Study Number:	ARQ-151-201
NCT #:	NCT03638258
Official Title:	A Phase 2b 12-Week Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety, Efficacy and Pharmacokinetics of ARQ-151 Cream 0.3% and ARQ-151 Cream 0.15% Administered QD in Subjects with Chronic Plaque Psoriasis
SAP Date:	24-May-2019

STATISTICAL ANALYSIS PLAN

Protocol Number:	ARQ-151-201
Study Title:	A Phase 2b 12-Week Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety, Efficacy, and Pharmacokinetics of ARQ-151 Cream 0.3% and ARQ-151 Cream 0.15% Administered QD in Subjects with Chronic Plaque Psoriasis
Development Phase of Study:	Phase 2b
Sponsor:	Arcutis, Inc. 2945 Townsgate Road, Suite 110 Westlake Village, CA 91361
Sponsor Contact:	David Berk, MD Vice President, Clinical Development
Statistical Analysis Plan based on Protocol Version:	Amendment 1, 12 November 2018
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Statistical Analysis Plan Version:	Version 1

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Approved by:

SIGNATURE: [redacted] DATE: May 29, 2019

David Berk, MD
Vice President, Clinical Development
Arcutis, Inc.

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

SAP Change History

Only final versions will be documented in the Change History.

Version	Date	Summary of Changes	Author
1	24MAY2019	Original document	[redacted]

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	Adverse Event(s)
BSA	Body Surface Area
CRF(s)	Case Report Form(s)
C-SSRS	Columbia-Suicide Severity Rating Scale
DLQI	Dermatology Life Quality Index
ECG	Electrocardiogram
IGA	Investigator's Global Assessment
I-IGA	Intertriginous IGA
ITT	Intent-to-Treat
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
mPASI	Modified Psoriasis Area and Severity Index
N	Sample Size
NRS	Numerical Rating Score
PHQ-8	Patient Health Questionnaire Depression Scale
PK	Pharmacokinetic
PP	Per-Protocol
PSD	Patient Symptoms Diary
QD	Once a Day
SAE(s)	Serious Adverse Event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	Standard Deviation
TEAE(s)	Treatment-Emergent Adverse Event(s)
WHO	World Health Organization
WHO-DD	World Health Organization Drug Dictionary
WHO-ATC	World Health Organization-Anatomical Therapeutic Chemical Classification System
WI-NRS	Worst Itch Numerical Rating Scale
WPAI	Work Productivity and Activity Impairment

2. INTRODUCTION

Roflumilast is a phosphodiesterase 4 (PDE-4) inhibitor approved globally to reduce the risk of exacerbations in patients with severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis. Roflumilast and its active metabolite, roflumilast N-oxide, are high affinity selective inhibitors of PDE-4 (a major cyclic-3′,5′-adenosine monophosphate (cyclic AMP)-metabolizing enzyme), whose activity leads to accumulation of intracellular cyclic AMP. There are four different subtypes of PDE-4: PDE-4a, PDE-4b, PDE-4c, and PDE-4d, each with several isoforms (splicing variants). IC50 values of both roflumilast and roflumilast N-oxide for the different PDE-4 isoforms and subtypes are mostly sub-nanomolar and single digit nanomolar (Hatzelmann 2010). The PDE-4 family of enzymes are the most prevalent phosphodiesterases in immune cells and inhibition of PDE-4 subtypes has been associated with anti-inflammatory effects in many biological systems.

Psoriasis is a chronic inflammatory skin disease characterized by raised, well-demarcated, erythematous oval plaques with adherent silvery scales. Numerous past reports have suggested a deficiency of cyclic AMP-dependent protein kinases in human psoriatic skin (Brion 1986). More recently, various cytokines produced by Th1 and Th17 cells have been shown to play a crucial role in the pathogenesis of psoriasis. It has been postulated that the anti-inflammatory effects of PDE-4 inhibitors may provide a beneficial therapeutic intervention in the treatment of chronic plaque psoriasis, and recently Otezla® (apremilast) a PDE-4 inhibitor has been approved for the oral treatment of chronic plaque psoriasis.

The past 15 years have witnessed a transformation in the systemic treatment of moderate to severe psoriasis with the advent of biological therapies. However, for patients with milder forms of disease, best treated with topical options, the therapeutic landscape really has not changed in several decades. Topical steroids come in all shapes and forms, but the lower potency steroids are not effective and the higher potency steroids are beset with issues of local skin atrophy and the potential for hypothalamic-pituitary axis suppression when applied over larger body surface areas and for prolonged periods of time. Vitamin D has been the other staple of topical psoriasis treatment but it is irritating, not suitable for use on the face or intertriginous areas, and its efficacy is rather modest. Hence, there is substantial medical need for additional topical approaches in the treatment of psoriasis. Arcutis, Inc is developing a topical formulation of roflumilast for the treatment of chronic plaque psoriasis. [redacted]

3. STUDY OBJECTIVES

To assess the safety, pharmacokinetics and efficacy of ARQ-151 cream 0.3% and ARQ-151 cream 0.15% vs. vehicle applied QD for 12 weeks to individuals treated with 2 to 20% (inclusive) Body Surface Area (BSA) of chronic plaque psoriasis.

4. STUDY DESIGN

4.1 Overall Study Design

This is a parallel group, double blind, vehicle-controlled study in which ARQ-151 cream 0.3%, ARQ-151 cream 0.15% or vehicle cream QD is applied for 84 days to subjects with between 2% to 20% (inclusive) BSA of chronic plaque psoriasis.

A total of up to approximately 300 subjects will be enrolled at approximately 30 study sites in the United States and Canada. Subjects will be adult (≥18 y/o) males or females with chronic plaque psoriasis. Subjects must have an Investigator's Global Assessment (IGA) of disease severity of at least Mild ('2') at Baseline. Subjects with an IGA of 'Mild' (2) will be limited to 20% of total enrollment. Subjects with an IGA of 'Severe' (4) will be limited to 15% of total enrollment. Subjects must have at least 2% and no more than 20% BSA of chronic plaque psoriasis. All psoriasis lesions on a subject will be treated including the face, trunk, genitals/skin folds, or limbs (excluding the scalp). The palms and soles will be treated but will not be counted towards any measurements of efficacy (IGA, BSA, Modified Psoriasis Area and Severity Index (mPASI)). For subjects with intertriginous area involvement, and with severity of the intertriginous area lesions at least 'mild' (IGA≥2) at Baseline, Intertriginous IGA (I-IGA) score will be recorded at weeks 4, 6, 8 and 12. The same IGA used for the primary endpoint (whole body) will also be used for I-IGA, but only intertriginous areas will be evaluated for I-IGA, not the rest of the body.

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 5 of the protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

Assignment of drug or vehicle will be made at a 1:1:1 ratio according to a computer-generated randomization list. Randomization will take place at Baseline after the patient has been found to be fully eligible for participation. Kits containing tubes of study medication will be assigned to each subject using an internet-based randomization system (IWRS). A subject may receive more than one kit for the treatment period.

The kits and tubes are blinded and each kit is numbered with a unique kit number.

4.1.3 Blinding

This is a double-blind study, therefore neither the subjects nor the Investigator, clinical team, and study sponsor will be aware of which treatment an individual has received.

If the situation requires emergency unblinding this will be done by investigator using the study IWRS system after discussion with Medical Monitor and the Sponsor's CMO.

The treatment assignments for all enrolled subjects will be unblinded only after the conclusion of the study. Specifically, the blind will be broken only after all data are verified, entered into the database, and validated; subject evaluability assessments are performed and entered into the database; and the database is locked.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

mPASI is one of the measurements used for the severity of psoriasis. mPASI combines the assessment of the severity of lesions and the area affected into a single score in the range 0 (no disease) to 72 (maximal disease). [redacted]

[redacted]

5.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint is as follows:

- Success in Investigator Global Assessment (IGA) of disease severity, defined as an IGA of 'Clear' or 'Almost Clear' at Week 6.

5.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints are as follows:

- IGA score of 'clear' or 'almost clear' at weeks 2, 4, 8, and 12.
- Percent change from Baseline in mPASI at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Percent BSA affected at weeks 2, 4, 6, 8, and 12.
- IGA score of 'clear' or 'almost clear' PLUS a 2-grade improvement from Baseline at weeks 2, 4, 6, 8 and 12.
- For subjects with intertriginous area involvement, and with severity of the intertriginous lesions at least 'mild' (I-IGA≥2) at Baseline, 'I-IGA' score of 'clear' or 'almost clear' at weeks 2, 4, 6, 8 and 12.
- Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) pruritus score at weeks 2, 4, 6, 8, and 12.
- In subjects with WI-NRS pruritus score ≥ 6 at Baseline, a 4-point reduction in WI-NRS pruritus score at 2, 4, 6, 8, and 12 weeks as compared to Baseline.

- Change from Baseline in Modified Psoriasis Area Severity Index-75 (mPASI-75) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-90 (mPASI-90) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Total Patient Symptoms Diary (PSD) at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Itch-related Sleep Loss score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Dermatology Life Quality Index (DLQI) score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in responses to the questions of Total Patient Symptom Diary (PSD) at weeks 2, 4, 6, 8, and 12.

Change from Baseline will be calculating by subtracting the score at Baseline from the post-baseline score. Percent change from Baseline will be calculated by dividing change from Baseline by the Baseline score, multiplied by 100.

5.1.3 Additional Efficacy Endpoints

The exploratory endpoints are as follows:

- Change from Baseline in Fatigue Numerical Rating Score (NRS) score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Work Productivity and Activity Impairment (WPAI) score at weeks 2, 4, 6, 8, and 12.

Change from Baseline will be calculating by subtracting the score at Baseline from the post-baseline score.

5.2 Safety Endpoints

Safety will be evaluated through examination of data collected during physical examinations, 12-lead Electrocardiograms (ECGs), local tolerability assessments, vital signs, counts and percentages of subjects who gain or lose >5% and >10% body weight, clinical laboratory parameters, Patient Health Questionnaire Depression Scale (PHQ-8), Columbia-Suicide Severity Rating Scale (C-SSRS) and adverse events (AEs) as outlined in the Schedule of Visits and Assessments. If deemed necessary, additional safety assessments will be performed at the discretion of the Principal Investigator.

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® (Version 9.4 or later) unless otherwise stated. No interim analyses are planned. Except where noted, all statistical tests will be two-sided and will be performed at the 0.05 level of significance. No adjustment will be made for multiplicity.

Descriptive statistics will be used to provide an overview of the efficacy, safety, and pharmacokinetic results. For categorical parameters, the number and percentage of subjects in each category will be presented. The denominator for percentage will be based on the number of subjects appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include n (number of subjects), mean, standard deviation (SD), median, minimum and maximum. Appropriate inferential statistics will be used for the primary, secondary, and exploratory efficacy variables.

The primary method of handling missing efficacy data will be a mixture of linear interpolation and last observation carried forward (LOCF).

The efficacy analysis performed on the Intent-to-Treat (ITT) population is considered the primary analysis. The efficacy analysis performed on the Per-Protocol (PP) population is considered supportive analysis.

The number of subjects in each analysis set will be summarized. Reasons for study withdrawal during the blinded study will be summarized using frequencies and percentages by treatment group. Reported AEs, medical history terms and prior and concomitant procedures and therapies will be classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Prior and concomitant medications will be classified on the basis of World Health Organization Drug Dictionary (WHO-DD) terminology.

6.1.1 Statistical Analysis

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

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

6.1.2 Baseline Definition

Baseline is defined as the last non-missing assessment prior to first dose of study drug.

6.1.3 Visit Windowing

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

Analysis Windows for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Window (Days)
Week 2	15	8 to 22
Week 4	29	23 to 36
Week 6	43	37 to 50
Week 8	57	51 to 71
Week 12	85	72 to 99
Week 16	113	100 to 127

Data collected at early termination and unscheduled visits prior to study day 8 will not be analyzed, with the exception of those identified as baseline values. Data collected at visits after study day 127 will not be included in analyses.

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

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

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

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

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

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

6.1.4 Adjustments for Covariates

The Baseline score will be used as a covariate for each endpoint analyzed.

6.1.5 Handling of Dropouts or Missing Data

The primary method of handling missing efficacy data will be a mixture of linear interpolation and LOCF. Linear interpolation will be used for all instances where subjects have observed values for at least one assessment both preceding and following the missing assessment. If an unscheduled assessment occurs between the preceding or following scheduled assessment and the missing assessment, the unscheduled assessment will be used in the linear interpolation. The actual study day of assessment will be used for the preceding and following assessments, and planned study day will be used for the missing assessment. IGA and I-IGA values imputed with linear interpolation will be rounded to the nearest integer. If the missing assessment is not followed by at least one observed assessment, the method of LOCF will be used.

6.1.6 Interim Analyses and Data Monitoring

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

6.1.7 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site. Every effort will be made to promote consistency in study execution at each investigational site. Sites will be pooled for analyses.

6.1.8 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons or multiplicity will be made.

6.1.9 Use of an Efficacy Subset of Subjects

Subjects randomized to study drug who were at least 80% compliant with the study drug, did not miss more than three consecutive doses, and who do not have major protocol deviations will form the Per Protocol (PP) Population. The major protocol deviations will be defined at the time of evaluability evaluation, the time between the database soft lock and hard lock before unblinding.

Excluding subjects who have major protocol deviations will decrease the variability in treatment response and will allow for a better determination of efficacy of ARQ-151 Cream 0.3% and ARQ-151 Cream 0.15%.

6.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

6.1.11 Examination of Subgroups

Subset analyses will be conducted for the ITT population for the subgroups baseline IGA and baseline I-IGA. I-IGA will be dichotomized into presence or absence of I-IGA ≥ 2 at baseline. These analyses will contain only descriptive statistics of the primary efficacy endpoint.

6.2 Disposition of Subjects

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

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

6.3 Protocol Deviations

Protocol deviations leading to exclusion from the PP population will be tabulated. In addition to protocol deviations leading to exclusion from the PP population, the protocol deviations listed below will be presented in a data listing.

- Baseline PHQ-8 score greater than or equal to 15
- Received incorrect treatment
- Baseline mPASI less than 2
- Baseline IGA of Clear or Almost Clear
- Missed visit
- Missed IGA at attended visit
- Missed I-IGA at attended visit
- Missed safety labs at attended visit

6.4 Data Sets Analyzed

Subjects will be presented/summarized based on the primary reason for exclusion. The primary reason for exclusion for each population is the first inclusion condition a subject fails to meet based on the order listed below.

6.4.1 Intent-to-Treat Population

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

6.4.2 Safety Population

All subjects in the ITT population who have at least one post-baseline safety assessment will be included in the safety population and analyzed according to the treatment group they received. In the event a subject receives more than one treatment, they will be analyzed based on the treatment they received for the majority of the study. All safety analyses will be performed using the safety population.

6.4.3 Per-Protocol Population

All subjects in the safety population who were at least 80% compliant with study medication, did not miss more than 3 consecutive doses, and showed no other serious protocol violations will be included in the PP population and analyzed according to the treatment group they received. All efficacy analyses will be performed on the PP population.

6.4.4 Pharmacokinetic Population

All subjects receiving the active drug with quantifiable plasma concentrations of roflumilast will be included in the PK population.

6.5 Demographic and Other Baseline Characteristics

All summaries will be done on the ITT, PP, safety, and PK populations.

Sex, race, and ethnicity will be summarized by counts and percentages. Age (years) will be summarized with descriptive statistics.

Height, Weight, BSA, IGA, mPASI, WI-NRS, DLQI, Itch-Related Sleep Loss, and Total PSD will be summarized at baseline with descriptive statistics.

Medical histories will be coded using the MedDRA dictionary and presented in a by-subject listing.

6.6 Analysis of Efficacy

6.6.1 Primary Efficacy Analysis

The primary efficacy endpoint is success in IGA, defined as an IGA of 'Clear' or 'Almost Clear' at Week 6. The primary efficacy endpoint will be analyzed with a logistic regression with a factor of treatment group and the respective Baseline IGA score as a covariate. Statistical comparison between the active treatment arms and vehicle arms will be facilitated by using contrasts.

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

6.6.2 Secondary Efficacy Analysis

The secondary efficacy endpoints will include:

- IGA score of 'clear' or 'almost clear' at weeks 2, 4, 8, and 12.
- Percent change from Baseline in mPASI at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Percent BSA affected at weeks 2, 4, 6, 8, and 12.
- IGA score of 'clear' or 'almost clear' PLUS a 2-grade improvement from Baseline at weeks 2, 4, 6, 8 and 12.
- For subjects with intertriginous area involvement, and with severity of the intertriginous lesions at least 'mild' (I-IGA≥2) at Baseline, 'I-IGA' score of 'clear' or 'almost clear' at weeks 2, 4, 6, 8 and 12.
- For subjects with intertriginous area involvement, and with severity of the intertriginous lesions at least 'mild' (I-IGA≥2) at Baseline, 'I-IGA' score of 'clear' or 'almost clear' and a 2-point improvement from Baseline at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in WI-NRS pruritus score at weeks 2, 4, 6, 8, and 12.
- In subjects with WI-NRS pruritus score ≥ 6 at baseline, a 4-point reduction in WI-NRS pruritus score at weeks 2, 4, 6, 8, and 12 as compared to Baseline.
- Change from Baseline in Modified Psoriasis Area Severity Index-75 (mPASI-75) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-90 (mPASI-90) improvement at weeks 2, 4, 6, 8, and 12.

- Change from Baseline in Modified Psoriasis Area Severity Index-100 (mPASI-100) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Total PSD at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Itch-related Sleep Loss score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in DLQI score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in responses to the questions of PSD at weeks 2, 4, 6, 8, and 12.

Change from Baseline will be calculated by subtracting the score at Baseline from the post-baseline score. Percent change from Baseline will be calculated by dividing change from Baseline by the Baseline score, multiplied by 100.

The IGA, I-IGA, WI-NRS, and mPASI dichotomous endpoints will be analyzed with a logistic regression with a factor of treatment group and the respective Baseline score as a covariate. The remainder of the endpoints will be considered continuous and analyzed with an analysis of covariance with a factor of treatment group and the respective Baseline score as a covariate. Statistical comparisons between the active treatment arms and vehicle arm will be facilitated by using contrasts.

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

6.6.3 Exploratory Efficacy Analysis

There are two exploratory endpoints:

- Change from Baseline in Fatigue NRS score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in WPAI score at weeks 2, 4, 6, 8, and 12.

Only descriptive statistics will be used to analyze these endpoints. Change from Baseline will be calculating by subtracting the score at Baseline from the post-baseline score.

6.7 Safety Evaluation

The following analyses will be performed; however, no formal inferential statistics will be done on safety assessments.

Descriptive statistics will be presented by visit and treatment group for quantitative safety data and frequency counts will be compiled for classification of qualitative safety data. Summaries of local tolerability will be presented by visit and treatment group.

6.7.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of days of exposure, total number of applications, total amount of study drug used, number of missed applications, and number and percentage of subjects who are compliant. A subject will be considered compliant with the dosing regimen if the subject applied at least 80% of the expected number of applications while enrolled in the study and does not miss more than 3 consecutive doses.

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

The total number of applications is as follows:

(Date of Last Application – Date of First Application + 1) – (Number of Days marked as missed dose on the Case Report Form (CRF)).

The expected number of applications is as follows:

Expected Date of Last Application – Date of Randomization + 1

Where the Expected Date of Last Application is the date of the Week 12 visit or the date of the discontinuation visit for subjects who discontinue prior to Week 12.

