Sponsor	Arcutis Biotherapeutics, Inc.
Protocol Title:	A Phase 2b, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-154 Foam 0.3% Administered QD in Adolescents and Adults with Scalp and Body Psoriasis
Protocol Number:	ARQ-154-204
Premier Research PCN:	ARCU210101
Document Version:	Final 2.0
Document Date:	09-Dec-2020

Approvals

Role	Signatures	Date (dd-Mmm-yyyy)
Lead Biostatistician	Print Name: Sign Name:	09-Dec-2020 | 06:20:07 EST
Premier Senior Reviewer	Print Name: Sign Name:	09-Dec-2020 | 08:35:32 EST
Arcutis Biotherapeutics, Inc. Representative	Print Name: Sign Name:	09-Dec-2020 | 14:14:38 PST

Document History

Version	Date	Section	Description of Change/Purpose
1.0	12-Nov-2020	N/A	N/A
2.0	04-Dec-2020	8.1	Text from this section describing the primary endpoint analysis (including sensitivity analysis) was accidentally removed when accepting changes from the redlined version of SAP draft v0.3. This text was not in redline, so the deletion was unexpected and therefore not noticed once the draft was upversioned to final v1.0. The exact text from draft v0.3 was copied back into the SAP; no other changes were made to the SAP.

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1. Overview

This statistical analysis plan (SAP) describes the planned analysis and reporting for Arcutis Biotherapeutics, Inc. protocol number ARQ-154-204 (A Phase 2b, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-154 Foam 0.3% Administered QD in Adolescents and Adults with Scalp and Body Psoriasis), dated 13-Jan-2020 Amendment Version 1.0. Reference materials for this statistical plan include the protocol and the accompanying sample data collection documents. Operational aspects related to collection and timing of planned clinical assessments are not repeated in this SAP unless relevant to the planned analysis.

The structure and content of this SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on Statistical Principles in Clinical Trials[1]. All work planned and reported for this SAP will follow internationally accepted guidelines, published by the American Statistical Association[3] and the Royal Statistical Society[1], for statistical practice.

The planned analyses identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post-hoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data. Any post-hoc or unplanned, exploratory analysis performed will be clearly identified as such in the final CSR.

The statistical plan described hereafter is an *a priori* plan. It will be submitted to file prior to any unblinded inferential or descriptive analysis of data pertaining to Arcutis Biotherapeutics, Inc.'s study ARQ-154-204. Any amendments to this plan that occur after unblinding for an interim analysis will be performed by a study statistician who remains blinded to treatment codes and outcomes.

ARQ-154 foam 0.3% will be described as "roflumilast foam 0.3%" throughout this document and the tables, listings, and figures (TLFs).

2. Study Objectives and Endpoints

2.1. Study Objectives

2.1.1. Primary Objective

The primary objective is to assess the safety and efficacy of roflumilast foam 0.3% vs vehicle administered daily (QD) x 8 weeks in adolescents and adults with scalp and body plaque psoriasis.

2.2. Study Endpoints

2.2.1. Safety Endpoints

The safety endpoints of this study include the following:

- Local tolerability assessments

- Clinical laboratory parameters
- Adverse events (AEs)
- Columbia-Suicide Severity Rating Scale (C-SSRS)
- Patient Health Questionnaire depression scale (PHQ-8)
- Modified PHQ-Adolescents (PHQ-A)
- Vital signs
- Physical examinations

2.2.2. Efficacy Endpoints

2.2.2.1. Primary Efficacy Endpoint

The primary efficacy endpoint of this study is Scalp-Investigator Global Assessment (S-IGA) Success at Week 8, defined as achievement of an S-IGA score of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline.

2.2.2.2. Secondary Efficacy Endpoints

The secondary efficacy endpoints of this study include the following:

- Body-IGA (B-IGA) Success at Week 8, defined as achievement of B-IGA score of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline
- Psoriasis Scalp Severity Index (PSSI)-75 (subjects who achieve a 75% reduction in PSSI from Baseline) at Week 8
- For subjects with baseline Scalp Itch - Numeric Rating Scale (SI-NRS) score ≥4, achievement of ≥4-point improvement from baseline in SI-NRS at Week 8
- For subjects with baseline SI-NRS score ≥4, achievement of ≥4-point improvement from baseline in SI-NRS at Week 4
- For subjects with baseline SI-NRS score ≥4, achievement of ≥4-point improvement from baseline in SI-NRS at Week 2
- Time to success in PSSI-50
- Change and percent change from baseline in total Psoriasis Symptoms Diary (PSD) score at Week 8
- Change and percent change from baseline in total PSD score at Week 4
- PSSI-90 (subjects who achieve a 90% reduction in PSSI from Baseline) at Week 8

2.2.2.3. Exploratory Efficacy Endpoints

The exploratory efficacy endpoints of this study include the following:

- Psoriasis Area Severity Index (PASI)-75 (subjects who achieve a 75% reduction in PASI from Baseline) at Week 8
- Time to success in PASI-50
- Change and percent change from baseline modified PASI (mPASI) at Weeks 2, 4, 8, and 9
- For subjects with baseline Worst Itch - Numeric Rating Scale (WI-NRS) score ≥4, achievement of ≥4-point improvement from baseline in WI-NRS at Weeks 2, 4, and 8
- Change and percent change from baseline in Dermatology Life Quality Index (DLQI)/ Children's DLQI (CDLQI) total scores at Weeks 2, 4, and 8

- Change and percent change from baseline in % BSA affected by disease at Weeks 2, 4, and 8

The exploratory endpoints below are not defined in the protocol explicitly but are based on other efficacy assessments collected:

- Change and percent change from baseline in SI-NRS at Weeks 2, 4, and 8
- Change and percent change from baseline in PASI at Weeks 2, 4, 8, and 9
- PASI-90 (subjects who achieve a 90% reduction in PASI from Baseline), PASI-75 (subjects who achieve a 75% reduction in PASI from Baseline), and PASI-50 (subjects who achieve a 50% reduction in PASI from Baseline) at Weeks 2, 4, 8, and 9
- Change and percent change from baseline in WI-NRS at Weeks 2, 4, and 8

3. Overall Study Design and Plan

3.1. Overall Design

This is a parallel group, double blind, vehicle-controlled study in which roflumilast foam 0.3% or vehicle foam is applied QD x 8 weeks to adolescent and adults with scalp and body psoriasis of at least mild severity (S-IGA and B-IGA with a score of at least "2"), involving up to 25% body surface area (BSA) (scalp and body, not including palms/soles).

Approximately 300 subjects will be enrolled. After having met all inclusion criteria, and none of the exclusion criteria, subjects will be randomized in a 2:1 ratio to roflumilast foam 0.3% QD or vehicle foam QD, which will be applied to all psoriasis lesions (including the scalp, face, trunk, and intertriginous areas; palms and soles will be treated but will not be counted towards any measurements of efficacy). Screening will be for up to 4 weeks followed by an 8-week Treatment Phase, with a Follow-up Visit 1 week after last dose. The anticipated maximum duration of subject participation is approximately 13 weeks.

Subjects will have to apply the study drug once a day in the evening, with the exception of Day 0, Week 2 (Visit 3), and Week 4 (Visit 4), when the study drug is applied at the study site in the morning. Participants have to record the date and time each dose has been applied with details including missed doses and any additional comments.

3.2. Sample Size and Power

There are approximately 300 subjects planned for this study. Approximately 200 subjects will receive roflumilast foam 0.3% QD; approximately 100 subjects will receive vehicle foam QD. The sample size was selected to provide an adequate number of subjects to compare the efficacy of roflumilast treatment to vehicle and to provide an adequate number of subjects needed for a safety database.

This sample size provides 96% power at the α=0.05 level to detect a 22.4% difference between treatment groups for S-IGA Success at Week 8 using a 2-sided Chi-squared test. The results from a recent phase 2b study (ARQ-151-201) of roflumilast cream compared to vehicle treatment were used to estimate the treatment difference, and it is assumed that the S-IGA response in the present study are similar to IGA responses seen with roflumilast cream. Specifically, in the phase 2b trial, 32.2% of subjects reported IGA success in the roflumilast cream 0.3% group and 9.8% of subjects reported IGA success in the vehicle group.

The number of subjects to be enrolled will also provide sufficient power for most secondary

endpoints.

3.3. Study Population

Study population consists of male and female subjects aged 12 years or older with no more than 25% BSA of scalp and body psoriasis. Subjects should have a minimum S-IGA of at least "Moderate" (3) and B-IGA of "Mild" (2) at Baseline. Note that the original protocol allowed subjects having an S-IGA of "Mild" (2) to be enrolled, and some subjects were enrolled and treated with an S-IGA of "Mild" before the amendment under which this SAP operates was put into effect (i.e., Amendment Version 1.0, dated 13-Jan-2020).

3.4. Treatments Administered

Subjects who meet the eligibility criteria will be randomized to 1 of the 2 following treatment groups in a 2:1 ratio (active:vehicle):

- Roflumilast foam 0.3% QD
- Matching vehicle foam QD.

3.5. Method of Assigning Subjects to Treatment Groups

Subjects will be randomized and assigned to active drug or vehicle will be made at a 2:1 ratio according to a computer-generated randomization list. Randomization will be stratified by country, baseline S-IGA (S-IGA=2 vs. S-IGA ≥3), and baseline B-IGA (B-IGA=2 vs. B-IGA ≥3).

3.6. Blinding and Unblinding

This is a double-blind study; therefore, neither the subjects nor the investigator, clinical personnel, or sponsor will be aware of which treatment a subject has received. Emergency unblinding will be done using the study internet-based randomization system (interactive web-response system; IWRS) system in consultation with the medical monitor and the sponsor's chief medical officer (CMO).

3.7. Schedule of Events

A detailed schedule of events for the study is provided in Table 1.

Table 1: Schedule of Events

Study Procedure	Screen	Baseline Day 0	Wk 2 Day 14	Wk 4 Day 28	Wk 8 Day 56	Wk 9 Day 63
Visit	**1**	**2**	**3**	**4**	**5**	**6**
Visit Window	**-4 weeks**		**+/- 3 days**	**+/- 5 days**	**+/- 5 days**	**+/- 5 days**
Informed consent/assent	X					
Medical history	X					
Physical examination[a]	X	X			X	
I/E criteria	X	X				
Randomization		X				
Hematology, Serum Chemistries, and Urine Analysis	X	X		X	X	
Vital signs, height[b], weight[b]	X	X	X	X	X	X
S-IGA[c], B-IGA[c], PSSI[c], BSA[c], PASI/mPASI	X	X	X	X	X	X
Scalp Itch NRS, WI-NRS pruritus, DLQI, CDLQI, PSD[d]	X	X	X	X	X	
Application Site Reaction Assessment/Local tolerability[e]		X		X	X	
C-SSRS, PHQ-8/PHQ-A[f]	X	X		X	X	
Medical Photography[g]		X	X	X	X	
Pregnancy test[h]	X	X		X	X	
PK draws[i]		X		X	X	
IP/vehicle application in clinic[j]		X	X	X		
Dispense IP kit[k]		X	X	X		
Dispense/review diary		X	X	X	X	
Weigh IP kit[l]		X	X	X	X	
Compliance calculation[m]		X	X	X	X	
Adverse event assessment[n]	X	X	X	X	X	X
Concomitant medications	X	X	X	X	X	X

Footnote:

[a] Limited physical examination: skin, lungs, and heart only

[b] Height will be collected at Baseline and Week 8. Weight will be collected at all study visits. Subject to void prior to weight being taken. Remove any jackets, outerwear and shoes. Remove any objects of significant weight (i.e. cell phones, wallet, key chains). A 5% unintentional weight loss should be reported to the medical monitor.

[c] S-IGA will be a 5-point scale ranging from clear (0) to severe (4) and is evaluated for the scalp only. B-IGA will use the same scale as S-IGA, but will evaluate the entire body (except the scalp, palms, and soles). PSSI is scored on a 0-72 scale and evaluates the scalp only. Total BSA and scalp BSA affected by psoriasis will be determined (except the palms and soles). PASI/mPASI assessment should exclude palms and soles. S-IGA and B-IGA should be completed prior to other physician assessments.

[d.] Subjects will complete the WI-NRS pruritus, Scalp Itch-NRS, DLQI, CDLQI (for adolescents) and PSD questionnaires.

[e.] Local Tolerability Assessments: the Investigator local tolerability assessment of skin irritation (Berger and Bowman skin irritation score) should be performed prior to the investigational product application at Day 0, Weeks 4 and 8. **Note for**

investigator tolerability assessments: reactions at the site of product application, which may occur post-Baseline, should be differentiated from the preexisting inflammation associated with the subject's psoriasis. Subjects will perform the local tolerability 10-15 minutes post-IP application at Day 0 and Week 4, and recall assessment at Week 8 for the subject's '0-3' burning/stinging assessment.

[f] Adolescents and adults will complete the C-SSRS. Adults will complete the PHQ-8. Adolescents will complete a modified version of the PHQ-A (PHQ-9 modified for Adolescents).

[g] At selected sites, medical photography will be obtained for target lesions. All efforts will be made to de-identify the subjects. Subjects who are unwilling to participate in the medical photography will be allowed to opt out of this procedure.

[h] A pregnancy test will be administered to all females of child-bearing potential. A serum pregnancy test will be performed at the Screening visit only. A urine pregnancy test will be performed at Day 0, Week 4, and Week 8. A negative result is required for continued participation in the study, and results must be available prior to dispensing of the IP at each visit.

[i] PK draws will be collected at Days 0, Weeks 4 and 8 pre-dose (within 1 hour) for all subjects. Serial PK will be obtained in a subset of approximately 15 subjects on Days 0 and 28 at 1, 2, 4, 6 (all + 20 min), and 24 hours (+ 2 hours) post-dose

[j] Subjects to apply assigned IP in clinic at Day 0, Weeks 2 and 4.

[k] Kits will be dispensed based on %BSA affected. See IP Handling Manual for details.

[l] The entire kit should be weighed and recorded at every visit. See IP Handling Manual for details.

[m] Compliance calculation is described in the IP Handling Manual

[n] Any emergent AEs will be followed in the clinic for up to one month at the Investigator's discretion until resolved or otherwise judged as clinically stable.

4. Statistical Analysis and Reporting

4.1. Introduction

Data processing, tabulation of descriptive statistics, calculation of inferential statistics, and graphical representations, will be performed primarily using SAS (release 9.4 or higher). If the use of other software is warranted for analyses conducted by Premier Research, the final statistical methodology report will detail what software was used for what purposes.

Continuous (quantitative) variable summaries will include the number of subjects (n) with nonmissing values, mean, standard deviation (SD), median, minimum, and maximum.

Categorical (qualitative) variable summaries will include the frequency and percentage of subjects who are in the particular category or each possible value. In general, the denominator for the percentage calculation will be based upon the total number of subjects in the study population for the treatment group, unless otherwise specified.

Unless otherwise indicated, all statistical tests will be conducted at the familywise α=0.05 significance level using 2-tailed tests, and *P* values will be reported. Corresponding 95% confidence intervals (CIs) will be presented for statistical tests. Details for splitting the familywise α to control for multiple comparisons will be discussed in Section 6.1.3.

4.2. Interim Analysis and Data Monitoring

No interim efficacy analyses are planned.

5. Analysis Populations

The following analysis populations are planned for this study:

- **Safety Population (SAF):** The Safety population will include all subjects who are enrolled and received at least 1 confirmed dose of investigational product (IP). This population will be used for all safety analyses.
- **Intent-To-Treat Population (ITT):** The ITT population will include all randomized subjects. This population will be the primary analysis population for the analysis of efficacy endpoints, along with subject disposition.
- **Modified Intent-To-Treat Population (mITT):** The mITT population includes all randomized subjects with the exception of subjects who missed the Week 8 S-IGA assessment specifically due to novel coronavirus disease-19 (COVID-19) disruptions. This population will be the sensitivity analysis population for the analysis of primary and secondary efficacy endpoints.
- **Scalp Pruritus ITT Population (SPRU4-ITT):** The SPRU4-ITT population is a subset of the ITT population and includes subjects with SI-NRS score ≥4 at baseline. This population will be used for the analysis of achievement of a 4-point reduction in SI-NRS score as compared to baseline for this subset of ITT subjects.
- **Scalp Pruritus mITT Population (SPRU4-mITT):** The SPRU4-mITT population is a subset of the mITT population and includes subjects with SI-NRS score ≥4 at baseline. This population will be used for the analysis of achievement of a 4-point reduction in SI-NRS score as compared to baseline for this subset of mITT subjects.
- **Pruritus ITT Population (PRU4-ITT):** The PRU4-ITT population is a subset of the ITT population and includes subjects with WI-NRS score ≥4 at baseline. This population will be used for the analysis of achievement of a 4-point reduction in WI-NRS score as compared to baseline for this subset of ITT subjects.
- **Pruritus mITT Population (PRU4-mITT):** The PRU4-mITT population is a subset of the mITT population and includes subjects with WI-NRS score ≥4 at baseline. This population will be used for the analysis of achievement of a 4-point reduction in WI-NRS score as compared to baseline for this subset of mITT subjects.
- **Pharmacokinetic Population (PK):** The PK population will include all subjects receiving the active drug with sufficient plasma concentrations of roflumilast to define a profile, as determined by the pharmacokineticist. This population will be used for analyses of PK parameters.

6. General Issues for Statistical Analysis

6.1. Statistical Definitions and Algorithms

6.1.1. Baseline

For most efficacy assessments (i.e., S-IGA, B-IGA, PSSI, PASI/mPASI, and % BSA) and all safety assessments except PHQ-8/PHQ-A, the last observation recorded before the first application of study drug will be used as the baseline observation for all calculations of change

from baseline. For other efficacy and safety assessments with a 24-hour or greater recall period (i.e., SI-NRS, WI-NRS, PSD, DLQI/CDLQI, and PHQ-8/PHQ-A), for the previously-named assessments where time is missing (and therefore we are assuming that the assessment was collected before first dose of study drug as per the protocol), or for subject local tolerability (which is expected to be post-dose), the last observation recorded on or before the day of first application of study drug will be used as the baseline observation for all calculations of change from baseline.

For assessments that are collected both before and after application of study drug at the Baseline Day 0 visit, the last observation recorded before the first dose of study will be used as the baseline observation. For assessments collected only after application of study drug, no baseline will be defined (except for subject local tolerability). If the tolerability assessments are not done as per protocol Section 5.1.8, those records will be excluded from the analysis.

6.1.2. Adjustments for Covariates

Subgroup analyses may be generated for the baseline covariates.

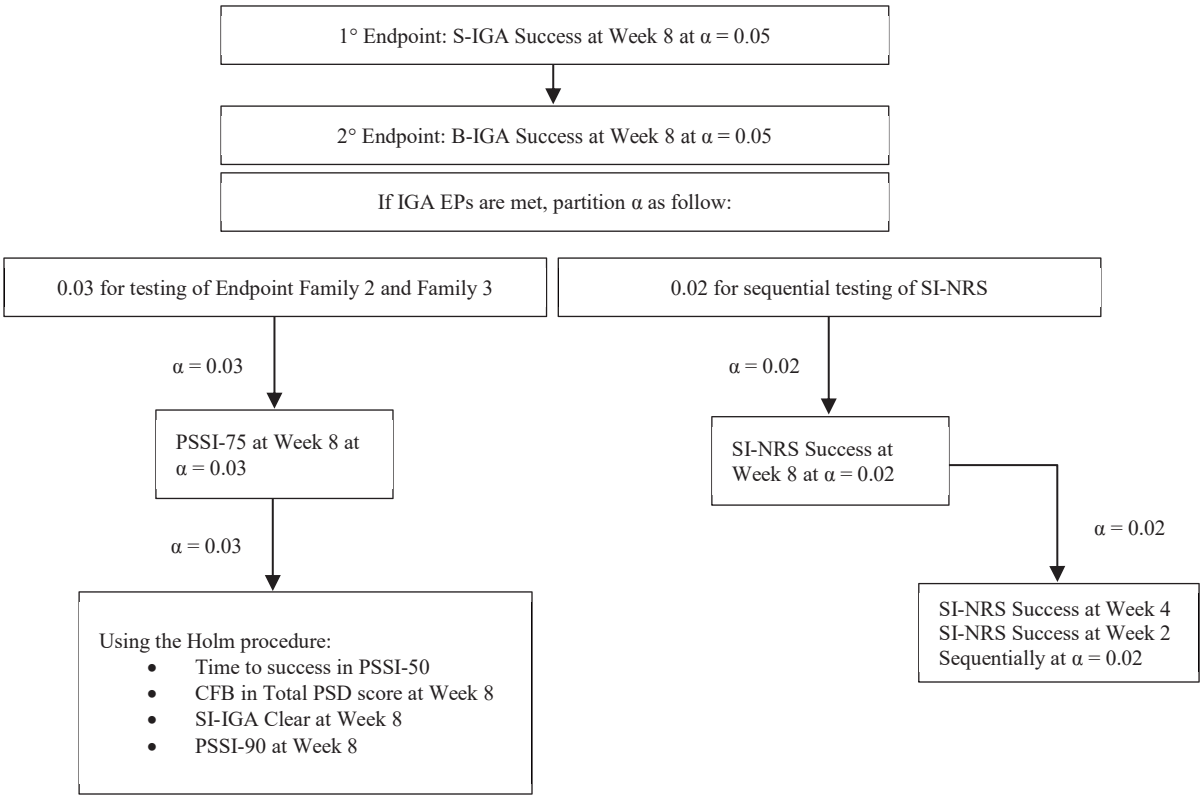
6.1.3. Multiple Comparisons

To control for multiple comparisons among the secondary endpoints, the following testing plan will be used, as outlined in Figure 1.

Upon demonstration of statistical significance for S-IGA Success at Week 8, the secondary endpoint of B-IGA Success at Week 8 will be tested hierarchically at the 5% significance level.

If the test for B-IGA Success at Week 8 is significant, the α of 0.05 will be split to test 2 families of secondary endpoints. The first family comprise the PSSI-75, which will be tested at the $\alpha = 0.03$ level. If the test of PSSI-75 is statistically significant, then $\alpha = 0.03$ will be used with a Holm testing procedure to test the 4 endpoints of time to success in PSSI-50, change from baseline in Total PSD score at Week 8, change from baseline in Total PSD score at Week 4, and PSSI-90 at Week 8. The remaining $\alpha = 0.02$ will be used to test the second family, comprising the SI-NRS at Week 8, the SI-NRS at Week 4, and the SI-NRS at Week 2. The tests within this second family will be hierarchical, beginning with the endpoint at Week 8, followed by Week 4 and Week 2.

Figure 1: Primary and Secondary Endpoint Testing



Achievement of IGA success is a score of "clear" or "almost clear" plus a 2-grade improvement from baseline.
SI-WRS Success is a 4-point reduction in SI-NRS among subjects with SI-NRS ≥ 4 at baseline.
B-IGA = Body-Investigator Global Assessment; EP = endpoint; CFB = change from baseline; PSSI = Psoriasis Scalp Severity Index; S-IGA = Scalp-Investigator Global Assessment; SI-NRS = Scalp Itch - Numeric Rating Scale.

6.1.4. Handling of Dropouts or Missing Data

6.1.4.1. Imputation of Missing Data

Any subject who prematurely withdraws from the study will have their last available data assigned to an analysis window as described in Section 6.1.5.

For the primary efficacy endpoint of S-IGA score, the primary analysis will impute missing values using a regression-based multiple imputation model. This is a three step process.

1. The first step is to understand the pattern of missingness. In order to perform the multiple imputation, a monotone missing pattern has to be achieved. For example, if there exists values for baseline and Week 8 visits, but missing values for the Week 2 or 4 visits, Markov-Chain Monte-Carlo (MCMC) method will be used to impute the small amount of missing data that may be missing at the intermediate visits that is required to make the missing data pattern monotone before applying the multiple imputation algorithm. This method uses a non-informative Jeffreys prior to derive the posterior mode from the expectation-maximization (EM) algorithm as the starting values for the MCMC method. MCMC method will use seed of 34978264. The S-IGA score will be treated as a continuous variable for this step. To avoid values that could not be observed in practice, imputed values will be constrained to be integers in the range of 0 to 4.

    a. The table below will determine the number of datasets to be imputed in this step. Determine the proportion of datapoints with non-monotone pattern across all visits and subjects which could be derived as a percentage of number of nonmonotone data points/total number of expected data points.

    This can be determined as $\frac{number\ of\ non\ montone\ visits}{total\ number\ of\ visits\ across\ all\ subjects} * 100$

Non-monotone Missing Data	Number of Imputed Datasets
≤ 2%	1
> 2% to ≤ 5%	3
> 5%	10

2. Once the monotone pattern is achieved, the next step is to implement the imputation algorithm. For this, the Predictive Mean Matching method (PMM) will be used. This method is particularly helpful if the normality assumption is violated. For subjects with complete data up to a particular visit, a PMM model will be fit that includes the outcome at that visit as the dependent variable and as independent variables, S-IGA score outcomes at previous visits, treatment group, and country using a seed of 51192215. This process will be repeated 25 times, resulting in a total of 25 to 250 complete analysis

datasets, depending on the number of imputed monotone datasets that are required. The seed may be changed after unblinding in case of any issues with the imputation process, and it will be documented in the CSR if any change is required.

3. For each completed dataset, compute the necessary derived variables. The dichotomous success rate (clear or almost clear with at least a 2-point change from baseline) will be derived. The results obtained will be analyzed using the Cochran-Mantel-Haenszel (CMH) analysis for each of the complete analysis data sets stratified by baseline S-IGA score category, baseline B-IGA score category, and country. The results will be combined into one multiple imputation inference (odds ratio, associated CI, and *P* value) using PROC MIANALYZE as illustrated[4].

This approach to imputation should be superior to other strategies such as carrying forward the last available observation, which may yield unrealistic imputed values. Also, the use of multiple imputation avoids the problem of artificially increasing power through data imputation associated with single-imputation methods because it accounts for the uncertainty associated with the imputation. Other missing data will not be imputed, with the exception of incomplete dates as described in Section 6.1.8. For responder analyses, missing data will be treated as a nonresponse with the exception of S-IGA. Only observed data will be summarized using descriptive statistics.

The SAS pseudo code for the multiple imputation process is listed below:

Step 1:

```
proc mi data=example seed=34978264 nimpute=XX round=1 out=example_1;
  mcmc impute=monotone;
  var <baseline score> …… <visit8 score>;
run;
```

Step 2:

```
proc mi data=example_1 seed=51192215 nimpute=XX  out=example_2;
  class <treatment> <country>;
  monotone regpmm(<baseline score> …… <visit8 score>);
  var <treatment> <country> <baseline score> …… <visit8 score>;
run;

XX will be the determined based on the proportion of missing data across visits.
```

Step 3: This step involves running CMH test stratified by baseline S-IGA score category, baseline B-IGA score category, and country on each completed dataset and combining the results using PROC MIANALYZE.

```
proc freq data=example noprint;
  by <imputationnumber> <visit> ;
  tables <country> * <BL S-IGA cat> * <BL B-IGA cat> * <treatment> *
         <outcome> / cmh alpha=0.05;
  output out=example_stat cmh;
run;
```

In order to apply PROC MIANALYZE, normalizing transformations have to be applied to odds ratio. *P* values are obtained using Wilson Hilferty transformation as illustrated[4].

