to Last Dose Interval	xxxxxxxxxx	xxxxxxxxxx		
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
xxxxxx	xxxx	xxxxxxxx	54-01 First to Last Dose Interval	xxxxxxxxxx	xxxxxxxxxx		
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-01 Dosing Deviation	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
xxxxxx	xxxx	xxxxxxxx	54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	
			54-07 Dosing Interval	xxxxxxxxxx	xxxxxxxxxx	x	xxx xx xxxxxxxxx

[1] From SGT-54-01 or SGT-54-02
[2] From SGT-54-7
Note: Dosing from the SGT-54-01 or 54-02 study was pulled forward for only subject who received E-BPO 5% Cream in the Phase 3 study.

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

Listing sorted by Subject and Start Date of Dosing Interval.

Listing 16.2.5.4: Study Medication Dispensation
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Dispensation	Pump Number Assigned	Instructions Given to the Subject by the Investiator Regarding When to Apply the Study Product	Reason Why a New Pump Was Not Dispensed
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx xxxx xx x x xxxx xxxx	
			xxxx x	xxxxxxxxxx	xxxx	xx xxxx xxxxxxx xx x x xxxxxx xx	
			xxxx x	xxxxxxxxxx	xxxx	xxxxxxxx xxxxxxxxxx xxxx xx x x xxxx xx	
			xxxx x	xxxxxxxxxx	xxxx	xxxx x xxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxx xx xxxx xxxxxxx xx x x xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxx	x xxxxx xxx xx	
			xxxx x	xxxxxxxxxx	xxxx		
			xxxx x	xxxxxxxxxx	xxxx	xxxxxxxxxx xxxx xx x x xxxx xxxxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxx	xxxxxxx xxxx xx x x xxxx xxxx	
			xxxx x	xxxxxxxxxx	xxxx	xx xxxx xxxxxxx xx x x xxxxxx xxxxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxxxxxxxx xxxx xx x x xxxx xxxxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxx x xxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxx xx xxxx xxxxxxx xx x x xxxxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxxx x xxxxx xxx xx	
			xxxx x	xxxxxxxxxx	xxxx		
			xxxx x	xxxxxxxxxx	xxxx	xxxxxxxxxx xxxx xx x x xxxx xxxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxx xx xxxx xxxxxxx xx x x xxxxxxx	
			xxxx x	xxxxxxxx			x xxxxx xxxxx xxxxxxxxx xx xxx x xxx xxx
			xxxx x	xxxxxxxxxx	xxxx	xxxx xx xxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxxxxxxxx xxxx xx x x xxxx xxxxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxx xx xxxx xxxxxxx xx x x xxxxxx xxxxxx	
			xxxx x	xxxxxxxxxx	xxxx	x xxxxx xxx xx	
			xxxx x	xxxxxxxxxx	xxxx	xxxxxx xxxxx xx x x xxxxx xxxx xxx xxxx	
			xxxx x	xxxxxxxxxx	xxxx	xxxxxxxxxx xxxx xx x x xxxx xxxxxx	

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

Note to programmers: If a pump was not dispensed, NOT DONE will print in the date column. Listing sorted by Subject and Visit Number.

Listing 16.2.5.5: Study Medication Accountability Log
(Page xx of yy)

Subject	Age/Sex	Eval	Pump Number	Dispensing Date	Dispensing Weight (g)	Return Date	Return Weight (g)	Amount Used (g)
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxx xxxx		xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxx xxxx				
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx
			xxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx

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

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

Subject	Age/Sex	Eval	Visit	SGT-54-07 Analysis Visit	Date of Assessment	Evaluator Initials	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xxxxx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xxxxxxxxxx
			xxxx xxxxx	xxxx x	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
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	SGT-54-07 Analysis Visit	Date of Assessment	Evaluator Initials	Papules	Pustules	Total Inflammatory Lesion Count	Nodules/ Cysts
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xxxxx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx x	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xx	xxxx x	xxxxxxxxxx	xxx	xx	xx	xx	x
			xxxx xxxxx	xxxx x	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)

Listing 16.2.6.3.2: RosaQoL
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Visit	SGT-54-07 Analysis 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
S: xxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
A: xxx																								
E: x																								
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
S: xxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
A: xxx																								
E: x																								
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
S: xxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
A: xxx																								
E: x																								
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	xxxxxxxx	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
Note: Full RosaQoL question text is available in Listing 16.2.6.3.1.