Compliance will be calculated as a percentage as 100 times the total number of applications divided by the expected number of applications.

6.7.2 Adverse Events

All treatment-emergent AEs (TEAEs) occurring during the study will be recorded and classified on the basis of MedDRA terminology for the safety population. TEAEs are those AEs with an onset on or after the date of first study drug treatment. All AEs with incomplete onset date information will be considered treatment-emergent unless the available information indicates that this is not possible. All TEAEs will be summarized by treatment group, the number of subjects reporting TEAEs, system organ class, preferred term, severity, relationship, and seriousness. Each subject will be counted only once within a system organ class or a preferred term using the event with the greatest relationship and greatest severity.

Comparisons between treatment groups will be made by tabulating the frequency of subjects with one or more TEAEs (classified into MedDRA terms) during the study.

Serious AEs (SAEs) will be listed by subject. Treatment-emergent SAEs will be summarized by treatment group, severity, and relationship to study treatment.

All information pertaining to AEs noted during the study will be listed by subject, detailing the verbatim description given by the Investigator, preferred term, system organ class, start date, stop date, severity, action taken regarding study drug, corrective treatment, outcome, and drug relatedness. The event onset will also be shown relative (in number of days) to date of first application. In addition a listing of subjects who prematurely discontinue from the study due to AEs will also be provided.

6.7.3 Clinical Laboratory Evaluation

Laboratory test results will be summarized by treatment group and visit as observed values and changes from Baseline using descriptive statistics. Additionally, shifts from Baseline to Week 4 and Week 12 in laboratory test results based on normal ranges will be summarized with frequency counts and percentages.

Individual laboratory test results, as well as abnormal laboratory results, will be presented in a by-subject listing.

6.7.4 Other Observations Related to Safety

6.7.4.1 Electrocardiogram Measurements

Descriptive statistics of actual values and changes from baseline will be provided by treatment group and visit for the following ECG parameters: heart rate (HR), RR duration, QRS duration, PR duration, QT duration, QTc Interval, QTcB interval, QTcF interval. Investigator and cardiologist interpretation of the ECG will be summarized by counts and percentages.

Individual ECG parameters, as well as interpretations, will be presented in a by-subject listing.

6.7.4.2 Vital Signs

Descriptive statistics of actual values and changes from baseline will be provided by treatment group and visit for the following parameters: temperature, systolic blood pressure, diastolic blood pressure, heart rate, and weight. Additionally, counts and percentages of subjects who gain or lose > 5% body weight will be summarized by visit in a table.

6.7.4.3 Physical Examination

Abnormal physical examination findings will recorded as AEs and included in the AE summaries.

6.7.4.4 Medical History

Medical history for all subjects will be presented in a by-subject listing.

6.7.4.5 Local Tolerance Assessments

For the investigator's assessment and subject local tolerability assessment of sensation following drug application, the numeric application site reaction scores will be summarized individually by using number and percentage of subjects by visit. In addition, a by-subject listing of investigator and subject assessments will be provided.

6.7.4.6 Patient Health Questionnaire Depression Scale

The PHQ-8 will be analyzed by a shift in state of severity using 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)

In addition, a by-subject listing of results will be provided.

6.7.4.7 Columbia-Suicide Severity Rating Scale

The C-SSRS will be analyzed per the C-SSRS Scoring and Data Analysis Guide (Nilsson 2013).

6.7.4.8 Prior and Concomitant Medications

Prior and concomitant medication information for all randomized subjects will be presented in a by-subject listing. Summary tables will be presented by World Health Organization-Anatomical Therapeutic Chemical Classification System (WHO-ATC) therapeutic category and product.

6.8 Other Evaluations

6.8.1 Pharmacokinetic Evaluation

Plasma drug concentrations at pre-dose will be summarized using descriptive statistics, reporting n, mean, standard deviation, median, minimum, and maximum.

7. DETERMINATION OF SAMPLE SIZE

The sample size was not powered based on data for the primary endpoint to provide statistical significance because of the absence of previous primary endpoint data. However, based on efficacy data from the Phase 1/2a study, this Phase 2b study is expected to provide reliable information regarding the efficacy and safety of the drug products.

8. CHANGES IN THE PLANNED ANALYSES

The Per-Protocol population was updated to exclude subjects with more than three consecutive missed doses in order to fully capture compliant subjects.

A covariate of the respective Baseline score was added to the models used for analysis of the primary and secondary endpoints.

A secondary efficacy analysis endpoint of 'clear' or 'almost clear' plus a 2-point improvement from Baseline for Intertriginous Investigator Global Assessment (I-IGA) at weeks 2, 4, 6, 8, and 12 was added.

A secondary efficacy analysis endpoint for change from Baseline in Modified Psoriasis Area Severity Index-100 (mPASI-100) at weeks 2, 4, 6, 8, and 12 was added.

Week 2 was added to all secondary and exploratory efficacy endpoints.

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Table 14.0.1: Summary of Subject Enrollment and Evaluability

	ARQ-151 Cream 0.3%	ARQ-151 Cream 0.15%	Vehicle Cream
Number of Subjects in the ITT Population	xx	xx	xx
Number of Subjects Included from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Safety Population			
No Post-Baseline Safety Assessment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included from the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded in the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the PP Population			
Less than 80% Compliant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missed 3 or More Consecutive Doses	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other Serious Protocol Violations	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included from the PK Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded in the PK Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Evidence of Dosing with Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Insufficient Plasma Concentrations	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: ITT population includes all randomized subjects.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Completed Study			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation			
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

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

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Age (years)			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
N	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
N	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
N	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Repeat Table 14.1.1.1 for the following:
Table 14.1.1.2: Summary of Subject Demographics (Per-Protocol Population)
Table 14.1.1.3: Summary of Subject Demographics (Safety Population)
Table 14.1.1.4: Summary of Subject Demographics (PK Population)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 1 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Whole Body Investigator Global Assessment Score			
N	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intertriginous Area Investigator Global Assessment Score[a]			
N	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Itch-Related Sleep Loss Score			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 2 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Body Surface Area (%) Affected by Psoriasis			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
WI-NRS Score			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Total Psoriasis Symptom Diary (PSD) Score			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 3 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Dermatology Life Quality Index (DLQI) Score			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Height (cm)			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Weight (kg)			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.2.1 for the following:
Table 14.1.2.2: Summary of Subject Baseline Characteristics (Per-Protocol Population)
Table 14.1.2.3: Summary of Subject Baseline Characteristics (Safety Population)
Table 14.1.2.4: Summary of Subject Baseline Characteristics (PK Population)

Table 14.1.3: Summary of Medical History by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xxx)	ARQ-151 Cream 0.15% (N=xxx)	Vehicle Cream (N=xxx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more medical histories that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

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

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

ATC Level 2 Term[a] Preferred Name	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more prior medications that map to the WHO-DD (Version March 1, 2018). At each level of summarization (ATC Level 2 Term or Preferred Name) subjects are counted once.
Note: Table includes all medications used prior to date of first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

ATC Level 2 Term[a] Preferred Name	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more concomitant medications that map to the WHO-DD (Version March 1, 2018). At each level of summarization (ATC Level 2 Term or Preferred Name) subjects are counted once.
Note: Table includes all medications used on or after date of first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1: Analysis of Primary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' at Week 6 (Intent-to-Treat Population)

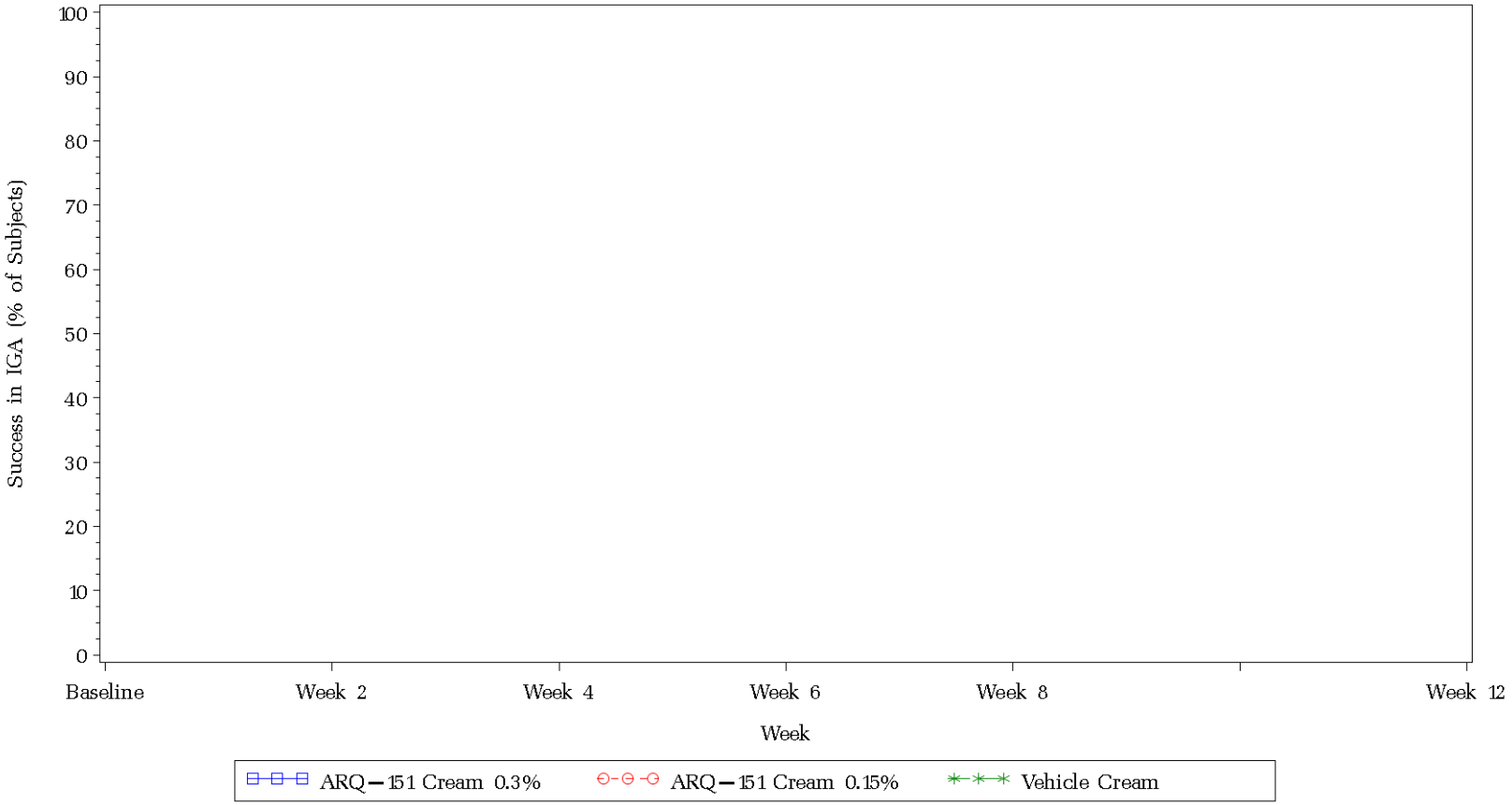
	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
IGA Score of Clear or Almost Clear at Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline IGA score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.1.1 for the following:

Table 14.2.1.2: Analysis of Primary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' at Week 6 (Per-Protocol Population)

Figure 14.2.1.1: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' by Visit
(Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Figure 14.2.1.1 for the following:
Figure 14.2.1.2: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' by Visit (Per-Protocol Population)

Table 14.2.2.1: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' (Intent-to-Treat Population)

IGA Score of Clear or Almost Clear	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline IGA score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

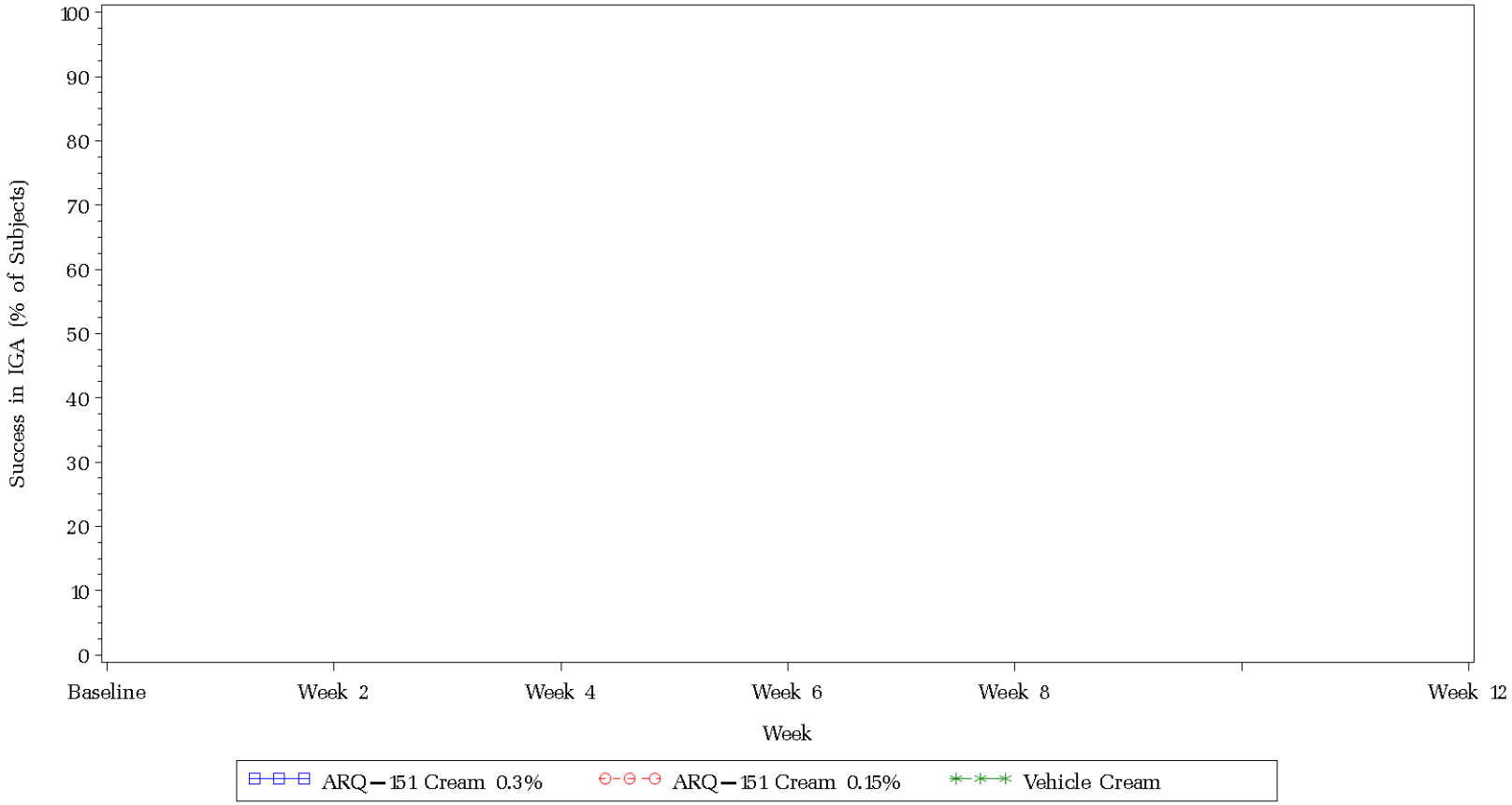
Repeat Table 14.2.2.1 for the following:
Table 14.2.2.2: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' (Per-Protocol Population)

Table 14.2.3.1: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline (Intent-to-Treat Population)

IGA Score of Clear or Almost Clear Plus a 2-Grade Improvement from Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline IGA score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.3.1 for the following:
Table 14.2.3.2: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline (Per-Protocol Population)

Figure 14.2.3.1: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline by Visit (Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Figure 14.2.3.1 for the following:
Figure 14.2.3.2: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline by Visit (Per-Protocol Population)

Table 14.2.3.3: Summary of Proportion of Subjects Achieving an Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline by Investigational Site
(Intent-to-Treat Population)

Investigational Site	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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Table 14.2.4.1.1: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear'
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

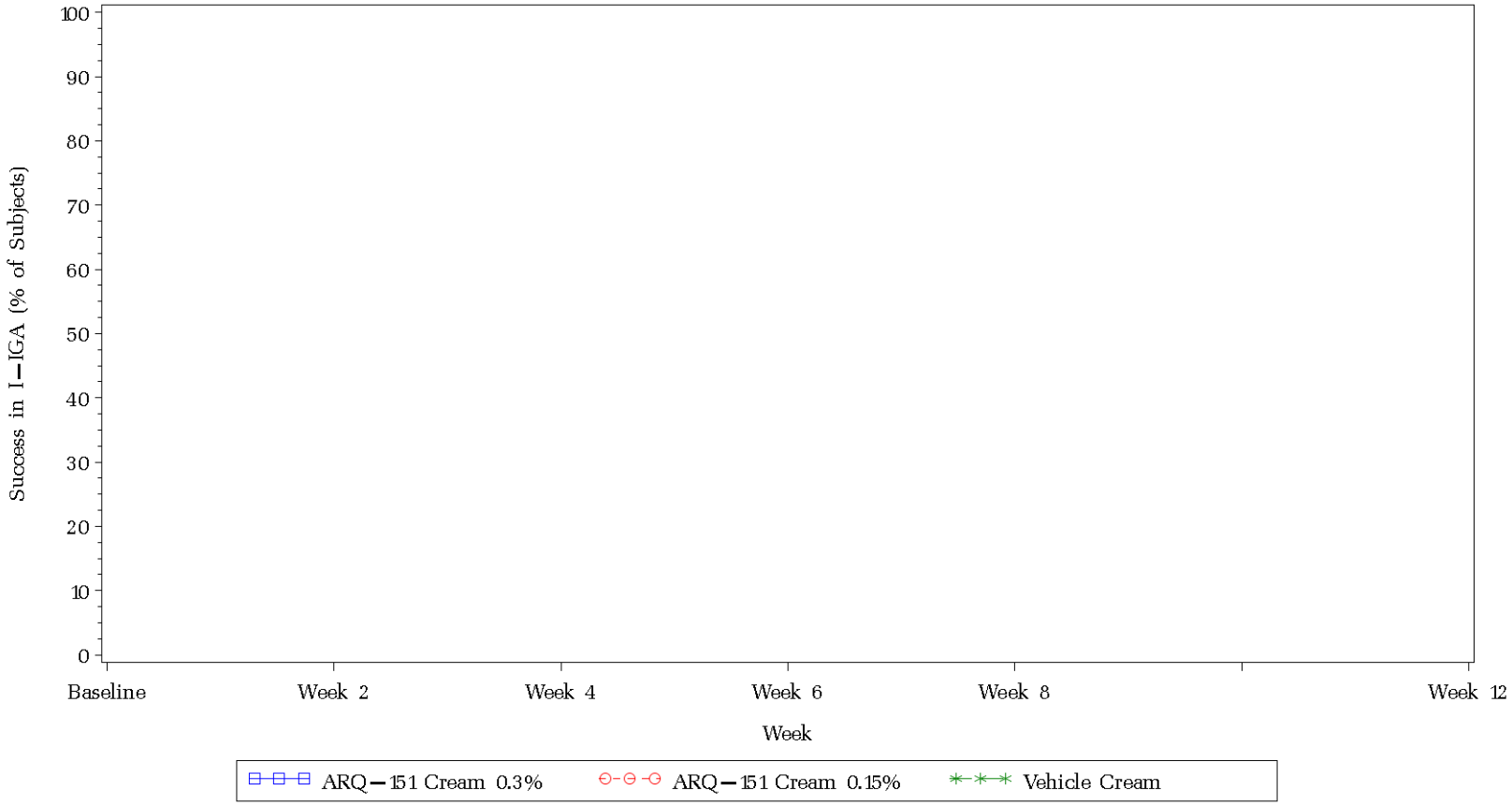
I-IGA Score of Clear or Almost Clear Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline I-IGA score.
Restricted to subjects with an I-IGA severity score of at least "Mild" at baseline.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.4.1.1 for the following:

Table 14.2.4.1.2: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' (Per-Protocol Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

Figure 14.2.4.1.1: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear'
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Figure 14.2.4.1.1 for the following:
Figure 14.2.4.1.2: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least ‘Mild’ at Baseline who Achieved a Score of ‘Clear’ or ‘Almost Clear’ (Per-Protocol Population: Subjects with I-IGA Severity of at Least ‘Mild’ at Baseline)

Table 14.2.4.2.1: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' Plus a 2 Grade Improvement from Baseline
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

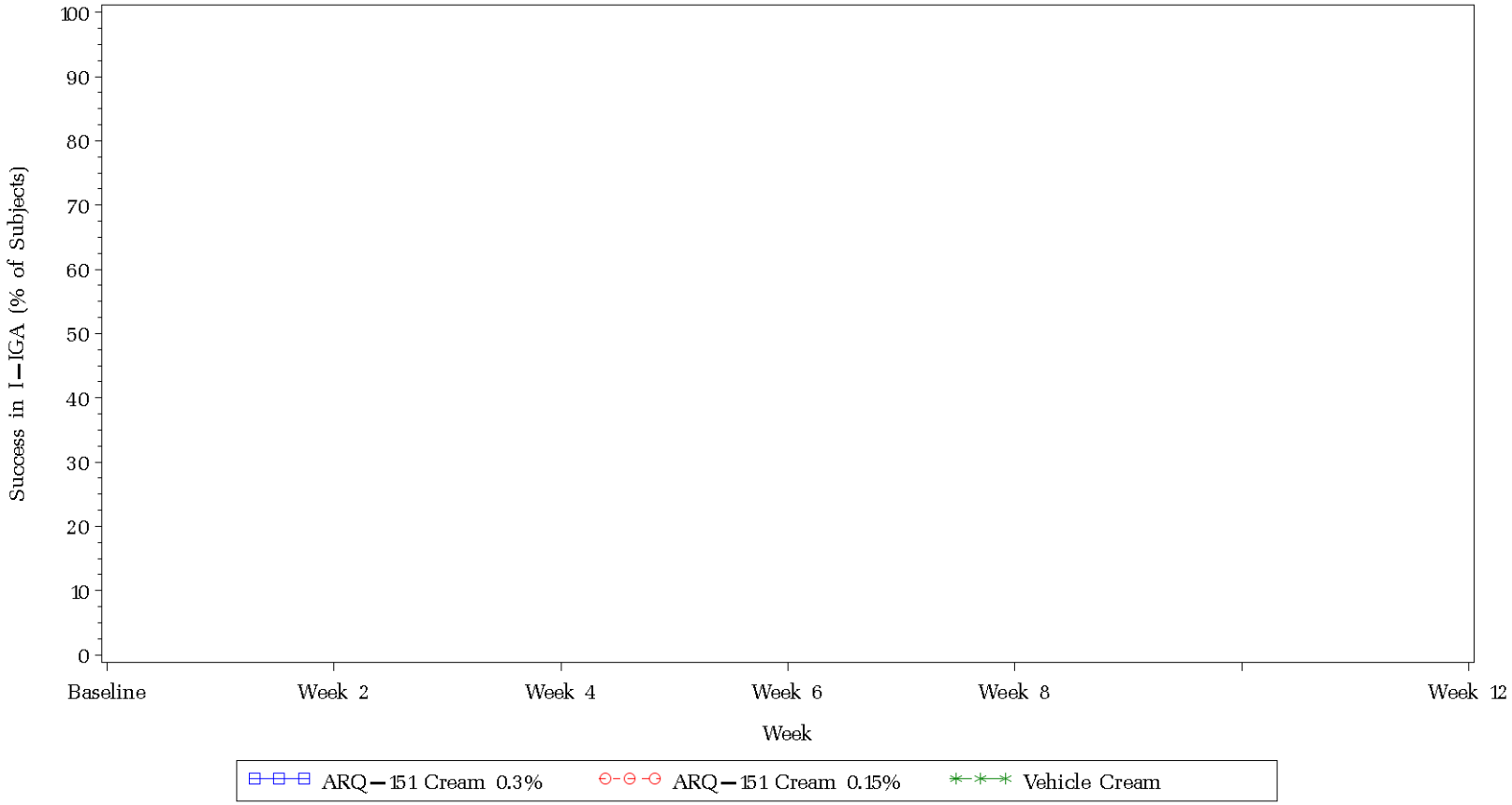
I-IGA Score of Clear or Almost Clear Plus a 2 Grade Improvement from Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline I-IGA score.
Restricted to subjects with an I-IGA severity score of at least "Mild" at baseline.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.4.2.1 for the following:

Table 14.2.4.2.2: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' Plus a 2 Grade Improvement from Baseline (Per-Protocol Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

Figure 14.2.4.2.1: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' Plus a 2 Grade Improvement from Baseline
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Figure 14.2.4.2.1 for the following:
Figure 14.2.4.2.2: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least ‘Mild’ at Baseline who Achieved a Score of ‘Clear’ or ‘Almost Clear’ Plus a 2 Grade Improvement from Baseline (Per-Protocol Population: Subjects with I-IGA Severity of at Least ‘Mild’ at Baseline)

Table 14.2.5.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 1 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 2 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 3 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 4 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 5 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

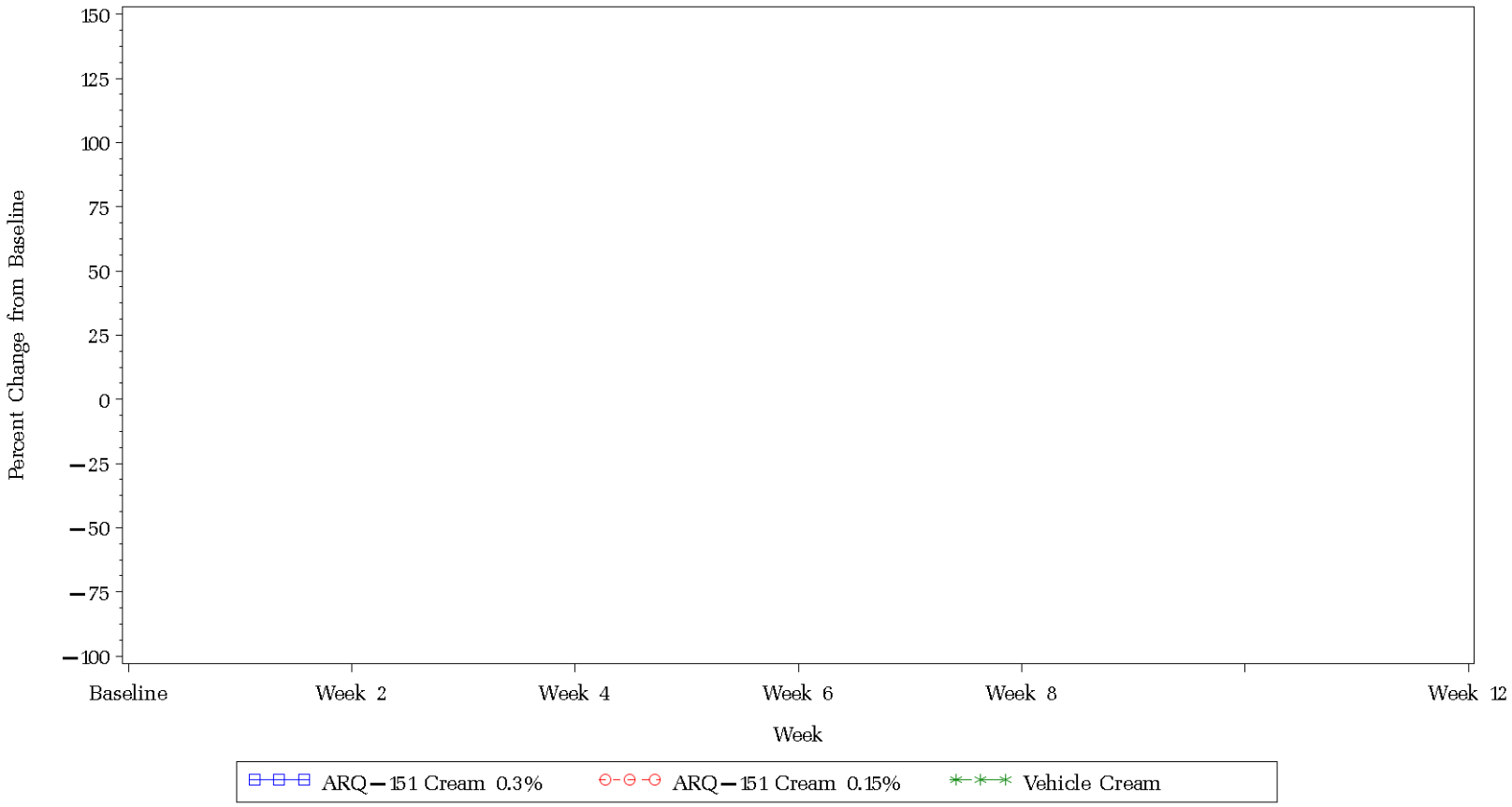
[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 6 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.5.1 for the following:
Table 14.2.5.2: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI) (Per-Protocol Population)

Figure 14.2.5.1: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 3)

Reduction in mPASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline mPASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 3)

Reduction in mPASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline mPASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 3)

Reduction in mPASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline mPASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.6.1 for the following:

Table 14.2.6.2 Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline (Per-Protocol Population)

Table 14.2.7.1: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.7.1 for the following:
Table 14.2.7.2: Dichotomized Percent Reduction(s) in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline (Per-Protocol Population)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 1 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 2 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 3 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 4 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 5 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 6 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.8.1 for the following:
Table 14.2.8.2: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected (Per-Protocol Population)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 1 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 2 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 3 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 4 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 5 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.9.1 for the following:

Table 14.2.9.2: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score (Per-Protocol Population)

Table 14.2.10.1.1: Analysis of Secondary Endpoint: Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline
(Intent-to-Treat Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

4 Point Reduction in WI-NRS Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline WI-NRS score.
Restricted to subjects with a baseline WI-NRS Score of 6 or greater.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.10.1.1 for the following:

Table 14.2.10.1.2: Analysis of Secondary Endpoint: Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline (Per-Protocol Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

Table 14.2.10.2.1: Summary of Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline
(Intent-to-Treat Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

4 Point Reduction in WI-NRS Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
Restricted to subjects with a baseline WI-NRS Score of 6 or greater.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.10.2.1 for the following:

Table 14.2.10.2.2: Summary of Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline (Per-Protocol Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 4 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 5 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 6 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.11.1 for the following:

Table 14.2.11.2: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline (Per-Protocol Population)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 4 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 5 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 6 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.12.1 for the following:
Table 14.2.12.2: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline (Per-Protocol Population)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 1 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 2 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 3 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 4 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 5 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.13.1 for the following:
Table 14.2.13.2: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score (Per-Protocol Population)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 1 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 2 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 3 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 4 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 5 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.14.1 for the following:

Table 14.2.14.2: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score (Per-Protocol Population)

Table 14.2.15.1: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score
(Intent-to-Treat Population)
(Page 1 of 3)

NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.15.1: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score
(Intent-to-Treat Population)
(Page 2 of 3)

NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.15.1: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score
(Intent-to-Treat Population)
(Page 3 of 3)

NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.15.1 for the following:
Table 14.2.15.2: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score (Per-Protocol Population)

Table 14.2.16.1: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score
(Intent-to-Treat Population)
(Page 1 of xx)

<Score Type>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.16.1: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score
(Intent-to-Treat Population)
(Page 2 of xx)

<Score Type>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.16.1: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score
(Intent-to-Treat Population)
(Page 3 of xx)

<Score Type>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.16.1 for the following:

Table 14.2.16.2: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score (Per-Protocol Population)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 1 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 2 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 3 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 4 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 5 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 6 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.17.1 for the following:
Table 14.2.17.2: Summary of Whole Body Investigator Global Assessment (IGA) (Per-Protocol Population)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 1 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 2 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 3 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 4 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 5 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 6 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.18.1 for the following:
Table 14.2.18.2: Summary of Intertriginous Area Investigator Global Assessment (I-IGA) (Per-Protocol Population)

Table 14.3.0.1.1: Summary of Extent of Exposure
(Safety Population)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Number of Doses			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Amount of Drug Applied (g)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Compliant[a]			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] A subject is considered compliant with the dosing regimen if the subject applied at least 80% of the expected doses during the dosing period and did not miss more than 3 consecutive doses.

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

Table 14.3.0.2.1: Summary of Pre-Dose Pharmacokinetic Concentrations
(PK Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.0.2.1: Summary of Pre-Dose Pharmacokinetic Concentrations
(PK Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.0.2.2: Summary of Additional Pharmacokinetic Concentrations
(PK Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
72 hr (3 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
120 hr (5 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
168 hr (7 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
216 hr (9 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 1 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Baseline			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Baseline			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome			
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 2 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Week 4			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Week 4			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 3 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Week 8			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Week 8			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

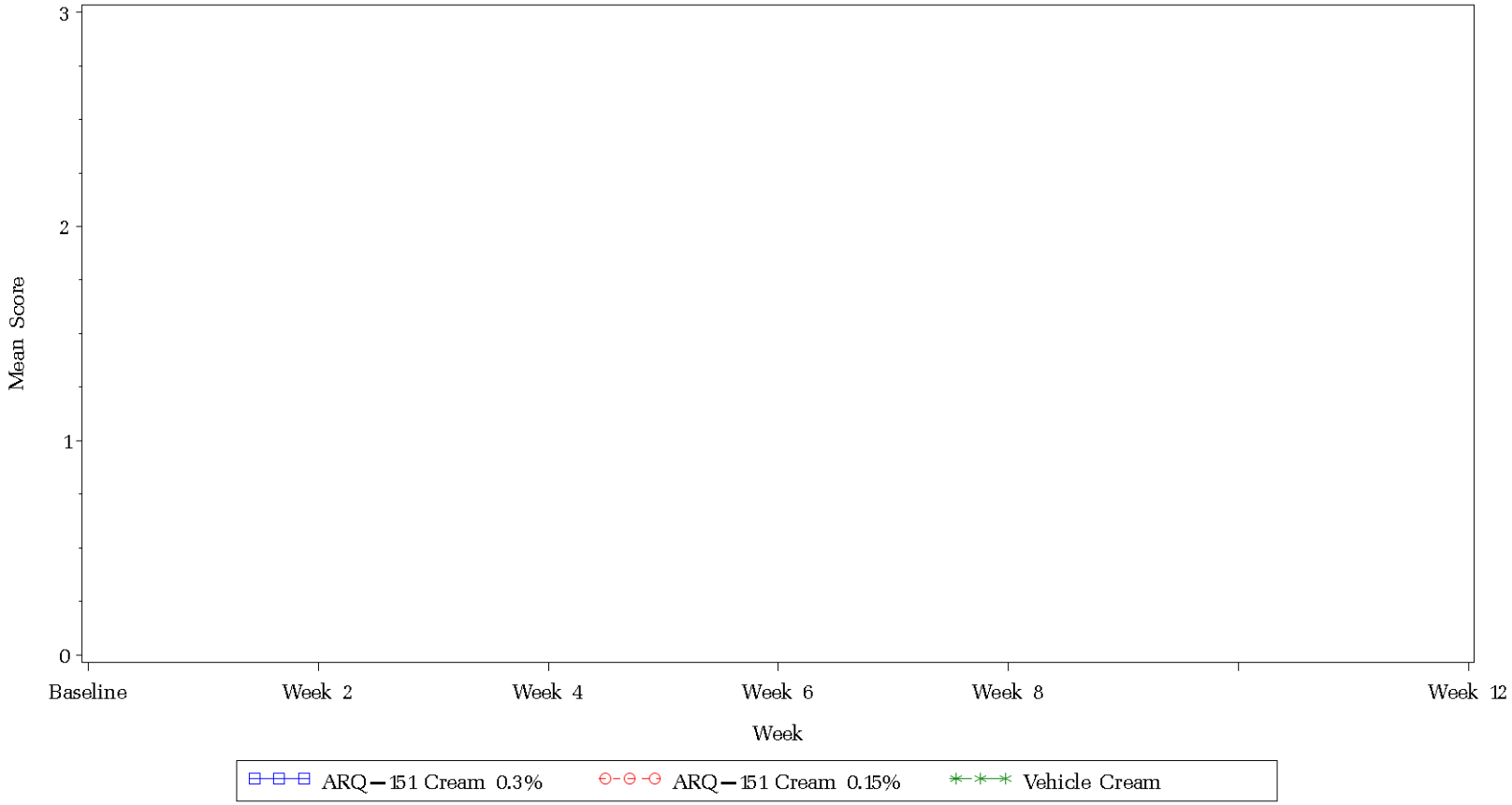
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 4 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Week 12			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Week 12			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Figure 14.3.1.1: Subject Local Tolerability Sensation Following Drug Application
(Safety Population)



Note: 0 (No sensation), 1 (Slight warm, tingling sensation; not really bothersome), 2 (Definite warm, tingling sensation that is somewhat bothersome), 3 (Hot, tingling/stinging sensation that has caused definite discomfort)
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1: Number of Patients with Suicidal Ideation, Suicidal Behavior, and Self-Injurious Behavior without Suicidal Intent Based on the Colombia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population)

Events during treatment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Suicidal Ideation (1-5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1) Wish to be dead	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2) Non-specific active suicidal thoughts	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3) Active suicidal ideation with any methods (not plan) without intent to act	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4) Active suicidal ideation with some intent to act, without specific plan	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5) Active suicidal ideation with specific plan and intent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior (6-10)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6) Preparatory acts or behavior	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
7) Aborted attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
8) Interrupted attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
9) Non-fatal suicide attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
10) Completed suicide	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation or Behavior (1-10)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Self-injurious behavior without suicidal intent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Number of Patients with Suicide-Related Treatment-Emergent Events Based on the Colombia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population)

Treatment-emergent (TE) Events	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
TE suicidal ideation (1-5) compared to recent history [a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TE serious suicidal ideation (0-3 to 4-5) compared to recent history [b]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Emergence of serious suicidal ideation (0 to 4-5) compared to recent history[c]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Improvement in suicidal ideation at endpoint compared with baseline[d]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Emergence of suicidal behavior (6-10) compared to all prior history [e]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] N=Number of enrolled patients with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the comparison period is non-missing and <5.
[b] N=Number of enrolled patients with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the comparison period is 0-3.
[c] N=Number of enrolled patients with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the comparison period is 0.
[d] N=Number of enrolled patients whose suicidal ideation score is non-missing and >0 just prior to treatment.
[e] N=number of enrolled patients with with at least one post-baseline C-SSRS assessment and who did not have suicidal behavior (6-10) prior to treatment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.1: Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)