6.1.4.2. Tipping Point Analysis

As a sensitivity analysis to the multiple imputation analysis as described in Section 6.1.4.1 for the S-IGA primary endpoint, a tipping point analysis will be performed in order to determine the inflection point at which the inference under the MNAR assumption changes substantially. This will be used to check the robustness of the imputation.

The sensitivity analysis will be performed by using a specified sequence of shift parameters, which will adjust the imputed values for observations in the active treatment group. The range of shift parameters to be included in this analysis are -1.5 to 1.5 by 0.2. Once the likely point of the shift is determined, the analysis will be rerun using an expanded range around the suspected tipping point, with greater precision (i.e., to 2 decimal places, by 0.01). Thus, the value at which the results of the analysis are shifted from significant (i.e., $\alpha \leq 0.05$) to non-significant (i.e., $\alpha > 0.05$) will be determined.

Step 1 of the analysis will be the same as for the multiple imputation analysis as described in Section 6.1.4.1. However, Step 2 of the analysis is where the shift parameters will be applied. Step 3 will be similar to the multiple imputation analysis described in Section 6.1.4.1, however, the BY statement in PROC FREQ will also include the shift parameter (i.e., `by <shift parameter> <imputation number> <shift parameter> <visit>`); this will also be included in the PROC MIANALYZE steps. Pseudo-code for Step 2 is as follows:

```
proc mi data=example_1 seed=51192215 nimpute=XX  out=example_2;
  class <treatment> <country> ;
  monotone regpmm(<baseline score> …… <visit8 score>);
  var <treatment> <country> <baseline score> …… <visit8 score>;
  mnar adjust( <visit2 score> / shift=YY adjustobs=(treatment = 'Vehicle') );
  mnar adjust( <visit4 score> / shift=YY adjustobs=(treatment = 'Vehicle') );
  mnar adjust( <visit8 score> / shift=YY adjustobs=(treatment = 'Vehicle') );
run;

XX will be the determined based on the proportion of missing data across visits.
YY will encompass the range of shift parameters as pre-specified above.
```

6.1.5. Analysis Visit Windows

Visits will be analyzed as scheduled. Unscheduled, early termination, and/or repeated measurements will only be included if a scheduled measurement is not available and the unscheduled, early termination, or repeated measurement falls within the analysis visit windows as described in Table 2. The windows follow the Schedule of Events in Table 1. Unscheduled/repeated measurements will be listed.

Table 2: Analysis Visit Windows

Visit Name	Visit Number	Target Start Day	Lower Limit	Upper Limit
Week 2	3	14	2	22
Week 4	4	28	23	42

Visit Name	Visit Number	Target Start Day	Lower Limit	Upper Limit
Week 8	5	56	43	61
Week 9	6	63	62	--

6.1.6. Pooling of Sites

Not applicable.

6.1.7. Derived Variables

- **S-IGA success** = S-IGA of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline.
- **B-IGA success** = B-IGA of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline.
- **SI-NRS 4-point reduction** = achievement of a 4-point reduction in SI-NRS pruritus score at Weeks 2, 4, and 8 compared to baseline, calculated only for subjects with an SI-NRS pruritus score of ≥ 4 at baseline.
- **WI-NRS 4-point reduction** = achievement of a 4-point reduction in WI-NRS pruritus score at Weeks 2, 4, and 8 compared to baseline, calculated only for subjects with a WI-NRS pruritus score of ≥ 4 at baseline.
- **PSSI** = (erythema score + induration + desquamation) × extent of scalp affected (range 0 to 72). Erythema, induration, and desquamation are scored on a scale of 0 to 4, where 0 = absent and 4 = severest possible; extent of scale affected is scored on a scale of 0 to 6, where 0 = 0% of involved area and 6 = 90-100% of involved area.
- **PSSI-50** = achievement of a 50% reduction in PSSI from baseline
- **PSSI-75** = achievement of a 75% reduction in PSSI from baseline
- **PSSI-90** = achievement of a 90% reduction in PSSI from baseline
- **PSSI-100** = achievement of a 100% reduction in PSSI from baseline
- **Time to PSSI-50 (days)** = date of first PSSI-50 achievement – Day 1 date + 1. Subjects not achieving PSSI-50 will be censored at day of study discontinuation or date lost to follow-up, whichever is later. Due COVID-19-related site closures, some discontinuation visits occurred much later than Week 9, so time to PSSI-50 may be after Week 9.
- **Time to PSSI-75 (days)** = date of first PSSI-75 achievement – Day 1 date + 1. Subjects not achieving PSSI-75 will be censored at day of study discontinuation or date lost to follow-up, whichever is later. Due COVID-19-related site closures, some discontinuation visits occurred much later than Week 9, so time to PSSI-75 may be after Week 9.

- **Time to PSSI-90 (days)** = date of first PSSI-90 achievement – Day 1 date + 1. Subjects not achieving PSSI-90 will be censored at day of study discontinuation or date lost to follow-up, whichever is later. Due COVID-19-related site closures, some discontinuation visits occurred much later than Week 9, so time to PSSI-90 may be after Week 9.

- **PASI** = $(0.1\times[E_h + T_h + S_h]\times A_h) + (0.2\times[E_a + T_a + S_a]\times A_a) + (0.3\times[E_t + T_t + S_t]\times A_t) + (0.4\times[E_l + T_l + S_l]\times A_l)$

  where E, T, and S are erythema, thickness, and scaling, respectively, scored on a scale of 0 to 4, A is estimated area of skin involved, graded on a scale of 0 to 6, and h, a, t, and l are head, arms, trunk, and legs, respectively (range for total score 0 to 72). If any of the component scores are missing, the PASI cannot be calculated.

- **PASI-50** = achievement of a 50% reduction in PASI from baseline

- **PASI-75** = achievement of a 75% reduction in PASI from baseline

- **PASI-90** = achievement of a 90% reduction in PASI from baseline

- **Time to PASI-50** = date of first PASI-50 achievement – Day 1 date + 1. Subjects not achieving PASI-50 will be censored at day of study discontinuation or date lost to follow-up, whichever is later. Due COVID-19-related site closures, some discontinuation visits occurred much later than Week 9, so for purposes of this calculation, the upper limit for time to PASI-50 will be capped at Day 68 (Week 9).

- **mPASI** = $(0.1\times[E_h + T_h + S_h]\times pA_h) + (0.2\times[E_a + T_a + S_a]\times pA_a) + (0.3\times[E_t + T_t + S_t]\times pA_t) + (0.4\times[E_l + T_l + S_l]\times pA_l)$

  where E, T, and S are erythema, thickness, and scaling, respectively, scored on a scale of 0 to 4, pA is estimated area of skin involved as an actual percentage (i.e., percentage in the eCRF/10) if the percent involvement is <10% OR as graded on a scale of 0 to 6, and h, a, t, and l are head, arms, trunk, and legs, respectively (range for total score 0 to 72). If any of the component scores are missing, the mPASI cannot be calculated.

- **DLQI Score** = sum of the 10 questions (individual questions scored as Very much=3, A lot=2, A little=1, Not at all=0, with Not relevant recoded to 0; Question 7: Yes=3, No=0, with Not relevant recoded to 0; range for score 0 to 30). If 1 item is missing, that item is scored as 0. If 2 or more items are missing, the score should not be calculated.

- **CDLQI Score** = sum of the 10 questions (individual questions scored as Very much=3, Quite a lot=2, Only a little=1, Not at all=0; Question 7: if the last week was school time, the question was scored as Very much=3, Quite a lot=2, Only a little=1, Not at all=0, with Prevented school recoded to 3, and if the last week was vacation, the standard responses apply; range for score 0 to 30). If 1 item is missing, that item is scored as 0. If 2 or more items are missing, the score should not be calculated.

- **PSD Total score =** sum of the 16 questions (individual questions scored 0 to 10, where higher scores indicate more severe symptoms; range for total score 0 to 160). If 1 or more items are missing, the score is not calculated.

- **Compliance** = number of applications divided by the expected number of IP applications for each subject. Compliance will be calculated using drug accountability data over the entire treatment period for each subject, up to treatment completion or discontinuation.

  - **Number of expected IP applications** = 56 for subjects who complete the study or number of days between first and last application of IP (last treatment date - first treatment date + 1) for subjects who discontinue early from the study.

  - **Number of IP applications =** number of expected IP applications – missed IP applications as collected in the electronic case report form (eCRF).

- **Weight of IP (g)** = returned can weight – dispensed can weight.

- **Body mass index (BMI) (kg/m^2)** = [weight (kg) / height (cm) / height (cm)] x 10,000.

- **BMI Categories**

  - Underweight: BMI < 18.5
  - Normal: 18.5 ≤ BMI ≤ 24.9
  - Overweight: 25.0 ≤ BMI ≤ 29.9
  - Obese: BMI ≥ 30.0

- **Change from baseline** = value at current time point – value at baseline.

- **Treatment emergent AE (TEAE)** = any AE with an onset date/time after the first application of IP.

- **PHQ-8** = sum of the 8 questions (individual questions scored as Not at all=0, Several days=1, More than half the days=2, and Nearly every day=3; range for score 0 to 24). If more than 1 item is missing, the score should not be calculated. If 1 item is missing, the score is calculated as (sum of answered items*8)/number of answered items.

- **PHQ-A** = sum of the 8 questions (individual questions scored as Not at all=0, Several days=1, More than half the days=2, and Nearly every day=3, (range for score 0 to 24). If 1 item is missing, the score should not be calculated. If 1 item is missing, the score is calculated as (sum of answered items*8)/number of answered items.

- **C-SSRS Suicidal Ideation** = A "yes" answer at any time during treatment to any 1 of the 5 suicidal ideation questions (Categories 1-5: Wish to be Dead, Nonspecific Active Suicidal Thoughts, Active Suicidal Ideation with Any Methods (Not Plan) without Intent

to Act, Active Suicidal Ideation with Some Intent to Act, without Specific Plan, and Active Suicidal Ideation with Specific Plan and Intent).

- **C-SSRS Suicidal Behavior** = A "yes" answer at any time during treatment to any 1 of the 5 suicidal behavior questions (Categories 6-10: Preparatory Acts or Behavior, Aborted Attempt, Interrupted Attempt, Actual Attempt (nonfatal), Completed Suicide).

- **C-SSRS Suicidal Ideation or Behavior** = A "yes" answer at any time during treatment to any 1 of the 10 suicidal ideation and behavior questions (Categories 1-10) on the C-SSRS.

- **Completion of Study** = Completion of the primary efficacy assessment (S-IGA) at Week 8. This may differ than what was recorded in the eCRF.

6.1.8. Data Adjustments/Handling/Conventions

All collected data will be presented in Clinical Data Interchange Standards Consortium (CDISC) datasets. Data not subject to analysis according to this plan will not appear in any tables or graphs but will be included only in the CDISC datasets.

All *P* values will be displayed in 4 decimals and rounded using standard scientific notation (e.g., 0.XXXX). If a *P* value less than 0.0001 occurs it will be shown in tables as <0.0001; similarly, if a *P* value greater than 0.9999 occurs it will be shown in tables as >0.9999.

Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 23.0 thesaurus.

A treatment-related AE is any AE with a relationship to the study drug of possibly, probably, likely, or missing.

For partial AE and medication start dates:

- If the year is unknown, then do not impute the date but assign a missing value.
- If the year is known, but the month or month and day is unknown, then:
    - If the year matches the year of first dose date and the end date (if present) is after first dose date, then impute as the month and day of the first dose date.
    - Otherwise, assign 01 January.
- If the year and month are known, but the day is unknown, then:
    - If the month and year match the month and year of the first dose date, then impute as the day of the first dose date.
    - Otherwise, assign 01.

For partial AE and medication end dates:

- If the year is unknown, then do not impute the date but assign as missing value.
- If the year is known, but the month or month and day is unknown, then:

- If the year matches the year of the last date of the study (date of last contact if subject lost to follow-up; date of completion or early termination otherwise), then impute as the month and day of the last date of the study.
- Otherwise, assign 31 December.

- If the year and month are known, but the day is unknown, then:
  - If the month and year match the month and year of the last date of the study, then impute as the day of the last date of the study.
  - Otherwise, assign the last day of the month.

These conventions will be applied to AE and medication onset dates and times with the following precaution: if the missing date and time reflect the date and time of onset of an AE, the modified date and time will be constructed to match the first documented date/time post drug administration while preserving the order in which the AE was reported in the eCRF.

In cases where variables for questionnaires were derived in the eCRF (e.g., total scores) and a derivation is indicated in Section 6.1.7, the results as derived by statistics (as opposed to the results derived in the eCRF) will be used in analysis.

6.2. Special Handling for COVID-19 Disruptions

In some cases, study visits will have to be delayed/not performed as a result of COVID-19 disruptions (e.g., sites were closed or subjects were under stay-at-home orders). Where possible, study sites may collect post-baseline data from subjects remotely by telephone, traditional mail, and/or email; this will be clearly documented in the source. If possible, sites should adhere to the protocol visit window for remote data collection.

Investigator assessments and subject questionnaires normally completed directly in the electronic patient reported outcomes (ePRO) tablet during on-site visits should be completed on the appropriate paper source documents. The following assessments/questionnaires are approved to be collected via telemedicine/remotely:

- WI-NRS/SI-NRS
- DLQI/CDLQI
- C-SSRS
- PHQ-8/PHQ-A
- Subject Local Tolerability
- PSD

The following assessments cannot be completed via telemedicine/remotely:

- S-IGA/B-IGA
- BSA
- Investigator Local Tolerability
- PASI/mPASI
- PSSI
- Subject Weight

Study visits and procedures must be followed per protocol whenever possible. Any specific changes in study conduct that deviate from the protocol should be communicated to the institutional review board and Sponsor. All protocol deviations which occurred as a result of COVID-19 disruptions (e.g., visits out of window, missed assessments, etc.) will be differentiated from other protocol deviations.

Subjects who were affected by COVID-19 disruptions by either missing their Week 8 visit or being discontinued before having a Week 8 visit due to COVID-19 related disruptions will be excluded from the mITT population, as described in Section 5.

7. Study Subjects and Demographics

7.1. Disposition of Subjects and Withdrawals

Disposition will include tabulations of the number of subjects randomized into each treatment group, the number of subjects who received treatment, subjects completing study, tabulated reasons for discontinuation from the study, including whether or not the subject did not complete the study due to COVID-19 disruption and reasons, and number of subjects in each analysis population. Disposition will be summarized for all subjects who were entered into database by treatment group and overall.

7.2. Protocol Deviations

The number of subjects with major protocol deviations and/or eligibility deviations will be summarized in categories by treatment group and overall for subjects in Safety population.

7.3. Demographics and Other Baseline Characteristics

Summary statistics for age, age category (12-17, ≥18), gender (including child-bearing potential), race, ethnicity, height, weight, percent BSA, BMI, and baseline disease characteristics (S-IGA, B-IGA, PSSI, SI-NRS, PSD total score, PASI, mPASI, WI-NRS, DLQI, and CDLQI) will be presented by treatment group and overall.

A summary of treatment history, including history of response, intolerance, or contraindication to topical corticosteroids and/or topical vitamin D derivatives, and psoriasis involvement on knees and/or elbows and genitalia will be provided.

For the continuous variables, the number of nonmissing values and the mean, SD, minimum, median and maximum will be tabulated.

For ordinal variables such as the S-IGA, B-IGA, SI-NRS, and WI-NRS, summary statistics including the mean, median, and range of the ordinal variable will be presented, as well as frequency counts of each level of the ordinal variable.

For the categorical variables, the counts and proportions of each value will be tabulated.

These analyses will be conducted for the ITT, mITT, and Safety populations, except for treatment history summary, which will only be summarized on the Safety population.

7.4. Exposure and Compliance

The number of IP applications by each subject based on diary data will be summarized using descriptive statistics appropriate for continuous variables.

The amount of IP each subject used based on can weight will be summarized descriptively by treatment group using continuous methods.

A subject will be considered compliant with the dosing regimen if the subject applies at least 80% of the expected applications during the IP application period and does not miss more than 3 consecutive doses.

Investigational product application compliance will be calculated based on number of applications divided by the expected number of IP applications. Compliance will be summarized descriptively by treatment group using the following categories:

>100%

≥80% - ≤100%

<80%

8. Efficacy Analysis

The order of testing for the primary and secondary endpoints is discussed in Section 6.1.3. Exploratory endpoints are not included in the testing strategy.

8.1. Primary Efficacy Analysis

8.1.1. Scalp Investigator Global Assessment (S-IGA)

The S-IGA is an ordinal scale with 5 severity grades which is reported only in integers. Table 3 illustrates the description of each severity grade.

Table 3: S-IGA

Score	Grade	Description
0	Clear	Plaque thickening = no elevation or thickening over normal skin Scaling = no evidence of scaling Erythema = none (no residual red coloration but post-inflammatory hyperpigmentation may be present)
1	Almost Clear	Plaque thickening = none or possible thickening but difficult to ascertain if there is a slight elevation above normal skin level Scaling = none or residual surface drying and scaling Erythema = light pink coloration
2	Mild	Plaque thickening = slight but definite elevation Scaling = fine scales partially or mostly covering the lesions Erythema = light red coloration

Score	Grade	Description
3	Moderate	Plaque thickening = moderate elevation with rounded or sloped edges Scaling = most lesions at least partially covered Erythema = definite red coloration
4	Severe	Plaque thickening = marked or very marked elevation typically with hard or sharp edges Scaling = non-tenacious or thick tenacious scale, covering most or all of lesions Erythema = very bright red coloration; extreme red coloration; deep red coloration

For this study, the primary estimand is the odds of achieving S-IGA success at 8 weeks; that is, the ratio of the odds of achieving S-IGA success at 8 weeks roflumilast foam 0.3% relative to the odds of success at 8 weeks of using a matching vehicle cream. In the course of the 8-week randomized treatment period, subjects may be exposed to possible known or unknown intercurrent events that could possibly impact the estimand, such as treatment discontinuation due to a specific adverse effect or perhaps a lack of effect. The "Treatment Policy Strategy" has been adopted for handling all known or unknown intercurrent events in this study. To this end, the ITT principle will serve as the analytical basis for interpreting the estimand. In other words, the odds ratio of achieving S-IGA success for roflumilast foam 0.3% relative to vehicle at 8 weeks will be evaluated regardless of the occurrence of any such intercurrent event. This estimand shall be estimated using the CMH approach. This approach produces an estimate that is the combined odds ratio resulting from adjusting for the possible effects of 3 classification factors: country, baseline S-IGA category (2 vs. ≥3) and baseline B-IGA category (2 vs. ≥3).

Categorical Data Analysis

The primary efficacy endpoint is success in S-IGA of disease severity, defined as an S-IGA of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline at Week 8.

The primary endpoint will be analyzed using a CMH test stratified by country, baseline S-IGA category, and baseline B-IGA category. Statistical significance will be concluded at the 5% significance level (2-sided) or less, as discussed in Section 6.1.3. Odds ratios and 95% CIs for the odds ratios will be provided. Additionally, the 95% Wilson CIs for proportion of successes in each treatment group will be presented.

For the primary analysis, missing S-IGA scores will be imputed using multiple imputation as described in Section 6.1.4.1. These imputations will result in a minimum of 25 to a maximum of 250 complete analysis datasets, depending on the number of imputed monotone datasets required. The CMH analyses will be performed separately for each of the complete analysis data sets, and the results will be combined into one multiple imputation inference (estimated treatment effect and associated CI and *P* value). As a sensitivity analysis, the above described CMH test will be performed on the nonimputed data.

Sensitivity analyses of the primary endpoint will also be performed using the original (nonimputed) dataset. These will include a repeated measures logistic regression model (GEE) with S-IGA success as the dependent variable and treatment, country, visit, and baseline S-IGA score as the independent variables.

Achievement of a score of clear will also be analyzed using the CMH test, on nonimputed data.

A tipping point analysis will be performed as described in Section 6.1.4.2. For the tipping point analysis, a figure will be provided that displays the *P* values in the analysis plotted against the range of shift parameters; included in this figure will be the shift parameters and *P* values for the range of shift parameters to provide information on where the analysis tips from significant to non-significant.

Subgroup Analyses – Observed Data

For the primary endpoint of IGA success (S-IGA of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline at Week 8), the CMH analysis will be performed on the following subgroups, using observed data:

- Topical Corticosteroids – Naïve Subjects
- Topical Vitamin D Derivatives – Naïve Subjects
- Psoriasis involvement on the knee and/or elbow
- Subjects who achieved both S-IGA and B-IGA success at Week 8
- By Study Site

Subgroup Analyses – Multiple Imputation Data

For the primary endpoint of IGA success (S-IGA of "Clear" or "Almost Clear" plus a 2-grade improvement from baseline at Week 8), the CMH analysis will be performed on the following subgroups, using multiple imputation data:

- Baseline S-IGA = 3
- Baseline S-IGA = 4
- Age Category = 12-17 years
- Age Category = ≥18 years
- Subjects who achieved both S-IGA and B-IGA success at Week 8

Continuous Data Analysis

Analysis of change from baseline in S-IGA scores at Weeks 2, 4, 8, and 9 will be performed using descriptive summaries (mean, median, inter-quartile range) by treatment group and study visit. These descriptive statistics will also be presented based on the multiple imputation data.

All Analyses

All other missing data for all other analyses and summaries will remain missing and will not be imputed. All weeks will be included in these analyses, although only Week 8 using the ITT population will be included in the testing strategy.

The primary efficacy analysis will be based on ITT population, and all of the above analyses will be repeated for the mITT population.

8.2. Secondary Efficacy Analysis

All secondary efficacy analyses will be performed using the ITT and mITT populations, unless otherwise specified.

8.2.1. Body Investigator Global Assessment (B-IGA)

The scale, grade, and description for the B-IGA is identical to the S-IGA, as discussed in Section 8.1.

Achievement of a B-IGA score of "clear" or "almost clear" PLUS a 2-grade improvement from baseline at Weeks 2, 4, 8, and 9 will be analyzed similar to the primary efficacy endpoint using CMH test stratified by country, baseline S-IGA category, and baseline B-IGA category, with the exception that missing data will not be replaced (i.e., observed data). Odds ratios and 95% CIs of the odds ratios will be provided. Additionally, the 95% Wilson CIs for proportion of successes in each treatment group will be presented. In addition, the number and percentage of subjects in each category will be summarized by treatment and visit. Only the Week 8 results using the ITT population will be included in the testing strategy.

Analysis of change from baseline in B-IGA scores at Weeks 2, 4, 8, and 9 will be performed using descriptive summaries (mean, median, inter-quartile range) by treatment group and study visit.

8.2.2. Psoriasis Scalp Severity Index (PSSI)

The PSSI is used to measure the severity of psoriasis, combining the assessment of the severity of scalp lesions and the area of scalp affected into a single score ranging from 0 (no disease) to 72 (maximal disease). The PSSI score will be analyzed as follows:

- Change and percent change from baseline to Weeks 2, 4, 8, and 9 in the PSSI will be analyzed using descriptive summaries and an analysis of covariance (ANCOVA) with terms for country, baseline S-IGA category, and baseline B-IGA category, and baseline PSSI score as a covariate. Statistical comparisons between the treatment groups will be obtained using contrasts. The least-squares (LS) means, standard errors, 95% CIs, and *P* values will be presented.
- Frequencies and percentages of subjects achieving PSSI-50, PSSI-75, PSSI-90, and PSSI-100 will be presented by study week and treatment group. Additionally, these endpoints will be analyzed similar to the primary efficacy endpoint using a CMH test stratified by country, baseline S-IGA category, and baseline B-IGA category, on observed data. Only the PSSI-75 and PSSI-90 at Week 8 using the ITT population will be included in the testing strategy. Odds ratios and 95% CIs of the odds ratios will be provided. Additionally, the 95% Wilson CIs for proportion of successes in each treatment group will be presented.
- Time to achieving PSSI-50, PSSI-75, and PSSI-90 will be summarized using Kaplan-Meier methods and the difference between treatment groups evaluated using the log-rank statistic, and 95% CIs of the median for each treatment group will be presented. In addition, a Cox proportional hazards model that includes the stratification factors will be run and the hazard ratio and associated 95% Wald CIs will be presented. Time to achieving PSSI-50 using the ITT population will also be included in the testing strategy. Time to achieving PSSI-75 or PSSI-90 using the ITT population will not be included in the testing strategy, but will be considered as a supportive analysis.

8.2.3. Scalp Itch – Numeric Rating Scale (SI-NRS)

The SI-NRS scale ranges from 0 to 10 with 0 being "no scalp itch" and 10 equaling "worst scalp itch imaginable." This will be determined by asking the subject's assessment of worst scalp itch over the past 24 hours. The SI-NRS will be analyzed as follows:

- Change and percent change from baseline to Weeks 2, 4, and 8 in SI-NRS will be analyzed using descriptive summaries and an ANCOVA with terms for country, baseline S-IGA category, and baseline B-IGA category, and baseline SI-NRS score as a covariate. Statistical comparisons between the treatment groups will be obtained using contrasts. The LS means, standard errors, 95% CIs, and *P* values will be presented.
- In subjects with a baseline SI-NRS score ≥4, achievement of a ≥4-point improvement from baseline in SI-NRS score at Weeks 2, 4, and 8 will be analyzed using CMH tests stratified by country, baseline S-IGA category, and baseline B-IGA similar to the primary analysis above, with the exception that missing data will not be replaced. Odds ratios and 95% CIs of the odds ratios will be provided. Additionally, the 95% Wilson CIs for proportion of successes in each treatment group will be presented. This will be summarized using SPRU-ITT and SPRU-mITT populations.

8.2.4. Psoriasis Symptoms Diary (PSD)

The PSD assesses the severity of symptoms or how bothersome are the symptoms of psoriasis. The PSD will be analyzed as follows:

- Change and percent change from baseline to Weeks 2, 4, and 8 in the PSD individual item and total scores will be analyzed using descriptive statistics and an ANCOVA (total score only) with terms for country, baseline S-IGA category, and baseline B-IGA category, and baseline PSD score as a covariate. Statistical comparisons between the treatment groups will be obtained using contrasts. The LS means, standard errors, 95% CIs, and *P* values will be presented. Only change from baseline in PSD total score at Weeks 4 and 8 using the ITT population will be included in the testing strategy.

8.3. Exploratory Efficacy Analysis

Exploratory efficacy analysis will be performed for subjects belonging to ITT and mITT populations.