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

Listing sorted by Subject and Visit Number

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

Subject	Age/Sex	Eval	Visit	SGT-54-07 Analysis Visit	Date of Assessment	Total Score[1]	Symptom[2]	Functional[3]	Emotional[4]
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
xxxxxx	xxxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx
			xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xx	xx	xx	xx

[1] Total Score calculated from the unweighted mean of all RosaQoL questions.
[2] Symptom Subscale Score calculated from items 2, 6, 9, 16, 17, 18, and 19.
[3] Functional Subscale Score calculated from items 13, 15, and 21.
[4] 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)

Listing sorted by Subject and Visit Number

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

Subject	Age/Sex	Eval	Visit	SGT-54-07 Analysis Visit	Date of Assessment	Evaluator Initials	Assessment	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Rosacea Erythema	xxxxxxxxxx
							Telangiectasia	xxxxxxxxxx

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

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

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

Subject	Age/Sex	Eval	Visit	SGT-54-07 Analysis Visit	Date of Assessment	Evaluator Initials	Test	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
							Scaling	xxx xxxx
							Itching	xxxxxxxxxxxx
							Burning/Stinging	xxxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
							Scaling	xxx xxxx
							Itching	xxxxxxxxxxxx
							Burning/Stinging	xxxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
							Scaling	xxx xxxx
							Itching	xxxxxxxxxxxx
							Burning/Stinging	xxxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
							Scaling	xxx xxxx
							Itching	xxxxxxxxxxxx
							Burning/Stinging	xxxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
							Scaling	xxx xxxx
							Itching	xxxxxxxxxxxx
							Burning/Stinging	xxxxxxxxxxx
			xxxx x	xxxx x	xxxxxxxxxx	xxx	Dryness	xxxxxxxx
							Scaling	xxx xxxx
							Itching	xxxxxxxxxxxx
							Burning/Stinging	xxxxxxxxxxx

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
(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
(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: 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 xxxxxxxxxx T: xxxxxxxxxxx xxxxxxxxxx O: xxxxxxxxxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx

[1] Day is calculated as date – date of first application of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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
(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 of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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
(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: xxxxxxxxxxxxxxxxx	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 of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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
(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 xxxxxxxxxxx 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: xxxxxxxxxxxxxxxxx	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 of E-BPO 5% Cream (from SGT-54-01/SGT-54-02 or SGT-54-07) 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
(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 xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
xxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx	
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxxxxxx	
			xxxx x	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
xxx	xxxx	xxxxxxxx	xxxxxxxxx			xxx xxxxxxxxx
			xxxxxxxxx			xxx xxxxxxxxx
			xxxx x			xxx xxxxxxxxx
			xxxx x			xxx xxxxxxxxx
			xxxx xx			xxx xxxxxxxxx
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	
			xxxx xx	xxxxxxxxxx	xxxxxxxx	

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

Listing sorted by Subject and Visit Number.

Listing 16.2.8.2: Physical Examination
(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	
					xxxxxxxxxxxxxx	xxxxxxxxx xxxxxxxxx xxxx	
					xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx xxxxx xxxx xxx	
					xxxxxxxxx	xxxxxxxxx xx xxxx xxxxxx	
			xxxx xxxxx	xxxxxxxxxx	xxxxx		
					xxxx		
					xxxxxxxx		
					xxxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxxxx	xxxxxx	
					xxxx	xxxxxx	
					xxxxxxx	xxxxxx	
					xxxxxxxxxxxxxx	xxxxxxxxx xxxxxxxxx xxxx	
					xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx xxxxx xxxx xxx	
					xxxxxxxxx	xxxxxxxxx xx xxxx xxxxxx	
			xxxx xxxxx	xxxxxxxxxx	xxxxx		
					xxxx		
					xxxxxxxx		
					xxxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxxx	xxx xxxx	xxx xxxxxxxxxx
					xxxxxxxxxxxxxx	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
(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).