PHQ-8 Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx		
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
n	xx	xx	xx
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
n	xx	xx	xx
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12			
n	xx	xx	xx
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.3.2: Shift Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)
(Page 1 of 3)

PHQ-8 for (ARQ-151 Cream 0.3%)

	Week 4				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 8				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 12				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: None = Minimal Depression (0 to 4); Mild = Mild Depression (5 to 9); Moderate = Moderate Depression (10 to 14);
Moderately Severe = Moderately Severe Depression (15 to 19); Severe = Severe Depression (20 to 24).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.2: Shift Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)
(Page 2 of 3)

PHQ-8 for (ARQ-151 Cream 0.15%)

	Week 4				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 8				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 12				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: None = Minimal Depression (0 to 4); Mild = Mild Depression (5 to 9); Moderate = Moderate Depression (10 to 14);
Moderately Severe = Moderately Severe Depression (15 to 19); Severe = Severe Depression (20 to 24).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.2: Shift Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)
(Page 3 of 3)

PHQ-8 for (Vehicle Cream)

	Week 4				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 8				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 12				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: None = Minimal Depression (0 to 4); Mild = Mild Depression (5 to 9); Moderate = Moderate Depression (10 to 14);
Moderately Severe = Moderately Severe Depression (15 to 19); Severe = Severe Depression (20 to 24).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.1: Overall Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Subjects with any TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of TEAEs	xx	xx	xx
Subjects with any Related TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related TEAEs	xx	xx	xx
Subjects with any Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx
Subjects with any Related Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related Serious TEAEs	xx	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Drug due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity By Subject			
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject			
Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.4.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.3: Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.4: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.5: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.6: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Subjects with any Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx
Subjects with any Related Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related Serious TEAEs	xx	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Drug due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity By Subject			
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject			
Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.4.7: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.8: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.9: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.1.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.5.1.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Repeat Table 14.3.1.5.1.1: Summary of Chemistry Laboratory Results

For the following tables:
Table 14.3.1.5.1.2: Summary of Hematology Laboratory Results (Safety Population)
Table 14.3.1.5.1.3: Summary of Quantitative Urinalysis Laboratory Results (Safety Population)

Table 14.3.1.5.2.1: Shift Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of x)

<Test name> (<units>)	ARQ-151 Cream 0.3% (N=xx)			ARQ-151 Cream 0.15% (N=xx)			Vehicle Cream (N=xx)		
	Week 4			Week 4			Week 4		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	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%)
WNL	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%)
ANL	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 12			Week 12			Week 12		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	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%)
WNL	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%)
ANL	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%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.5.2.1: Shift Summary of Chemistry Laboratory Results

For the following tables:
Table 14.3.1.5.2.2: Shift Summary of Hematology Laboratory Results (Safety Population)
Table 14.3.1.5.2.3: Shift Summary of Quantitative Urinalysis Laboratory Results (Safety Population)

Table 14.3.1.6.1: Summary of Electrocardiogram (ECG) Parameters
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.6.1: Summary of Electrocardiogram (ECG) Parameters
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.6.2: Shift Summary of Overall Electrocardiogram (ECG) Assessments
(Safety Population)
(Page 1 of x)

Overall ECG Assessment		ARQ-151 Cream 0.3% (N=xx)		ARQ-151 Cream 0.15% (N=xx)		Vehicle Cream (N=xx)	
		Week 4		Week 4		Week 4	
	Baseline	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 12		Week 12		Week 12	
	Baseline	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 3 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 4 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.2: Summary of Change in Body Weight Compared to Baseline
(Safety Population)
(Page 1 of 2)

Change in Body Weight Compared to Baseline[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Percentages may sum to over 100% due to the possibility of being included in more than one category.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.7.2: Summary of Change in Body Weight Compared to Baseline
(Safety Population)
(Page 2 of 2)

Change in Body Weight Compared to Baseline[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Percentages may sum to over 100% due to the possibility of being included in more than one category.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

S: Subject A: Age/Sex E: Eval	F: Date of First Dose of Drug L: Date of Last Dose of Drug	Primary Reason for Study Completion/Discontinuation	Date of Completion/Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxx xxxx xxxxxxxx xxxxx	xxxxxxxxxx xxxx

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

Note to programmer: concatenate 'Describe' text onto Primary Reason where applicable.

Listing 16.2.1.2: Discontinued Subjects
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	F: Date of First Dose of Drug L: Date of Last Dose of Drug	Primary Reason for Study Completion/Discontinuation	Date of Completion/Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxx xxxx xxxxxxxx xxxxx	xxxxxxxxxx xxxx

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

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

Subject	Age/Sex	Eval	Criterion Category	Criterion Identifier	Description
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx xxxxx xxxxxxxxxxx xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxxx xxx xxxxxxxx xxxx
			xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx xxxxxxx x xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxxx xxx xxxxxxxx xxxxxx xxxxxxx x xxxxxxxxx xxxxx xxx
			xxxxxxxxx	xx	xxxxxxxx xxxx xxxxxx xxxx xxxxxxxxxxxx xxxxxx xxxxxxxxx xxxxxxxxx xxx xxxxxxxx xxxxx xx xxxx xxxx xx xxx xx xxxx xxxx xxx xxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx
			xxxxxxxxx	xx	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx xxxxxxxx xxx xxxxx xxxxxxxxx xxxx

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

Listing sorted by Subject, Criterion Category, and Criterion Identifier.

Listing 16.2.2.2: Protocol Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Protocol Deviation
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xxxxxxxxxxx xxxxxx xxxxxxxx xxxxxxxxxx xx xxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx x xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxxx xxxxx xxx xxxxxxxx xxxx xxxxxx xxxx xxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx x xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxx xxxx xxxxxx xxxx xxxxxxx

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

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

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

Listing sorted by Subject, and Population.

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

Subject	Eval	B: Date of Birth S: Sex	D: Date/Time of Informed Consent A: Age at Consent	R: Race E: Ethnicity	C: Childbearing Potential B: Birth Control Method	P: Did the Subject Consent to Photography? D: Date of Photography Consent
xxxxxx	xxxxxxxx	B: xxxxxxxxxx S: xxxx	D: xxxx-xx-xxTxx:xx:xx A: xx	R: xxxxx xx xxxxxxx E: xxx xxxxxxxx xx	C: xx B:	P: xxx D: xxxxxxxxxx
xxxxxx	xxxxxxxx	B: xxxxxxxxxx S: xxxxxx	D: xxxx-xx-xxTxx:xx:xx A: xx	R: xxxxx E: xxx xxxxxxxx xx	C: xxx B: xxxxxxxxxx xxxxxxxx	P: xx D:
xxxxxx	xxxxxxxx	B: xxxxxxxxxx S: xxxxxx	D: xxxx-xx-xxTxx:xx:xx A: xx	R: xxxxx E: xxx xxxxxxxx xx	C: xxx B: xxxx xxxxxxxxxxxxx	P: xxx D: xxxxxxxxxx

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

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

MedDRA System Organ Class	MedDRA Preferred Term	Condition/Surgery Verbatim Term
x xxx xxxxx	xxxx xxx xxxxx	xxxx xxxxxxxxxx xx xxxxxx
		xxxxx xxx xxxxxx xx
xxxx x xxxxxxxxx	xxxxxxx xxxxxxxxxxxx	xxxx xxxxxx xxxxxxxxxx xx xxxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx xxxxxxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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

Subject	Age/Sex	Eval	Condition/Surgery Verbatim Term	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Onset Date E: End Date
xxxxxx	xxxx	xxxxxxxx	xxxxxx xxxxxxx (xxxxxxxx xxxxx)	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx
			xxxxxxxx xxxxxxxxxx	P: xxxxxxx xxxxxxxx S: xxxxxx xxxxxxxxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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

ATC Level 2 Term	Preferred Name	Medication Name	I: Indication R: Route
xxxxxx xxxxxx xx xxx	xxxxxxxxxx	xxxxxxxxxx	I: xxxxxxx xxxxxxxx R: xxxx
	xxxxxxx x	xxxxxx	I: xxxxxxx xxxxxxxx xxxxxxxxxxxx R: xxxx
	xxxxxxxxx	xxxxxxxxx	I: xxxxxxx xxxxxxxx xxxx xxxxx xxxxxxxx R: xxxx

Note: Preferred Name and ATC Level 2 Term map to the WHO-DD (Version March 1, 2018).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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

Subject	Age/Sex	Eval	M: Medication Name P: Preferred Name A: ATC Level 2 Term I: Indication	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	D: Dose U: Units F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx	D: xx U: xx F: xxxx R:xxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx	D: xxxxx U: xx F: xx R:xxxx
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx	D: xxx U: xx F: xx R:xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: Preferred Name and ATC Level 2 Term map to the WHO-DD (Version March 1, 2018).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route. If ongoing, include 'Ongoing' in place of End Date. Concatenate Topical Area Treated onto route where applicable.

Listing 16.2.4.4.1: Unique Therapies and Procedures Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Procedure/Therapy Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, MedDRA Preferred Term, and Procedure/Therapy Verbatim Term.

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

S: Subject A: Age/Sex E: Eval	Procedure/Therapy Verbatim Term	I: Indication A: Anatomical Area	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Start Date E: End Date
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxx xxxxxxx (xxxxxxxx xxxxx)	I: xxxxxxxxxx A: xxxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx
	xxxxxx xxxxxxx xxxxxxx	I: xxxxxxxxxx xxxxx A:	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxx xxxxxxxxxxxxx	I: xxxxxxxxxx xxxxx A: xxxx xxx xxxxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Procedure/Therapy, Indication. If ongoing, include 'Ongoing' in place of End Date.

Listing 16.2.4.5: Physical Examination
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Visit	Date	Body System Assessed	Finding	Abnormal Finding Specification
S: xxxxxx A: xxxx E: xxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxx	Heart	xxxxxxxxxx	xxxxxxx xxxxx
			Lungs	xxxxx xxxxxxx	
			Skin (Other than Psoriasis)	xxxxxxxx	
			<Other, specify>	xxxx xxx xx	xxxxxxxxxxx xxx xxxxxx
	xxxxxxxxxxx	xxxxxxxxxx	Heart	xxxxxxxx	
			Lungs	xxxxx xxxxxxx	
			Skin (Other than Psoriasis)	xxxxxxxx	
	xxxx xx	xxxxxxxxxx	Heart	xxxxxxxx	
			Lungs	xxxxx xxxxxxx	
			Skin (Other than Psoriasis)	xxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxx	Heart	xxxxxxxxxx	
			Lungs	xxxxxxxxx xx	xxxxxx
			Skin (Other than Psoriasis)	xxxx xxxxxxxx	
	xxxxxxxxxxx	xxxxxxxxxx	Heart	xxxxxx xxxxx	
			Lungs	xxxxxxx	
			Skin (Other than Psoriasis)	xxxxxxxxxx	
	xxxx xx	xxxxxxxxxx	Heart	xxxxxxxx	
			Lungs	xxxxx xxxxxxx	
			Skin (Other than Psoriasis)	xxxxxxxx	

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

Listing sorted by Subject, Visit, Date, Body System Assessed.

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

Subject	Age/Sex	Eval	Visit	Visit Date	Study Day[1]	Within Visit Window	Days Out of Window[2]
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	xxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx to xxxxxxxxxx	x	xxx	
			xxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx	
			xxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	

[1] Day is calculated as date – baseline date for dates prior to baseline visit. Otherwise, day is calculated as date – baseline date + 1 for dates on or after baseline visit.
[2] Populated only for post baseline visits that are planned and out of window.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Visit Date.

Listing 16.2.5.2: Drug Accountability
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Kit Number	Date Dispensed	Date Returned	Tube ID	Dispensed Weight (g)	Returned Weight (g)
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
			xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
			xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
			xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x

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

Listing sorted by Subject, Kit Number, Date Dispensed, Date Returned, and Tube ID.

Listing 16.2.5.3: Study Drug Application
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date/Time of Study Drug Application	Study Drug Applied in Clinic?	Pre-Dose Weight (g)	Post-Dose Weight (g)	Reason Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xx			xxx xxx xxxxx
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xx			xxx xxx xxxxx
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	

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

Listing sorted by Subject, Date/Time of Study Drug Application, Visit.

Listing 16.2.5.4: Dosing Compliance
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	D: Date of First Dose R: Date of Last Dose	Number of Days of Exposure	Calculated[1] Number of Doses	Amount of Study Drug Used (g)	Maximum Number of Missed Consecutive Doses	Percent Compliant	Compliant?[2]
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxxxxxxxxx R: xxxxxxxxxxx	xx	xx	xxxx	x	xxx	xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxxxxxxxxx R: xxxxxxxxxxx	xx	xx	xxxx	x	xxx	xx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxxxxxxxxx R: xxxxxxxxxxx	xx	xx	xxxx		xxxx	xxx

[1] The total number of doses was calculated from the date of first dose and the date of last known dose minus the missed doses plus additional dose deviations.
[2] A subject was considered compliant with the dosing regimen if the subject applied at least 80% of the expected doses during the study drug application period and did not miss more than 3 consecutive doses.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.5.5: Dosing Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Dose	Date of Dosing Deviation	Number of Doses Applied
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x
				xxxxxxxxxx	x
				xxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x
				xxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x
				xxxxxxxxxx	x

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

Listing sorted by Subject, and Date of Dosing Deviation.

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

S: Subject A: Age/Sex E: Eval	Visit	Date of Assessment	Whole Body Investigator Global Assessment Score	Does the Subject have Intertriginous Area involvement?	Intertriginous Investigator Global Assessment Score	Evaluator Initials
S: xxxxxx A: xxxx E: xxxxxxxx	SCREENING	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	BASELINE	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 2	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 4	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 6	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 8	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 12	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 16	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
S: xxxxxx A: xxxx E: xxxxxxxx	SCREENING	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	BASELINE	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	WEEK 2	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	WEEK 4	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	WEEK 6	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 8	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 12	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 16	xxxxxxxxxx	x x xxxxxxxx	xx		xxx

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

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.6.2: Body Surface Area (BSA) Involved with Psoriasis
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	BSA[1] (%)	Evaluator Initials
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxx	xxxxxxxxxx	xx.x	xxx
			xxxxxxxxx	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx xx	xxxxxxxxxx	xx.x	xxx
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxx	xxxxxxxxxx	xx.x	xxx
			xxxxxxxxx	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx x	xxxxxxxxxx	xx.x	xxx
			xxxx xx	xxxxxxxxxx	xx.x	xxx

[1] Body Surface Area (BSA) involved with psoriasis (excluding the scalp, palms and soles).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date of Assessment.

Listing 16.2.6.3: Modified Psoriasis Area and Severity Index (mPASI)
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date E: Evaluator Initials	Affected Area	Percent of Skin Involved	Parameter Score Erythema (redness)	Parameter Score Induration (thickness)	Parameter Score Desquamation (scaling)
S: xxxxxx A: xxxx E: xxxxxxxxx	V: SCREENING D: xxxxxxxxxx E: xxx	Arms	xx-xx	x - xxxxxxx xxxxxxxx	x - xxxxxxx xxxxxxxx	x - xxxxxxx xxxxxxxx
		Head	xx-xx	x - xxxxxxx xxxxxxxx	x - xxxxxxx xxxxxxxx	x - xxxxxxx xxxxxxxx
		Legs	xx-xx	x - xxxx	x - xxxx	x
		Trunk	x.x	x - xxxx	x - xxxx	x
	V: BASELINE D: xxxxxxxxxx E: xxx	Arms	x.x	x	x	x
		Head	x.x	x - xxxxxxx xxxxxxxx	x - xxxxxxx xxxxxxxx	x - xxxxxxx xxxxxxxx
		Legs	xx-xx	x - xxxx	x - xxxx	x
		Trunk	xx-xx	x - xxxx	x - xxxx	x
	V: WEEK 2 D: xxxxxxxxxx E: xxx	Arms	xx-xx	x	x	x
		Head	xx-xx	x	x	x
		Legs	xx-xx	x - xxxx	x - xxxx	x - xxxx
		Trunk	xx-xx	x - xxxx	x - xxxx	x - xxxx
	V: WEEK 6 D: xxxxxxxxxx E: xxx	Arms	xx-xx	x - xxxx	x - xxxx	x
		Head	xx-xx	x - xxxx	x	x - xxxx
		Legs	x.x	x - xxxx	x - xxxx	x - xxxx
		Trunk	xx-xx	x - xxxx	x - xxxx	x - xxxx

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

Listing sorted by Subject, Visit, Date, and Affected Area. If < 10% of skin involved, present actual percent involved.

Listing 16.2.6.4: Numeric Rating Scale (NRS) Assessments/Sleep Loss
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Assessment	Patient Reported Severity Score
xxxxxx	xxxx	xxxxxxxx	SCREENING	xxxxxxxxxx	xxxxxxxxxx	x - xx xxxxxxx
					xxxxxxxxxx xx	xx - xxxxx xxxxxxxxxx xxxx
					xxxxxxxxxxxxxxxxxxxxx	x
			BASELINE	xxxxxxxxxx	xxxxxxxxxx	x
					xxxxxxxxxx xx	x
					xxxxxxxxxxxxxxxxxxxxx	x - xx xxxx-xxxxxxx xxxxx xxxx
			WEEK 2	xxxxxxxxxx	xxxxxxxxxx	x
					xxxxxxxxxx xx	x
					xxxxxxxxxxxxxxxxxxxxx	x - xx xxxx-xxxxxxx xxxxx xxxx
			WEEK 4	xxxxxxxxxx	xxxxxxxxxx	x - xx xxxx
					xxxxxxxxxx xx	x
					xxxxxxxxxxxxxxxxxxxxx	x - xx xxxx-xxxxxxx xxxxx xxxx
			WEEK 6	xxxxxxxxxx	xxxxxxxxxx	x - xx xxxx
					xxxxxxxxxx xx	x
					xxxxxxxxxxxxxxxxxxxxx	x - xx xxxx-xxxxxxx xxxxx xxxx
			WEEK 8	xxxxxxxxxx	xxxxxxxxxx	x - xx xxxx
					xxxxxxxxxx xx	x
					xxxxxxxxxxxxxxxxxxxxx	x - xx xxxx-xxxxxxx xxxxx xxxx
			WEEK 12	xxxxxxxxxx	xxxxxxxxxx	x - xx xxxx
					xxxxxxxxxx xx	x
					xxxxxxxxxxxxxxxxxxxxx	x - xx xxxx-xxxxxxx xxxxx xxxx

Note: Score is the patient-reported severity of this symptom at its highest intensity during the previous 24-hour period.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, and Assessment.

Listing 16.2.6.5.1: Dermatology Life Quality Index (DLQI) Questionnaire Descriptions

Number	DLQI Question
1	Over the last week, how itchy, sore, painful or stinging has your skin been?
2	Over the last week, how embarrassed or self conscious have you been because of your skin?
3	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?
4	Over the last week, how much has your skin influenced the clothes you wear?
5	Over the last week, how much has your skin affected any social or leisure activities?
6	Over the last week, how much has your skin made it difficult for you to do any sport?
7a	Over the last week, has your skin prevented you from working or studying?
7b	If "No", over the last week how much has your skin been a problem at work or studying?
8	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?
9	Over the last week, how much has your skin caused any sexual difficulties?
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?

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

Listing sorted by Question Number.