The exploratory endpoints include:

- Achievement of success in PASI-90, PASI-75, and PASI-50 at Weeks 2, 4, 8, and 9
- Time to success in PASI-50
- Change and percent change from baseline in PASI/mPASI at Weeks 2, 4, 8, and 9
- Change and percent change from baseline in WI-NRS at Weeks 2, 4, and 8
- For subjects with baseline WI-NRS score ≥4, achievement of ≥4-point improvement from baseline in WI-NRS at Weeks 2, 4, and 8 (summarized on the PRU4-ITT and PRU4-mITT populations)

- Change and percent change from baseline in DLQI/CDLQI total scores at Weeks 2, 4, and 8
- Change and percent change from baseline in % BSA affected by disease at Weeks 2, 4, 8, and 9

Time to success in PASI-50 and change and percent change from baseline for all relevant exploratory endpoints will be summarized descriptively; additionally, all endpoints will be analyzed using an ANCOVA with terms for country, baseline S-IGA category, and baseline B-IGA category, and baseline assessment score as a covariate. Statistical comparisons between the treatment groups will be obtained using contrasts. The LS means, standard errors, 95% CIs, and *P* values will be presented. Achievement of success in PASI-50, PASI-75, and PASI-90; achievement of success in mPASI-50, mPASI-75, and mPASI-90; and improvement in WI-NRS will be presented using proportions. Odds ratios and 95% CIs of the odds ratios will be provided. Additionally, the 95% Wilson CIs for proportion of successes in each treatment group will be presented.

For efficacy analysis purposes, the data that is collected by the ePRO will be used for % BSA affected by disease summarization.

9. Safety and Tolerability Analysis

Safety will be evaluated from reported AEs, physical examinations, local tolerability assessments, changes in clinical laboratory values, changes in vital signs/weight, C-SSRS, PHQ-8, and modified PHQ-A results. No inferential statistical tests will be performed.

All safety analyses will be performed on the Safety population.

9.1. Adverse Events

All AEs, TEAEs, and SAEs will be coded using the MedDRA dictionary version 23.0.

A TEAE is defined as an AE that started post application of IP at the Baseline visit through study completion. An overall summary of TEAEs will be provided; this will present number and percent of subjects who reported at least 1 of the following: TEAE (including all TEAEs, TEAEs by maximum severity, and TEAEs by greatest relationship), SAE, discontinued the study due to a TEAE, or a TEAE resulting in death.

The number and percent of subjects reporting TEAEs, grouped by MedDRA system organ class (SOC) and preferred term, will be tabulated by severity or greatest relationship to study IP and treatment group. In the case of multiple occurrences of the same TEAE within the same subject, each subject will only be counted once for each preferred term. Additionally, the number and percent of subjects reporting related TEAEs will be summarized by MedDRA preferred term and treatment group.

In the summaries showing severity and relationship to study medication the event with the maximum severity (mild < moderate < severe) or strongest relationship (not related < related) will be reported. If a particular event is missing the severity and/or relationship, then the strongest possible severity or relationship will be assumed for analysis (severity = severe, relationship = likely).

In the AE data listings, all AEs will be displayed. Any AEs that are treatment emergent will be flagged.

9.1.1. Adverse Events Leading to Withdrawal

A summary of incidence rates (frequencies and percentages) of TEAEs leading to withdrawal of study drug by treatment group, SOC, and preferred term will be prepared for the Safety population. Additionally, this table will be repeated for TEAEs leading to withdrawal from the study. No inferential statistical tests will be performed.

A data listing of AEs leading to withdrawal of study drug will also be provided, displaying details of the event(s) captured on the eCRF.

9.1.2. Deaths and Serious Adverse Events

Any deaths that occur during the study will be listed.

Serious adverse events (SAEs) will be listed and tabulated by SOC and preferred term and presented by treatment group, severity, and relationship to study treatment.

9.2. Local Tolerability Assessments

The investigator's assessment of the application site reaction will be summarized by study visit using both categorical methods (number and percentage of subjects with each score) as well as continuous methods (e.g., mean, median). Categorical summaries will be provided for dermal response as well as other effects. No inferential statistical tests will be performed.

The subject's assessment of the application site reaction will be summarized similarly.

9.3. Clinical Laboratory Evaluations

Laboratory test results will be summarized descriptively by treatment and study visit as both observed values and change from baseline values for continuous hematology, chemistry, and urinalysis results. Categorical urinalysis results will be summarized using frequencies by study visit and treatment.

The number of subjects with clinical laboratory values below, within, or above the normal range by study visit and in relation to baseline will be tabulated for each clinical laboratory analyte by treatment group (shift table).

Abnormal results will be flagged in the listings. In addition, pregnancy test results and hormonal laboratory results will be listed.

9.4. Vital Signs

Descriptive summaries of observed values and changes from baseline will be calculated for systolic blood pressure, diastolic blood pressure, heart rate, height, weight, BMI, and oral body temperature by treatment group and visit.

The number of subjects who gain or lose ≥5% of their baseline body weight during the course of the study, as well as subjects who gain or lose ≥10% of their baseline body weight over the course of the study, will be summarized by treatment group. This summary will be repeated by intentionality of weight loss (intentional or unintentional, as captured on the eCRF).

Shift tables for subjects who shift from their baseline BMI category as defined in Section 6.1.7 (underweight, normal, overweight, obese) to a different BMI category throughout the course of the study will be provided by treatment group and visit. This summary will be repeated by intentionality of weight loss (intentional or unintentional, as captured on the eCRF).

9.5. PHQ-8 and Modified PHQ-A

Data for PHQ-8 and modified PHQ-A will be classified using each subject's total score at a time point into a category based on the following scoring system:

- None – Minimal depression (0 to 4)
- Mild depression (5 to 9)
- Moderate depression (10 to 14)
- Moderately severe depression (15 to 19)
- Severe depression (20 to 24)

Shift tables showing the category of severity at each visit by treatment group will be presented.

9.6. C-SSRS

The C-SSRS is a questionnaire that prospectively assesses Suicidal Ideation and Suicidal Behavior. At the Screening study visit, "Baseline/Screening" version of the C-SSRS will be used. This version assesses Suicidal Ideation and Suicidal Behavior during the subject's lifetime and during the past 6 months. For the Screening visit, "lifetime" experience of the subject with Suicidal Ideation and Suicidal Behavior will be summarized. From Baseline visit, the "Since Last Visit" version will be used.

Suicidality data collected on the C-SSRS will be listed for all subjects. Tables will include results from the Suicidal Ideation and Suicidal Behavior sections of the C-SSRS. Frequencies and percentages of subjects with a response of "Yes" at any point on the Suicidal Ideation and Suicidal Behavior items will be summarized by study visit and treatment group.

9.7. Physical Examination

The number and percentage of subjects with normal and abnormal findings in the physical examination will be displayed at each study visit and treatment group.

9.8. Concomitant Medication

Prior and concomitant medications will be summarized descriptively by treatment, Anatomical Therapeutic Chemical (ATC) Class Level 4, and Preferred Term using counts and percentages.

Prior medications will be presented separately from concomitant medications. Medications that started before the first application of IP will be considered prior medications whether or not they were stopped prior to the first application of study drug. Any medications continuing or starting after the first application of study drug will be considered to be concomitant. If a medication starts before the first application of study drug and continues after the first application of study drug it will be considered both prior and concomitant.

Medications will be coded using World Health Organization (WHO) Drug Global B3, version September 2019.

10. Changes from Planned Analysis

The following analysis populations have been added:

- The mITT population has been added to handle situations where a subject was unable to attend the Week 8 visit or discontinued from the study before the Week 8 visit due to COVID-19 disruptions;
- The SPRU4-ITT and SPRU4-mITT populations have been added to facilitate SI-NRS analysis on the ITT and mITT populations, respectively; and
- The PRU4-ITT and PRU4-mITT populations have been added to facilitate WI-NRS analysis on the ITT and mITT populations, respectively.

These populations are not included in the protocol.

The PP population and associated analyses have been removed at the request of the Sponsor, as they were considered to be uninformative.

Additional exploratory endpoints have been added in the SAP which are not specified in the protocol. They are:

- Change and percent change from baseline in SI-NRS at Weeks 2, 4, and 8
- Change and percent change from baseline in PASI at Weeks 2, 4, 8, and 9
- Change and percent change from baseline in WI-NRS at Weeks 2, 4, and 8

Additionally, odds ratios and 95% CIs of odds ratios for comparisons between treatment groups, and 95% Wilson CIs for proportion of successes in each treatment group for binary outcomes will be provided.

Additional efficacy analyses have been added in the SAP which are not specified in the protocol, as requested by the Sponsor. They are:

- Analysis of S-IGA success based on the following subgroups (both ITT and mITT populations, observed data only):
    - Topical corticosteroids – naïve subjects
    - Topical vitamin D derivatives – naïve subjects
    - Subjects with psoriasis involvement on the knee and/or elbow
    - Subjects who achieved S-IGA and B-IGA success at Week 8
    - By study site
- Analysis of S-IGA score of clear (included in the fixed-sequence testing strategy)
- Analysis of S-IGA success based on the following subgroups (both ITT and mITT

populations, multiple imputation data only):
  - Baseline S-IGA = 3
  - Baseline S-IGA = 4
  - Age Category: 12-17 years
  - Age Category: ≥18 years
  - Subjects who achieved S-IGA and B-IGA success at Week 8
- Achievement of success in PSSI-100
- Time to achievement of PSSI-75 and PSSI-90
- Achievement of success in mPASI-50, mPASI-75, and mPASI-90

Additional safety analyses have been added in the SAP which are not specified in the protocol, as requested by the Sponsor. They are:

- Incidence of TEAEs leading to study discontinuation by SOC and preferred term
- Incidence of related TEAEs by preferred term
- Summarization of weight loss categories by intentionality of weight lose
- Shift tables for BMI categories

11. Other Planned Analysis

11.1. Pharmacokinetic Analysis

All PK collection information from the eCRF will be presented in a listing. Concentration data and PK parameters will be summarized by timepoint (concentrations data) and treatment group using summary statistics. In addition, PK concentration and parameter listings will be presented.

12. References

1. US Federal Register. (1998) International Conference on Harmonization; Guidance on Statistical Principles for Clinical Trials. Department of Health and Human Services: Food and Drug Administration [Docket No. 97D-0174]. Federal Register Volume 63, Number 179, pages 49583-49598. September 16, 1998.
2. ASA. (2016) Ethical Guidelines for Statistical Practice. Prepared by the Committee on Professional Ethics, April 2016. http://www.amstat.org/about/ethicalguidelines.cfm
3. RSS. (2014) The Royal Statistical Society: Code of Conduct, 2014. http://www.rss.org.uk/Images/PDF/join-us/RSS-Code-of-Conduct-2014.pdf.
4. Ratitch, B., Lipkovich, I., & O'Kelly, M. (2013). *Combining Analysis Results from Multiply Imputed Categorical Data*. PharmaSUG. https://www.pharmasug.org/proceedings/2013/SP/PharmaSUG-2013-SP03.pdf

13. Tables, Listings, and Figures

All TLFs will have a header showing the sponsor company name and protocol and a footer showing the version of SAS, the file name and path, and the source of the data (e.g., listing number).

13.1. Planned Table Descriptions

The following are planned summary tables for protocol number ARQ-154-204. The table numbers and page numbers are place holders only and will be determined when the tables are produced.

13.1.1. Demographic Data

Table 4: Demographic Data Summary Tables

Number	Population	Title
Table 14.1.1	All Randomized	Summary of Subject Disposition
Table 14.1.2.1	Safety	Summary of Demographics and Baseline Characteristics
Table 14.1.2.2	ITT	Summary of Demographics and Baseline Characteristics
Table 14.1.2.3	mITT	Summary of Demographics and Baseline Characteristics
Table 14.1.3	Safety	Previous Treatment History of Scalp and Body Psoriasis
Table 14.1.4	Safety	Summary of Protocol Deviations
Table 14.1.5	Safety	Summary of Prior Medications by ATC Class Level 4 and Preferred Term
Table 14.1.6	Safety	Summary of Study Drug Exposure and Compliance

13.1.2. Efficacy Data

Table 5: Efficacy Data Summary Tables

Number	Population	Title
Table 14.2.1.1	ITT	Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Observed Data
Table 14.2.1.2	mITT	Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Observed Data
Table 14.2.1.3	ITT	Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Multiple Imputation
Table 14.2.1.4	mITT	Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Multiple Imputation

Number	Population	Title
Table 14.2.1.5.1	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results
Table 14.2.1.5.2	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Topical Corticosteroids – Naïve Subjects
Table 14.2.1.5.3	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Topical Vitamin D Derivatives – Naïve Subjects
Table 14.2.1.5.4	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Subjects with Psoriasis Involvement on the Knee and/or Elbow
Table 14.2.1.5.5	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Subjects who Achieved S-IGA and B-IGA Success at Week 8
Table 14.2.1.5.6	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit and Study Site – Observed Data Categorical Results
Table 14.2.1.6.1	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results
Table 14.2.1.6.2	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Topical Corticosteroids – Naïve Subjects
Table 14.2.1.6.3	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Topical Vitamin D Derivatives – Naïve Subjects
Table 14.2.1.6.4	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Subjects with Psoriasis Involvement on the Knee and/or Elbow

Number	Population	Title
Table 14.2.1.6.5	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Categorical Results Subjects who Achieved S-IGA and B-IGA Success at Week 8
Table 14.2.1.6.6	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit and Study Site – Observed Data Categorical Results
Table 14.2.1.7.1	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results
Table 14.2.1.7.2	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Baseline S-IGA = 3
Table 14.2.1.7.3	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Baseline S-IGA = 4
Table 14.2.1.7.4	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Age Category = 12-17 Years
Table 14.2.1.7.5	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Age Category = ≥18 Years
Table 14.2.1.7.6	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Subjects who Achieved S-IGA and B-IGA Success at Week 8
Table 14.2.1.8.1	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results
Table 14.2.1.8.2	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Baseline S-IGA = 3

Number	Population	Title
Table 14.2.1.8.3	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Baseline S-IGA = 4
Table 14.2.1.8.4	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Age Category = 12-17 Years
Table 14.2.1.8.5	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Age Category = ≥18 Years
Table 14.2.1.8.6	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation Categorical Results Subjects who Achieved S-IGA and B-IGA Success at Week 8
Table 14.2.1.9	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Tabulation of Fitted Point Estimates from Generalized Estimating Equations for Binary Response
Table 14.2.1.10	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data Tabulation of Fitted Point Estimates from Generalized Estimating Equations for Binary Response
Table 14.2.1.11	ITT	Summary of Scalp Investigator Global Assessment (S-IGA) – Score of Clear – Observed Data
Table 14.2.1.12	mITT	Summary of Scalp Investigator Global Assessment (S-IGA) – Score of Clear – Observed Data
Figure 14.2.1.11	ITT	Plot of Scalp Investigator Global Assessment (S-IGA) Tipping Point Analysis P Values vs Shift Parameters
Figure 14.2.1.12	mITT	Plot of Scalp Investigator Global Assessment (S-IGA) Tipping Point Analysis P Values vs Shift Parameters
Table 14.2.2.1	ITT	Summary and Change from Baseline in Body Investigator Global Assessment (B-IGA) Grades by Study Visit
Table 14.2.2.2	mITT	Summary and Change from Baseline in Body Investigator Global Assessment (B-IGA) Grades by Study Visit
Table 14.2.2.3	ITT	Summary of Body Investigator Global Assessment (B-IGA) Grades and Success by Study Visit Categorical Results

Number	Population	Title
Table 14.2.2.4	mITT	Summary of Body Investigator Global Assessment (B-IGA) Grades and Success by Study Visit Categorical Results
Table 14.2.3.1	ITT	Summary and Change from Baseline in PSSI Scores by Study Visit
Table 14.2.3.2	mITT	Summary and Change from Baseline in PSSI Scores by Study Visit
Table 14.2.3.3	ITT	Summary of Achievement of PSSI-50, PSSI-75, PSSI-90, and PSSI-100 by Study Visit
Table 14.2.3.4	mITT	Summary of Achievement of PSSI-50, PSSI-75, PSSI-90, and PSSI-100 by Study Visit
Table 14.2.3.5	ITT	Time to Achievement of PSSI-50, PSSI-75, and PSSI-90
Table 14.2.3.6	mITT	Time to Achievement of PSSI-50, PSSI-75, and PSSI-90
Table 14.2.3.7	ITT	Summary of PSSI Scores by Study Visit – ANCOVA
Table 14.2.3.8	mITT	Summary of PSSI Scores by Study Visit – ANCOVA
Table 14.2.4.1	ITT	Summary and Change from Baseline in Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit
Table 14.2.4.2	mITT	Summary and Change from Baseline in Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit
Table 14.2.4.3	SPRU4-ITT	Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score Success by Study Visit
Table 14.2.4.4	SPRU4-mITT	Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score Success by Study Visit
Table 14.2.4.5	ITT	Summary of Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit – ANCOVA
Table 14.2.4.6	mITT	Summary of Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit – ANCOVA
Table 14.2.5.1	ITT	Summary and Change from Baseline in Psoriasis Symptom Diary (PSD) Total and Individual Item Scores by Study Visit
Table 14.2.5.2	mITT	Summary and Change from Baseline in Psoriasis Symptom Diary (PSD) Total and Individual Item Scores by Study Visit
Table 14.2.5.3	ITT	Summary of Psoriasis Symptom Diary (PSD) Total Scores by Study Visit – ANCOVA
Table 14.2.5.4	mITT	Summary of Psoriasis Symptom Diary (PSD) Total Scores by Study Visit – ANCOVA
Table 14.2.6.1	ITT	Summary and Change from Baseline in PASI/mPASI by Study Visit
Table 14.2.6.2	mITT	Summary and Change from Baseline in PASI/mPASI by Study Visit
Table 14.2.6.3	ITT	Summary of PASI/mPASI by Study Visit – ANCOVA
Table 14.2.6.4	mITT	Summary of PASI/mPASI by Study Visit – ANCOVA

Number	Population	Title
Table 14.2.6.5	ITT	Summary of Achievement of PASI-50, PASI-75, and PASI-90 by Study Visit
Table 14.2.6.6	mITT	Summary of Achievement of PASI-50, PASI-75, and PASI-90 by Study Visit
Table 14.2.6.7	ITT	Time to Achievement of PASI-50
Table 14.2.6.8	mITT	Time to Achievement of PASI-50
Table 14.2.6.9	ITT	Summary of Achievement of mPASI-50, mPASI-75, and mPASI-90 by Study Visit
Table 14.2.6.10	mITT	Summary of Achievement of mPASI-50, mPASI-75, and mPASI-90 by Study Visit
Table 14.2.7.1	ITT	Summary and Change from Baseline in Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit
Table 14.2.7.2	mITT	Summary and Change from Baseline in Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit
Table 14.2.7.3	ITT	Summary of Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit – ANCOVA
Table 14.2.7.4	mITT	Summary of Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit – ANCOVA
Table 14.2.7.5	PRU4-ITT	Worst Itch – Numeric Rating Scale (WI-NRS) Pruritus Score Success by Study Visit
Table 14.2.7.6	PRU4-mITT	Worst Itch – Numeric Rating Scale (WI-NRS) Pruritus Score Success by Study Visit
Table 14.2.8.1	ITT	Summary and Change from Baseline in Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit
Table 14.2.8.2	mITT	Summary and Change from Baseline in Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit
Table 14.2.8.3	ITT	Summary of Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit – ANCOVA
Table 14.2.8.4	mITT	Summary of Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit – ANCOVA
Table 14.2.9.1	ITT	Summary and Change from Baseline in % Body Surface Area (BSA) Affected by Disease by Study Visit
Table 14.2.9.2	mITT	Summary and Change from Baseline in % Body Surface Area (BSA) Affected by Disease by Study Visit
Table 14.2.9.3	ITT	Summary of % Body Surface Area (BSA) Affected by Disease by Study Visit – ANCOVA
Table 14.2.9.4	mITT	Summary of % Body Surface Area (BSA) Affected by Disease by Study Visit – ANCOVA

13.1.3. Safety Data

Table 6: Safety Data Summary Tables

Number	Population	Title
14.3.1 Displays of Adverse Events		
Table 14.3.1.1	Safety	Summary of Treatment Emergent Adverse Events
Table 14.3.1.2	Safety	Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Table 14.3.1.3	Safety	Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity
Table 14.3.1.4	Safety	Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Relationship to Study Drug
Table 14.3.1.5	Safety	Incidence of Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term
Table 14.3.1.6	Safety	Incidence of Treatment Emergent Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term
Table 14.3.1.7	Safety	Incidence of Related Treatment Emergent Adverse Events by Preferred Term
14.3.2 Summary of Deaths, Other Serious and Significant Adverse Events		
Table 14.3.2.1	Safety	Incidence of Serious Adverse Events by System Organ Class and Preferred Term
Table 14.3.2.2	Safety	Incidence of Serious Adverse Events by System Organ Class, Preferred Term, and Relationship to Study Drug
Table 14.3.2.3	Safety	Incidence of Serious Adverse Events by System Organ Class, Preferred Term, and Maximum Severity
14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events		
Table 14.3.3.1	Safety	Listing of Adverse Events Leading to Study Drug Discontinuation
Table 14.3.3.2	Safety	Listing of Serious Adverse Events
Table 14.3.3.3	Safety	Listing of Deaths
14.3.4 Abnormal Laboratory Value		
NA		
14.3.5 Laboratory Data Summary Tables		
Table 14.3.5.1.1	Safety	Summary of Serum Chemistry Laboratory Results by Study Visit
Table 14.3.5.1.2	Safety	Shift from Baseline in Clinical Chemistry Laboratory Results by Study Visit
Table 14.3.5.2.1	Safety	Summary of Hematology Laboratory Results by Study Visit
Table 14.3.5.2.2	Safety	Shift from Baseline in Hematology Laboratory Results by Study Visit

Number	Population	Title
Table 14.3.5.3.1	Safety	Summary of Quantitative Urinalysis Laboratory Results by Study Visit
Table 14.3.5.3.2	Safety	Shift from Baseline in Quantitative and Qualitative Urinalysis Laboratory Results by Study Visit
Table 14.3.5.3.3	Safety	Summary of Qualitative Urinalysis Laboratory Results by Study Visit
14.3.6 Other Safety Data Summary Tables		
Table 14.3.6.1	Safety	Shift from Baseline in Patient Health Questionnaire (PHQ-8)/Modified PHQ-Adolescents by Study Visit
Table 14.3.6.2.1	Safety	Summary of Investigator Local Tolerability Assessment by Study Visit
Table 14.3.6.2.2	Safety	Summary of Investigator Local Tolerability Assessment (Dermal Response) by Study Visit Categorical Results
Table 14.3.6.2.3	Safety	Summary of Investigator Local Tolerability Assessment (Other Effects) by Study Visit Categorical Results
Table 14.3.6.3.1	Safety	Summary of Subject Local Tolerability Assessment by Study Visit
Table 14.3.6.3.2	Safety	Summary of Subject Local Tolerability Assessment by Study Visit Categorical Results
Table 14.3.6.4.1	Safety	Summary of Vital Signs by Study Visit
Table 14.3.6.4.2	Safety	Shift from Baseline in Weight by Study Visit
Table 14.3.6.4.3	Safety	Shift from Baseline in Weight by Study Visit and Weight Loss Intentional/Non-Intentional Categories
Table 14.3.6.4.4	Safety	Shift from Baseline in BMI Categories by Study Visit
Table 14.3.6.4.5	Safety	Shift from Baseline in BMI Categories by Study Visit and Weight Loss Intentional/Non-Intentional Categories
Table 14.3.6.5	Safety	Summary of Columbia-Suicide Severity Rating Scale (C-SSRS) Suicidal Ideation and Suicidal Behavior by Study Visit
Table 14.3.6.6	Safety	Summary of Physical Examination by Study Visit
Table 14.3.6.7	Safety	Summary of Concomitant Medications by ATC Class Level 4 and Preferred Term
14.4 Pharmacokinetic and Pharmacodynamic Summary Tables		
14.4.1.1	PK	Summary of Pharmacokinetic Results by Study Visit and Time Point
14.4.1.2	PK	Summary of Pharmacokinetic Parameters by Study Visit

13.2. Planned Listing Descriptions

The following are planned data and patient/subject data listings for protocol number ARQ-154-204.

In general, one listing will be produced per eCRF domain. All listings will be sorted by treatment, site, and subject number. All calculated variables will be included in the listings. Screen failures will only be presented in Listing 16.2.2.1.

In all listings a blank line will be placed between each subject. Within a data listing, if an item appears line after line (e.g., repetition of subject number), then only the first occurrence will be displayed.

In data listings, the information for one subject will be kept on one page if at all possible, rather than splitting a subject's information across pages.

Table 7: Planned Listings

Number	Population	Title
16.2.1 Subject Discontinuations/Completions		
Listing 16.2.1.1	All Subjects	Subject Disposition
Listing 16.2.1.2	All Subjects	Subject Visits
16.2.2 Protocol Deviations		
Listing 16.2.2.1	All Subjects	Inclusion and Exclusion Criteria Not Met
Listing 16.2.2.2	All Subjects	Protocol Deviations
16.2.3 Subjects Excluded from the Efficacy Analyses		
Listing 16.2.3.1	All Subjects	Subject Randomization
Listing 16.2.3.2	All Subjects	Analysis Populations
16.2.4 Demographic Data and Other Baseline Characteristics		
Listing 16.2.4.1.1	All Subjects	Subject Demographics
Listing 16.2.4.1.2	All Subjects	Baseline Characteristics
Listing 16.2.4.2	All Subjects	Medical History
16.2.5 Compliance and/or Drug Concentration Data		
Listing 16.2.5.1	All Subjects	Study Drug Application at the Study Site
Listing 16.2.5.2	All Subjects	Cans
Listing 16.2.5.3	All Subjects	Diary Dispensation
Listing 16.2.5.4	All Subjects	Compliance (CRF)
Listing 16.2.5.5	All Subjects	Missed Doses
Listing 16.2.5.6	PK	Pharmacokinetic Blood Collection
Listing 16.2.5.7	PK	Pharmacokinetic Calculated Parameters

Number	Population	Title
16.2.6 Individual Efficacy Response Data		
Listing 16.2.6.1	All Subjects	Scalp Investigator Global Assessment (S-IGA)
Listing 16.2.6.2	All Subjects	Body Investigator Global Assessment (B-IGA)
Listing 16.2.6.3	All Subjects	Psoriasis Scalp Severity Index (PSSI)
Listing 16.2.6.4	All Subjects	Scalp Itch – Numeric Rating Scale (SI-NRS)
Listing 16.2.6.5	All Subjects	Psoriasis Symptoms Diary (PSD)
Listing 16.2.6.6	All Subjects	Psoriasis Area Severity Index (PASI)/Modified PASI (mPASI)
Listing 16.2.6.7	All Subjects	Worst Itch – Numeric Rating Scale (WI-NRS)
Listing 16.2.6.8	All Subjects	Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI)
Listing 16.2.6.9	All Subjects	Body Surface Area (BSA) (excluding Palms and Soles)
16.2.7 Adverse Event Listings (by Subject)		
Listing 16.2.7.1	All Subjects	Adverse Events
16.2.8 Laboratory Values (by Subject)		
Listing 16.2.8.1.1	All Subjects	Clinical Laboratory Data: Clinical Chemistry
Listing 16.2.8.1.2	All Subjects	Clinical Laboratory Data: Hematology
Listing 16.2.8.1.3	All Subjects	Clinical Laboratory Data: Urinalysis
Listing 16.2.8.1.4	All Subjects	Clinical Laboratory Data: Serum and Urine Pregnancy Test
16.2.9 Other Clinical Observations and Measurements (by Subject)		
Listing 16.2.9.1	All Subjects	Investigator Local Tolerability Assessments
Listing 16.2.9.2	All Subjects	Subject Local Tolerability Assessments
Listing 16.2.9.3.1	All Subjects	Vital Signs
Listing 16.2.9.3.2	All Subjects	Vital Signs - Weight
Listing 16.2.9.4	All Subjects	Physical Examination
Listing 16.2.9.5	All Subjects	Medical Photography
Listing 16.2.9.6	All Subjects	Prior and Concomitant Medications
Listing 16.2.9.7	All Subjects	Patient Health Questionnaire (PHQ-8)/Modified PHQ-Adolescents (PHQ-A)
Listing 16.2.9.8	All Subjects	Columbia-Suicide Severity Rating Scale (C-SSRS)

14. Table, Listing, and Figure Shells

14.1. Standard Layout for all Tables, Listings, and Figures

The following standard layout will be applied to all TLFs in support of this study. Note that programming notes may be added if appropriate after each TLF shell.

Figure 2: Standardized Layout

Arcutis Biotherapeutics, Inc. Page X of Y
Protocol: ARQ-154-204 <Version>

<Table, Listing, Figure> xx.x.x
<Title of Table Listing or Figure>
<Study Population and if applicable subgroup Description>

Body of Table, Listing or Figure

<Note: If directly Applicable>
Footnote 1 *<if applicable>* Recommendation is to keep footnotes to a minimum
Footnote 2 *<if applicable>*
Footnote n *<if applicable>*
Footnote n+1 *<pgm path and name>, <date>*

14.2. Planned Table Shells

See Figure 3 below.

Figure 3: Planned Table Shells

Table 14.1.1
Summary of Subject Disposition
All Randomized Subjects

Status	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Study Populations:			
ITT Population [1]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Safety Population [2]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
mITT Population [3]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
SPRU4-ITT Population [4]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
SPRU4-mITT Population [4]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
PRU4-ITT Population [5]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
PRU4-mITT Population [5]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
PK Population [6]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: COVID-19 = novel coronavirus disease-19; eCRF = electronic case report form; ITT = Intent-to-treat; IP = investigational product; mITT = modified intent-to-treat; PI = principal investigator; PK = pharmacokinetic; PRU4 = Subjects with WI-NRS Pruritus Score ≥4 at Baseline; S-IGA = scalp investigator global assessment; SI-NRS = Scalp Itch – Numeric Rating Scale; SPRU4 = Subjects with SI-NRS Pruritus Score ≥4 at Baseline; WI-NRS = Worst Itch – Numeric Rating Scale.
Note: Percentages are n/Number of subjects randomized within planned treatment and overall*100.
[1] The ITT population includes all randomized subjects.
[2] The Safety population includes all subjects who are enrolled and received at least 1 confirmed dose of IP.
[3] The mITT population includes all randomized subjects with the exception of subjects who missed the Week 8 disease assessment specifically due to COVID-19 disruptions.[4] The SPRU4-ITT and SPRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with SI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in SI-NRS pruritus score as compared to Baseline.
[5] The PRU4-ITT and PRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with WI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in WI-NRS pruritus score as compared to Baseline.
[6] The PK population includes all subjects receiving the active drug with sufficient plasma concentrations of roflumilast to define a profile, as determined by the pharmacokineticist.
[7] Based on completion of the S-IGA assessment at the Week 8 visit; if a subject is marked as not completing the study in the eCRF but completed the S-IGA assessment at the Week 8 visit before discontinuation, that subject will be considered as a completer for purposes of this summary, and reason for discontinuation is not summarized.
Reference Listings: 16.2.1.1, 16.2.3

Table 14.1.1 (cont.)
Summary of Subject Disposition
All Randomized Subjects

Status	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Completed Study [7]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ongoing in Study	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prematurely Discontinued from Study [7]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Reason for Discontinuation:	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Withdrawal by Subject	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Sponsor's Decision	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
PI's Decision	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Non-Compliance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Protocol Violation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lost to Follow-up	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Adverse Event	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Death	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Pregnancy	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Programming note: *only display reason for discontinuation if COMPLFL=N, regardless of ADSL.DCREAS.*

Abbreviations: COVID-19 = novel coronavirus disease-19; eCRF = electronic case report form; ITT = Intent-to-treat; IP = investigational product; mITT = modified intent-to-treat; PI = principal investigator; PK = pharmacokinetic; PRU4 = Subjects with WI-NRS Pruritus Score ≥4 at Baseline; S-IGA = scalp investigator global assessment; SI-NRS = Scalp Itch – Numeric Rating Scale; SPRU4 = Subjects with SI-NRS Pruritus Score ≥4 at Baseline; WI-NRS = Worst Itch – Numeric Rating Scale.
Note: Percentages are n/Number of subjects randomized within planned treatment and overall*100.
[1] The ITT population includes all randomized subjects.
[2] The Safety population includes all subjects who are enrolled and received at least 1 confirmed dose of IP.
[3] The mITT population includes all randomized subjects with the exception of subjects who missed the Week 8 disease assessment specifically due to COVID-19 disruptions.[4] The SPRU4-ITT and SPRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with SI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in SI-NRS pruritus score as compared to Baseline.
[5] The PRU4-ITT and PRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with WI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in WI-NRS pruritus score as compared to Baseline.
[6] The PK population includes all subjects receiving the active drug with sufficient plasma concentrations of roflumilast to define a profile, as determined by the pharmacokineticist.
[7] Based on completion of the S-IGA assessment at the Week 8 visit; if a subject is marked as not completing the study in the eCRF but completed the S-IGA assessment at the Week 8 visit before discontinuation, that subject will be considered as a completer for purposes of this summary, and reason for discontinuation is not summarized.
Reference Listings: 16.2.1.1, 16.2.3

Table 14.1.1 (cont.)
Summary of Subject Disposition
All Randomized Subjects

Status	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Prematurely Discontinued from the Study Due to COVID-19 Disruption	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Reason for Discontinuation:			
XXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: COVID-19 = novel coronavirus disease-19; eCRF = electronic case report form; ITT = Intent-to-treat; IP = investigational product; mITT = modified intent-to-treat; PI = principal investigator; PK = Pharmacokinetic; PRU4 = Subjects with WI-NRS Pruritus Score ≥4 at Baseline; S-IGA = scalp investigator global assessment; SI-NRS = Scalp Itch – Numeric Rating Scale; SPRU4 = Subjects with SI-NRS Pruritus Score ≥4 at Baseline; WI-NRS = Worst Itch – Numeric Rating Scale.
Note: Percentages are n/Number of subjects randomized within planned treatment and overall*100.
[1] The ITT population includes all randomized subjects.
[2] The Safety population includes all subjects who are enrolled and received at least 1 confirmed dose of IP.
[3] The mITT population includes all randomized subjects with the exception of subjects who missed the Week 8 disease assessment specifically due to COVID-19 disruptions.[4] The SPRU4-ITT and SPRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with SI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in SI-NRS pruritus score as compared to Baseline.
[5] The PRU4-ITT and PRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with WI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in WI-NRS pruritus score as compared to Baseline.
[6] The PK population includes all subjects receiving the active drug with sufficient plasma concentrations of roflumilast to define a profile, as determined by the pharmacokineticist.
[7] Based on completion of the S-IGA assessment at the Week 8 visit; if a subject is marked as not completing the study in the eCRF but completed the S-IGA assessment at the Week 8 visit before discontinuation, that subject will be considered as a completer for purposes of this summary, and reason for discontinuation is not summarized.
Reference Listings: 16.2.1.1, 16.2.3

Programming note: *"Ongoing in Study" row will be removed once the database has hardlocked and all subjects have completed the study. For COVID-19 Disruption, list only the reasons for discontinuation as populated in the database.*

Table 14.1.2.1
Summary of Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Age (years)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Age Category			
12-17 years	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
≥18 years	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Gender			
Male	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Female	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Child-Bearing Potential? [1]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ethnicity			
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%)
Race			
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%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
More than One Race	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.7, 16.2.9.4.1, 16.2.9.4.2

Table 14.1.2 (cont.)
Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Height (cm)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Weight (kg)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Body Mass Index (kg/m^2)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Body Surface Area (%) Affected by Disease			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.6, 16.2.6.7, 16.2.6.8, 16.2.9.3.1, 16.2.9.3.2

Table 14.1.2.1 (cont.)
Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline S-IGA			
Clear	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Almost Clear	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Baseline S-IGA - Numeric			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline B-IGA			
Clear	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Almost Clear	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Baseline B-IGA - Numeric			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.6, 16.2.6.7, 16.2.6.8, 16.2.9.3.1, 16.2.9.3.2

Table 14.1.2.1 (cont.)
Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline PSSI - Numeric			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline SI-NRS - Numeric [2]			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline SI-NRS [2]			
0	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
4	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
5	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
6	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
7	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
8	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
9	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
10	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.6, 16.2.6.7, 16.2.6.8, 16.2.9.3.1, 16.2.9.3.2

Table 14.1.2.1 (cont.)
Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline PSD Total Score			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline PASI			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline mPASI			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.6, 16.2.6.7, 16.2.6.8, 16.2.9.3.1, 16.2.9.3.2

Table 14.1.2.1 (cont.)
Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline WI-NRS - Numeric [3]			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline WI-NRS [3]			
0	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
4	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
5	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
6	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
7	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
8	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
9	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
10	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.6, 16.2.6.7, 16.2.6.8, 16.2.9.3.1, 16.2.9.3.2

Table 14.1.2.1 (cont.)
Demographics and Baseline Characteristics
Safety Population

Variable Statistic or Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline DLQI			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Baseline CDLQI			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Abbreviations: S-IGA = scalp investigator global assessment; B-IGA = body investigator global assessment; PSSI = Psoriasis Scalp Severity Index; SI-NRS = Scalp Itch – Numeric Rating Scale; PSD = Psoriasis Symptoms Diary; PASI = Psoriasis Area Severity Index; mPASI = modified PASI; WI-NRS = Worst Itch – Numeric Rating Scale; DLQI = Dermatology Life Quality Index; CDLQI = Children's DLQI.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100.
[1] Only captured for female subjects; percentages are based on the number of female subjects in the Safety population.
[2] The SI-NRS was determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable".
[3] The WI-NRS was determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch".
Reference Listings: 16.2.4.1.1, 16.2.4.1.2, 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4, 16.2.6.5, 16.2.6.6, 16.2.6.7, 16.2.6.8, 16.2.9.3.1, 16.2.9.3.2

Table 14.1.2.2
Summary of Demographics and Baseline Characteristics
ITT Population

**(Same shell as Table 14.1.2.1; subjects are summarized by planned treatment, not treatment received;
Update Note: footnote as Percentages are n/Number of subjects in the ITT population within planned treatment and overall*100.)**

Table 14.1.2.3
Summary of Demographics and Baseline Characteristics
mITT Population

**(Same shell as Table 14.1.2.1; subjects are summarized by planned treatment, not treatment received;
Update Note: footnote as Percentages are n/Number of subjects in the mITT population within planned treatment and overall*100.)**

Table 14.1.3
Previous Treatment History of Scalp and Body Psoriasis
Safety Population

Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Inadequate Response, Intolerance or Contraindication to			
Topical Corticosteroids	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Topical Vitamin D Derivatives	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subject has Psoriasis Involvement on			
Knees and/or Elbow	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Genitalia	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Subjects with a response of “Yes” are summarized.
Reference Listing: 16.2.4.2

Programming note: *Only display Missing rows if a subject does not have an answer to the questions on the CRF regarding previous treatment and/or psoriasis involvement.*

Table 14.1.4
Summary of Protocol Deviations
Safety Population

Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with Any Protocol Deviations	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with Major Protocol Deviations	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Only major protocol deviations are presented. Subjects with any protocol deviations row can include counts from major and minor deviations. Subjects with one or more deviations within a type of protocol deviation were counted only once. Protocol Deviations were collected throughout the study.
Reference Listing: 16.2.2.2

Programming note: *the structure of this table may change depending on the information in the protocol deviations file.*

Table 14.1.5
Summary of Prior Medications by ATC Class Level 4 and Preferred Term
Safety Population

ATC Class Level 4 Preferred Term	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 Prior Medication	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
ATC Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
ATC Class 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: ATC = Anatomic Therapeutic Chemical; PT = preferred term; WHO-DDE = World Health Organization-Drug Dictionary Enhanced.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Medications were coded using WHO-DDE Global B3 version September 2019. Prior medications are all medications that were started before the application of study drug. Medications are displayed by alphabetical order of ATC Level 4 classification, then descending frequency of PT within ATC, and then alphabetically by PT. Subjects were counted only once for each ATC and PT.

Reference Listing: 16.2.9.6

Programming note: *ATC & PT text should be presented as is from the dataset.*

Table 14.1.6
Summary of Study Drug Exposure and Compliance
Safety Population

Variable Statistic / Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Total Number of IP Applications		
n	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X
Min, Max	XX, XX	XX, XX
Total Weight of IP Applied (g) [1]		
n	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X
Min, Max	XX, XX	XX, XX
Compliance [2]		
>100%	XX (XX.X%)	XX (XX.X%)
≥ 80% - ≤100%	XX (XX.X%)	XX (XX.X%)
< 80%	XX (XX.X%)	XX (XX.X%)
> 3 Consecutive Missed Doses	XX (XX.X%)	XX (XX.X%)
Compliant [3]	XX (XX.X%)	XX (XX.X%)

Abbreviation: IP = investigational product.
Note: n is the number of subjects in the Safety Population. Percentages are n/Number of subjects in the Safety Population within treatment received*100.
[1] Total weight of IP is determined by subtracting returned can weight from the dispensed can weight.
[2] Compliance is calculated based on number of applications divided by the expected number of IP applications for each subject*100.
[3] A subject is considered compliant if the subject applies at least 80% of the expected applications during the IP application period and does not miss more than 3 consecutive doses.
Reference Listings: 16.2.5.1, 16.2.5.2, 16.2.5.4

Table 14.2.1.1
Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Observed Data
ITT Population

Study Visit	Roflumilast Foam 0.3% (N=XX)		Vehicle (N=XX)	
Statistic	Observed	Change	Observed	Change
Baseline				
n	XX		XX	
Mean (SD)	XX.X (X.XX)		XX.X (X.XX)	
Median	XX.X		XX.X	
Min, Max	XX, XX		XX, XX	
Q1, Q3	XX.X		XX.X	
Week 2				
n	XX	XX	XX	XX
Mean (SD)	XX.X (X.XX)	XX.X (X.XX)	XX.X (X.XX)	XX.X (X.XX)
Median	XX.X	XX.X	XX.Xs	XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
Q1, Q3	XX.X	XX.X	XX.X	XX.X

Repeat for Week 4, Week 8, Week 9.

Abbreviation: S-IGA = scalp investigator global assessment.
Note: Subjects are summarized by planned treatment. S-IGA is a static qualitative evaluation of overall psoriasis severity involving an ordinal scale with 5 severity grades (reported only in integers of 0 to 4) where 0 = Clear; 1 = Almost Clear; 2 = Mild; 3 = Moderate; 4 = Severe. Baseline is the last non-missing measurement taken before the first application of study drug. Change from baseline is calculated as result – baseline result.
Reference Listing: 16.2.6.1

Table 14.2.1.2
Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Observed Data
mITT Population

(Same shell as Table 14.2.1.1)

Table 14.2.1.3
Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Multiple Imputation
ITT Population

(Same shell as Table 14.2.1.1; add "B-IGA = body investigator global assessment" to abbreviations in alphabetical order; Programming note: update "Note:" portion of footnote to add in the following text just after "Note:": Separate multiple imputation steps were used for monotone and non-monotone missing data. For monotone missing pattern, a predictive mean matching model was used to impute missing value for a subject at particular visit having baseline S-IGA score, treatment group, and country as independent variables and study visit as dependent variable. For non-monotone missing IGA values, Markov-Chain Monte Carlo (MCMC) method was used to impute the data at intermediate visits to make the missing data pattern into monotone before applying the predictive mean matching multiple imputation algorithm.)

Table 14.2.1.4
Summary and Change from Baseline in Scalp Investigator Global Assessment (S-IGA) Grades by Study Visit – Multiple Imputation
mITT Population

(Same shell as Table 14.2.1.1; add "B-IGA = body investigator global assessment" to abbreviations in alphabetical order; Programming note: update "Note:" portion of footnote to add in the following text just after "Note:": Separate multiple imputation steps were used for monotone and non-monotone missing data. For monotone missing pattern, a predictive mean matching model was used to impute missing value for a subject at particular visit having baseline S-IGA score, treatment group, and country as independent variables and study visit as dependent variable. For non-monotone missing IGA values, Markov-Chain Monte Carlo (MCMC) method was used to impute the data at intermediate visits to make the missing data pattern into monotone before applying the predictive mean matching multiple imputation algorithm.)

Table 14.2.1.5.1
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
ITT Population

Study Visit Category/Statistic	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Baseline	XX	XX
0 = Clear	XX (XX.X%)	XX (XX.X%)
1 = Almost Clear	XX (XX.X%)	XX (XX.X%)
2 = Mild	XX (XX.X%)	XX (XX.X%)
3 = Moderate	XX (XX.X%)	XX (XX.X%)
4 = Severe	XX (XX.X%)	XX (XX.X%)
Week 2	XX	XX
0 = Clear	XX (XX.X%)	XX (XX.X%)
1 = Almost Clear	XX (XX.X%)	XX (XX.X%)
2 = Mild	XX (XX.X%)	XX (XX.X%)
3 = Moderate	XX (XX.X%)	XX (XX.X%)
4 = Severe	XX (XX.X%)	XX (XX.X%)
S-IGA Success [1]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [2]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [3]	X.XX (X.XX, X.XX)	
P value [3]	X.XXXX	

Repeat for all Week 4, Week 8, and Week 9.

Abbreviations: B-IGA = body investigator global assessment; CI = confidence interval; S-IGA = scalp investigator global assessment.
Note: Percentages are n/Number of subjects in the ITT population within planned treatment at each visit*100. Baseline is the last non-missing measurement taken before the first application of study drug.
[1] S-IGA Success ("Yes") is defined as an S-IGA score of "Clear" or "Almost Clear" plus a ≥2-grade improvement from baseline; "No" otherwise.
[2] 95% CIs for "Yes" are obtained using Wilson method.
[3] The odds ratio, 95% CI, and P value are obtained from Cochran Mantel Haenszel test (stratified by country, baseline S-IGA category, and baseline B-IGA category) comparing roflumilast foam 0.3% to vehicle.
Reference Listings: 16.2.6.1, 16.2.6.2

Table 14.2.1.5.2
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
ITT Population - Topical Corticosteroids - Naïve Subjects

(Same shell as Table 14.2.1.5.1; add 16.2.4.2 to reference listings; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that are topical corticosteroids – naïve subjects within planned treatment at each visit*100.")

Table 14.2.1.5.3
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
ITT Population - Topical Vitamin D Derivative - Naïve Subjects

(Same shell as Table 14.2.1.5.1; add 16.2.4.2 to reference listings; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that are topical vitamin D derivative – naïve subjects within planned treatment at each visit*100.")

Table 14.2.1.5.4
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
ITT Population - Subjects with Psoriasis Involvement on the Knee and/or Elbow

(Same shell as Table 14.2.1.5.1; add 16.2.4.2 to reference listings; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that have psoriasis involvement on the knee and/or elbow within planned treatment at each visit*100.")

Table 14.2.1.5.5
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
ITT Population - Subjects who Achieved S-IGA and B-IGA Success at Week 8

(Same shell as Table 14.2.1.5.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that achieved both S-IGA and B-IGA success at Week 8 within planned treatment at each visit*100.")

Table 14.2.1.5.6
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
ITT Population – by Study Site

Study Site: SITENAM (Site SITEID)

Study Visit Category/Statistic	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Baseline	XX	XX
0 = Clear	XX (XX.X%)	XX (XX.X%)
1 = Almost Clear	XX (XX.X%)	XX (XX.X%)
2 = Mild	XX (XX.X%)	XX (XX.X%)
3 = Moderate	XX (XX.X%)	XX (XX.X%)
4 = Severe	XX (XX.X%)	XX (XX.X%)
Week 2	XX	XX
0 = Clear	XX (XX.X%)	XX (XX.X%)
1 = Almost Clear	XX (XX.X%)	XX (XX.X%)
2 = Mild	XX (XX.X%)	XX (XX.X%)
3 = Moderate	XX (XX.X%)	XX (XX.X%)
4 = Severe	XX (XX.X%)	XX (XX.X%)
S-IGA Success [1]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [2]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [3]	X.XX (X.XX, X.XX)	
P value [3]	X.XXXX	

Repeat for all Week 4, Week 8, and Week 9.

Abbreviations: B-IGA = body investigator global assessment; CI = confidence interval; S-IGA = scalp investigator global assessment.
Note: Percentages are n/Number of subjects in the ITT population within planned treatment and study site at each visit*100. Baseline is the last non-missing measurement taken before the first application of study drug.
[1] S-IGA Success ("Yes") is defined as an S-IGA score of "Clear" or "Almost Clear" plus a ≥2-grade improvement from baseline; "No" otherwise.
[2] 95% CIs for "Yes" are obtained using Wilson method.
[3] The odds ratio, 95% CI, and P value are obtained from Cochran Mantel Haenszel test (stratified by country, baseline S-IGA category, and baseline B-IGA category) comparing roflumilast foam 0.3% to vehicle.
Reference Listings: 16.2.6.1, 16.2.6.2

Programming note: *sort by ADSL.SITEID. Format study site as shown (e.g., "Study Site Name (Site 01)").*

Table 14.2.1.6.1
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
mITT Population

(Same shell as Table 14.2.1.5)

Table 14.2.1.6.2
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
mITT Population - Topical Corticosteroids - Naïve Subjects

(Same shell as Table 14.2.1.5.2; add 16.2.4.2 to reference listings; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that are topical corticosteroids – naïve subjects within planned treatment at each visit*100.")

Table 14.2.1.6.3
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
mITT Population - Topical Vitamin D Derivative - Naïve Subjects

(Same shell as Table 14.2.1.5.3; add 16.2.4.2 to reference listings; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that are topical vitamin D derivative – naïve subjects within planned treatment at each visit*100.")

Table 14.2.1.6.4
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
mITT Population - Subjects with Psoriasis Involvement on the Knee and/or Elbow

(Same shell as Table 14.2.1.5.4; add 16.2.4.2 to reference listings; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT that have psoriasis involvement on the knee and/or elbow within planned treatment at each visit*100.")

Table 14.2.1.6.5
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
mITT Population - Subjects who Achieved S-IGA and B-IGA Success at Week 8

(Same shell as Table 14.2.1.5.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that achieved both S-IGA and B-IGA success at Week 8 within planned treatment at each visit*100.")

Table 14.2.1.6.6
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Categorical Results
mITT Population – by Study Site

(Same shell as Table 14.2.1.5.6;)

Table 14.2.1.7.1
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
ITT Population

(Same shell as Table 14.2.1.5.1; add "B-IGA = body investigator global assessment" to abbreviations in alphabetical order; update "Note:" portion of footnote to add in the following text just after "Note:": Separate multiple imputation steps were used for monotone and non-monotone missing data. For monotone missing pattern, a predictive mean matching model was used to impute missing value for a subject at particular visit having baseline S-IGA score, treatment group, and country as independent variables and study visit as dependent variable. For non-monotone missing IGA values, Markov-Chain Monte Carlo (MCMC) method was used to impute the data at intermediate visits to make the missing data pattern into monotone before applying the predictive mean matching multiple imputation algorithm.**)**

Table 14.2.1.7.2
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
ITT Population – Baseline S-IGA = 3

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that have a baseline S-IGA score of 3 within planned treatment at each visit*100.")

Table 14.2.1.7.3
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
ITT Population – Baseline S-IGA = 4

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that have a baseline S-IGA score of 4 within planned treatment at each visit*100.")

Table 14.2.1.7.4
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
ITT Population – Age Category = 12-17 Years

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that are between 12 and 17 years of age, inclusive, within planned treatment at each visit*100.")

Table 14.2.1.7.5
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
ITT Population – Age Category = ≥18 Years

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that are aged 18 years or older within planned treatment at each visit*100.")

Table 14.2.1.7.6
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
ITT Population – Subjects who Achieved S-IGA and B-IGA Success at Week 8

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the ITT population that achieved both S-IGA and B-IGA success at Week 8 within planned treatment at each visit*100.")

Table 14.2.1.8.1
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
mITT Population

(Same shell as Table 14.2.1.7.1)

Table 14.2.1.8.2
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
mITT Population – Baseline S-IGA = 3

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that have a baseline S-IGA score of 3 within planned treatment at each visit*100.")

Table 14.2.1.8.3
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
mITT Population – Baseline S-IGA = 4

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that have a baseline S-IGA score of 4 within planned treatment at each visit*100.")

Table 14.2.1.8.4
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
mITT Population – Age Category = 12-17 Years

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that are between 12 and 17 years of age, inclusive, within planned treatment at each visit*100.")

Table 14.2.1.8.5
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
mITT Population – Age Category = ≥18 Years

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that are aged 18 years or older within planned treatment at each visit*100.")

Table 14.2.1.8.6
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Multiple Imputation
Categorical Results
mITT Population – Subjects who Achieved S-IGA and B-IGA Success at Week 8

(Same shell as Table 14.2.1.7.1; change "Percentages" footnote to be "Percentages are n/Number of subjects in the mITT population that achieved both S-IGA and B-IGA success at Week 8 within planned treatment at each visit*100.")