Listing 16.2.6.5.2: Dermatology Life Quality Index (DLQI) Questionnaire
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	1	2	3	4	5	6	7a	7b	8	9	10
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x

Note: Questions 1-6, 7b-10: 1 = Very much, 2 = A lot, 3 = A little, 4 = Not at all.
Question 7a: 1 = Yes, 0 = No.
NR = Not relevant.
ND = Not done.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of assessment

Listing 16.2.6.6.1: Work Productivity and Activity Impairment (WPAI) Questionnaire Descriptions

Number	WPAI Question
1	Are you currently employed (working for pay)?
2	During the past seven days, how many hours did you miss from work because of problems associated with your psoriasis? Include hours you missed on sick days, times you went in late, left early, etc., because of your psoriasis. Do not include time you missed to participate in this study.
3	During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?
4	During the past seven days, how many hours did you actually work?
5	During the past seven days, how much did your psoriasis affect your productivity while you were working?
6	During the past seven days, how much did your psoriasis affect your ability to do your regular daily activities, other than work at a job?

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

Listing sorted by Question Number.

Listing 16.2.6.6.2: Work Productivity and Activity Impairment (WPAI) Questionnaire
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date of Assessment	1. Employed	2. Psoriasis Hours Missed	3. Other Hours Missed	4. Hours Worked	5. Productivity Affected	6. Regular Activities Affected
S: xxxxxx A: xx xxxx E: xx xx	V: xxxx D: xxxxxxx	xxx	xxx.x	xxx.x	xxx.x	x	x
	V: xxxx D: xxxxxxx	xxx	xxx.x	xxx.x	xxx.x	x	x
S: xxxxxx A: xx xxxx E: xx xx	V: xxxx D: xxxxxxx	xxx	xxx.x	xxx.x	xxx.x	x	x
	V: xxxx D: xxxxxxx	xxx	xxx.x	xxx.x	xxx.x	x	x

Note: Questions 2 - 5 are answered conditionally based on the response to Question 1.
Questions 2 - 4 are reported in hours.
Question 5: Scaled (0 - Psoriasis had no effect on my) to (10 - Psoriasis completely prevented me from working).
Question 6: Scaled (0 - Psoriasis had no effect on my daily activities) to (10 - Psoriasis completely prevented me from doing my daily activities).
ND = Not done.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of assessment

Listing 16.2.6.7: Columbia-Suicide Severity Rating Scale (C-SSRS)
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date	Question	Time Period	Response
S: xxxxxx A: xxxx E: xxxxxxxxx	V: SCREENING D: xxxxxxxxxx	xxxx xx xx xxxx	xxxxxxxx xxxx x xxxxxx	xx xxx xxxx
		xxx xxxxxxx xxxxx xxxxxxxx xxxxxxx	xxxxxxxx	xxx
		xxx xxxxxxx xxxxx xxxxxxxx xxxxxxx xxx xxxx xxxxxxxx xxxxx xx xxx xxxxxx xxxxxxx xxxxxxx xxxx xxxxx xx xxx xxxxxxx xxxxxxx xxxx xxxxxx xxxxxxx xxxxxxx xxxx xxxxx xxxx xxx xxxxxx xxxx xxxxxx xxxxxxx	xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx	xx xx xx xx xx xxx xx x
		xxx xxxx xxxxx xxxx xxxx xxxx xxxx xxxx xx xxx xxxx xxxxx xxxxxxx xxx xxx xxxx xx xxxx xxxx xxxxxxx xxxxxxx xxx xxxxxxx xxxxxx xx xxx xxxxxx xxxxxxxxxx xxxxxxxx xxxxxxxxx xxxxxxx	xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx xxxxxxxx xxxx x xxxxxx	xxx xxxx x xxx xxxx xxx xxxx x x xxx xx xx xxx xxxx xx xxx xxxx xx xx xxx xxxxx xxx xxxx
	V: BASELINE D: xxxxxxxxxx	xxxx xx xx xxxx	xxxxx xxxx xxxxx	xx
		xxx xxxxxxx xxxxx xxxxxxxx xxxxxxx xxx xxxxxxx xxxxx xxxxxxxx xxxxxxx xxx xxxx xxxxxxxx xxxxx xx xxx	xxxxx xxxx xxxxx xxxxx xxxx xxxxx	xx xx

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

Listing sorted by Subject, Visit, Date, Question (in order in CRF), and Time Period (in order in CRF). All additional information (such as description, number of attempts) will be concatenated onto the response for the main question.

Listing 16.2.6.8.1: Patient Health Questionnaire Depression Scale (PHQ-8) Question Descriptions

Number	PHQ-8 Question
1	How often during the past 2 weeks were you bothered by: Little interest or pleasure in doing things?
2	How often during the past 2 weeks were you bothered by: Feeling down, depressed, or hopeless?
3	How often during the past 2 weeks were you bothered by: Trouble falling or staying asleep, or sleeping too much?
4	How often during the past 2 weeks were you bothered by: Feeling tired or having little energy?
5	How often during the past 2 weeks were you bothered by: Poor appetite or overeating?
6	How often during the past 2 weeks were you bothered by: Feeling bad about yourself, or that you are a failure, or have let yourself or your family down?
7	How often during the past 2 weeks were you bothered by: Trouble concentrating on things, such as reading the newspaper or watching television?
8	How often during the past 2 weeks were you bothered by: 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?

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

Listing sorted by Question Number.

Listing 16.2.6.8.2: Patient Health Questionnaire Depression Scale (PHQ-8)
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	1	2	3	4	5	6	7	8
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x

Note: For all Questions: 0 = Not at all, 1 = Several days, 2 = More than half the days, 3 = Nearly every day, ND = Not Done.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.6.9.1: Psoriasis Symptom Diary (PSD) Questionnaire Descriptions

Number	PSD Question
1	Overall, how severe was your psoriasis-related itching over the past 24 hours?
2	Overall, how bothered were you by your psoriasis-related itching over the past 24 hours?
3	Overall, how severe was your psoriasis-related stinging over the past 24 hours?
4	Overall, how bothered were you by your psoriasis-related stinging over the past 24 hours?
5	Overall, how severe was your psoriasis-related burning over the past 24 hours?
6	Overall, how bothered were you by your psoriasis-related burning over the past 24 hours?
7	Overall, how severe was your psoriasis-affected skin cracking over the past 24 hours?
8	Overall, how bothered were you by your psoriasis-affected skin cracking over the past 24 hours?
9	Overall, how severe was your psoriasis-related pain over the past 24 hours?
10	Overall, how bothered were you by your psoriasis-related pain over the past 24 hours?
11	Overall, how severe was your psoriasis scaling over the past 24 hours?
12	Overall, how bothered were you by your psoriasis scaling over the past 24 hours?
13	Overall, how noticeable did you think the colour of your psoriasis-affected skin was over the past 24 hours?
14	Overall, how much did you try to hide your psoriasis-affected skin over the past 24 hours?
15	Overall, how much did your psoriasis cause you to avoid activities with other people over the past 24 hours?
16	Overall, how embarrassed were you because of your psoriasis over the past 24 hours?

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

Listing sorted by Question Number.

Listing 16.2.6.9.2: Psoriasis Symptom Diary (PSD) Questionnaire
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxxxxxx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx x	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
			xxxx xx	xxxxxxxxxx	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: Questions 1, 3, 5, 7, 9, 11: Scaled (0 - None) to (10 - As bad as you can imagine)
Questions 2, 4, 6, 8, 10, 12: Scaled (0 - Not bothered at all) to (10 - As bothered as you can imagine)
Question 13: Scaled (0 - Not at all noticeable) to (10 - As noticeable as you can imagine)
Question 14: Scaled (0 - Did not try to hide at all) to (10 - Totally avoided being seen by others)
Question 15: Scaled (0 - You did not avoid other people) to (10 - Avoided other people as much as you ever have)
Question 16: Scaled (0 - No embarrassment) to (10 - As embarrassed as you can imagine)
ND = Not done.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of assessment

Listing 16.2.6.10: Photography Information
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Were Photographs Taken?	Date of Photograph
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx xx	xxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xx	
			xxxx x	xxx	xxxxxxxxxx
			xxxx xx	xxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxx	xxxxxxxxxx
			xxxx x	xx	
			xxxx x	xxx	xxxxxxxxxx
			xxxx x	xxx	xxxxxxxxxx
			xxxx xx	xxx	xxxxxxxxxx

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

Listing sorted by Subject, Visit, and Date of Photograph.

Listing 16.2.7.1.1: Investigator Local Tolerability Assessment
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date E: Evaluator Initials	Dermal Response	Other Effects Assessed?	Other Effects Present	Locations where Other Effects are Present
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxx D: xxxxxxxxxx xxxx E: xxx	xxxx xxxxxxxx xxxxxxxx	xxx	xxxxxx xxxxxxxx xxxxxx xxxx xxxxxxxx	xxxx xxxxx xxxx xxxxx xxxx xxxx
	V: xxxxxxxx D: xxxxxxxxxx xxxx E: xxx	xxxx xxxxxxxx xxxxxxxx xxxxxxxxx xxxxxx	xxx	xxxxxx xxx xxxxxxxx	xxxx xxxxx xxxxxxx
	V: xxxxxxxx D: xxxxxxxxxx xxxx E: xxx	xxxx xxxxxxxx xxxxxxxx xxxxxxxxx xxxxxx	xxx	xxxxxx xxx xxxxxxxx	xxxx
	V: xxxxxxxx D: xxxxxxxxxx xxxx E: xxx	xxxx xxxxxxxx xxxxxxxx xxxxxxxxx xxxxxx	xxx	xxxxxx xxx xxxxxxxx	xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxx D: xxxxxxxxxx xxxx E: xxx	xxxx xxxxxxxx xxxxxxxx	xxx	xxxxxx xxxxxxxx xxxx xx xxxxx xxxx xxxxxxx xxxx xxxxxxx	xxxx xxxxx xxxx xxxx
	V: xxxxxxxx D: xxxxxxxxxx xxxx E: xxx	xxxx xxxxxxxx xxxxxxxx xxxxxxxxx xxxxxx	xxx	xxxxxx xxx xxxxxxxx	xxxx

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

Listing sorted by Subject, Visit, and Date.

Listing 16.2.7.1.2: Subject Local Tolerability Assessment
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date of Assessment	Subject Reported Tolerability
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxxxxxxxxx	x xxxxxxxxx
			xxxx x	xxxxxxxxxx	x xxxxxxxxx
			xxxx x	xxxxxxxxxx	x xxxx
			xxxx xx	xxxxxxxxxx	x xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxxxxxxxxx	x xxxx
			xxxx x	xxxxxxxxxx	x xxxx
			xxxx x	xxxxxxxxxx	x xxxx
			xxxx xx	xxxxxxxxxx	x xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxxxxxxxxx	x xxxx
			xxxx x	xxxxxxxxxx	x xxxxxxx
			xxxx x	xxxxxxxxxx	x xxxx
			xxxx xx	xxxxxxxxxx	x xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxx	xxxxxxxxxx	x xxxx
			xxxx x	xxxxxxxxxx	x xxxx
			xxxx x	xxxxxxxxxx	x xxxx
			xxxx xx	xxxxxxxxxx	x xxxx

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

Listing sorted by Subject, Visit, and Date of Assessment.

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

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxx xxxxxxxxx xxxxxx xxxxxxxxx	xxxxxxx	xxxxxx
		xxxxxx
	xxxxxxxxxxxx	xxxxxxxxxxxx
xxx xxx xxxxxxxxx xxxxxxxxx	xxxxxxx	xxxxxxx
xxx xxxxxxxxx	xxxxxx xxxxxx xxxxxxx	xxxxxxxxx xxxxxx xxxxxx
xxxxxxxxxxxxxxx xxxxxxxxx	xxxxxxxxx xxxx	xxxxxxxxx xxxx
	xxxxxxxxx xxxxxxxxxxxx	xxxxx xxxxxxxxx xxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.7.2.2: Treatment-Emergent Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	A: Adverse Event C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	G: Grade[2] R: Relationship to Study Drug O: Outcome	S: Serious Event? A: In Treatment Area? T: Action Taken with Study Drug E: Action Taken to Treat Event
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx A: xxxx T: xxx E: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx A: xxxx T: xxx E: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx A: xx T: xxx E: xxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.7.2.3: Serious Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	A: Adverse Event C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	G: Grade[2] R: Relationship to Study Drug O: Outcome	S: Serious Evemt? A: In Treatment Area? T: Action Taken with Study Drug E: Action Taken to Treat Event
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx A: xxxx T: xxx E: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx A: xxxx T: xxx E: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	G: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xxx A: xx T: xxx E: xxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.7.2.4: Subjects Who Permanently Discontinued Study Drug Due to Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval F: Date of First Dose L: Date of Last Dose	R: Primary Reason for Study Completion/Discontinuation S: Date of Study Completion/Discontinuation (Day)[1] V: Last Visit Attended	Adverse Events A: Adverse Event Description C: System Organ Class P: Preferred Term	G: Grade[2] R: Relationship to Study Drug A: Action Taken	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxx A: xxxx E: xxxxxxxxx F: xxxxxxxxxx L: xxxxxxxxxx	R: xxxxxxx xxxxx S: xxxxxxxxxx xxxx V: xxxx x	A: xxxxxxxx xxx C: xxxxxxxxx xxxx P: xxxxxxxxx xxxxxxx xxxx xxxxxxxxx	G: xxxxx x R: xxxxxxxxx A: xxxxxxx xxxxxxxxx xxxxxx	S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.8.1: Urine Pregnancy Test Results
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxx xx	xxxxxxxxxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxx xx	xxxxxxxxxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxxxxxxx
			xxxxxxxxx xx	xxxxxxxxxx	xxxxxxxx
			xxxx xx	xxxxxxxxxx	xxxxxxxx

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

Listing sorted by Subject, Visit, and Date.

Listing 16.2.8.2.1: Laboratory Test Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date/Time C: Category	Laboratory Test	Results (Units)	Reference Range Normal Range	Reference Range Indicator (CS[1])
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx C: xxxxxxxxxx	xxxxxxxxxxxxxxxxx	xx (xx)	x to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx (x)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx (x)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx (xx)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx xx (xx)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xxx xxxxxx	xxxxx xxxx xxxx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxx xxxxx
		xxxxxxxxxxxxxxxxx	xx (xx)	x to xx	xxxxxx xxxx

[1] Clinically Significant per Investigator.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date/Time, Category, and Lab Test.

Listing 16.2.8.2.2: Abnormal Laboratory Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date/Time C: Category	Laboratory Test	Results (Units)	Reference Range Normal Range	 Indicator (CS[1])
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx C: xxxxxxxxxx	xxxxxxxxxxxxxxxxx	xx (xx)	x to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx (x)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx (x)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx (xx)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xx xx (xx)	xx to xx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xxx xxxxxx	xxxxx xxxx xxxx	xxxxxx xxxx
		xxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxx xxxxx
		xxxxxxxxxxxxxxxxx	xx (xx)	x to xx	xxxxxx xxxx

[1] Clinically Significant per Investigator.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date/Time, Category, and Lab Test.

Listing 16.2.8.3: 12-lead Electrocardiogram Test Results
Treatment Group
(Page x of xx)

Subject	Age/Sex	Eval	V: Visit D: Date/Time of ECG	Category	Evaluator	ECG Parameter	Result (Units)
xxxxxxxxx	xxxx	xxxxxxxx	V: xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx
			D: xxxx-xx-xxTxx:xx:xx		xxxxxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
xxxxxxxxx	xxxx	xxxxxxxx	V: xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx
			D: xxxx-xx-xxTxx:xx:xx		xxxxxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx
						xxxxxxxxxx	xxxx xxxxx xx

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

Listing sorted by Subject, Visit, Date/Time, Category, and ECG Parameter.

Listing 16.2.8.4: Vital Signs
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Vital Sign	Result	Units
xxxxxx	xxxx	xxxxxxxx	SCREENING	xxxxxxxxxx	Temperature	xxxx	x
					Heart Rate	xx	xxxxxxxxx
					Systolic Blood Pressure	xxx	xxxx
					Diastolic Blood Pressure	xx	xxxx
			BASELINE	xxxxxxxxxx	Temperature	xxxx	x
					Heart Rate	xx	xxxxxxxxx
					Systolic Blood Pressure	xxx	xxxx
					Diastolic Blood Pressure	xx	xxxx
					Height	xx	xx
					Weight	xxx	xx
			xxxx x	xxxxxxxxxx	Temperature	xxxx	x
					Heart Rate	xx	xxxxxxxxx
					Systolic Blood Pressure	xxx	xxxx
					Diastolic Blood Pressure	xx	xxxx
					Weight	xxx	xx
			xxxx x	xxxxxxxxxx	Temperature	xxxx	x
					Heart Rate	xx	xxxxxxxxx
					Systolic Blood Pressure	xxx	xxxx
					Diastolic Blood Pressure	xx	xxxx
					Weight	xxx	xx

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

Listing sorted by Subject, Visit, Date, and Vital Sign (in the order displayed in the CRF).

Listing 16.2.8.5: Pharmacokinetics Blood Sample Collections
Treatment Group
(Page x of xx)

S: Subject A: Age/Sex E: Eval	Visit	Date/Time of Pre-Dose PK Sample	Percent BSA Being Treated	Additional PK Sample Collections[1]	Date/Time PK Sample Obtained
S: xxxxxx A: xxxx E: xxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xx.x%	72-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
				120-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
				168-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
				216-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
S: xxxxxx A: xxxx E: xxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xx.x%		
S: xxxxxx A: xxxx E: xxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx:xx	xx.x%	72-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
				120-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
				168-Hour PK Sample	xxxx-xx-xxTxx:xx:xx
				216-Hour PK Sample	xxxx-xx-xxTxx:xx:xx

[1] Additional PK samples are collected on a conditional basis, date and time the PK sample was obtained is included in the listing.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date/Time of Pre-Dose PK Sample, and Date/Time PK Sample Obtained.

STATISTICAL ANALYSIS PLAN

Protocol Number:	ARQ-151-201
Study Title:	A Phase 2b 12-Week Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety, Efficacy, and Pharmacokinetics of ARQ-151 Cream 0.3% and ARQ-151 Cream 0.15% Administered QD in Subjects with Chronic Plaque Psoriasis
Development Phase of Study:	Phase 2b
Sponsor:	Arcutis, Inc. 2945 Townsgate Road, Suite 110 Westlake Village, CA 91361
Sponsor Contact:	David Berk, MD Vice President, Clinical Development
Statistical Analysis Plan based on Protocol Version:	Amendment 1, 12 November 2018
Statistical Analysis Plan Date:	11JUN2019
Statistical Analysis Plan Version:	Version 2

Authored by:

SIGNATURE: [redacted] DATE: 12 JUN 2019

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Approved by:

SIGNATURE: [redacted] DATE: Jun 11, 2019

David Berk (Jun 11, 2019)

David Berk, MD
Vice President, Clinical Development
Arcutis, Inc.

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

SAP Change History

Only final versions will be documented in the Change History.