Table 14.2.1.9
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Tabulation of Fitted Point Estimates from Generalized Estimating Equations for Binary Response
ITT Population

	Roflumilast Foam 0.3% (N=XX)		Vehicle (N=XX)		Treatment Difference (Roflumilast Foam 0.3% vs Vehicle) [3]		
Study Visit	n [1]	Responder [2]	n [1]	Responder [2]	Odds Ratio	95% CI for OR	P value
Week 2	XX	XX.X %	XX	XX.X %	X.XX	(XX.XX, XX.XX)	X.XXXX
Week 4	XX	XX.X %	XX	XX.X %	X.XX	(XX.XX, XX.XX)	X.XXXX
Week 8	XX	XX.X %	XX	XX.X %	X.XX	(XX.XX, XX.XX)	X.XXXX
Week 9	XX	XX.X %	XX	XX.X %	X.XX	(XX.XX, XX.XX)	X.XXXX

Abbreviations: CI = Confidence interval; OR = odds ratio; S-IGA = scalp investigator global assessment.
Note: Percentages are n/Number of subjects in the ITT population within planned treatment at each visit*100. Baseline is the last non-missing measurement taken before the first application of study drug.
[1] Number of subjects at each visit.
[2] Number of subjects with an S-IGA score of “Clear” or “Almost Clear” plus a ≥2-grade improvement from baseline.
[3] Estimates for odds ratio, 95% CI for odds ratio, and P value are from a generalized estimating equations for binary response model, with S-IGA success as the dependent variable and treatment, country, visit, and baseline S-IGA score as the independent variables. An unstructured correlation matrix was used to model the within subject correlation. In case of convergence issues, other covariance structures will be used including Toeplitz, compound symmetry or Autoregressive (1) (AR[1]) covariance structure will be used, following this sequence until convergence is achieved. The odds ratio is the estimate of the odds of having S-IGA response for subjects treated with roflumilast foam 0.3% relative to that for subjects treated with vehicle.
Reference Listing: 16.2.6.1

Table 14.2.1.10
Summary of Scalp Investigator Global Assessment (S-IGA) Grades and Success by Study Visit – Observed Data
Tabulation of Fitted Point Estimates from Generalized Estimating Equations for Binary Response
mITT Population

(Programming note: Same as table shell 14.2.1.9)

Table 14.2.1.11
Summary of Scalp Investigator Global Assessment (S-IGA) – Score of Clear – Observed Data
ITT Population

Study Visit Category/Statistic	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Week 2	XX	XX
S-IGA Clear [1]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [2]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [3]	X.XX (X.XX, X.XX)	
P value [3]	X.XXXX	

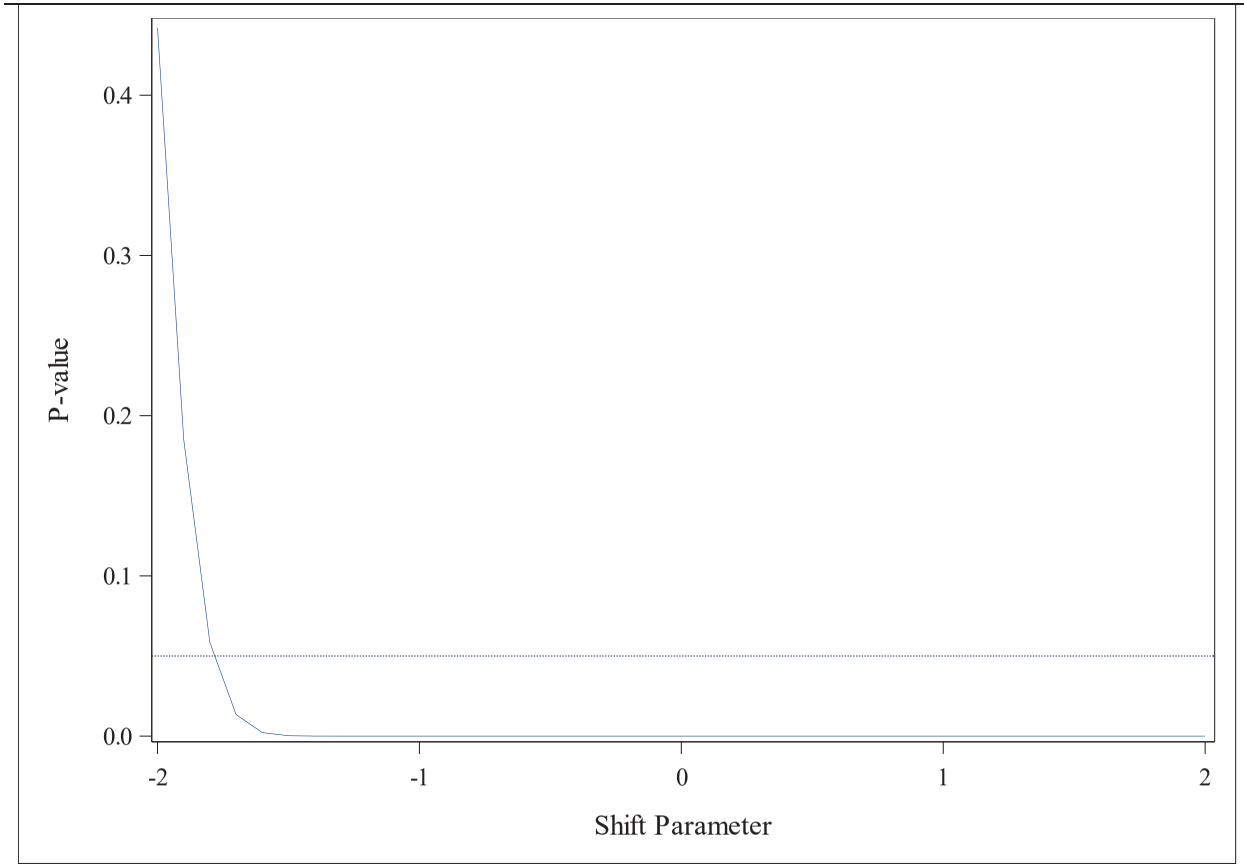
Repeat for all Week 4, Week 8, and Week 9.

Abbreviations: CI = confidence interval; S-IGA = scalp investigator global assessment.
Note: Percentages are n/Number of subjects in the ITT population within planned treatment at each visit*100. Baseline is the last non-missing measurement taken before the first application of study drug.
[1] S-IGA Clear ("Yes") is defined as an S-IGA score of "Clear"; "No" otherwise.
[2] 95% CIs for "Yes" are obtained using Wilson method.
[3] The odds ratio, 95% CI, and P value are obtained from Cochran Mantel Haenszel test (stratified by country, baseline S-IGA category, and baseline B-IGA category) comparing roflumilast foam 0.3% to vehicle.
Reference Listing: 16.2.6.1

Table 14.2.1.12
Summary of Scalp Investigator Global Assessment (S-IGA) – Score of Clear – Observed Data
mITT Population

(Same as table shell 14.2.1.11)

Figure 14.2.1.13
Plot of Scalp Investigator Global Assessment (S-IGA) Tipping Point Analysis
P Values vs Shift Parameters
ITT Population



Shift Parameter	P value
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	0.0585
X.XX	0.0513
X.XX	0.0448
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX
X.XX	X.XXXX

Abbreviation: MNAR = missing not at random.
Note: A tipping point analysis was performed in order to determine the inflection point at which the inference under the MNAR assumption for multiple imputation changes substantially and is used to check the robustness of the imputation. Shift parameters from -1.5 to 1.5 by 0.2 were initially used to determine approximately where results of the analysis are shifted from significant (i.e., P ≤ 0.05) to non-significant (i.e., P > 0.05). Once this was determined, the range around the approximate inflection point was expanded to include values with greater precision (i.e., to 2 decimal places, by 0.01); this expanded range of shift parameters and P values are presented here. If this tipping point value is considered clinically implausible, then there is evidence of efficacy with respect to the primary endpoint despite missing data.

Figure 14.2.1.14
Plot of Scalp Investigator Global Assessment (S-IGA) Tipping Point Analysis
P Values vs Shift Parameters
mITT Population

(Programming note: Same as figure shell 14.2.1.13)

Table 14.2.2.1
Summary and Change from Baseline in Body Investigator Global Assessment (B-IGA) Grades by Study Visit
ITT Population

(Programming note: Same as table shell 14.2.1.1; update reference listing to Reference Listing: 16.2.6.2**; Update any instances of S-IGA to B-IGA)**

Table 14.2.2.2
Summary and Change from Baseline in Body Investigator Global Assessment (B-IGA) Grades by Study Visit
mITT Population

(Programming note: Same as table shell 14.2.1.1; update reference listing to Reference Listing: 16.2.6.2**; Update any instances of S-IGA to B-IGA)**

Table 14.2.2.3
Summary of Body Investigator Global Assessment (B-IGA) Grades and Success by Study Visit
Categorical Results
ITT Population

(Programming note: Same as table 14.2.1.5; update reference listing to Reference Listings: 16.2.6.1, 16.2.6.2**; Update any instances of S-IGA to B-IGA)**

Table 14.2.2.4
Summary of Body Investigator Global Assessment (B-IGA) Grades and Success by Study Visit
Categorical Results
mITT Population

(Programming note: Same as table 14.2.1.5; update reference listing to Reference Listing: 16.2.6.2**; Update any instances of S-IGA to B-IGA)**

Table 14.2.3.1
Summary and Change from Baseline in PSSI Scores by Study Visit
ITT Population

Study Visit	Roflumilast Foam 0.3% (N=XX)			Vehicle (N=XX)		
Statistic	Observed	Change	% Change	Observed	Change	% Change
Baseline						
n	XX			XX		
Mean (SD)	XX.X (X.XX)			XX.X (X.XX)		
Median	XX.X			XX.X		
Min, Max	XX, XX			XX, XX		
Q1, Q3	XX.X			XX.X		
Week 2						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (X.XX)	XX.X (X.XX)	XX.X (X.XX)	XX.X (X.XX)	XX.X (X.XX)	XX.X (X.XX)
Median	XX.X	XX.X	XX.X	XX.Xs	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Q1, Q3	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

Repeat for Week 4, Week 8, Week 9.

Abbreviation: PSSI = Psoriasis Scalp Severity Index.
Note: Subjects are summarized by planned treatment. PSSI total score is calculated as (erythema score + induration + desquamation) × extent of scalp affected. The score ranges from 0 to 72. Erythema, induration, and desquamation are scored on a scale of 0 to 4, where 0 = absent and 4 = severest possible; extent of scale affected is scored on a scale of 0 to 6, where 0 = 0% of involved area and 6 = 90-100% of involved area. Baseline is the last non-missing measurement taken before the first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.
Reference Listing: 16.2.6.3

Table 14.2.3.2
Summary and Change from Baseline in PSSI Scores by Study Visit
mITT Population

(Programming note: Same as table 14.2.3.1)

Table 14.2.3.3
Summary of Achievement of PSSI-50, PSSI-75, PSSI-90, and PSSI-100 by Study Visit
ITT Population

Study Visit Category/Statistic	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Week 2	XX	XX
PSSI-50 [1]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [5]	(X.XX, X.XX)	
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [6]	X.XX (X.XX, X.XX)	
P value [6]	X.XXXX	
PSSI-75 [2]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [5]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [6]	X.XX (X.XX, X.XX)	X.XX (X.XX, X.XX)
P value [6]	X.XXXX	

Continue for PSSI-90 [3] and PSSI-100 [4]; Repeat for Week 4, Week 8, and Week 9.

Abbreviations: B-IGA = body investigator global assessment; CI = confidence interval; S-IGA = scalp investigator global assessment; PSSI = Psoriasis Scalp Severity Index.
Note: Percentages are n/Number of subjects in the ITT population within planned treatment at each visit*100. Baseline is the last non-missing measurement taken before the first application of study drug.
[1] PSSI-50 is populated with "Yes" when there is an achievement of a 50% reduction in PSSI total score from baseline; "No" otherwise.
[2] PSSI-75 is populated with "Yes" when there is an achievement of a 75% reduction in PSSI total score from baseline; "No" otherwise.
[3] PSSI-90 is populated with "Yes" when there is an achievement of a 90% reduction in PSSI total score from baseline; "No" otherwise.
[4] PSSI-100 is populated with "Yes" when there is an achievement of a 100% reduction in PSSI total score from baseline; "No" otherwise.
[5] 95% CI for "Yes" are obtained using Wilson method.
[6] The odds ratio, 95% CI, and P value are obtained from Cochran Mantel Haenszel test (stratified by country, baseline S-IGA score category, and baseline B-IGA score category) comparing roflumilast foam 0.3% to vehicle.
Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.3

Table 14.2.3.4
Summary of Achievement of PSSI-50, PSSI-75, PSSI-90, and PSSI-100 by Study Visit
mITT Population

(Programming note: Same as table 14.2.3.3.)

Table 14.2.3.5
Time to Achievement of PSSI-50, PSSI-75, and PSSI-90
ITT Population

Variable Statistic	Roflumilast Foam 0.3% (N=XXX)	Vehicle (N=XXX)
Time to Achieve PSSI-50 (Days) [1]		
n	XXX	XXX
Events/Censors [2]	XX/XX	XX/XX
Mean (SD)	X.X (X.XX)	X.X (X.XX)
Median	X.X	X.X
Min, Max	X, XX	X, XX
Kaplan-Meier Estimate of Time to Achieve PSSI-50 (Days)		
Median (95% CI)	X.X (X.X, X.X)	X.X (X.X, X.X)
P value [3]	X.XXXX	
Cox Proportional Hazards Model [4]		
Hazard Ratio	X.XXX	
(95% Wald CI for Hazard Ratio)	(X.XXX, X.XXX)	

Repeat for "Time to Achieve PSSI-75 (Days) [5]" and "Time to Achieve PSSI-90 (Days) [6]"

Abbreviations: CI = confidence interval; NE = not estimable; PSSI = Psoriasis Scalp Severity Index; SD = standard deviation.
Note: Subjects are summarized by planned treatment. Censored values are not included in the descriptive statistics. Only subjects who achieved PSSI-50, PSSI-75, or PSSI-90 are included in the relevant descriptive statistics.
[1] PSSI-50 is achievement of 50% reduction in PSSI from baseline. Time to PSSI-50 is calculated as date of PSSI-50 achievement - Day 1 date + 1.
[2] Subjects who did not achieve PSSI-50, PSSI-75, or PSSI-90 were censored at day of discontinuation or date lost to follow-up, whichever is earlier.
[3] P value was obtained from the log rank test where roflumilast foam 0.3% was compared to vehicle.
[4] The hazard ratio and 95% Wald CI are obtained from a Cox Proportional Hazards model with country, baseline S-IGA score category, and baseline B-IGA score category as factors in the model, comparing roflumilast foam 0.3% to vehicle.
[5] PSSI-75 is achievement of 75% reduction in PSSI from baseline. Time to PSSI-75 is calculated as date of PSSI-75 achievement - Day 1 date + 1.
[6] PSSI-90 is achievement of 90% reduction in PSSI from baseline. Time to PSSI-90 is calculated as date of PSSI-90 achievement - Day 1 date + 1.
Reference Listing: 16.2.6.3

Table 14.2.3.6
Time to Achievement of PSSI-50, PSSI-75, and PSSI-90
mITT Population

(Programming note: Same as table 14.2.3.6.)

Table 14.2.3.7
Summary of PSSI Scores by Study Visit – ANCOVA
ITT Population

Study Visit Category Statistic [1]	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Week 2		
Change from Baseline		
n	XX	XX
LS Mean Change from Baseline (SE)	X.XX (X.XXX)	X.XX (X.XXX)
(95% CI for LS Mean Change from Baseline)	(X.XX, X.XX)	(X.XX, X.XX)
P value for LS Mean Change from Baseline) [2]	X.XXXX	
LS Mean Difference from Vehicle (SE)	(X.XX, X.XX)	
(95% CI for Difference from Vehicle)	X.XX (X.XXX)	
P value for Difference from Vehicle [3]	X.XXXX	

Continue for Percent Change from Baseline. Repeat for Week 4, Week 8, Week 9.

Abbreviations: ANCOVA = analysis of covariance; B-IGA = body investigator global assessment; CI = confidence interval; LS = least-squares; PSSI = Psoriasis Scalp Severity Index; S-IGA = scalp investigator global assessment; SE = standard error.
Note: Subjects are summarized by planned treatment. PSSI total score is calculated as (erythema score + induration + desquamation) × extent of scalp affected. The score ranges from 0 to 72. Erythema, induration, and desquamation are scored on a scale of 0 to 4, where 0 = absent and 4 = severest possible; extent of scale affected is scored on a scale of 0 to 6, where 0 = 0% of involved area and 6 = 90-100% of involved area.
[1] Estimates for LS means (change/percent change from baseline and difference from vehicle [i.e., change/percent change from baseline for roflumilast foam 0.3% minus change from baseline for vehicle]) and accompanying 95% CIs, and P values are from an ANCOVA with country, baseline S-IGA score category, baseline B-IGA score category, and baseline PSSI score as independent variables. Baseline is the last non-missing measurement taken before the first application of study drug. Percent change from baseline is calculated as (result – baseline result)*100.
[2] P value for testing change/percent change from baseline is zero.
[3] P value for testing difference (roflumilast foam 0.3% minus vehicle) in change/percent change from baseline from is zero.
Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.5

Table 14.2.3.8
Summary of PSSI Scores by Study Visit – ANCOVA
mITT Population

(Programming note: Same as table 14.2.3.7.)

Table 14.2.4.1
Summary and Change from Baseline in Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit
ITT Population

(Programming note: Same as table 14.2.3.1. Update abbreviation row to display "SI-NRS = Scalp Itch – Numeric Rating Scale". Change reference listing to Reference Listing: 16.2.6.4**. Update the footnotes as** "Note: Subjects are summarized by planned treatment. The SI-NRS will be determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable". Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.")

Table 14.2.4.2
Summary and Change from Baseline in Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit
mITT Population

(Programming note: Same as table 14.2.4.1.)

Table 14.2.4.3
Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score Success by Study Visit
ITT Population, Subjects with SI-NRS Pruritus Score ≥4 at Baseline (SPRU4-ITT Population)

Study Visit/ Category/Statistic	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Week 2	XX	XX
SI-NRS Success [1]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [2]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [3]	X.XX (X.XX, X.XX)	
P value [3]	X.XXXX	

Repeat for all Week 4, Week 8, and Week 9.

Abbreviations: B-IGA = body investigator global assessment; CI = confidence interval; S-IGA = scalp investigator global assessment; SI-NRS = Scalp Itch – Numeric Rating Scale.
Note: Percentages are n/Number of subjects in the SPRU4-ITT population within planned treatment at each visit*100. Baseline is the last non-missing measurement taken on or before the day first application of study drug.
[1] SI-NRS success ("Yes") is defined as an achievement of a ≥4-point improvement from baseline score of ≥4; "No" otherwise.
[2] 95% CIs for "Yes" are obtained using Wilson method.
[3] The odds ratio, 95% CI, and P value are obtained from Cochran Mantel Haenszel test (stratified by country, baseline S-IGA score category, and baseline B-IGA score category) comparing roflumilast foam 0.3% to vehicle.
Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.4

Table 14.2.4.4
Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score Success by Study Visit
mITT Population, Subjects with SI-NRS Pruritus Score ≥4 at Baseline (SPRU4-mITT Population)

(Programming note: Same as table 14.2.4.3. Change "Note:" to be "Note: Percentages are n/Number of subjects in the SPRU4-mITT population within planned treatment at each visit*100.**")**

Table 14.2.4.5
Summary of Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit – ANCOVA
ITT Population

(Programming note: Same as table 14.2.3.7. Update [1] as to use "SI-NRS score" instead of "PSSI score". Update abbreviation row to display "SI-NRS = Scalp Itch – Numeric Rating Scale"Change reference listing to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.4**. Update the Note as** "Note: Subjects are summarized by planned treatment. The SI-NRS will be determined by asking the subject's assessment of worst itch of scalp over the past 24 hours. The scale is from 0 to 10, which ranges from "no scalp itch" to "worst scalp itch imaginable". Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Percent change from baseline is calculated as (result – baseline result)*100.")**

Table 14.2.4.6
Summary of Scalp Itch – Numeric Rating Scale (SI-NRS) Pruritus Score by Study Visit – ANCOVA
mITT Population

(Programming note: Same as table 14.2.4.5.)

Table 14.2.5.1
Summary and Change from Baseline in Psoriasis Symptom Diary (PSD) Total and Individual Item Scores by Study Visit
ITT Population

(Programming note: Same as table 14.2.3.1, except add header rows at the top for
"Item: Total Score",
"Item: How severe was your psoriasis-related itching?",
"Item: How bothered were you by your psoriasis-related itching?",
"Item: How severe was your psoriasis-related stinging?",
"Item: How bothered were you by your psoriasis-related stinging?",
"Item: How severe was your psoriasis-related burning?",
"Item: How bothered were you by your psoriasis-related burning?",
"Item: How severe was your psoriasis-affected skin cracking?",
"Item: How bothered were you by your psoriasis-affected skin cracking?",
"Item: How severe was your psoriasis-related pain?",
"Item: How bothered were you by your psoriasis-related pain?",
"Item: How severe was your psoriasis scaling?",
"Item: How bothered were you by your psoriasis scaling?",
"Item: How noticeable did you think the color of your psoriasis-affected skin was?",
"Item: How much did you try to hide your psoriasis affected skin?",
"Item: How much did your psoriasis cause you to avoid activities with other people?",
"Item: How embarrassed were you because of your psoriasis?"
Change abbreviation from PSSI to PSD = Psoriasis Symptom Diary. Change reference listings to Reference Listing: 16.2.6.5**. Update footnoteas "The** PSD total score is calculated as sum of the 16 questions (individual questions scored 0 to 10, where higher scores indicate more severe symptoms). The total score ranges from 0 to 160. If 1 or more items are missing, the total score was not calculated. Baseline is the last non-missing measurement taken on or before the day first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.**")**

Table 14.2.5.2
Summary and Change from Baseline in Psoriasis Symptom Diary (PSD) Total and Individual Item Scores by Study Visit
mITT Population

(Programming note: Same as table 14.2.5.1.)

Table 14.2.5.3
Summary of Psoriasis Symptom Diary (PSD) Total Scores by Study Visit – ANCOVA
ITT Population

(Programming note: Same as table 14.2.3.7. Update [1] as to use "PSD total score" instead of "PSSI score". Change abbreviation from PSSI to PSD = Psoriasis Symptom Diary. Change reference listings to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.5**. Update the Note as** "Note: Subjects are summarized by planned treatment. Baseline is the last non-missing measurement taken before the first application of study drug. PSD total score is calculated as sum of the 16 questions (individual questions scored 0 to 10, where higher scores indicate more severe symptoms). The score ranges from 0 to 160. If 1 or more items are missing, the score is not calculated."**)**

Table 14.2.5.4
Summary of Psoriasis Symptom Diary (PSD) Total Scores by Study Visit – ANCOVA
mITT Population

(**Programming note: Same as table 14.2.5.3.)**

Table 14.2.6.1
Summary and Change from Baseline in PASI/mPASI by Study Visit
ITT Population

(Programming note: Same as table 14.2.3.1, except add header rows at the top for "Scale: PASI" or "Scale: mPASI". Add Abbreviations "PASI = Psoriasis Area Severity Index" and "mPASI = modified PASI" in alphabetical order. Change reference listing to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.6**. Update [1] as** "PASI is calculated as (0.1×[Eh + Th + Sh]×Ah) + (0.2×[Ea + Ta + Sa]×Aa) + (0.3×[Et + Tt + St]×At) + (0.4×[El + Tl + Sl]×Al), where E, T, and S are erythema, thickness, and scaling, respectively, scored on a scale of 0 to 4, A is estimated area of skin involved, graded on a scale of 0 to 6, and h, e, t, and l are head, arms, trunk, and legs respectively. The total score ranges from 0 to 72. mPASI is calculated similar to PASI except that for subjects with < 10% of any particular involved anatomic area, the mPASI will be calculated using the actual percentage of the anatomical area involved rather than the 0 to 6 estimated area score (e.g., 0.1 for 1%, 0.2 for 2%, 0.3 for 3%, … 0.9 for 9%). Lower scores indicate improvement. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.")

Table 14.2.6.2
Summary and Change from Baseline in PASI/mPASI by Study Visit
mITT Population

(Programming note: Same as table 14.2.6.1)

Table 14.2.6.3
Summary of PASI/mPASI by Study Visit – ANCOVA
ITT Population

(Programming note: Same as table 14.2.5.3, except add header rows at the top for "Scale: PASI" or "Scale: mPASI". Replace instances of PSD with PASI/mPASI. Add the following to Abbreviations "PASI = Psoriasis Area Severity Index" and "mPASI = modified Psoriasis Area Severity Index" in alphabetical order. Change reference listings to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.6**. Replace PSD Total Score text in the note footnote with** "PASI is calculated as $(0.1\times[E_h + T_h + S_h]\times A_h) + (0.2\times[E_a + T_a + S_a]\times A_a) + (0.3\times[E_t + T_t + S_t]\times A_t) + (0.4\times[E_l + T_l + S_l]\times A_l)$, where E, T, and S are erythema, thickness, and scaling, respectively, scored on a scale of 0 to 4, A is estimated area of skin involved, graded on a scale of 0 to 6, and h, e, t, and l are head, arms, trunk, and legs respectively. The total score ranges from 0 to 72. mPASI is calculated similar to PASI except that for subjects with < 10% of any particular involved anatomic area, the mPASI will be calculated using the actual percentage of the anatomical area involved rather than the 0 to 6 estimated area score (e.g., 0.1 for 1%, 0.2 for 2%, 0.3 for 3%, …, 0.9 for 9%). Lower scores indicate improvement."**)**

Table 14.2.6.4
Summary of PASI/mPASI by Study Visit – ANCOVA
mITT Population

(Programming note: Same as table 14.2.6.3.)

Table 14.2.6.5
Summary of Achievement of PASI-50, PASI-75, and PASI-90 by Study Visit
ITT Population

Study Visit Category/Statistic	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)
Week 2	XX	XX
PASI-50 [1]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [4]	(X.XX, X.XX)	
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [5]	X.XX (X.XX, X.XX)	
P value [5]	X.XXXX	
PASI-75 [2]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [4]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [5]	X.XX (X.XX, X.XX)	X.XX (X.XX, X.XX)
P value [5]	X.XXXX	
PASI-90 [3]		
Yes	XX (XX.X%)	XX (XX.X%)
95% CI [4]	(X.XX, X.XX)	(X.XX, X.XX)
No	XX (XX.X%)	XX (XX.X%)
Odds Ratio (95% CI) [5]	X.XX (X.XX, X.XX)	X.XX (X.XX, X.XX)
P value [5]	X.XXXX	

Repeat for Week 4, Week 8, and Week 9.

Abbreviations: B-IGA = body investigator global assessment; CI = confidence interval; S-IGA = scalp investigator global assessment; PASI = Psoriasis Area Severity Index.
Note: Percentages are n/Number of subjects in the ITT population within planned treatment at each visit*100. Baseline is the last non-missing measurement taken before the first application of study drug.
[1] PASI-50 is populated with "Yes" when there is an achievement of a 50% reduction in PASI total score from baseline; "No" otherwise.
[2] PASI-75 is populated with "Yes" when there is an achievement of a 75% reduction in PASI total score from baseline; "No" otherwise.
[3] PASI-90 is populated with "Yes" when there is an achievement of a 90% reduction in PASI total score from baseline; "No" otherwise.
[4] 95% CIs for "Yes" are obtained using Wilson method.
[5] The odds ratio, 95% CI, and P value are obtained from Cochran Mantel Haenszel test (stratified by country, baseline S-IGA score category, and baseline B-IGA score category) comparing roflumilast foam 0.3% to vehicle.
Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.6

Table 14.2.6.6
Summary of Achievement of PASI-50, PASI-75, and PASI-90 by Study Visit
mITT Population

(**Programming note: Same as table 14.2.6.5)**

Table 14.2.6.7
Time to Achievement of PASI-50
ITT Population

(Programming note: Same as table 14.2.3.5. Replace instances of PSSI-50 with PASI-50 and update the abbreviations accordingly. Change the reference listings to 16.2.6.1, 16.2.6.2, 16.2.6.6)

Table 14.2.6.8
Time to Achievement of PASI-50
mITT Population

(Programming note: Same as table 14.2.3.5. Replace instances of PSSI-50 with PASI-50 and update the abbreviations accordingly. Change the reference listings to 16.2.6.1, 16.2.6.2, 16.2.6.6)

Table 14.2.6.9
Summary of Achievement of mPASI-50, mPASI-75, and mPASI-90 by Study Visit
ITT Population

(**Same shell as Table 14.2.6.5; change all instances of PASI to mPASI)**

Table 14.2.6.10
Summary of Achievement of mPASI-50, mPASI-75, and mPASI-90 by Study Visit
mITT Population

(**Same shell as Table 14.2.6.5; change all instances of PASI to mPASI)**

Table 14.2.7.1
Summary and Change from Baseline in Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit
ITT Population

(Programming note: Same as table 14.2.3.1. Change reference listing to Reference Listing: 16.2.6.7**. Update abbreviation row to display "WI-NRS = Worst Itch – Numeric Rating Scale". Update footnote as follows:** "Note: Subjects are summarized by planned treatment. The WI-NRS will be determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch". Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.**")**

Table 14.2.7.2
Summary and Change from Baseline in Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit
mITT Population

(Programming note: Same as table 14.2.7.1)

Table 14.2.7.3
Summary of Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit – ANCOVA
ITT Population

(Programming note: Same as table 14.2.3.7; Replace instances of PSD with WI-NRS in [1]. Change reference listings to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.7. Update abbreviation row to display "WI-NRS = Worst Itch – Numeric Rating Scale". Update the baseline definition to read, "Baseline is the last non-missing measurement taken on or before the day first application of study drug.**" Replace PSD Total Score text in the note footnote with "**The WI-NRS will be determined by asking the subject's assessment of worst itch over the past 24 hours. The scale is from 0 to 10, which ranges from "no itch" to "worst imaginable itch". Lower scores indicate improvement.**")**

Table 14.2.7.4
Summary of Worst Itch – Numeric Rating Scale (WI-NRS) by Study Visit – ANCOVA
mITT Population

(Programming note: Same as table 14.2.7.3)

Table 14.2.7.5
Worst Itch – Numeric Rating Scale (WI-NRS) Pruritus Score Success by Study Visit
ITT Population, Subjects with WI-NRS Pruritus Score ≥4 at Baseline (PRU4-ITT Population)

(**Programming note: Same as table 14.2.4.3, except replace all instances of SI-NRS with WI-NRS. Update abbreviation row to display "WI-NRS = Worst Itch – Numeric Rating Scale". Change reference listings to** Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.7**.)**

Table 14.2.7.6
Worst Itch – Numeric Rating Scale (WI-NRS) Pruritus Score Success by Study Visit
mITT Population, Subjects with WI-NRS Pruritus Score ≥4 at Baseline (PRU4-mITT Population)

(**Programming note: Same as table 14.2.7.5.)**

Table 14.2.8.1
Summary and Change from Baseline in Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit
ITT Population

(Programming note: Same as table 14.2.3.1, except add header rows at the top for "Scale: DLQI" and "Scale: "CDLQI". Add "DLQI = Dermatology Life Quality Index" and "CDLQI = Children's DLQI" to abbreviations in alphabetical order. Change reference listing to Reference Listing: 16.2.6.8**. Update footnotes as** "Note: Subjects are summarized by planned treatment. The DLQI/CDLQI score is calculated as sum of all the 10 questions at each visit and ranges between 0-30. The individual questions are scored as "Very much" or "Yes"= 3, "A lot" = 2, "A Little" = 1, "Not at all" or "Not Relevant" = 0. If 1 item is missing, it is scored as 0 for that item. If 2 or more items are missing, the score should not be calculated. Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.**")**

Table 14.2.8.2
Summary and Change from Baseline in Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit
mITT Population

(Programming note: Same as table 14.2.8.1)

Table 14.2.8.3
Summary of Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit – ANCOVA
ITT Population

(Programming note: Same as table 14.2.3.7, except add header rows at the top for "Scale: DLQI" and "Scale: "CDLQI". Add "DLQI = Dermatology Life Quality Index" and "CDLQI = Children's DLQI" to abbreviations in alphabetical order. Change reference listings to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.8**. Replace instances of PSD with DLQI/CDLQI in [1]. Replace PSD Total Score text in the note footnote with** "The DLQI/CDLQI score is calculated as sum of all the 10 questions at each visit and ranges between 0-30. The individual questions are scored as "Very much" or "Yes"= 3, "A lot" = 2, "A Little" = 1, "Not at all" or "Not Relevant" = 0. If 1 item is missing, it is scored as 0 for that item. If 2 or more items are missing, the score should not be calculated. Lower scores indicate improvement. Baseline is the last non-missing measurement taken on or before the day first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.")**

Table 14.2.8.4
Summary of Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) by Study Visit – ANCOVA
mITT Population

(Programming note: Same as table 14.2.8.4)

Table 14.2.9.1
Summary and Change from Baseline in % Body Surface Area (BSA) Affected by Disease by Study Visit
ITT Population

(**Programming note: Same as table 14.2.3.1. Add "BSA = body surface area" to abbreviations in alphabetical order. Change reference listing to** Reference Listing: 16.2.6.9**. Update footnotes as** "Note: Subjects are summarized by planned treatment. Baseline is the last non-missing measurement taken before the first application of study drug. Change from baseline is calculated as result – baseline result. Percent change from baseline is calculated as (change from baseline/baseline)*100.**")**

Table 14.2.9.2
Summary and Change from Baseline in % Body Surface Area (BSA) Affected by Disease by Study Visit
mITT Population

(**Programming note: Same as table 14.2.9.2)**

Table 14.2.9.3
Summary of % Body Surface Area (BSA) Affected by Disease by Study Visit – ANCOVA
ITT Population

(Programming note: Same as table 14.2.3.7. Add "BSA = body surface area" and "ePRO = electronic patient reported outcomes" to abbreviations in alphabetical order. Change reference listings to Reference Listings: 16.2.6.1, 16.2.6.2, 16.2.6.9**. Replace instances of PSD with BSA in [1]. Replace PSD Total Score text in the note footnote with "**BSA collected on the ePRO tablet will be used for summarization."**)**

Table 14.2.9.4
Summary of % Body Surface Area (BSA) Affected by Disease by Study Visit – ANCOVA
mITT Population

(Programming note: Same as table 14.2.9.3)

Table 14.3.1.1
Summary of Treatment Emergent Adverse Events
Safety Population

Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 TEAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Maximum Severity of TEAE [1]			
Grade 1 (Mild)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 2 (Moderate)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 3 (Severe)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 4 (Life-threatening consequences)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 5 (Death related to AE)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with a Related TEAE [2]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with a TEAE Leading to Discontinuation of Study Drug	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with an SAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with a Grade 5 TEAE [3]	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: AE = adverse event; CTCAE = Common Terminology Criteria for Adverse Events; IP = investigational product; SAE = serious adverse event; TEAE = treatment emergent adverse event.
Note: Percentages are n/Number of subjects in the Safety population within treatment received*100. A TEAE is defined as an AE that started post application of IP at the baseline visit through study completion.
[1] Severity grades are reported according to the CTCAE version 4.0. Subjects are counted only once at the worst severity. If a severity designation is missing, it will be considered as severe.
[2] AEs with a relationship of possibly, probably, likely, or missing were considered related.
[3] A Grade 5 TEAE is a TEAE leading to death.
Reference Listing: 16.2.7.1

Table 14.3.1.2
Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 TEAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: AE = adverse event; IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. AEs were coded using MedDRA version 23.0. A TEAE is defined as an AE that started post application of IP at the baseline visit through study completion. Subjects are counted once for each system organ class (SOC) and once for each preferred term (PT). AEs are displayed alphabetically by SOC, then by descending frequency of PT within SOC, and then alphabetically by PT.
Reference Listing: 16.2.7.1

Programming note: *SOC & PT text should be presented as is from the dataset.*

Table 14.3.1.3
Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity
Safety Population

System Organ Class Preferred Term Maximum Severity [1]	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 TEAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 1 (Mild)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 2 (Moderate)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 3 (Severe)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 4 (Life-threatening consequences)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 5 (Death related to AE)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1			
Any Event (Total)			
Grade 1 (Mild)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 2 (Moderate)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 3 (Severe)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 4 (Life-threatening consequences)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 5 (Death related to AE)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1			
Grade 1 (Mild)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Grade 2 (Moderate)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			

Abbreviations: AE = adverse event; CTCAE = Common Terminology Criteria for Adverse Events; IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. AEs were coded using MedDRA version 23.0. A TEAE is defined as an AE that started post application of IP at the baseline visit through study completion. Subjects are counted once for each system organ class (SOC) and once for each preferred term (PT) at the maximum severity.
[1] Severity grades are reported according to the CTCAE version 4.0. The severity shown is the greatest severity reported for a particular subject (Grade 5 [Death related to AE] > Grade 4 [Life-threatening consequences] > Grade 3 [Severe] > Grade 2 [Moderate] > Grade 1 [Mild]). AEs with a missing severity were counted as Severe. AEs are displayed alphabetically by SOC, then by descending frequency of PT within SOC, and then alphabetically by PT.
Reference Listing: 16.2.7.1

Programming note: *SOC & PT text should be presented as is from the dataset.*

Table 14.3.1.4
Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship [1]	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 TEAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: AE = adverse event; IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. AEs were coded using MedDRA version 23.0. A TEAE is defined as an AE that started post application of IP at the baseline visit through study completion. Subjects are counted once for each system organ class (SOC) and once for each preferred term (PT) at the greatest relationship category. The relationship shown is the greatest relationship reported for a particular subject (Related > Not Related). AEs with a missing relationship were counted as Related. AEs are displayed alphabetically by SOC, then by descending frequency of PT within SOC, and then alphabetically by PT.
[1] Related = Probably Related, Possibly Related, Likely Related, and Missing; Not Related = Unrelated and Unlikely Related.
Reference Listing: 16.2.7.1

Programming note: *SOC & PT text should be presented as is from the dataset.*

Table 14.3.1.5
Incidence of Treatment Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term
Safety Population

(Same shell as Table 14.3.1.2)

Table 14.3.1.6
Incidence of Treatment Emergent Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term
Safety Population

(Same shell as Table 14.3.1.2)

Table 14.3.1.7
Incidence of Related Treatment Emergent Adverse Events by Preferred Term
Safety Population

Preferred Term	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 Related TEAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 4	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 5	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 6	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 7	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 8	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 9	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 10	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 11	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			

Abbreviations: AE = adverse event; CTCAE = Common Terminology Criteria for Adverse Events; IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. AEs were coded using MedDRA version 23.0. A TEAE is defined as an AE that started post application of IP at the baseline visit through study completion. Related TEAEs are AE marked Probably Related, Possibly Related, Likely Related, or missing. Subjects are counted once for each once for each preferred term (PT). AEs are displayed by descending frequency of PT, and then alphabetically by PT in case of ties.

Programming note: *PT text should be presented as is from the dataset.*

Table 14.3.2.1
Incidence of Serious Adverse Events by System Organ Class and Preferred Term
Safety Population

(Same shell as Table 14.3.1.2; first-row text is "Subjects with at least 1 SAE**"; add** SAE = serious adverse event**)**

Table 14.3.2.2
Incidence of Serious Adverse Events by System Organ Class, Preferred Term, and Relationship to Study Drug
Safety Population

(Same shell as Table 14.3.1.4; first-row text is "Subjects with at least 1 SAE**"; add** SAE = serious adverse event**)**

Table 14.3.2.3
Incidence of Serious Adverse Events by System Organ Class, Preferred Term, and Maximum Severity
Safety Population

(Same shell as Table 14.3.1.3; first-row text is "Subjects with at least 1 SAE**"; add** SAE = serious adverse event**)**

Table 14.3.3.1
Listing of Adverse Events Leading to Study Drug Discontinuation
Safety Population

Subject ID	Treatment Received	System Organ Class/ Preferred Term/ Verbatim Term	Start Date/Time (Study Day)/ End Date/Time (Study Day)	CTCAE Toxicity Grade/ Relationship	Outcome/ Study Drug Action Taken/ Other Action Taken	Serious?/ Criteria Met
XXXXX	XXXXXXXX	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMONYYYY/hh:mm (X)/ DDMONYYYY/hh:mm (X)	XXXXXXXXX/ XXXXXXXXXX	XXXXXXXXX/ XXXXXXXXXXX/ XXXXXXXXX	XX
XXXXX	XXXXXXXX	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMONYYYY/hh:mm (X)/ DDMONYYYY/hh:mm (X)	XXXXXXXXX/ XXXXXXXXXX	XXXXXXXXX/ XXXXXXXXXXX/ XXXXXXXXX	XX
		XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMONYYYY/hh:mm (X)/ DDMONYYYY/hh:mm (X)	XXXXXXXXX/ XXXXXXXXXX	XXXXXXXXX/ XXXXXXXXXXX/ XXXXXXXXX	XXX/ XXXXXXXXX

Abbreviations: CTCAE = Common Terminology Criteria for Adverse Events; MedDRA = Medical Dictionary for Regulatory Activities.
Note: Study day is calculated relative to the date of first application of study drug. AEs were coded using MedDRA version 23.0. Severity grades are reported according to the CTCAE version 4.0.

Programming note: *If time missing, display "- -:- -". "Other Action Taken" will be either None, Concomitant Medication, Non-drug Therapy, Hospitalization or Prolongation of Hospitalization, Discontinued Study or Other; if specify text is needed, concatenate "Concomitant Medication:" or "Other:" with the text. If Serious? is Yes, concatenate all serious criteria marked as Yes with a semicolon. If no events meet the criteria for display, present "No events are reported." SOC & PT text should presented as is from the dataset.*

Table 14.3.3.2
Listing of Serious Adverse Events
Safety Population

(Same shell as Table 14.3.3.1)

Table 14.3.3.3
Listing of Deaths
Safety Population

(Same shell as Table 14.3.3.1)

Table 14.3.5.1.1
Summary of Clinical Chemistry Laboratory Results by Study Visit
Safety Population

Parameter: XXXXXXX (unit)

Study Visit	Roflumilast Foam 0.3% (N=XX)		Vehicle (N=XX)		Overall (N=XX)	
Statistic	Observed	Change	Observed	Change	Observed	Change
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
Week 4						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

Repeat for Week 8. Continue for other parameters. Sort alphabetically by parameter.

Note: Subjects are summarized by treatment received and overall. Baseline is the last non-missing measurement taken before the first application of study drug.
Reference Listing: 16.2.8.1.1

Table 14.3.5.1.2
Shift from Baseline in Clinical Chemistry Laboratory Results by Study Visit
Safety Population

Parameter: XXXXXXX (unit)

		Baseline Grade									
		Roflumilast Foam 0.3% (N=XX)					Vehicle (N=XX)				
Study Visit	Post-Baseline Grade	Missing	Low	Normal	High	Total	Missing	Low	Normal	High	Total
Week 4	Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Low	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	High	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 8	Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Low	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	High	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Repeat for Overall. Repeat all for clinical chemistry parameters (excluding serum HCG results).

Note: Percentages are n/Number of subjects in the Safety population within treatment received*100. Baseline is the last non-missing measurement taken before the first application of study drug.
Reference Listing: 16.2.8.1.1

Table 14.3.5.2.1
Summary of Hematology Laboratory Results by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.1; Reference Listing: 16.2.8.1.2)

Table 14.3.5.2.2
Shift from Baseline in Hematology Laboratory Results by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.2; Reference Listing: 16.2.8.1.2)

Table 14.3.5.3.1
Summary of Quantitative Urinalysis Laboratory Results by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.1; Reference Listing: 16.2.8.1.3)

Table 14.3.5.3.2
Shift from Baseline in Quantitative and Qualitative Urinalysis Laboratory Results by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.2; Reference Listing: 16.2.8.1.3)

Table 14.3.5.3.3
Summary of Qualitative Urinalysis Laboratory Results by Study Visit
Safety Population

Study Visit Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline			
XXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 4			
XXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 8			
XXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
XXXXXXXX	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Baseline is the last non-missing measurement taken before the first application of study drug.
Reference Listing: 16.2.8.1.3

Table 14.3.6.1
Shift from Baseline in Patient Health Questionnaire (PHQ-8)/Modified PHQ-Adolescents by Study Visit
Safety Population

Scale: PHQ-8

	Baseline Category						
	Roflumilast Foam 0.3% (N=XX)						
Study Visit Category [1]	Missing	None	Mild	Moderate	Moderately Severe	Severe	Total
Week 4							
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
None	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderately Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 8							
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
None	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderately Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Repeat for Vehicle and Overall. Repeat for Scale: PHQ-A

Abbreviations: PHQ-8 = patient health questionnaire (8 questions); PHQ-A = patient health questionnaire - adolescents.
Note: Percentages are n/Number of subjects in the Safety population within scale (PHQ-8 or PHQ-A) and treatment received and overall*100. Baseline is the last non-missing measurement taken on or before the day of first application of study drug. The PHQ total score is calculated as sum of the 8 questions (individual questions scored as Not at all=0, Several days=1, More than half the days=2, and Nearly every day=3). The total score ranges from 0 to 24. If more than 1 item is missing the score was not calculated. If 1 item is missing the score is calculated as (sum of answered items*8)/number of answered items. The PHQ-8 was filled out by adults and the modified PHQ-A was filled out by adolescents.
[1] If the total score ranges from 0 to 4, it is classified as None – Minimal Depression; 5 – 9 classified as Mild; 10 – 14 classified as Moderate; 15-19 classified as Moderately Severe; 20 – 24 classified as Severe Depression.
Reference Listing: 16.2.9.7

Table 14.3.6.2.1
Summary of Investigator Local Tolerability Assessment (Dermal Response) by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.1; Reference Listing: 16.2.9.1; Repeat for Week 4, Week 8; Add this line at the end in note footnote – "Lower scores indicate no evidence of irritation while higher scores indicate worsening reaction. These assessments should be done prior to the IP application in the study site. Subjects not meeting this condition on baseline visit are completely removed from the table summary.")

Table 14.3.6.2.2
Summary of Investigator Local Tolerability Assessment (Dermal Response) by Study Visit
Categorical Results
Safety Population

Study Visit Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline			
0 = No evidence of irritation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
1 = Minimal erythema	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
2 = Definite erythema	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
3 = Erythema and papules	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
4 = Definite edema	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
5 = Erythema, edema and papules	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
6 = Vesicular eruption	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
7 = Strong reaction spreading beyond application site			
Week 4			
0 = No evidence of irritation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
1 = Minimal erythema	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
2 = Definite erythema	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
3 = Erythema and papules	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
4 = Definite edema	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
5 = Erythema, edema and papules	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
6 = Vesicular eruption	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
7 = Strong reaction spreading beyond application site	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Repeat for Week 8			

Abbreviation: IP = investigational product.
Note: Percentages are n/Number of subjects in the Safety Population within treatment received and overall*100. Baseline is the last non-missing measurement taken before the first application of study drug. These assessments should be done prior to the IP application in the study site. Subjects not meeting this condition on baseline visit are completely removed from the table summary.
Reference Listing: 16.2.9.1

Table 14.3.6.2.3
Summary of Investigator Local Tolerability Assessment (Other Effects) by Study Visit
Categorical Results
Safety Population

Study Visit Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline			
A = Slight glazed appearance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
B = Marked glazing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
C = Glazing with peeling and cracking	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
D = Glazing with fissures	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
E = Film of dried serous exudates	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
F = Small petechial erosions and/or scabs	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
G = No other effects	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 4			
A = Slight glazed appearance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
B = Marked glazing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
C = Glazing with peeling and cracking	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
D = Glazing with fissures	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
E = Film of dried serous exudates	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
F = Small petechial erosions and/or scabs	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
G = No other effects	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Repeat for Week 8			

Abbreviation: IP = investigational product.
Note: Percentages are n/Number of subjects in the Safety Population within treatment received and overall*100. Baseline is the last non-missing measurement taken before the first application of study drug. These assessments should be done 10 - 15 minutes after the application of IP in the study site. Subjects not meeting this condition on baseline visit are completely removed from the table summary.
Reference Listing: 16.2.9.1

Table 14.3.6.3.1
Summary of Subject Local Tolerability Assessment by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.1; Reference Listing: 16.2.9.2; Repeat for Week 4, Week 8; add "IP = investigational product" to abbreviations; Add this line at the end in note footnote – "Lower scores indicate no sensation while higher scores indicate worsening/severe sensation. These assessments should be done 10 - 15 minutes after the application of IP in the study site. Subjects not meeting this condition on baseline visit are completely removed from the table summary." Change baseline definition to "Baseline for subject local tolerability assessment is the last non-missing measurement taken on the day of first application of study drug.")

Table 14.3.6.3.2
Summary of Subject Local Tolerability Assessment by Study Visit
Categorical Results
Safety Population

Study Visit Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Baseline			
0 = None (no sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
1 = Mild (slight warm, tingling sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
2 = Moderate (definite warm, tingling sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
3 = Severe (hot, tingling/stinging sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 4			
0 = None (no sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
1 = Mild (slight warm, tingling sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
2 = Moderate (definite warm, tingling sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
3 = Severe (hot, tingling/stinging sensation)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Repeat for Week 8			

Abbreviation: IP = investigational product.
Note: Percentages are n/Number of subjects in the Safety Population within treatment received and overall*100. Baseline for subject local tolerability assessment is the last non-missing measurement taken on the day of first application of study drug. These assessments should be done 10 - 15 minutes after the application of IP in the study site. Subjects not meeting this condition on baseline visit are completely removed from the table summary.
Reference Listing: 16.2.9.2

Table 14.3.6.4.1
Summary of Vital Signs by Study Visit
Safety Population

(Same shell as Table 14.3.5.1.1; visits include Baseline, Week 2, Week 4, Week 8, Week 9; parameters include Temperature (°C), Heart Rate (bpm), Systolic Blood Pressure (mmHg), Diastolic Blood Pressure (mmHg), Height (cm), Weight (kg), and BMI (kg/m^2) [1], where [1] goes to "[1] Body Mass Index (BMI) = weight (kg) / [height (m)]^2."; Reference Listings: 16.2.9.3.1, 16.2.9.4.2)

Table 14.3.6.4.2
Shift from Baseline in Weight by Study Visit
Safety Population

Study Visit Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Week 2			
Weight Loss ≥ 10%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Gain ≥ 10%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Loss ≥ 5%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Gain ≥ 5%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 4			
Weight Loss ≥ 10%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Gain ≥ 10%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Loss ≥ 5%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Gain ≥ 5%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 8			
Weight Loss ≥ 10%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Gain ≥ 10%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Loss ≥ 5%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Weight Gain ≥ 5%	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Continue for Week 9

Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Baseline is the last non-missing measurement taken before the first application of study drug.
Reference Listing: 16.2.9.3.2

Table 14.3.6.4.3
Shift from Baseline in Weight by Study Visit and Weight Loss Intentional/Non-Intentional Categories
Safety Population

(Same shell as Table 14.3.6.4.2, except will be presented by the following categories as headers in the by-line: "Weight Loss: Intentional" and "Weight Loss: Not Intentional or Missing").

Table 14.3.6.4.4
Shift from Baseline in BMI Categories by Study Visit
Safety Population

Study Visit	Post-Baseline Category [1]	Baseline Category: Roflumilast Foam 0.3% (N=XX)					
		Missing	Underweight	Normal	Overweight	Obese	Total
Week 2	Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Underweight	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Overweight	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Obese	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Week 4	Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Underweight	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Overweight	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Obese	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Repeat for Vehicle and Overall. Repeat all for Week 8.

Abbreviation: BMI = body mass index.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Baseline is the last non-missing measurement taken before the first application of study drug. BMI is derived as (weight in kg)/[(height in cm/100)^2].
[1] If BMI is below 18.5 then it is categorized as underweight; if BMI ranges between 18.5 – 24.9 then it is categorized as Normal; if BMI ranges between 25.0 – 29.9 then it is categorized as overweight; if BMI is ≥ 30.0 then it is categorized as obese.
Reference Listings: 16.2.9.4.1, 16.2.9.4.2

Table 14.3.6.4.5
Shift from Baseline in Weight by Study Visit and Weight Loss Intentional/Non-Intentional Categories
Safety Population

(Same shell as Table 14.3.6.4.5, except will be presented by the following categories as headers in the by-line: "Weight Loss: Intentional" and "Weight Loss: Not Intentional or Missing").

Table 14.3.6.5
Summary of Columbia-Suicide Severity Rating Scale (C-SSRS) Suicidal Ideation and Suicidal Behavior by Study Visit
Safety Population

Study Visit C-SSRS Section C-SSRS Item	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Screening			
Suicidal Ideation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Wish to be Dead	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Non-Specific Active Suicidal Thoughts	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Active Suicidal Ideation with Any Methods	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Active Suicidal Ideation with Some Intent	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Active Suicidal Ideation with Specific Plan	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Suicidal Behavior	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Actual Attempt	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Interrupted Attempt	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Aborted Attempt	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preparatory Acts or Behavior	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Suicidal Ideation or Behavior	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subject Engaged in Non-Suicidal Self-Injurious Behavior	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Repeat for Baseline Day 0, Week 4, Week 8; Add Suicide row for all visits except Screening.

Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. The number and percent of subjects who experience the event at least once during treatment are summarized. Subjects are counted once for each C-SSRS section and once for each C-SSRS item answered “Yes” during treatment period. “Baseline/Screening” version was used for Screening visit and “Since Last Visit” was used for all other visits.
Reference Listing: 16.2.9.8

Table 14.3.6.6
Summary of Physical Examination by Study Visit
Safety Population

Study Visit Body System Category	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Screening			
Skin			
Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Abnormal (NCS)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Abnormal (CS)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lungs			
Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Abnormal (NCS)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Abnormal (CS)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Heart			
Normal	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Abnormal (NCS)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Abnormal (CS)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Total	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Repeat for Baseline, Week 8

Abbreviations: CS = clinically significant; NCS = not clinically significant.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Baseline is the last non-missing measurement taken before the first application of study drug.
Reference Listing: 16.2.9.4

Table 14.3.6.7
Summary of Concomitant Medications by ATC Class Level 4 and Preferred Term
Safety Population

ATC Class Level 4 Preferred Term	Roflumilast Foam 0.3% (N=XX)	Vehicle (N=XX)	Overall (N=XX)
Subjects with at least 1 Concomitant Medication	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
ATC Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
ATC Class 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: ATC = Anatomic Therapeutic Chemical; PT = preferred term; WHO-DDE = World Health Organization-Drug Dictionary Enhanced.
Note: Percentages are n/Number of subjects in the Safety population within treatment received and overall*100. Medications were coded using WHO-DDE Global B3 version September 2019. Concomitant medications are all medications that were continuing or starting after first application of study drug. Medications are displayed by alphabetical order of ATC Level 4 classification, then descending frequency of PT within ATC, and then alphabetically by PT. Subjects were counted only once for each ATC and PT.
Reference Listing: 16.2.9.6

Programming note: *ATC & PT text should be presented as is from dataset.*

Table 14.4.1.1
Summary of Pharmacokinetic Concentration Results by Study Visit and Time Point
PK Population

Study Visit Time Point Statistic	Roflumilast Foam 0.3% (N=XX)
Baseline Day 0	
Predose	
n	XX
Mean (SD)	XX.X (XX.XX)
Median	XX.X
Min, Max	XX, XX
1 hour postdose	
n	XX
Mean (SD)	XX.X (XX.XX)
Median	XX.X
Min, Max	XX, XX
2 hours postdose	
n	XX
Mean (SD)	XX.X (XX.XX)
Median	XX.X
Min, Max	XX, XX

Programming note: Repeat for Baseline: 4 hours postdose, 6 hours postdose, and 24 hours postdose; Week 4: Predose, 1 hour postdose, 2 hours postdose, 4 hours postdose, 6 hours postdose, and 24 hours postdose; Week 8: Predose.