Version	Date	Summary of Changes	Author
1	24MAY2019	Original document	[redacted]
2	11JUN2019	Added PASI to efficacy analysis	[redacted]

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	Adverse Event(s)
BSA	Body Surface Area
CRF(s)	Case Report Form(s)
C-SSRS	Columbia-Suicide Severity Rating Scale
DLQI	Dermatology Life Quality Index
ECG	Electrocardiogram
IGA	Investigator's Global Assessment
I-IGA	Intertriginous IGA
ITT	Intent-to-Treat
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
mPASI	Modified Psoriasis Area and Severity Index
N	Sample Size
NRS	Numerical Rating Score
PASI	Psoriasis Area and Severity Index
PHQ-8	Patient Health Questionnaire Depression Scale
PK	Pharmacokinetic
PP	Per-Protocol
PSD	Patient Symptoms Diary
QD	Once a Day
SAE(s)	Serious Adverse Event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	Standard Deviation
TEAE(s)	Treatment-Emergent Adverse Event(s)
WHO	World Health Organization
WHO-DD	World Health Organization Drug Dictionary
WHO-ATC	World Health Organization-Anatomical Therapeutic Chemical Classification System
WI-NRS	Worst Itch Numerical Rating Scale
WPAI	Work Productivity and Activity Impairment

2. INTRODUCTION

Roflumilast is a phosphodiesterase 4 (PDE-4) inhibitor approved globally to reduce the risk of exacerbations in patients with severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis. Roflumilast and its active metabolite, roflumilast N-oxide, are high affinity selective inhibitors of PDE-4 (a major cyclic-3′,5′-adenosine monophosphate (cyclic AMP)-metabolizing enzyme), whose activity leads to accumulation of intracellular cyclic AMP. There are four different subtypes of PDE-4: PDE-4a, PDE-4b, PDE-4c, and PDE-4d, each with several isoforms (splicing variants). IC50 values of both roflumilast and roflumilast N-oxide for the different PDE-4 isoforms and subtypes are mostly sub-nanomolar and single digit nanomolar (Hatzelmann 2010). The PDE-4 family of enzymes are the most prevalent phosphodiesterases in immune cells and inhibition of PDE-4 subtypes has been associated with anti-inflammatory effects in many biological systems.

Psoriasis is a chronic inflammatory skin disease characterized by raised, well-demarcated, erythematous oval plaques with adherent silvery scales. Numerous past reports have suggested a deficiency of cyclic AMP-dependent protein kinases in human psoriatic skin (Brion 1986). More recently, various cytokines produced by Th1 and Th17 cells have been shown to play a crucial role in the pathogenesis of psoriasis. It has been postulated that the anti-inflammatory effects of PDE-4 inhibitors may provide a beneficial therapeutic intervention in the treatment of chronic plaque psoriasis, and recently Otezla® (apremilast) a PDE-4 inhibitor has been approved for the oral treatment of chronic plaque psoriasis.

The past 15 years have witnessed a transformation in the systemic treatment of moderate to severe psoriasis with the advent of biological therapies. However, for patients with milder forms of disease, best treated with topical options, the therapeutic landscape really has not changed in several decades. Topical steroids come in all shapes and forms, but the lower potency steroids are not effective and the higher potency steroids are beset with issues of local skin atrophy and the potential for hypothalamic-pituitary axis suppression when applied over larger body surface areas and for prolonged periods of time. Vitamin D has been the other staple of topical psoriasis treatment but it is irritating, not suitable for use on the face or intertriginous areas, and its efficacy is rather modest. Hence, there is substantial medical need for additional topical approaches in the treatment of psoriasis. Arcutis, Inc is developing a topical formulation of roflumilast for the treatment of chronic plaque psoriasis. [redacted]

3. STUDY OBJECTIVES

To assess the safety, pharmacokinetics and efficacy of ARQ-151 cream 0.3% and ARQ-151 cream 0.15% vs. vehicle applied QD for 12 weeks to individuals treated with 2 to 20% (inclusive) Body Surface Area (BSA) of chronic plaque psoriasis.

4. STUDY DESIGN

4.1 Overall Study Design

This is a parallel group, double blind, vehicle-controlled study in which ARQ-151 cream 0.3%, ARQ-151 cream 0.15% or vehicle cream QD is applied for 84 days to subjects with between 2% to 20% (inclusive) BSA of chronic plaque psoriasis.

A total of up to approximately 300 subjects will be enrolled at approximately 30 study sites in the United States and Canada. Subjects will be adult (≥18 y/o) males or females with chronic plaque psoriasis. Subjects must have an Investigator's Global Assessment (IGA) of disease severity of at least Mild ('2') at Baseline. Subjects with an IGA of 'Mild' (2) will be limited to 20% of total enrollment. Subjects with an IGA of 'Severe' (4) will be limited to 15% of total enrollment. Subjects must have at least 2% and no more than 20% BSA of chronic plaque psoriasis. All psoriasis lesions on a subject will be treated including the face, trunk, genitals/skin folds, or limbs (excluding the scalp). The palms and soles will be treated but will not be counted towards any measurements of efficacy (IGA, BSA, Psoriasis Area and Severity Index (PASI), Modified PASI (mPASI)). For subjects with intertriginous area involvement, and with severity of the intertriginous area lesions at least 'mild' (IGA≥2) at Baseline, Intertriginous IGA (I-IGA) score will be recorded at weeks 4, 6, 8 and 12. The same IGA used for the primary endpoint (whole body) will also be used for I-IGA, but only intertriginous areas will be evaluated for I-IGA, not the rest of the body.

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 5 of the protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

Assignment of drug or vehicle will be made at a 1:1:1 ratio according to a computer-generated randomization list. Randomization will take place at Baseline after the patient has been found to be fully eligible for participation. Kits containing tubes of study medication will be assigned to each subject using an internet-based randomization system (IWRS). A subject may receive more than one kit for the treatment period.

The kits and tubes are blinded and each kit is numbered with a unique kit number.

4.1.3 Blinding

This is a double-blind study, therefore neither the subjects nor the Investigator, clinical team, and study sponsor will be aware of which treatment an individual has received.

If the situation requires emergency unblinding this will be done by investigator using the study IWRS system after discussion with Medical Monitor and the Sponsor's CMO.

The treatment assignments for all enrolled subjects will be unblinded only after the conclusion of the study. Specifically, the blind will be broken only after all data are verified, entered into the database, and validated; subject evaluability assessments are performed and entered into the database; and the database is locked.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

PASI is one of the measurements used for the severity of psoriasis. PASI combines the assessment of the severity of lesions and the area affected into a single score in the range 0 (no disease) to 72 (maximal disease). The body is divided into four sections (head (h) (10% of a person's skin); arms (a) (20%); trunk (t) (30%); legs (l) (40%)). Each of these areas is scored by itself, and then the four scores are combined into the final PASI. For each section, the percent of area (A) of skin involved is estimated and then transformed into a grade from 0 to 6 (A):

0. 0% of involved area
1. < 10% of involved area
2. 10–29% of involved area
3. 30–49% of involved area
4. 50–69% of involved area
5. 70–89% of involved area
6. 90–100% of involved area

Within each area, the severity is estimated by three clinical signs: erythema ('E'; redness), induration ('T'; thickness) and desquamation ('S'; scaling). Severity parameters are measured on a scale of 0 to 4, from none to maximum severity possible.

To calculate the PASI, the sum of the severity rating for the three main signs are multiplied with the numerical value of the area affected and with the various percentages of the four body areas. These values are then added to complete the formula as follows:

PASI = 0.1 (Eh + Th + Sh) Ah + 0.2 (Ea + Ta + Sa) Aa + 0.3 (Et + Tt + St) At + 0.4 (El + Tl + Sl) Al

In addition to PASI, an mPASI will also be used for the severity of psoriasis. The mPASI will be calculated the same as the PASI except for subjects with < 10% of an involved anatomical area. For subjects with < 10% of an involved anatomical area the mPASI will be calculated using the actual percentage of the anatomical area involved (e.g. 0.1 for 1%, 0.2 for 2%, 0.3 for 3%, … 0.9 for 9%), corresponding to the actual percentage of that particular anatomical area of involvement. The resulting values will then be rounded to the nearest tenth prior to analysis.

5.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint is as follows:

- Success in Investigator Global Assessment (IGA) of disease severity, defined as an IGA of 'Clear' or 'Almost Clear' at Week 6.

5.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints are as follows:

- IGA score of 'clear' or 'almost clear' at weeks 2, 4, 8, and 12.
- Percent change from Baseline in PASI at weeks 2, 4, 6, 8, and 12.
- Percent change from Baseline in mPASI at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Percent BSA affected at weeks 2, 4, 6, 8, and 12.
- IGA score of 'clear' or 'almost clear' PLUS a 2-grade improvement from Baseline at weeks 2, 4, 6, 8 and 12.
- For subjects with intertriginous area involvement, and with severity of the intertriginous lesions at least 'mild' (I-IGA≥2) at Baseline, 'I-IGA' score of 'clear' or 'almost clear' at weeks 2, 4, 6, 8 and 12.
- Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) pruritus score at weeks 2, 4, 6, 8, and 12.
- In subjects with WI-NRS pruritus score ≥ 6 at Baseline, a 4-point reduction in WI-NRS pruritus score at 2, 4, 6, 8, and 12 weeks as compared to Baseline.

- Change from Baseline in Psoriasis Area Severity Index-75 (PASI-75) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Psoriasis Area Severity Index-90 (PASI-90) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Psoriasis Area Severity Index-100 (PASI-100) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-75 (mPASI-75) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-90 (mPASI-90) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-100 (mPASI-100) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Total Patient Symptoms Diary (PSD) at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Itch-related Sleep Loss score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Dermatology Life Quality Index (DLQI) score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in responses to the questions of Total Patient Symptom Diary (PSD) at weeks 2, 4, 6, 8, and 12.

Change from Baseline will be calculated by subtracting the score at Baseline from the post-baseline score. Percent change from Baseline will be calculated by dividing change from Baseline by the Baseline score, multiplied by 100.

5.1.3 Additional Efficacy Endpoints

The exploratory endpoints are as follows:

- Change from Baseline in Fatigue Numerical Rating Score (NRS) score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Work Productivity and Activity Impairment (WPAI) score at weeks 2, 4, 6, 8, and 12.

Change from Baseline will be calculating by subtracting the score at Baseline from the post-baseline score.

5.2 Safety Endpoints

Safety will be evaluated through examination of data collected during physical examinations, 12-lead Electrocardiograms (ECGs), local tolerability assessments, vital signs, counts and percentages of subjects who gain or lose >5% and >10% body weight, clinical laboratory parameters, Patient Health Questionnaire Depression Scale (PHQ-8), Columbia-Suicide Severity Rating Scale (C-SSRS) and adverse events (AEs) as outlined in the Schedule of Visits and Assessments. If deemed necessary, additional safety assessments will be performed at the discretion of the Principal Investigator.

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® (Version 9.4 or later) unless otherwise stated. No interim analyses are planned. Except where noted, all statistical tests will be two-sided and will be performed at the 0.05 level of significance. No adjustment will be made for multiplicity.

Descriptive statistics will be used to provide an overview of the efficacy, safety, and pharmacokinetic results. For categorical parameters, the number and percentage of subjects in each category will be presented. The denominator for percentage will be based on the number of subjects appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include n (number of subjects), mean, standard deviation (SD), median, minimum and maximum. Appropriate inferential statistics will be used for the primary, secondary, and exploratory efficacy variables.

The primary method of handling missing efficacy data will be a mixture of linear interpolation and last observation carried forward (LOCF).

The efficacy analysis performed on the Intent-to-Treat (ITT) population is considered the primary analysis. The efficacy analysis performed on the Per-Protocol (PP) population is considered supportive analysis.

The number of subjects in each analysis set will be summarized. Reasons for study withdrawal during the blinded study will be summarized using frequencies and percentages by treatment group. Reported AEs, medical history terms and prior and concomitant procedures and therapies will be classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA)

terminology. Prior and concomitant medications will be classified on the basis of World Health Organization Drug Dictionary (WHO-DD) terminology.

6.1.1 Statistical Analysis

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

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

6.1.2 Baseline Definition

Baseline is defined as the last non-missing assessment prior to first dose of study drug.

6.1.3 Visit Windowing

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

Analysis Windows for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Window (Days)
Week 2	15	8 to 22
Week 4	29	23 to 36
Week 6	43	37 to 50
Week 8	57	51 to 71
Week 12	85	72 to 99
Week 16	113	100 to 127

Data collected at early termination and unscheduled visits prior to study day 8 will not be analyzed, with the exception of those identified as baseline values. Data collected at visits after study day 127 will not be included in analyses.

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

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

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

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

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

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

6.1.4 Adjustments for Covariates

The Baseline score will be used as a covariate for each endpoint analyzed.

6.1.5 Handling of Dropouts or Missing Data

The primary method of handling missing efficacy data will be a mixture of linear interpolation and LOCF. Linear interpolation will be used for all instances where subjects have observed values for at least one assessment both preceding and following the missing assessment. If an unscheduled assessment occurs between the preceding or following scheduled assessment and the missing assessment, the unscheduled assessment will be used in the linear interpolation. The actual study day of assessment will be used for the preceding and following assessments, and planned study day will be used for the missing assessment. IGA and I-IGA values imputed with linear interpolation will be rounded to the nearest integer. If the missing assessment is not followed by at least one observed assessment, the method of LOCF will be used.

6.1.6 Interim Analyses and Data Monitoring

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

6.1.7 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site. Every effort will be made to promote consistency in study execution at each investigational site. Sites will be pooled for analyses.

6.1.8 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons or multiplicity will be made.

6.1.9 Use of an Efficacy Subset of Subjects

Subjects randomized to study drug who were at least 80% compliant with the study drug, did not miss more than three consecutive doses, and who do not have major protocol deviations will form the Per Protocol (PP) Population. The major protocol deviations will be defined at the time of evaluability evaluation, the time between the database soft lock and hard lock before unblinding.

Excluding subjects who have major protocol deviations will decrease the variability in treatment response and will allow for a better determination of efficacy of ARQ-151 Cream 0.3% and ARQ-151 Cream 0.15%.

6.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

6.1.11 Examination of Subgroups

Subset analyses will be conducted for the ITT population for the subgroups baseline IGA and baseline I-IGA. I-IGA will be dichotomized into presence or absence of I-IGA ≥ 2 at baseline. These analyses will contain only descriptive statistics of the primary efficacy endpoint.

6.2 Disposition of Subjects

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

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

6.3 Protocol Deviations

Protocol deviations leading to exclusion from the PP population will be tabulated. In addition to protocol deviations leading to exclusion from the PP population, the protocol deviations listed below will be presented in a data listing.

- Baseline PHQ-8 score greater than or equal to 15
- Received incorrect treatment
- [redacted]

- Baseline IGA of Clear or Almost Clear
- Missed visit
- Missed IGA at attended visit
- Missed I-IGA at attended visit
- Missed safety labs at attended visit

6.4 Data Sets Analyzed

Subjects will be presented/summarized based on the primary reason for exclusion. The primary reason for exclusion for each population is the first inclusion condition a subject fails to meet based on the order listed below.

6.4.1 Intent-to-Treat Population

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

6.4.2 Safety Population

All subjects in the ITT population who have at least one post-baseline safety assessment will be included in the safety population and analyzed according to the treatment group they received. In the event a subject receives more than one treatment, they will be analyzed based on the treatment they received for the majority of the study. All safety analyses will be performed using the safety population.

6.4.3 Per-Protocol Population

All subjects in the safety population who were at least 80% compliant with study medication, did not miss more than 3 consecutive doses, and showed no other serious protocol violations will be included in the PP population and analyzed according to the treatment group they received. All efficacy analyses will be performed on the PP population.

6.4.4 Pharmacokinetic Population

All subjects receiving the active drug with quantifiable plasma concentrations of roflumilast will be included in the PK population.

6.5 Demographic and Other Baseline Characteristics

All summaries will be done on the ITT, PP, safety, and PK populations.

Sex, race, and ethnicity will be summarized by counts and percentages. Age (years) will be summarized with descriptive statistics.

Height, Weight, BSA, IGA, mPASI, WI-NRS, DLQI, Itch-Related Sleep Loss, and Total PSD will be summarized at baseline with descriptive statistics.

Medical histories will be coded using the MedDRA dictionary and presented in a by-subject listing.

6.6 Analysis of Efficacy

6.6.1 Primary Efficacy Analysis

The primary efficacy endpoint is success in IGA, defined as an IGA of 'Clear' or 'Almost Clear' at Week 6. The primary efficacy endpoint will be analyzed with a logistic regression with a factor of treatment group and the respective Baseline IGA score as a covariate. Statistical comparison between the active treatment arms and vehicle arms will be facilitated by using contrasts.

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

6.6.2 Secondary Efficacy Analysis

The secondary efficacy endpoints will include:

- IGA score of 'clear' or 'almost clear' at weeks 2, 4, 8, and 12.
- Percent change from Baseline in PASI at weeks 2, 4, 6, 8, and 12.
- Percent change from Baseline in mPASI at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Percent BSA affected at weeks 2, 4, 6, 8, and 12.
- IGA score of 'clear' or 'almost clear' PLUS a 2-grade improvement from Baseline at weeks 2, 4, 6, 8 and 12.
- For subjects with intertriginous area involvement, and with severity of the intertriginous lesions at least 'mild' (I-IGA≥2) at Baseline, 'I-IGA' score of 'clear' or 'almost clear' at weeks 2, 4, 6, 8 and 12.

- For subjects with intertriginous area involvement, and with severity of the intertriginous lesions at least 'mild' (I-IGA≥2) at Baseline, 'I-IGA' score of 'clear' or 'almost clear' and a 2-point improvement from Baseline at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in WI-NRS pruritus score at weeks 2, 4, 6, 8, and 12.
- In subjects with WI-NRS pruritus score ≥ 6 at baseline, a 4-point reduction in WI-NRS pruritus score at weeks 2, 4, 6, 8, and 12 as compared to Baseline.
- Change from Baseline in Psoriasis Area Severity Index-75 (PASI-75) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Psoriasis Area Severity Index-90 (PASI-90) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Psoriasis Area Severity Index-100 (PASI-100) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-75 (mPASI-75) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-90 (mPASI-90) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Modified Psoriasis Area Severity Index-100 (mPASI-100) improvement at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Total PSD at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in Itch-related Sleep Loss score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in DLQI score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in responses to the questions of PSD at weeks 2, 4, 6, 8, and 12.

Change from Baseline will be calculated by subtracting the score at Baseline from the post-baseline score. Percent change from Baseline will be calculated by dividing change from Baseline by the Baseline score, multiplied by 100.

The IGA, I-IGA, WI-NRS, PASI, and mPASI dichotomous endpoints will be analyzed with a logistic regression with a factor of treatment group and the respective Baseline score as a covariate. The remainder of the endpoints will be considered continuous and analyzed with an analysis of covariance with a factor of treatment group and the respective Baseline score as a

covariate. Statistical comparisons between the active treatment arms and vehicle arm will be facilitated by using contrasts.

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

6.6.3 Exploratory Efficacy Analysis

There are two exploratory endpoints:

- Change from Baseline in Fatigue NRS score at weeks 2, 4, 6, 8, and 12.
- Change from Baseline in WPAI score at weeks 2, 4, 6, 8, and 12.

Only descriptive statistics will be used to analyze these endpoints. Change from Baseline will be calculating by subtracting the score at Baseline from the post-baseline score.

6.7 Safety Evaluation

The following analyses will be performed; however, no formal inferential statistics will be done on safety assessments.

Descriptive statistics will be presented by visit and treatment group for quantitative safety data and frequency counts will be compiled for classification of qualitative safety data. Summaries of local tolerability will be presented by visit and treatment group.

6.7.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of days of exposure, total number of applications, total amount of study drug used, number of missed applications, and number and percentage of subjects who are compliant. A subject will be considered compliant with the dosing regimen if the subject applied at least 80% of the expected number of applications while enrolled in the study and does not miss more than 3 consecutive doses.