Note: Subjects are summarized by treatment received. Results at the predose time point that occurred after dosing are excluded from this summary.
Reference Listing: 16.2.5.6

Table 14.4.1.2
Summary of Pharmacokinetic Parameters by Study Visit
PK Population

Parameter: XXXXXXXX

Study Visit Statistic	Roflumilast Foam 0.3% (N=XX)
Baseline Day 0	
n	XX
Mean (SD)	XX.X (XX.XX)
Median	XX.X
Min, Max	XX, XX
Week 4	
n	XX
Mean (SD)	XX.X (XX.XX)
Median	XX.X
Min, Max	XX, XX
Week 8	
n	XX
Mean (SD)	XX.X (XX.XX)
Median	XX.X
Min, Max	XX, XX

Programming note: Continue for all parameters.

Note: Subjects are summarized by treatment received.
Reference Listing: 16.2.5.7

14.3. Planned Listing Shells

Listing 16.2.1.1
Subject Disposition
All Subjects

Subject ID	Randomized Treatment	Did Subject Complete Study? [1]		Date of Completion/ Early Termination (Study Day)	Date of Last Study Visit (Study Day)	Reason for Early Termination [2]	Cause of Death/ Date of Death	Early Termination Due to COVID-19 Disruption
		eCRF	Derived					
XXXXXX	XXXXXX	Yes	Yes	DDMMMYYYY (XX)	DDMMMYYYY (XX)			
XXXXXX	XXXXXX	Yes	Yes	DDMMMYYYY (XX)	DDMMMYYYY (XX)			
XXXXXX	XXXXXX	Yes	Yes	DDMMMYYYY (XX)	DDMMMYYYY (XX)			
XXXXXX	XXXXXX	No	Yes	DDMMMYYYY (XX)	DDMMMYYYY (X)	XXXXXXXXXX: XXXXXXXXX		
XXXXXX	XXXXXX	No	Yes	DDMMMYYYY (XX)	DDMMMYYYY (XX)	XXXXXX	XXXXX/ DDMMMYYYY	XXX

Abbreviations: COVID-19 = novel coronavirus disease-19; eCRF = electronic case report form.
Note: Study day is calculated relative to the date of first application of study drug.
[1] The derived completion status is based on a subject completing the Week 8 visit; this is what is used in the subject disposition summary. The eCRF completion status is based on what was recorded in the eCRF.
[2] Based on the eCRF.

Programming Note: *If reason for early termination is Other, concatenate the specify text as follows: "Other: XXXXXXXXX". If reason for early termination is lost to follow-up, concatenate with date of last contact as follows: "Lost to follow-up; date of last contact: DDMMMYYYY".*

Listing 16.2.1.2
Subject Visits
All Subjects

Subject ID	Treatment Received	Was Visit Performed?	Visit	Visit Date (Study Day)	If Visit not Performed, COVID-19 Disruption Contributed to Missed Visit
XXXXXX	XXXXXX	Yes	XXXXXXX	DDMMMYYYY (XX)	
		Yes	XXXXXX	DDMMMYYYY (XX)	
		Yes	XXXXXXXXX	DDMMMYYYY (XX)	
		No	XXXXXXX		Yes
XXXXXX	XXXXXX	Yes	XXXXXXX	DDMMMYYYY (XX)	
		Yes	XXXXXX	DDMMMYYYY (XX)	

Abbreviation: COVID-19 = novel coronavirus disease-19.
Note: Study day is calculated relative to the date of first application of study drug.

Listing 16.2.2.1
Inclusion and Exclusion Criteria
All Subjects

Subject ID	Was Subject Rescreened?	Subject Screen Failed due to COVID-19 Disruption	Randomized Treatment	Date/Time (Study Day) of:			All Inclusion Criteria Met? [1]	Any Exclusion Criteria Met? [2]
				Screening	Informed Consent	If Adolescent, Date of Written Assent		
XXXXXX	XX		XXXXXX	DDMMMYYYY (-X)	DDMMMYYYY/hh:mm (-X)		Yes	No
XXXXXX	XX	XX		DDMMMYYYY		DDMMMYYYY	No: 05, 13	No
XXXXXX	XX	XX		DDMMMYYYY	DDMMMYYYY/hh:mm		No: 02	No
XXXXXX	XXX		XXXXXX	DDMMMYYYY (-X)		DDMMMYYYY (-X)	Yes	Yes: 02
XXXXXX	XX		XXXXXX	DDMMMYYYY (-X)	DDMMMYYYY (-X)		Yes	No
XXXXXX	XX		XXXXXX	DDMMMYYYY (-X)	DDMMMYYYY (-X)		Yes	No

Abbreviation: COVID-19 = novel coronavirus disease-19.
Note: Study day is calculated relative to the date of first application of study drug. If a subject is a rescreen, the latest date of screening and informed consent are presented.
[1] 02 = Males and females ages 12 years and older (inclusive) at the time of consent or assent (for adolescents); 05 = A Psoriasis Scalp Severity Index (PSSI) score of at least 6 at Baseline; 13 = Subjects are considered reliable and capable of adhering to the Protocol and visit schedule according to the Investigator judgment.
[2] 02 = Planned excessive exposure of treated area(s) to either natural or artificial sunlight, tanning bed or other LED.

Programming note: *If more than 1 inclusion or exclusion criterion number exists, concatenate with a comma as shown above. Decode any relevant criteria in the footnotes as shown in the example. If no criteria are present for a column, remove the [1] and/or [2] from the column header. Time is only collected for informed consent. If time is missing, display as shown in the shell. If subject rescreens, populate the latest date of screening and informed consent.*

Listing 16.2.2.2
Protocol Deviations
All Subjects

Subject ID	Treatment Received	Date of Protocol Violation Collection (Study Day)	Event Type	Violation Level	Description	COVID-19 Related	COVID-19 Infection	Action/Resolution
XXXXXX	XXXXXX	DDMONYYYY (XX)	XXXXXXXXXX	Minor	XXXXXXX			
		DDMONYYYY (XX)	XXXXXXXXXXXXX	Major	XXXXXXXXXXXXXX			
XXXXXX	XXXXXX	DDMONYYYY (XX)	XXXXXXXXXXX	XXXXX	XXXXXXXXXXXXXXXXXX			
		DDMONYYYY (XX)	XXXXXXXXXXXXXX	XXXXX	XXXXXXXXXX	XXX	XXX	
XXXXXX	XXXXXX	DDMONYYYY (XX)	XXXXXXXXXXX	XXXXX	XXXXXXXXXXXXXXXXXX	XX	XX	

Abbreviation: COVID-19 = novel coronavirus disease-19.
Note: Study day is calculated relative to the date of first application of study drug.

Programming note: *the structure of this listing may change depending on the information in the protocol deviations file.*

Listing 16.2.3.1
Subject Randomization
All Subjects

		Randomization			
Subject ID	Treatment Received	Randomized Treatment	Date/Time	Number	Stratification ID
XXXXXX	XXXXXX	XXXXX	DDMMMYYY/ hh:mm	XXXX	XXXX
XXXXXX	XXXXXXX	XXXXX	DDMMMYYY/ hh:mm	XXXX	XXXX
XXXXXX					

Listing 16.2.3.2
Analysis Populations
All Subjects

Subject ID	Treatment Received	Safety [1]	ITT [2]	mITT [3]	SPRU4-ITT [4]	SPRU4-mITT [4]	PRU4-ITT [5]	PRU4-mITT [5]	PK [6]	Primary Reason(s) for Exclusion [7]
XXXXXX	XXXXXX	Yes	Yes	No	Yes	XXX	XXX	XXX	XXX	Subject missed Week 8 disease assessment specifically due to COVID-19 disruptions.
XXXXXX	XXXXXXX	Yes	Yes	Yes	Yes	XXX	XXX	XXX	XXX	
XXXXXX		No	Yes	No	No	XXX	XXX	XXX	XXX	Subject did not receive at least 1 dose of IP.

Abbreviations: COVID-19 = novel coronavirus disease-19; ITT = intent-to-treat; IP = investigational product; mITT = modified intent-to-treat; NA = not applicable; PK = pharmacokinetic; PRU4 = Subjects with WI-NRS Pruritus Score ≥4 at Baseline; SI-NRS = Scalp Itch – Numeric Rating Scale; SPRU4 = Subjects with SI-NRS Pruritus Score ≥4 at Baseline; WI-NRS = Worst Itch – Numeric Rating Scale.
[1] The Safety Population includes all subjects who are enrolled and received at least 1 confirmed dose of IP.
[2] The ITT Population includes all subjects who are randomized.
[3] The mITT population includes all randomized subjects with the exception of subjects who missed the Week 8 S-IGA assessment specifically due to COVID-19 disruptions.
[4] The SPRU4-ITT and SPRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with SI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in SI-NRS pruritus score as compared to Baseline.
[5] The PRU4-ITT and PRU4-mITT populations are subsets of the ITT and mITT populations, respectively, and include subjects with WI-NRS pruritus score ≥ 4 at Baseline. These populations will be used for the analyses of achievement of a 4-point reduction in WI-NRS pruritus score as compared to Baseline.
[6] The PK population includes all subjects receiving the active drug with sufficient plasma concentrations of roflumilast to define a profile, as determined by the pharmacokineticist.
[7] Applies to the Safety, ITT, and mITT populations only.

Listing 16.2.4.1.1
Subject Demographics
All Subjects

Subject ID	Treatment Received	Sex	Child-Bearing Potential? If Yes, Specify Contraception	Year of Birth	Age (years) [1]	Ethnicity	Race	Photography Consent Obtained/ Date of Consent	PK Consent Obtained/ Date of Consent
XXXXXX	XXXXXX	XXXX	No	YYYY	XX	XXXXXXX	XXXXXXX	Yes/ DDMMMYYYY	Yes/ DDMMMYYYY
XXXXXX	XXXXXX	XXXXXX	No	YYYY	XX	XXXXXXX	XXXXXX	Yes/ DDMMMYYYY	Yes/ DDMMMYYYY
XXXXXX	XXXXXX	XXXX		YYYY	XX	XXXXXXX	XXXXXX	No	No
XXXXXX	XXXXXX	XXXX		YYYY	XX	XXXXXXX	XXXXX	Yes/ DDMMMYYYY	Yes/ DDMMMYYYY
XXXXXX	XXXXXX	XXXXXX	No	YYYY	XX	XXXXXXX	XXXXXX	Yes/ DDMMMYYYY	Yes/ DDMMMYYYY
XXXXXX	XXXXXX	XXXXX	Yes: XXXXXXX	YYYY	XX	XXXXXX	XXXXXX	XXX	XXX

Abbreviation: PK = pharmacokinetic.
[1] Age at Screening.

Programming Note: *If subject has multiple races, concatenate them. If child-bearing potential is Yes, concatenate type of contraception with ":" as shown in the shell.*

Listing 16.2.4.1.2
Baseline Characteristics
All Subjects

Subject ID	Treatment Received	Height (cm)	Weight (kg)	BSA (%)	S-IGA [1]	B-IGA [1]	SI-NRS [2]	WI-NRS [2]
XXXXXX	XXXXXX	XX.X	XX.X	XX.X	X = XXXXX	X = XXXXX	XX	XX
XXXXXX	XXXXXX	XX.X	XX.X	XX.X	X = XXXXX *	X = XXXXX *	XX	XX
XXXXXX	XXXXXX	XX.X	XX.X	XX.X	X = XXXXX	X = XXXXX	XX	XX
XXXXXX	XXXXXX	XX.X	XX.X	XX.X	X = XXXXX	X = XXXXX	XX	XX
XXXXXX	XXXXXX	XX.X	XX.X	XX.X	X = XXXXX	X = XXXXX	XX	XX
XXXXXX	XXXXXX	XX.X	XX.X	XX.X	X = XXXXX	X = XXXXX	XX	XX

Abbreviations: B-IGA = body investigator global assessment; BSA = body surface area; S-IGA = scalp investigator global assessment; SI-NRS = Scalp Itch – Numeric Rating Scale; WI-NRS = Worst Itch – Numeric Rating Scale.
Note: Weight and % BSA affected by disease are the values at Screening. Height was collected at Baseline Day 0.
[1] For S-IGA and B-IGA, baseline is the last non-missing measurement taken before the first application of study drug. * = Screening visit was used as baseline.
[2] For SI-NRS and WI-NRS, baseline is the last non-missing measurement taken on or before the day of first application of study drug.

Programming Note: *For S-IGA and B-IGA scores, if VISIT is not Baseline Day 0 for the record where ABLFL=Y, then add a * to the end of the concatenated numeric + text result, as shown in the shell.*

Listing 16.2.4.2
Medical History
All Subjects

Subject ID	Treatment Received	Subject History of Psoriasis Involvement	Type of History	Other Medical History Conditions	
				System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)
XXXXXX	XXXXXX	Knees/Elbow: Yes/ Genitalia: No	Topical Corticosteroids: Yes/ Topical Vitamin D Derivatives: No	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMMMYYYY (X)/ DDMMMYYYY (X)
				XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMMMYYYY (X)/ DDMMMYYYY (X)
				XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMMMYYYY (X)/ DDMMMYYYY (X)
XXXXXX	XXXXXX	Knees/Elbow: Yes/ Genitalia: No	Topical Corticosteroids: Yes/ Topical Vitamin D Derivatives: No	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX XXXXXXXXXXXX	DDMMMYYYY (X)/ Ongoing

Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities.
Note: Study day is calculated relative to the date of first application of study drug. Medical history was coded using MedDRA version 23.0. Only subjects with medical history recorded are listed.

Programming note: *SOC & PT text should be presented as is from the dataset.*

Listing 16.2.5.1
Study Drug Application at the Study Site
All Subjects

Subject ID	Treatment Received	Was Study Drug Application Performed at Study Site?	Study Visit	Date/Time of Application (Study Day)	Pre-Application Can Weight (g) Measurement	Post-Application Can Weight (g) Measurement	Applied Dose (g)	Reason Pre- and/or Post-Application Can Weight Measurement not Performed	Kit Number/ Can ID
XXXX	XXXXXX	Yes	XXXXXX	DDMMMYYYY/HH:MM (X)	XX	XX	XX		XXXX/ XX
			XXXXXX	DDMMMYYYY/HH:MM (XX)	XX.X	XX.X	XX.X		XXXX/ XX
			XXXXXX	DDMMMYYYY/HH:MM (XX)	XX	XX	XX		XXXX/ XX
		No: XXXXXX	XXXXXX						
XXXX	XXXXXX	Yes	XXXXXX	DDMMMYYYY/HH:MM (X)	XX	XX	XX		XXXX/ XX
			XXXXXX	DDMMMYYYY/HH:MM (XX)	XX	XX	XX.X		XXXX/ XX
			XXXXXX	DDMMMYYYY/HH:MM (XX)	XX	Not Done		XXXXXXXXXXXX	XXXX/ XX

Note: Study day is calculated relative to the date of first application of study drug.

***Programming note**: For Pre & Post-Application Can Weight Measurement columns, if the weight measurement is not performed, set the value to be "Not Done". If drug not administered, concatenate reason (COVID-19 Disruption or other specify text) as shown in shell.*

Listing 16.2.5.2
Cans
All Subjects

Subject ID	Treatment Received	Kit Number/ Can ID	Can Dispensed? Reason if No	Date Dispensed (Study Day)	Dispense Weight (g)	Can Returned? Reason if No	Date Returned (Study Day)	Return Weight (g)
XXXXX	XXXXXX	XXXXX/ XX	Yes	DDMMMYYYY (X)	XX.X	Yes	DDMMMYYYY (X)	XX.X
		XXXXX/ XX	Yes	DDMMMYYYY (X)	XX.X	Yes	DDMMMYYYY (X)	XX.X
		XXXXX/ XX	Yes	DDMMMYYYY (X)	ND	Yes	DDMMMYYYY (X)	ND
XXXXX	XXXXXX	XXXXX	No: XXXXX			No: XXXXX		

Abbreviation: ND = not done.
Note: Study day is calculated relative to the date of first application of study drug.

Programming note: within subject, sort by dispense date, return date, kit number and CAN ID.

Listing 16.2.5.3
Diary Dispensation
All Subjects

Subject ID	Treatment Received	Diary Dispensation Visit	Diary Dispensed?	Date Dispensed (Study Day)	Diary Returned Visit	Diary Returned and Reviewed?	Reason Diary not Returned	Date Returned (Study Day)
XXXXX	XXXXXX	XXXXXX	Yes	DDMMMYYYY (X)	XXXXXX	Yes		DDMMMYYYY (X)
		XXXXXX	Yes	DDMMMYYYY (X)	XXXXXX	Yes		DDMMMYYYY (X)
		XXXXXX	Yes	DDMMMYYYY (X)	XXXXXX	No	XXXXXXXXXX	
XXXXX	XXXXXX	XXXXX	No		XXXXXX	No	XXXXXXXXX	

Note: Study day is calculated relative to the date of first application of study drug.

Listing 16.2.5.4
Compliance (CRF)
All Subjects

Subject ID	Treatment Received	Study Visit	Subject Compliant with Medication?	Date of Compliance Check (Study Day)	Compliance [1]	Overall Compliance [2]	Was Subject Retrained if not Compliant with Medication
XXXXXX	XXXXXX	XXXXXX	XXX	DDMMMYYYY (X)	XX.X %	XX.X %	
		XXXXXX	XXX	DDMMMYYYY (X)	XX.X %		
		XXXXXX	XXX	DDMMMYYYY (X)	XX.X %		
XXXXXX	XXXXXX	XXXXXX	XXX	DDMMMYYYY (X)	XX.X %	XX.X%	
		XXXXXX	XXX	DDMMMYYYY (X)	XX.X %		
		XXXXXX	XX				XXX

Abbreviations: IP = investigational product; CRF = case report form.
Note: Study day is calculated relative to the date of first application of study drug.
[1] This data comes from CRF page, unless otherwise specified.
[2] Overall compliance was calculated based on number of applications divided by the expected number of IP applications for each subject. Number of expected IP applications was calculated as number of days between first and last application of IP (last treatment date - first treatment date + 1). Number of IP applications was calculated as number of expected IP applications - missed IP applications as collected in the CRF.

Programming note: Populate overall compliance only for the first visit.

Listing 16.2.5.5
Missed Doses
All Subjects

Subject ID	Treatment Received	Study Visit	Date of Missed Dose (Study Day)	Missed Dose due to COVID-19 Disruption?	Reason for Missed Dose
XXXXXX	XXXXXX	XXXXXX	DDMMMYYYY (X)	No	XXXXXXXXXXXXXX
		XXXXXX	DDMMMYYYY (X)	No	XXXXXXXXXXXXXX
XXXXXX	XXXXXX	XXXXXX	DDMMMYYYY (X)	Yes	XXXXXXXXXXXXXX
XXXXXX	XXXXXX	XXXXXX	DDMMMYYYY (X)	No	XXXXXXXXXXXXXX
		XXXXXX	DDMMMYYYY (X)	No	XXXXXXXXXXXXXX

Abbreviation: COVID-19 = novel coronavirus disease-19.
Note: Study day is calculated relative to the date of first application of study drug.

Programming note: *Only subjects with missed doses should be presented in this listing.*

Listing 16.2.5.6
Pharmacokinetic Blood Collection
All Consenting Subjects with Pharmacokinetic Data Collected

Subject ID	Treatment Received	PK Sample Collected at this Visit? Reason if No	Study Visit	PK Sample Collected Pre-Dose	PK Collection Time Point	Date/Time of Assessment (Study Day)	Accession Number	BSA Treated at the Time of PK Sample Collection	Roflumilast Concentration (unit)
XXXXXX	XXXXXX	XXX	XXXXXX	XXX	XXXXX	DDMMMYYY/ HH:MM (X)	XXXXX	XX.X %	XX.X
			XXXXXX	XXX	XXXXX	DDMMMYYY/ HH:MM (X)	XXXXX	XX %	XX.X
			XXXXXX	XXX	XXXXX	DDMMMYYY/ HH:MM (X)	XXXXX	XX %	XX.X
		No: XXXXXXXX	XXXXXX	XX	XXXXX				

Abbreviation: BLQ = Below the limit of quantification; BSA = body surface area; PK = pharmacokinetic.
Note: Study day is calculated relative to the date of first application of study drug.

Listing 16.2.5.7
Pharmacokinetic Calculated Parameters
PK Population

Subject ID	Treatment Received	Study Visit	AUC_{0-t} (unit)	AUC_{tau} (unit)	T_{max} (unit)	T_{lag} (unit)	T_{last} (unit)	C_{max} (unit)	C_{min} (unit)
XXXXX	XXXXXX	XXXXXX	XX	XX	XX	XX	XX	XX	XX
		XXXXXX	XX	XX	XX	XX	XX	XX	XX
		XXXXXX	XX	XX	XX	XX	XX	XX	XX
		XXXXXX	XX	XX	XX	XX	XX	XX	XX

Abbreviation: PK = pharmacokinetic.

Programming note: The above parameters are expected. However the final parameters provided by the pharmacokineticist will be listed and may be different than shown.

Listing 16.2.6.1
Scalp Investigator Global Assessment (S-IGA)
All Subjects

Subject ID	Randomized Treatment	Was Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Result	Text Result	Change from Baseline	S-IGA Success [2]
XXXXXX	XXXXXX	Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	XXXXXXXXXX		
		Yes	Yes: Delay in Assessment Collection	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	XXXXXXXXXX	X	Yes
		No: COVID-19 Disruption		XXXXXXX					
		Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	XXXXXXXXXX	X	Yes
XXXXXX	XXXXXX	Yes	Yes: Assessment Completed via Telemedicine	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	XXXXXXXXXX		
		No: XXXXXXXX		XXXXXXX	DDMMMYYYY/hh:mm (X)				

Abbreviations: COVID-19 = novel coronavirus disease-19; S-IGA = scalp investigator global assessment.
Note: Study day is calculated relative to the date of first application of study drug. Baseline is the last non-missing measurement taken before the first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.
[2] S-IGA Success ("Yes") is defined as an S-IGA score of "Clear" or "Almost Clear" plus a ≥2-grade improvement from baseline at Weeks 2, 4, 8, and 9; "No" otherwise.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.6.2
Body Investigator Global Assessment (B-IGA)
All Subjects

Programming note: Same as shell 16.2.6.1. Update any instances of S-IGA to B-IGA.

Listing 16.2.6.3
Psoriasis Scalp Severity Index (PSSI)
All Subjects

Subject ID	Randomized Treatment	Was Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Test	Numeric Result	Text Result	Change from Baseline	PSSI-50 [3]/ PSSI-75 [4]/ PSSI-90 [5]
XXXXXX	XXXXXX	Yes	No	XXXX	DDMMMYYYY/hh:mm (X)	Erythema	2	XXXX		
						Induration	2	XXXXX		
						Desquamation	2	XXXX		
						Sum of Severity Rating	6			
						Extent of Scalp Affected	2			
						PSSI Total Score [3]	12			
		Yes	Yes: Delay in Assessment Collection	XXXX	DDMMMYYYY/hh:mm (X)	Erythema	2	XXXXX	XX	
						Induration	3	XXXXX	XX	
						Desquamation	2	XXXX	XX	
						Sum of Severity Rating	7		XX	
						Extent of Scalp Affected	2		XX	
						PSSI Total Score [2]	14		XX	XX/XX/XX

Abbreviations: COVID-19 = novel coronavirus disease-19; PSSI = Psoriasis Scalp Severity Index.
Note: Study day is calculated relative to the date of first application of study drug. Baseline is the last non-missing measurement taken before the first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.
[2] PSSI total score is calculated as (erythema score + induration + desquamation) × extent of scalp affected. The score ranges from 0 to 72. Erythema, induration, and desquamation are scored on a scale of 0 to 4, where 0 = absent and 4 = severest possible; extent of scale affected is scored on a scale of 0 to 6, where 0 = 0% of involved area and 6 = 90-100% of involved area.
[3] PSSI-50 is populated with "Yes" when there is an achievement of a 50% reduction in PSSI total score from baseline.
[4] PSSI-75 is populated with "Yes" when there is an achievement of a 75% reduction in PSSI total score from baseline.
[5] PSSI-90 is populated with "Yes" when there is an achievement of a 90% reduction in PSSI total score from baseline.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell for Listing 16.2.6.1. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*
Only populate PSSI-50, PSSI-75, and PSSI-90 on PSSI Total Score row.

Listing 16.2.6.4
Scalp Itch – Numeric Rating Scale (SI-NRS)
All Subjects

Subject ID	Randomized Treatment	Was Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Result	Change from Baseline	SI-NRS Success (baseline ≥ 4) [2]
XXXXXX	XXXXXX	Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	9		
		Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X	Yes
		Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X	Yes
		Yes	Yes: Delay in Assessment Collection	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X	Yes
		Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X	Yes
XXXXXX	XXXXXX	Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X		
		No: XXXXXX		XXXXXXX	DDMMMYYYY/hh:mm (X)			

Abbreviations: COVID-19 = novel coronavirus disease-19; SI-NRS = Scalp Itch – Numeric Rating Scale.
Note: Study day is calculated relative to the date of first application of study drug. Subjects rate the intensity of their itch on an 11-point scale ranging from 0 (no itch) to 10 (worst itch imaginable). Higher score indicates greater itch intensity. Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.
[2] SI-NRS Success is defined as achievement of a 4-point reduction in SI-NRS pruritus score at Weeks 2, 4, 8, and 9 compared to baseline, calculated only for subjects with a pruritus score of ≥ 4 at baseline.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell for Listing 16.2.6.1. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.6.5
Psoriasis Symptoms Diary (PSD)
All Subjects

Subject ID	Randomized Treatment	Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date of Assessment (Study Day)	Question [2]	Result	Change from Baseline
XXXX	XXXXXX	Yes	No	XXXXX	DDMMMYYYY (XX)	How severe was your psoriasis-related itching?	1	
						How bothered were you by your psoriasis-related itching?	2	
						How severe was your psoriasis-related stinging?	3	
						How bothered were you by your psoriasis-related stinging?	4	
						How severe was your psoriasis-related burning?	5	
						how bothered were you by your psoriasis-related burning?	1	
						How severe was your psoriasis-affected skin cracking?	2	
						How bothered were you by your psoriasis-affected skin cracking?	3	
						How severe was your psoriasis-related pain?	4	
						How bothered were you by your psoriasis-related pain?	5	
						How severe was your psoriasis scaling?	1	
						How bothered were you by your psoriasis scaling?	2	
						How noticeable did you think the color of your psoriasis-affected skin was?	3	
						How much did you try to hide your psoriasis affected Skin?	5	
						How much did your psoriasis cause you to avoid activities with other people?	4	
						How embarrassed were you because of your psoriasis?	8	
						Total Score [3]	XX	

Abbreviations: COVID-19 = novel coronavirus disease-19; PSD = Psoriasis Symptoms Diary.
Note: Study day is calculated relative to the date of first application of study drug. Subjects rate the severity of symptoms or how bothersome the symptoms are on an 11-point scale ranging from 0 to 10. Higher score indicates more severe symptoms. Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.
[2] These questions are based on the psoriasis symptoms over the past 24 hours.
[3] Total score is calculated as sum of all 16 questions. The total score ranges from 0 to 160. If 1 or more items are missing, the score is not calculated.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell for Listing 16.2.6.1. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.6.6
Psoriasis Area Severity Index (PASI)/Modified PASI (mPASI)
All Subjects

Subject ID	Randomized Treatment	Was Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Area	Test	Numeric Result	Text Result	Change from Baseline
XXXXXX	XXXXXX	Yes	No	XXXX	DDMMMYYYY/ hh:mm (X)	Head	Erythema	2	XXXX	
							Induration	2	XXXXX	
							Desquamation	2	XXXX	
							% Area Affected	XX.X		
							Area Lesion score			
							Degree of Involvement			
							Head PASI Score			
						Arm	Erythema	2	XXXXX	
							Induration	2	XXXX	
							Desquamation	2	XXXXX	
							% Area Affected	XX.X		
							Area Lesion score			
							Degree of Involvement			
							Arm PASI Score			
				Repeat the same for Trunk, Legs						
						All	PASI Total Score [2]	XX		
							mPASI Total Score [3]	XX		

Abbreviations: COVID-19 = novel coronavirus disease-19; mPASI = modified Psoriasis Area Severity Index; PASI = Psoriasis Area Severity Index.
Note: Study day is calculated relative to the date of first application of study drug. Baseline is the last non-missing measurement taken before the first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.
[2] PASI total score is calculated as (0.1×[Eh + Th + Sh]×Ah) + (0.2×[Ea + Ta + Sa]×Aa) + (0.3×[Et + Tt + St]×At) + (0.4×[El + Tl + Sl]×Al) where E, T, and S are erythema, thickness, and scaling, respectively, scored on a scale of 0 to 4, A is estimated area of skin involved, graded on a scale of 0 to 6, and h, e, t, and l are head, arms, trunk, and legs, respectively. The range of total score is 0 to 72.
[3] mPASI total score is calculated same as PASI above, except that for subjects with < 10% of any particular involved anatomic area, the mPASI will be calculated using the actual percentage of the anatomical area involved rather than the 0 to 6 estimated area score (e.g., 0.1 for 1%, 0.2 for 2%, 0.3 for 3%, … 0.9 for 9%).

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell for Listing 16.2.6.1. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.6.7
Worst Itch – Numeric Rating Scale (WI-NRS)
All Subjects

Subject ID	Randomized Treatment	Was Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Result	Change from Baseline
XXXXXX	XXXXXX	Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	
		Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X
		Yes	Yes: Delay in Assessment Collection	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X
		Yes	No	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	X
XXXXXX	XXXXXX	Yes	Yes: Assessment Completed via Telemedicine	XXXXXXX	DDMMMYYYY/hh:mm (X)	X	
		No: XXXXXX		XXXXXXX	DDMMMYYYY/hh:mm (X)		

Abbreviations: COVID-19 = novel coronavirus disease-19; WI-NRS = Worst Itch – Numeric Rating Scale.
Note: Study day is calculated relative to the date of first application of study drug. Subjects rate the intensity of their itch on an 11-point scale ranging from 0 (no itch) to 10 (worst itch imaginable). Higher score indicates greater itch intensity. Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell for Listing 16.2.6.1. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.6.8
Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI)
All Subjects

Form Name: DLQI

Subject ID	Randomized Treatment	Study Visit	Assessment Completed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Date/Time of Assessment (Study Day)	Question	Numeric Result	Text Result	Change from Baseline
XXXX	XXXXXX	XXXXX	Yes	No	DDMMMYYYY/ hh:mm (XX)	1. Over the last week, how itchy, sore, painful or stinging has your skin been?	0	Not at all	
						2. Over the last week, how embarrassed or self conscious have you been because of your skin?	3	Very much	
						3. Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	3	Very much	
						4. Over the last week, how much has your skin influenced the clothes you wear?	3	Very much	
						5. Over the last week, how much has your skin affected any social or leisure activities?	2	A lot	
						6. Over the last week, how much has your skin made it difficult for you to do any sport?	1	A little	
						7. Over the last week, has your skin prevented you from working or studying? If "No", over the last week how much has your skin been a problem at work or studying?	3	Yes	
						8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	0	Not relevant	
						9. Over the last week, how much has your skin caused any sexual difficulties?	0	Not relevant	
						10. Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	3	Very much	
						DLQI Total Score [2]	18		

Programming note: Continue for other visits. If form name=CDLQI, then refer to Protocol Appendix 7 for Questions. Replace DLQI total Score with CDLQI Total Score [1] in the body of listing. Footnote will remain as is.

Abbreviations: COVID-19 = novel coronavirus disease-19; DLQI = Dermatology Life Quality Index; CDLQI = Children's Dermatology Life Quality Index.
Note: Study day is calculated relative to the date of the first application of study drug. Baseline is the last non-missing measurement taken on or before the day of first application of study drug. Change from baseline is calculated as Result – Baseline.
[1] Due to COVID-19 disruption.
[2] The DLQI total score ranges between 0-30 and calculated as sum of all the 10 questions at each visit, where "Not relevant" was recoded to 0 before calculation of this score. If 1 item is missing, it is scored as 0 for that item. If 2 or more items are missing, the score was not calculated. The CDLQI total score is calculated similar to DLQI total score.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell for Listing 16.2.6.1. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.6.9
Body Surface Area (BSA) (excluding Palms and Soles)
All Subjects

Subject ID	Randomized Treatment	Assessment Performed?	If Assessment Performed, did COVID-19 disruption cause or contribute to a delay in BSA Collection?	If Assessment Not Performed, did COVID-19 disruption cause or contribute to missed BSA Collection?	Study Visit	Date/Time of Assessment (Study Day)	Test	Result
XXXXXX	XXXXXX	XXX	XX		XXXXXX	DDMMMYYYY/hh:mm (XX)	Coverage Area (Head)	XX %
							Coverage Area (Lower Limbs)	XX %
							Coverage Area (Upper Limbs)	XX.X %
							Coverage Area (Trunk)	XX.X %
							BSA Result [1]	XX.X %
							BSA CRF [2]	XX.X %
		XX		XX	XXXXXX			
		XXX	XXX		XXXXXX	DDMMMYYYY (XX)	Coverage Area (Head)	XX %
							Coverage Area (Lower Limbs)	XX %
							Coverage Area (Upper Limbs)	XX.X %
							Coverage Area (Trunk)	XX.X %
							BSA Result [1]	XX.X %
							BSA CRF [2]	XX.X %

Abbreviations: BSA = body surface area; COVID-19 = novel coronavirus disease-19; CRF = case report form; ePRO = electronic patient report outcome.
Note: Study day is calculated relative to the date of first application of study drug.
[1] BSA result is calculated as sum of coverage areas of head, lower limbs, upper limbs and trunk. This is derived in the ePRO.
[2] BSA captured in the CRF data.

Listing 16.2.7.1
Adverse Events
All Subjects

Subject ID	Treatment Received	TEAE?	System Organ Class/ Preferred Term/ Verbatim Term	Start Date/Time (Study Day)/ End Date/Time (Study Day)	CTCAE Toxicity Grade/ Relationship	Outcome/ Action Taken/ Other Action Taken	Serious?/ Criteria Met	AE Lead to Study D/C?
XXXXX	XXXXXX	XXX	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXX XXXXXXXXXX	DDMMMYYYY/hh:mm (X)/ DDMMMYYYY/ hh:mm (X)	XXXXXXXXX/ XXXXXXXXXX	XXXXXXXXX/ XXXXXXXXXX/ XXXXXXXXXX	XX	XX
XXXXX	XXXXXX	XXX	XXXXXXXXXXXXXX/ XXXXXXXXXXXX XXXXXXXXXXXXX	DDMMMYYYY/ hh:mm (X)/ DDMONYYYY/ hh:mm (X)	XXXXXXXXX/ XXXXXXXXXX	XXXXXXXXX/ XXXXXXXXXX/ XXXXXXXXXX	XX	XX
		XX	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX XXXXXXXXXXXXX	DDMONYYYY/ hh:mm (X)/ Ongoing	XXXXXXXXX/ XXXXXXXXXX	XXXXXXXXX/ XXXXXXXXXX/ XXXXXXXXXX	XXX/ XXXXXXX	XXX

Abbreviations: AE = adverse event; CTCAE = Common Terminology Criteria for Adverse Events; D/C = discontinuation; IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event.
Note: Study day is calculated relative to the date of first application of study drug. AEs were coded using MedDRA version 23.0. All AEs that occur after the date/time of first application of IP will be considered TEAEs. Severity grades are reported according to the CTCAE version 4.0.

Programming note: *If time missing, display "- -:- -". If Serious? is Yes, concatenate all serious criteria marked as Yes with a semicolon. "Other Action Taken" will be either None, Concomitant Medication, Non-drug Therapy, Hospitalization or Prolongation of Hospitalization, Discontinued Study or Other; if specify text is needed, concatenate "Other:" with the text. If no events meet the criteria for display, present "No events are reported." SOC & PT text should be presented as is from the dataset.*

Listing 16.2.8.1.1
Clinical Laboratory Data: Clinical Chemistry
All Subjects

Subject ID	Treatment Received	Parameter (unit)	Study Visit	Date/Time of Assessment (Study Day)	Standard Results	Reference Range [1]	Reference Range Flag	Result Interpretation; Specify CS Finding	Accession Number	Comments/ Reason not Done
XXXXX	XXXXX	Alanine Aminotransferase (U/L)	XXXXX	DDMMMYYYY/hh:mm (X)	XX	XX – YY	High	Normal	XXXXX	
			XXXXX	DDMMMYYYY/hh:mm (X)	XX	XX – YY		Abnormal, NCS	XXXX	
			XXXXX	DDMMMYYYY/hh:mm (X)	XX	XX – YY	Low	Normal	XXXXX	
			XXXXX	DDMMMYYYY/hh:mm (X)	XX	XX – YY		Normal	XXXXX	
			XXXXX	DDMMMYYYY/hh:mm (X)	XX	XX – YY		Abnormal, CS; XXXXXXX	XXXXX	
		Alkaline Phosphatase (U/L)	XXXXX	DDMMMYYYY (X)	XX	XX – YY	Low	XXXXX	XXXXX	
			XXXXX	DDMMMYYYY/hh:mm/ hh:mm (X)	XX	XX – YY		XXXXX	XXXXX	
			XXXXX		ND					XXXXXXX
			XXXXX	DDMMMYYYY/hh:mm (X)	XX	XX – YY	High	XXXXXX	XXXXX	

Abbreviations: CS = clinically significant; NCS = not clinically significant; ND = not done.
Note: Study day is calculated relative to the date of first application of study drug. Time of assessment was provided by the central laboratory (ACM).
[1] Reference range is used to identify potentially clinically significant laboratory values.

Listing 16.2.8.1.2
Clinical Laboratory Data: Hematology
All Subjects

(Same shell as Listing 16.2.8.1.1)

Listing 16.2.8.1.3
Clinical Laboratory Data: Urinalysis
All Subjects

(Same shell as Listing 16.2.8.1.1)

Listing 16.2.8.1.4
Clinical Laboratory Data: Serum and Urine Pregnancy Test
Female Subjects

Subject ID	Treatment Received	Was Pregnancy Test Performed? Reason if No	Study Visit	Type of Test	Date/Time Performed (Study Day)	Result
XXXXX	XXXXXX	Yes	XXXXXX	Serum	DDMMMYYYY/hh:mm (XX)	XXXXXXXX
				Urine	DDMMMYYYY/hh:mm (XX)	XXXXXXXXX
			XXXXXX	Urine	DDMMMYYYY/hh:mm (XX)	XXXXXXXXX
XXXXX	XXXXXX	Yes	XXXXXX	Serum	DDMMMYYYY/hh:mm (XX)	XXXXXXXX
				Urine	DDMMMYYYY/hh:mm (XX)	XXXXXXXXX
		No: XXXXXXXXXX	XXXXXX	Urine		

Note: Study day is calculated relative to the date of first application of study drug. Time of assessment for serum pregnancy test was provided by the central laboratory (ACM).

Programming note: If time is missing, display it as --:--.

Listing 16.2.9.1
Investigator Local Tolerability Assessments
All Subjects

Subject ID	Treatment Received	Tolerability Assessment Performed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Dermal Response	Other Effects
XXXXXX	XXXXXX	Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
		Yes	Yes: Delay in Assessment Collection	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
		Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
XXXXXX	XXXXXX	Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
		Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
		Yes	Yes: Assessment Completed via Telemedicine	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
XXXXXX	XXXXXX	Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
		Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	X = XXXXXXXXX	X = XXXXXXXXX
		No: COVID-19 Disruption		XXXXXX			

Abbreviations: COVID-19 = novel coronavirus disease-19; IP = investigational product.
Note: Study day is calculated relative to the date of the first application of study drug. This assessment will be conducted by the investigator prior to the application of IP in the study site.
[1] Due to COVID-19 disruption.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.9.2
Subject Local Tolerability Assessments
All Subjects

Subject ID	Treatment Received	Tolerability Assessment Performed? Reason if No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Grade	Sensation Following the Application of IP
XXXXXX	XXXXXX	Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	0 = None	No sensation
		Yes	Yes: Delay in Assessment Collection	XXXXXX	DDMMMYYYY/hh:mm (XX)	1 = Mild	Slight warm, tingling sensation; not really bothersome
		Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	2 = Moderate	Definite warm, tingling sensation that is somewhat bothersome
XXXXXX	XXXXXX	Yes	No	XXXXXX	DDMMMYYYY/hh:mm (XX)	0 = None	No sensation
		Yes	Yes: Assessment Completed via Telemedicine	XXXXXX	DDMMMYYYY/hh:mm (XX)	3 = Severe	Hot tingling/stinging sensation that has caused definite discomfort
		No: COVID-19 Disruption		XXXXXX			

Abbreviations: COVID-19 = novel coronavirus disease-19; IP = investigational product.
Note: Study day is calculated relative to the date of the first application of study drug. This assessment will be performed at baseline visit 10 to 15 minutes after the application of IP in the study site.
[1] Due to COVID-19 disruption.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.9.3.1
Vital Signs
All Subjects

Subject ID	Treatment Received	Vital Signs Collected? Reason if No	Study Visit	Date of Assessment (Study Day)	Temp (°C)	Heart Rate (bpm)	Position	Blood Pressure (mmHg)		Height (cm)	BMI (kg/m^2)	Abnormal Findings/ Clinically Significant/ Description of Finding
								Systolic	Diastolic			
XXXXX	XXXXXX	Yes	XXXXX	DDMMMYYYY (X)	XX.X	XX	XXXX	XX	XX	XXX	XX.X	XX
		Yes	XXXXX	DDMMMYYYY (X)	XX.X	XX	XXXXX	XX	XX		XX.X	
		No: XXXXXX	XXXXX									
		Yes	XXXXX	DDMMMYYYY (X)	XX.X	XX	XXXXX	XX	XX	XXX	XX.X	XXX/ XXX/ XXXXXXX

Abbreviation: BMI = body mass index; Temp = temperature.
Note: Study day is calculated relative to the date of first application of study drug.
[1] BMI is derived as (weight in kg)/[(height in cm/100)^2]. Weight is collected at all visits. For visits up to Week 4, Baseline Day 0 height is used for BMI derivation. Week 8 and Week 9 BMI is derived using Week 8 height.

Programming note: *Concatenate reason not done as shown in the shell.*

Listing 16.2.9.3.2
Vital Signs - Weight
All Subjects

Subject ID	Treatment Received	Vital Signs Collected? Reason if No	Study Visit	Date of Assessment (Study Day)	Weight (kg)	Percent Change in Weight Since Baseline	Was Weight Loss Intentional?	Weight Loss due to Complications Associated with COVID-19	Underlying Reason for Weight Loss	Abnormal Findings/ Clinically Significant/ Description of Finding
XXXXX	XXXXXX	Yes	XXXXX	DDMMMYYYY (X)	XXX	XX	Yes	No	Weight loss was a result of dieting	XX
		Yes	XXXXX	DDMMMYYYY (X)	XXX	XX	Yes	No	Other: XXXXX	
XXXXX	XXXXXX	No: XXXXXXXX	XXXXX							XXX/ XXX/ XXXXXXX

Abbreviation: COVID-19 = novel coronavirus disease-19.
Note: Study day is calculated relative to the date of first application of study drug.

Programming note: *Concatenate reason not done as shown in the shell. If reason for weight loss is "Other", concatenate reason as shown in the shell.*

Listing 16.2.9.4
Physical Examination
All Subjects

Subject ID	Treatment Received	Physical Examination Performed? Reason if No	Study Visit	Date of Assessment (Study Day)	Body System	Result	Abnormal Findings	Clinically Significant?
XXXXXX	XXXXXXX	Yes	XXXXXXX	DDMMMYYYY (-X)	Skin	Normal		
					Lungs	Abnormal	XXXXXXXX	No
					Heart	Normal		
		Yes	XXXXXXX	DDMMMYYYY (-X)	Skin	Normal		
					Lungs	Abnormal	XXXXXXXX	No
					Heart	Normal		
		No: XXXXXXX	XXXXXXX					

Note: Study day is calculated relative to the date of first application of study drug.

Programming note: *Concatenate reason not done as shown in the shell.*

Listing 16.2.9.5
Medical Photography
All Subjects

Subject ID	Treatment Received	Photography Performed? Reason if No	If Yes, Delay in Assessment Collection [1]	Study Visit	Date of Assessment (Study Day)
XXXXXX	XXXXXX	Yes	No	XXXXXX	DDMMMYYYY (XX)
		Yes	No	XXXXXX	DDMMMYYYY (XX)
		Yes	Yes: Delay in Assessment Collection	XXXXXX	DDMMMYYYY (XX)
		Yes	No	XXXXXX	DDMMMYYYY (XX)
		No: XXXXXX		XXXXXX	

Abbreviation: COVID-19 = novel coronavirus disease-19.
Note: Study day is calculated relative to the date of first application of study drug.
[1] Due to COVID-19 disruption.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell. For the "If Yes, Delay in Assessment Collection" column, do the following: if the answer to did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection".*

Listing 16.2.9.6
Prior and Concomitant Medications
All Subjects

Subject ID	Country	Treatment Received	Prior/ Concomitant [1]	Indication	ATC Class (Level 4)/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)	Dose (unit)	Route/ Frequency
XXXXX	XXX	XXXXXX	Prior	XXXXXXXX	XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXX	DDMMMYYYY (X)/ DDMMMYYYY (X)	XXX (XXX)	XXXXXXXX/ XXXXXXX
			Both	XXXXXXXX	XXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXX	DDMMMYYYY (X)/ Ongoing	XXX (XXX)	XXXXXXXX/ XXXXXXX
			Concomitant	XXXXXXX	XXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXX	DDMMMYYYY (X)/ DDMMMYYYY (X)	XXX (XXX)	XXXXXXXX/ XXXXXXX

Abbreviation: ATC = anatomic therapeutic chemical; NA = Not applicable; WHO-DDE = World Health Organization-Drug Dictionary Enhanced.
Note: Study day is calculated relative to the date of first application of study drug. Medications were coded using WHO-DDE Global B3 version September 2019.
[1] Prior indicates medication that was started and stopped prior to dosing of study drug. Concomitant indicates medication that started during the treatment period. Both indicates medication that was started prior to dosing of study drug and continued during the treatment period.

Programming note: *If Dose unit, Route or Frequency is Other, display other specify text only (ie, do not display "Other: XXXXXX" but just "XXXXXX "). Sort by subject, start date, end date, ATC level 4 & PT. ATC & PT text should be presented as is from the dataset.*

Listing 16.2.9.7
Patient Health Questionnaire (PHQ-8)/Modified PHQ-Adolescents (PHQ-A)
All Subjects

Subject ID	Treatment Received	Assessment Completed? Reason If No	If Yes, Telemedicine or Delay in Assessment Collection [1]	Study Visit	Date/Time of Assessment (Study Day)	Form Name [2]	Question [3]	Result	Text Result
XXXXX	XXXXX	Yes	Yes: Delay in Assessment Collection	XXXXX	DDMMMYYYY/ hh:mm (XX)	PHQ-8	1. Little interest or pleasure in doing things	0	Not at all
							2. Feeling down, depressed, or hopeless	1	Several days
							3. Trouble falling or staying asleep, or sleeping too much	2	More than half the days
							4. Feeling tired or having little energy	3	Nearly every day
							5. Poor appetite or overeating	0	Not at all
							6. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	1	Several days
							7. Trouble concentrating on things, such as reading the newspaper or watching television	2	More than half the days
							8. Moving or speaking so slowly that other people could have noticed. Or the opposite-being so fidgety or restless that you have been moving around a lot more than usual	3	Nearly every day
							CRF-Calculated Total Score	XX	
							Total Score [4]	12	Moderate depression
		No: XXXXX		XXXXX	DDMMMYYYY/ hh:mm (XX)				

Abbreviations: COVID-19 = novel coronavirus disease-19; CRF = case report form; PHQ-8 = patient health questionnaire-8 questions; PHQ-A = patient health questionnaire-adolescents.
Note: Study day is calculated relative to the date of the first application of study drug.
[1] Due to COVID-19 disruption.
[2] Form name will be PHQ-8 for adults and Modified PHQ-A for adolescents.
[3] These questions are based on the "Over the last 2 weeks, how often have you been bothered by any of the following problems?" prompt.
[4] The total score is calculated as sum of all the 8 questions. If more than 1 item is missing the total score should not be calculated. If 1 item is missing, the total score is calculated as (sum of answered items*8)/number of answered items. If total score ranges between 0-4, it is categorized as None – Minimal depression; 5-9 = Mild depression; 10-14 = Moderate depression; 15-19 = Moderately severe depression; 20-24 = Severe depression.

Programming note: *Concatenate reason not done (COVID-19 Disruption or other specify text) as shown in the shell. For the "If Yes, Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Listing 16.2.9.8
Columbia-Suicide Severity Rating Scale (C-SSRS)
All Subjects

Subject ID	Treatment Received	Study Visit	Date/Time of Assessment (Study Day)	Reference Period	Telemedicine or Delay in Assessment Collection [1]	Category	Assessment	Result
XXXXXX	XXXXXX	XXXXXX	DDMMMYYYY/ hh:mm (XX)	Baseline/ Screening	Yes: Delay in Assessment Collection	Suicidal Ideation	1. Wish to be dead	XX
							If yes, describe: 2. Non-Specific Active Suicidal Thoughts	XX
							If yes, describe: 3. Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act	XX
							If yes, describe: 4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan	XX
							If yes, describe: 5. Active Suicidal Ideation with Specific Plan and Intent	XX
							If yes, describe:	
						Intensity of Ideation	Most Severe Ideation Type # (1-5)	X
							Description of Ideation	XXXXXXXXXXXXXXXX
							Frequency	1 = Less than once a week
							Duration	1 = Fleeting – few seconds or minutes
							Controllability	1 = Easily able to control thoughts

Programming note: Reference period will be either Baseline/Screening or Since Last Visit. Display the results following the order of C-SSRS questionnaire for all categories.

Abbreviations: COVID-19 = novel coronavirus disease-19; C-SSRS = Columbia-Suicide Severity Rating Scale.
Note: Study day is calculated relative to the date of first application of study drug. Assessments that are marked as Not Done are not included in the listing.
[1] Due to COVID-19 disruption.

Programming note: *For the "Telemedicine or Delay in Assessment Collection" column, do the following: if the answer to both questions (was assessment completed via telemedicine or was delayed) is No, display "No"; if the answer to only was assessment completed via telemedicine is yes, set to "Yes: Assessment Completed via Telemedicine"; if the answer to only did COVID-19 disruption cause/contribute to delay, set to "Yes: Delay in Assessment Collection"; if both are yes, set to "Yes: Assessment Completed via Telemedicine; Delay in Assessment Collection".*

Appendix 1: Premier Research Library of Abbreviations

Abbreviation	Definition
AE	adverse event
ANCOVA	analysis of covariance
ATC	anatomical therapeutic chemical
B-IGA	body investigator global assessment
BMI	body mass index
BSA	body surface area
CDISC	Clinical Data Interchange Standards Consortium
CDLQI	Children's Dermatology Life Quality Index
CI	confidence interval
CMH	Cochran-Mantel-Haenszel
COVID-19	novel coronavirus disease-19
CRF	case report form
CS	clinically significant
C-SSRS	Columbia Suicide Severity Rating Scale
DBP	diastolic blood pressure
DLQI	Dermatology Life Quality Index
eCRF	electronic case report form
ePRO	electronic patient report outcomes
FDA	Food and Drug Administration

Abbreviation	Definition
HR	heart rate
ICH	International Council for Harmonisation
ITT	intent-to-treat
LS	least-squares
MedDRA	Medical Dictionary for Regulatory Activities
mPASI	Modified Psoriasis Scalp Severity Index
NA	not applicable
NCS	nonclinically significant
PASI	Psoriasis Scalp Severity Index
PD	protocol deviation
PE	physical examination
PHQ-A	Modified PHQ-9 for Adolescents
PHQ-8	Patient Health Questionnaire depression scale
PK	pharmacokinetic
PP	per-protocol
PSD	Psoriasis Symptoms Diary
PSSI	Psoriasis Scalp Severity Index
RR	respiratory rate
SAE	serious adverse event
SAP	statistical analysis plan
SAS®	a software system used for data analysis

Abbreviation	Definition
SBP	systolic blood pressure
SD	standard deviation
S-IGA	scalp investigator global assessment
SI-NRS	scalp itch – numeric rating scale
SOC	system organ class
TEAE	treatment emergent adverse event
TLFs	tables, listings, and figures
WHO	World Health Organization
WHO-DD	world health organization drug dictionary
WI-NRS	worst itch – numeric rating scale