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

The total number of applications is as follows:

(Date of Last Application – Date of First Application + 1) – (Number of Days marked as missed dose on the Case Report Form (CRF)) + (Number of Additional Doses indicated on CRF).

The expected number of applications is as follows:

Expected Date of Last Application – Date of Randomization + 1

Where the Expected Date of Last Application is the date of the Week 12 visit or the date of the discontinuation visit for subjects who discontinue prior to Week 12.

Compliance will be calculated as a percentage as 100 times the total number of applications divided by the expected number of applications.

6.7.2 Adverse Events

All treatment-emergent AEs (TEAEs) occurring during the study will be recorded and classified on the basis of MedDRA terminology for the safety population. TEAEs are those AEs with an onset on or after the date of first study drug treatment. All AEs with incomplete onset date information will be considered treatment-emergent unless the available information indicates that this is not possible. All TEAEs will be summarized by treatment group, the number of subjects reporting TEAEs, system organ class, preferred term, severity, relationship, and seriousness. Each subject will be counted only once within a system organ class or a preferred term using the event with the greatest relationship and greatest severity.

Comparisons between treatment groups will be made by tabulating the frequency of subjects with one or more TEAEs (classified into MedDRA terms) during the study.

Serious AEs (SAEs) will be listed by subject. Treatment-emergent SAEs will be summarized by treatment group, severity, and relationship to study treatment.

All information pertaining to AEs noted during the study will be listed by subject, detailing the verbatim description given by the Investigator, preferred term, system organ class, start date, stop date, severity, action taken regarding study drug, corrective treatment, outcome, and drug relatedness. The event onset will also be shown relative (in number of days) to date of first application. In addition a listing of subjects who prematurely discontinue from the study due to AEs will also be provided.

6.7.3 Clinical Laboratory Evaluation

Laboratory test results will be summarized by treatment group and visit as observed values and changes from Baseline using descriptive statistics. Additionally, shifts from Baseline to Week 4 and Week 12 in laboratory test results based on normal ranges will be summarized with frequency counts and percentages.

Individual laboratory test results, as well as abnormal laboratory results, will be presented in a by-subject listing.

6.7.4 Other Observations Related to Safety

6.7.4.1 Electrocardiogram Measurements

Descriptive statistics of actual values and changes from baseline will be provided by treatment group and visit for the following ECG parameters: heart rate (HR), RR duration, QRS duration, PR duration, QT duration, QTc Interval, QTcB interval, QTcF interval. Investigator and cardiologist interpretation of the ECG will be summarized by counts and percentages.

Individual ECG parameters, as well as interpretations, will be presented in a by-subject listing.

6.7.4.2 Vital Signs

Descriptive statistics of actual values and changes from baseline will be provided by treatment group and visit for the following parameters: temperature, systolic blood pressure, diastolic blood pressure, heart rate, and weight. Additionally, counts and percentages of subjects who gain or lose > 5% body weight will be summarized by visit in a table.

6.7.4.3 Physical Examination

Abnormal physical examination findings will recorded as AEs and included in the AE summaries.

6.7.4.4 Medical History

Medical history for all subjects will be presented in a by-subject listing.

6.7.4.5 Local Tolerance Assessments

For the investigator's assessment and subject local tolerability assessment of sensation following drug application, the numeric application site reaction scores will be summarized individually by using number and percentage of subjects by visit. In addition, a by-subject listing of investigator and subject assessments will be provided.

6.7.4.6 Patient Health Questionnaire Depression Scale

The PHQ-8 will be analyzed by a shift in state of severity using 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)

In addition, a by-subject listing of results will be provided.

6.7.4.7 Columbia-Suicide Severity Rating Scale

The C-SSRS will be analyzed per the C-SSRS Scoring and Data Analysis Guide (Nilsson 2013).

6.7.4.8 Prior and Concomitant Medications

Prior and concomitant medication information for all randomized subjects will be presented in a by-subject listing. Summary tables will be presented by World Health Organization-Anatomical Therapeutic Chemical Classification System (WHO-ATC) therapeutic category and product.

6.8 Other Evaluations

6.8.1 Pharmacokinetic Evaluation

Plasma drug concentrations at pre-dose will be summarized using descriptive statistics, reporting n, mean, standard deviation, median, minimum, and maximum.

7. DETERMINATION OF SAMPLE SIZE

The sample size was not powered based on data for the primary endpoint to provide statistical significance because of the absence of previous primary endpoint data. However, based on efficacy data from the Phase 1/2a study, this Phase 2b study is expected to provide reliable information regarding the efficacy and safety of the drug products.

8. CHANGES IN THE PLANNED ANALYSES

The Per-Protocol population was updated to exclude subjects with more than three consecutive missed doses in order to fully capture compliant subjects.

A covariate of the respective Baseline score was added to the models used for analysis of the primary and secondary endpoints.

A secondary efficacy analysis endpoint of ‘clear’ or ‘almost clear’ plus a 2-point improvement from Baseline for Intertriginous Investigator Global Assessment (I-IGA) at weeks 2, 4, 6, 8, and 12 was added.

A secondary efficacy analysis endpoint for change from Baseline in Modified Psoriasis Area Severity Index-100 (mPASI-100) at weeks 2, 4, 6, 8, and 12 was added.

Week 2 was added to all secondary and exploratory efficacy endpoints.

An analysis of PASI was added for all planned mPASI analyses.

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	ARQ-151 Cream 0.3%	ARQ-151 Cream 0.15%	Vehicle Cream
Number of Subjects in the ITT Population	xx	xx	xx
Number of Subjects Included from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Safety Population			
No Post-Baseline Safety Assessment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included from the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded in the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the PP Population			
Less than 80% Compliant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missed 3 or More Consecutive Doses	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other Serious Protocol Violations	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included from the PK Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded in the PK Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Evidence of Dosing with Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Insufficient Plasma Concentrations	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: ITT population includes all randomized subjects.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Completed Study			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation			
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

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

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Repeat Table 14.1.1.1 for the following:
Table 14.1.1.2: Summary of Subject Demographics (Per-Protocol Population)
Table 14.1.1.3: Summary of Subject Demographics (Safety Population)
Table 14.1.1.4: Summary of Subject Demographics (PK Population)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 1 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Whole Body Investigator Global Assessment Score			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intertriginous Area Investigator Global Assessment Score[a]			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Itch-Related Sleep Loss Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 2 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Body Surface Area (%) Affected by Psoriasis			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
PASI			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
WI-NRS Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 3 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total Psoriasis Symptom Diary (PSD) Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Dermatology Life Quality Index (DLQI) Score			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Height (cm)			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Weight (kg)			
n	xx	xx	Xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.2.1 for the following:

Table 14.1.2.2: Summary of Subject Baseline Characteristics (Per-Protocol Population)
Table 14.1.2.3: Summary of Subject Baseline Characteristics (Safety Population)
Table 14.1.2.4: Summary of Subject Baseline Characteristics (PK Population)

Table 14.1.3: Summary of Medical History by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xxx)	ARQ-151 Cream 0.15% (N=xxx)	Vehicle Cream (N=xxx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more medical histories that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

ATC Level 2 Term[a] Preferred Name	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more prior medications that map to the WHO-DD (Version March 1, 2018). At each level of summarization (ATC Level 2 Term or Preferred Name) subjects are counted once.
Note: Table includes all medications used prior to date of first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

ATC Level 2 Term[a] Preferred Name	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more concomitant medications that map to the WHO-DD (Version March 1, 2018). At each level of summarization (ATC Level 2 Term or Preferred Name) subjects are counted once.
Note: Table includes all medications used on or after date of first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1: Analysis of Primary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' at Week 6 (Intent-to-Treat Population)

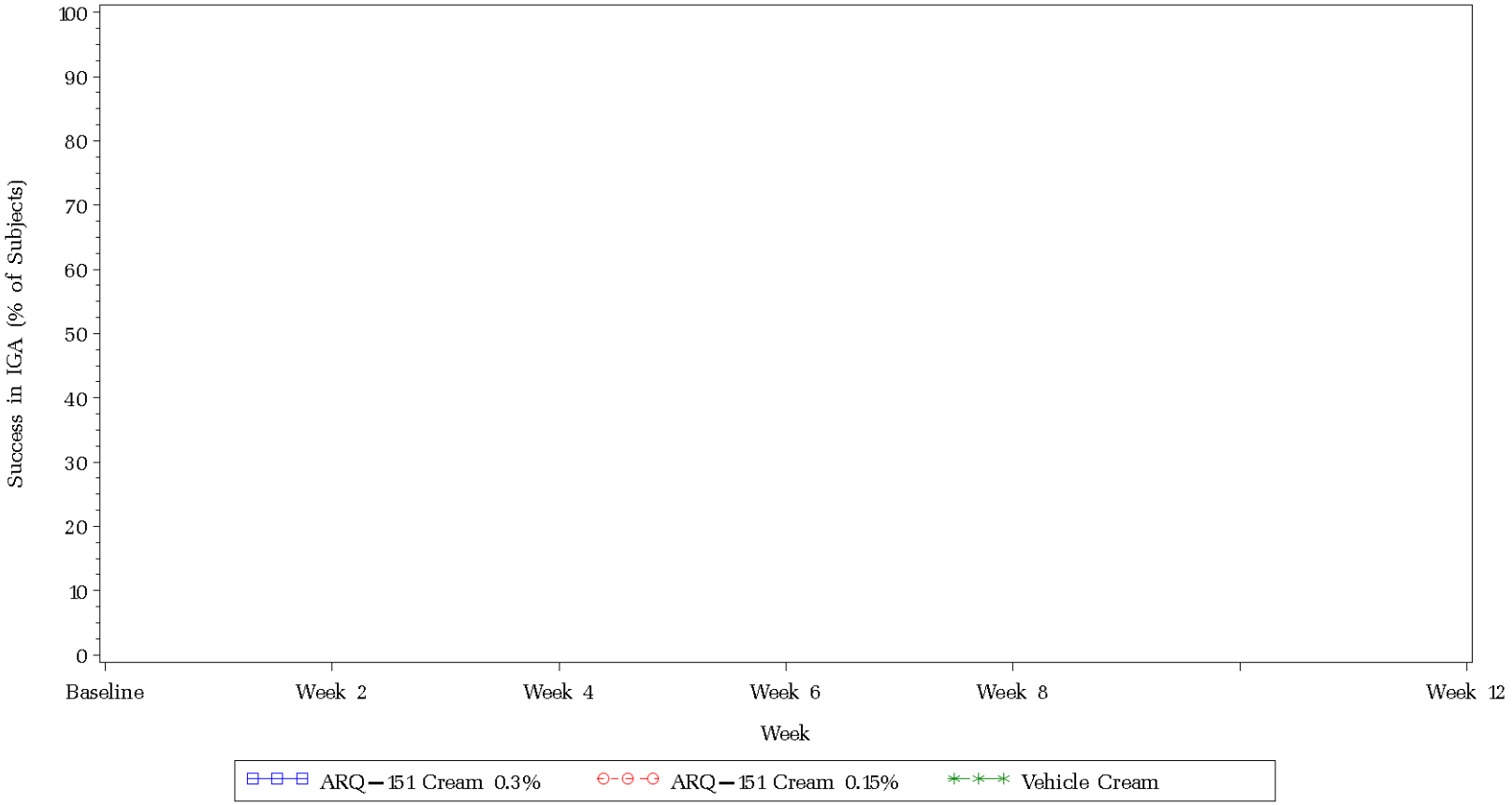
	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
IGA Score of Clear or Almost Clear at Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline IGA score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.1.1 for the following:

Table 14.2.1.2: Analysis of Primary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' at Week 6 (Per-Protocol Population)

Figure 14.2.1.1: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' by Visit
(Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Figure 14.2.1.1 for the following:
Figure 14.2.1.2: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' by Visit (Per-Protocol Population)

Table 14.2.2.1: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear'
(Intent-to-Treat Population)

IGA Score of Clear or Almost Clear	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline IGA score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

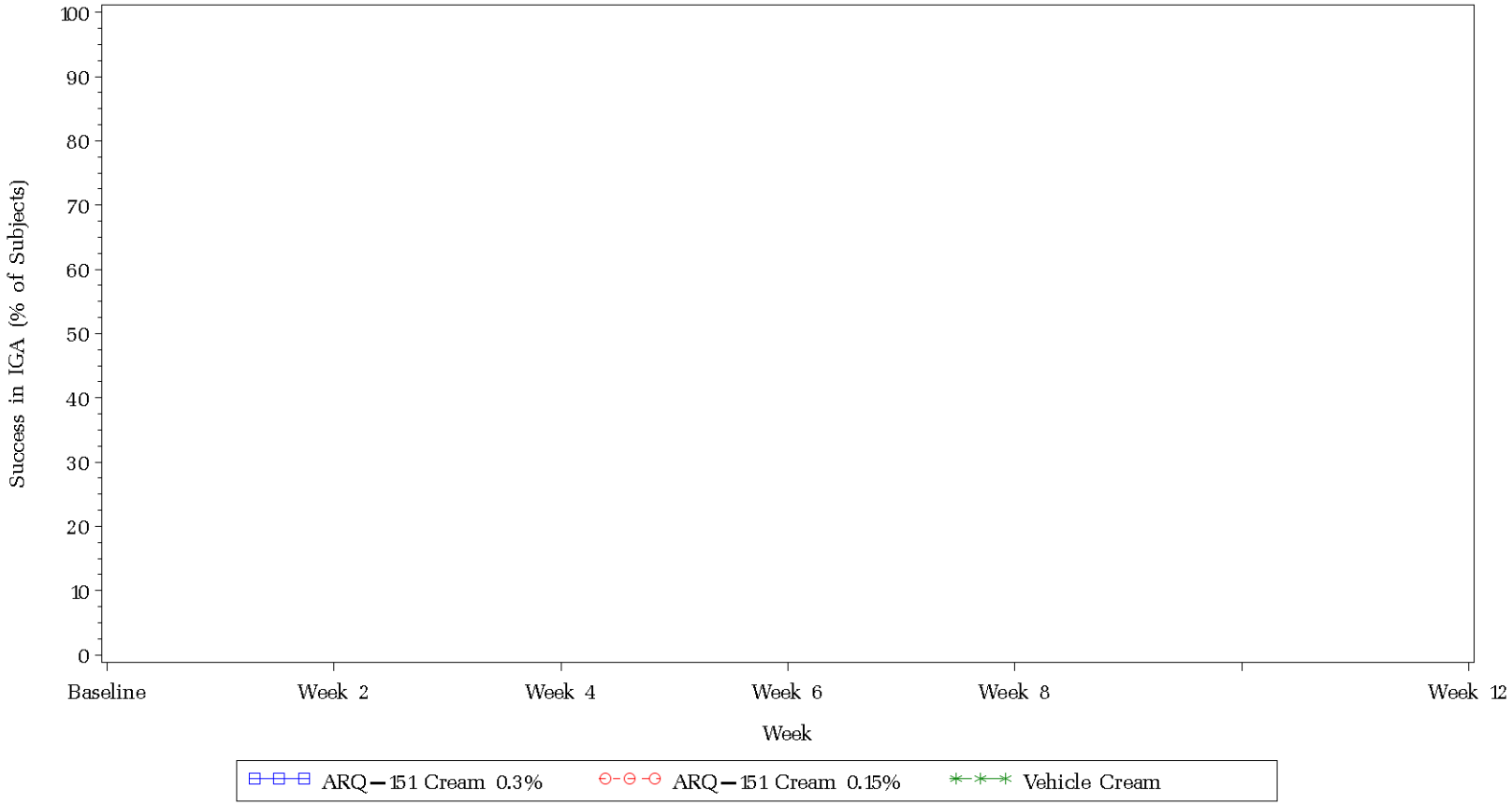
Repeat Table 14.2.2.1 for the following:
Table 14.2.2.2: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' (Per-Protocol Population)

Table 14.2.3.1: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline (Intent-to-Treat Population)

IGA Score of Clear or Almost Clear Plus a 2-Grade Improvement from Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline IGA score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.3.1 for the following:
Table 14.2.3.2: Analysis of Secondary Efficacy Endpoint: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline (Per-Protocol Population)

Figure 14.2.3.1: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline by Visit (Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Figure 14.2.3.1 for the following:
Figure 14.2.3.2: Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline by Visit (Per-Protocol Population)

Table 14.2.3.3: Summary of Proportion of Subjects Achieving an Investigator Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' Plus a 2-Grade Improvement from Baseline by Investigational Site
(Intent-to-Treat Population)

Investigational Site	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1.1: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear'
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

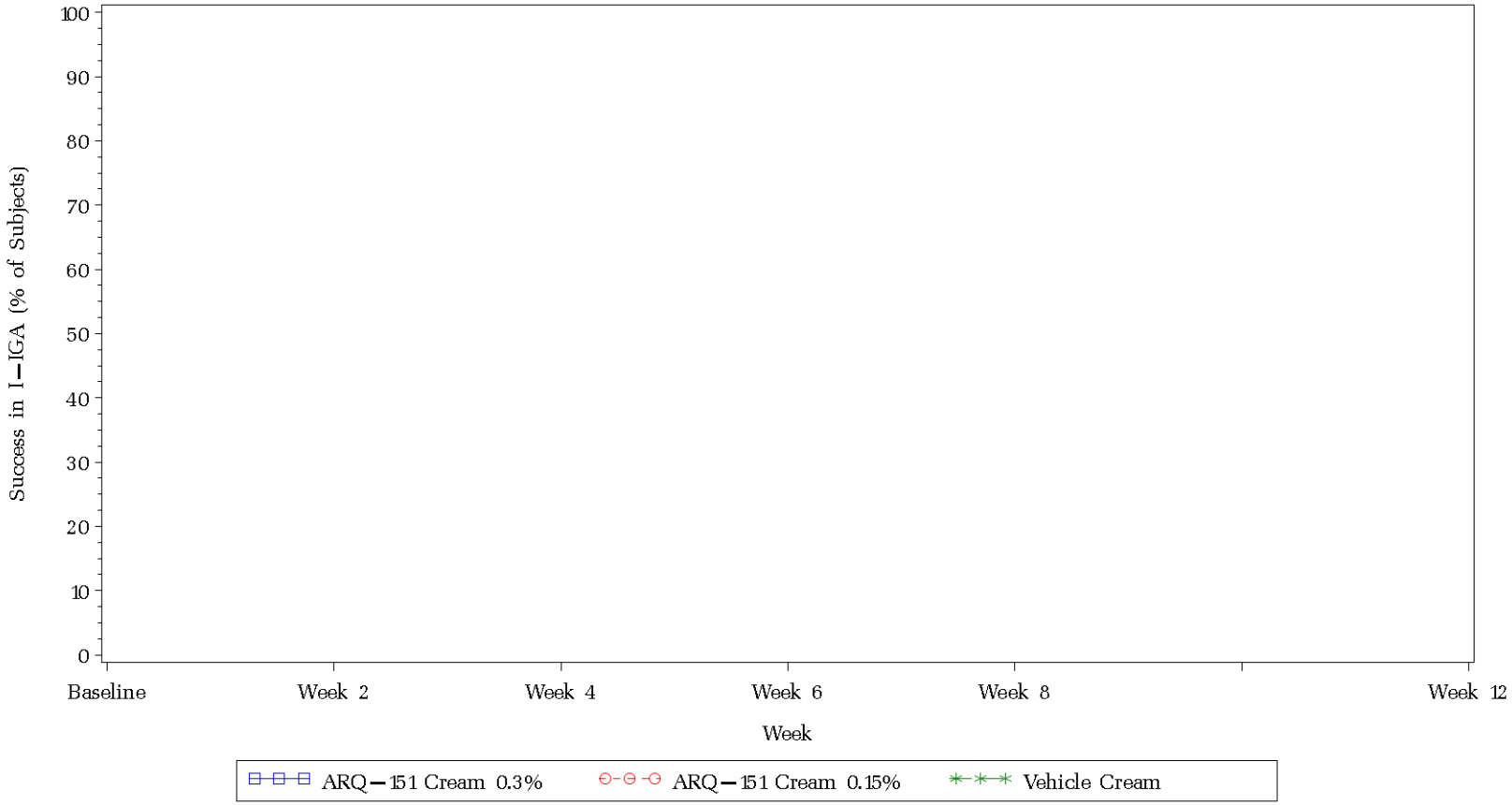
I-IGA Score of Clear or Almost Clear Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline I-IGA score.
Restricted to subjects with an I-IGA severity score of at least "Mild" at baseline.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.4.1.1 for the following:

Table 14.2.4.1.2: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' (Per-Protocol Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

Figure 14.2.4.1.1: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear'
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Figure 14.2.4.1.1 for the following:
Figure 14.2.4.1.2: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least ‘Mild’ at Baseline who Achieved a Score of ‘Clear’ or ‘Almost Clear’ (Per-Protocol Population: Subjects with I-IGA Severity of at Least ‘Mild’ at Baseline)

Table 14.2.4.2.1: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' Plus a 2 Grade Improvement from Baseline
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

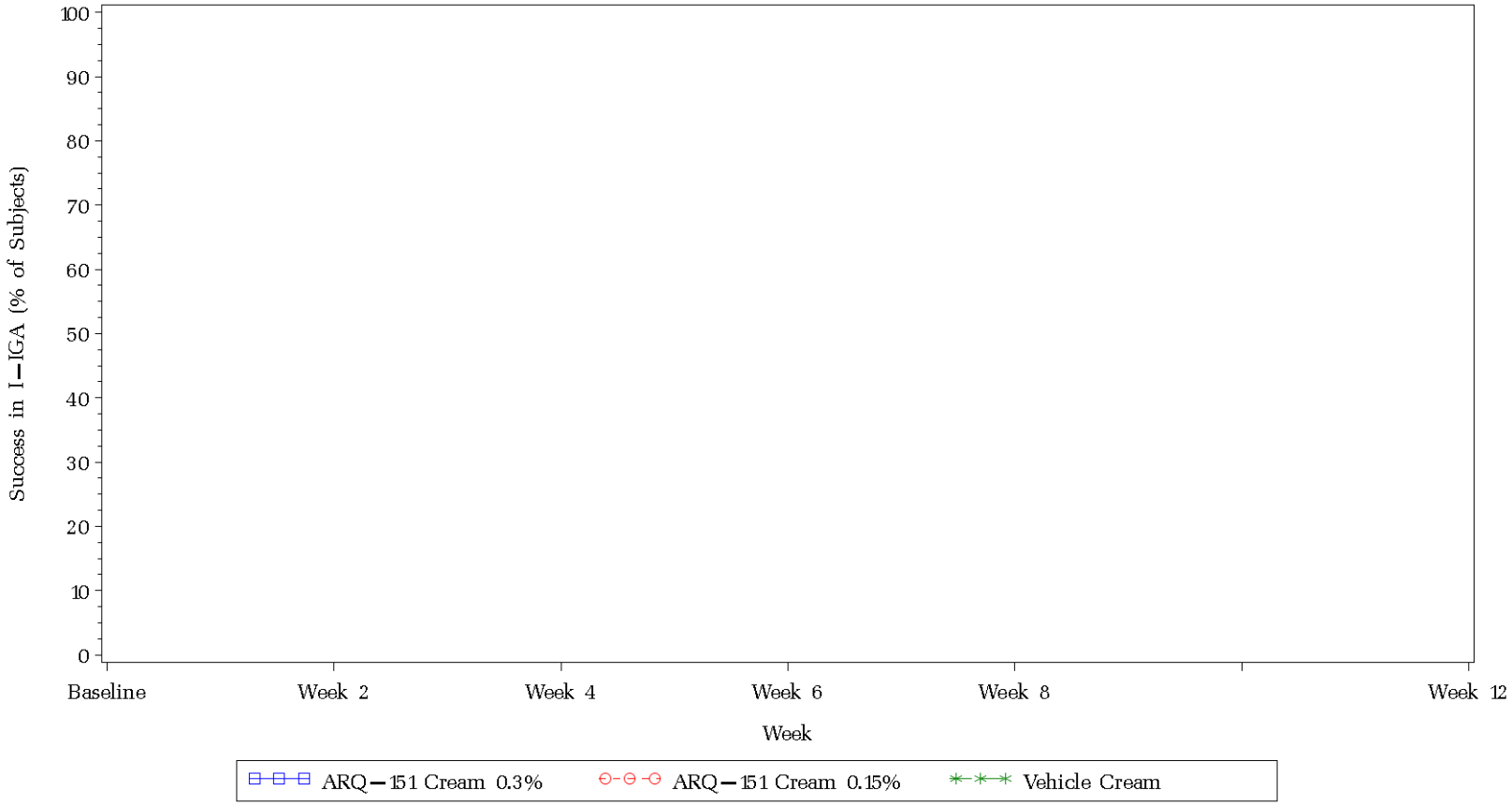
I-IGA Score of Clear or Almost Clear Plus a 2 Grade Improvement from Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline I-IGA score.
Restricted to subjects with an I-IGA severity score of at least "Mild" at baseline.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.4.2.1 for the following:

Table 14.2.4.2.2: Analysis of Secondary Efficacy Endpoint: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' Plus a 2 Grade Improvement from Baseline (Per-Protocol Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)

Figure 14.2.4.2.1: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least 'Mild' at Baseline who Achieved a Score of 'Clear' or 'Almost Clear' Plus a 2 Grade Improvement from Baseline
(Intent-to-Treat Population: Subjects with I-IGA Severity of at Least 'Mild' at Baseline)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Figure 14.2.4.2.1 for the following:
Figure 14.2.4.2.2: Subjects with an Intertriginous Area Investigator Global Assessment (I-IGA) Severity of at Least ‘Mild’ at Baseline who Achieved a Score of ‘Clear’ or ‘Almost Clear’ Plus a 2 Grade Improvement from Baseline (Per-Protocol Population: Subjects with I-IGA Severity of at Least ‘Mild’ at Baseline)

Table 14.2.5.1.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)
(Page 1 of 6)

PASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)
(Page 2 of 6)

PASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)
(Page 3 of 6)

PASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)
(Page 4 of 6)

PASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)
(Page 5 of 6)

PASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

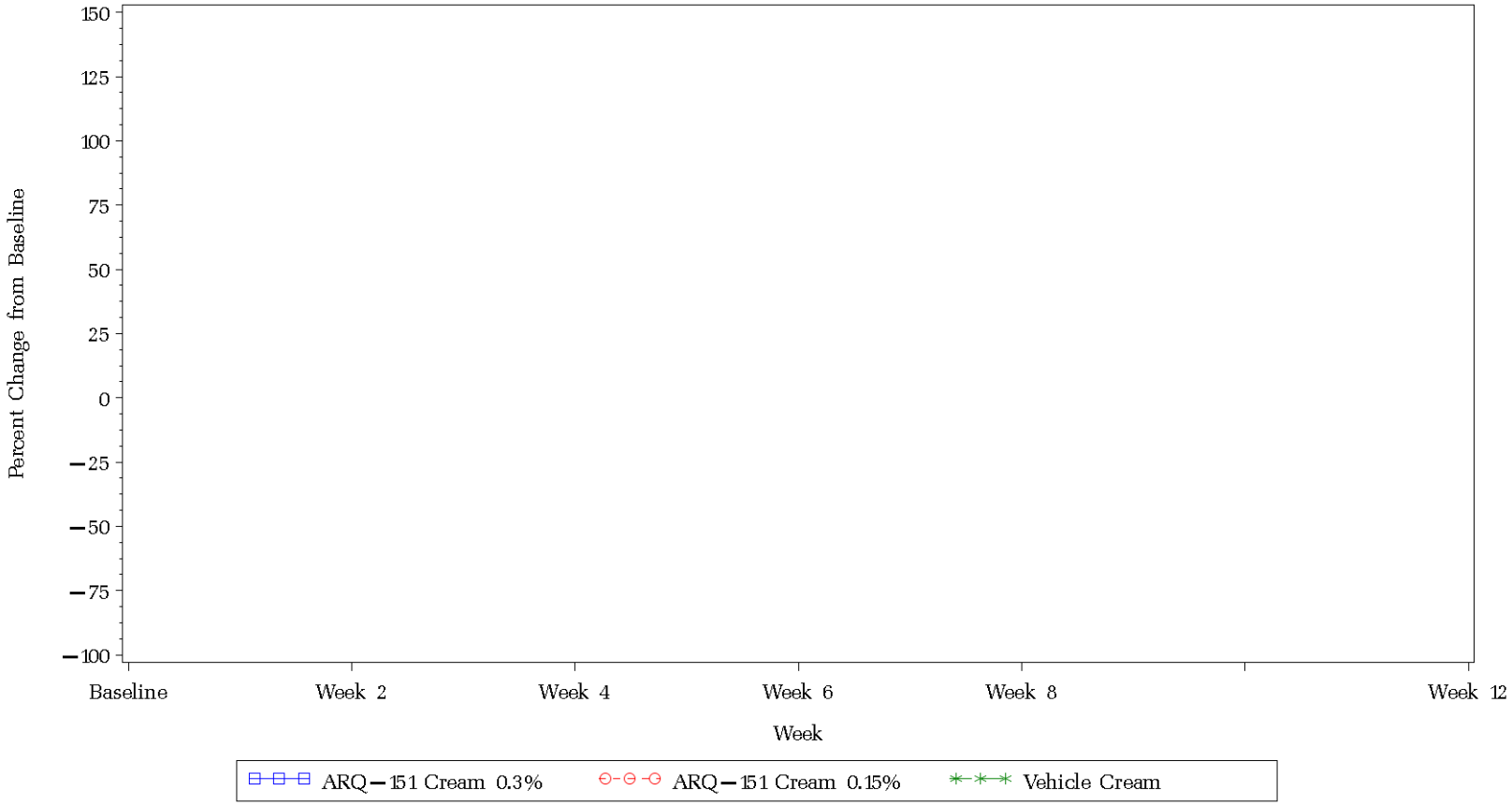
[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)
(Page 6 of 6)

PASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.5.1.1 for the following:
Table 14.2.5.1.2: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI) (Per-Protocol Population)

Figure 14.2.5.1.1: Percent Change from Baseline in Psoriasis Area and Severity Index (PASI)
(Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 1 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 2 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 3 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 4 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 5 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

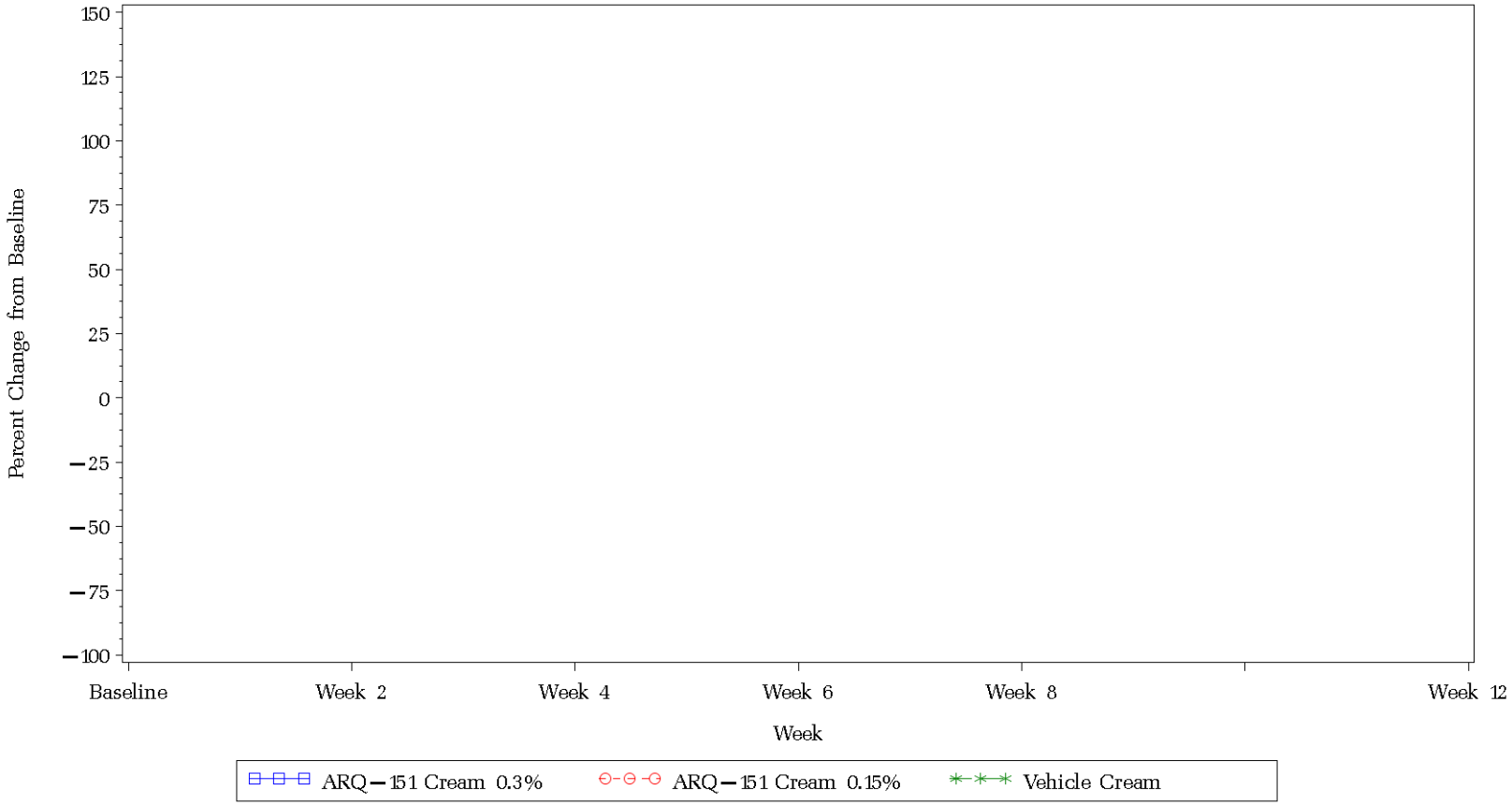
[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)
(Page 6 of 6)

mPASI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline mPASI score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.5.2.1 for the following:
Table 14.2.5.2.2: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI) (Per-Protocol Population)

Figure 14.2.5.2.1: Percent Change from Baseline in Modified Psoriasis Area and Severity Index (mPASI)
(Intent-to-Treat Population)



Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 3)

Reduction in PASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline PASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 3)

Reduction in PASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline PASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 3)

Reduction in PASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline PASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.6.1.1 for the following:

Table 14.2.6.1.2 Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline (Per-Protocol Population)

Table 14.2.6.2.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 3)

Reduction in mPASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline mPASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.2.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 3)

Reduction in mPASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline mPASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.2.1: Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 3)

Reduction in mPASI Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
75% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
90% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
100% Reduction			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline mPASI score.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.6.2.1 for the following:

Table 14.2.6.2.2 Analysis of Secondary Efficacy Endpoints: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline (Per-Protocol Population)

Table 14.2.7.1.1: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
75% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
75% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1.1: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
75% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
75% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1.1: Dichotomized Percent Reductions in Psoriasis Area and Severity Index (PASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
75% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16			
75% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in PASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.7.1.1 for the following:
Table 14.2.7.1.2: Dichotomized Percent Reduction(s) in Psoriasis Area and Severity Index (PASI) Compared to Baseline (Per-Protocol Population)

Table 14.2.7.2.1: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.2.1: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.2.1: Dichotomized Percent Reductions in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 3)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 16			
75% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
90% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
100% Reduction in mPASI Compared to Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.7.2.1 for the following:
Table 14.2.7.2.2: Dichotomized Percent Reduction(s) in Modified Psoriasis Area and Severity Index (mPASI) Compared to Baseline (Per-Protocol Population)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 1 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 2 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 3 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 4 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 5 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected
(Intent-to-Treat Population)
(Page 6 of 6)

BSA	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline BSA score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data at Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.8.1 for the following:
Table 14.2.8.2: Analysis of Secondary Efficacy Endpoint: Percent Change from Baseline in Body Surface Area (BSA) Affected (Per-Protocol Population)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 1 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 2 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 3 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 4 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score
(Intent-to-Treat Population)
(Page 5 of 5)

WI-NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline WI-NRS score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.9.1 for the following:

Table 14.2.9.2: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Worst Itch Numerical Rating Scale (WI-NRS) Pruritus Score (Per-Protocol Population)

Table 14.2.10.1.1: Analysis of Secondary Endpoint: Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline
(Intent-to-Treat Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

4 Point Reduction in WI-NRS Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 4			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 6			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 8			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	
Week 12			
Success	xx.x%	xx.x%	xx.x%
Failure	xx.x%	xx.x%	xx.x%
Contrast P-Value vs Vehicle Cream	x.xxx	x.xxx	

Note: P-values and estimates from a logistic regression with a factor of treatment group and a covariate of baseline WI-NRS score.
Restricted to subjects with a baseline WI-NRS Score of 6 or greater.
Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.10.1.1 for the following:

Table 14.2.10.1.2: Analysis of Secondary Endpoint: Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline (Per-Protocol Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

Table 14.2.10.2.1: Summary of Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline
(Intent-to-Treat Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

4 Point Reduction in WI-NRS Compared to Baseline	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 2			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
Restricted to subjects with a baseline WI-NRS Score of 6 or greater.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.10.2.1 for the following:

Table 14.2.10.2.2: Summary of Subjects with a Worst Itch Numerical Rating Scale (WI-NRS) Score ≥ 6 at Baseline and Achieved a 4 Point Reduction Compared to Baseline (Per-Protocol Population: Subjects with WI-NRS Score ≥ 6 at Baseline)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 4 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 5 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline
(Intent-to-Treat Population)
(Page 6 of 6)

Total PSD Score	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD score.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.11.1 for the following:

Table 14.2.11.2: Analysis of Secondary Efficacy Endpoint: Total Psoriasis Symptom Diary (PSD) Score Compared to Baseline (Per-Protocol Population)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 1 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 2 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 3 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 4 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 5 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.12.1: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline
(Intent-to-Treat Population)
(Page 6 of xx)

PSD Responses to Individual Questions <Question>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline PSD response.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.12.1 for the following:

Table 14.2.12.2: Analysis of Secondary Efficacy Endpoint: Improvement in Psoriasis Symptom Diary (PSD) Responses Compared to Baseline (Per-Protocol Population)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 1 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 2 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 3 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 4 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.13.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score
(Intent-to-Treat Population)
(Page 5 of 5)

Itch-Related Sleep Loss	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline Itch-Related Sleep Loss score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.13.1 for the following:
Table 14.2.13.2: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Itch-Related Sleep Loss Score (Per-Protocol Population)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 1 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 2 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 3 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 4 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.14.1: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score
(Intent-to-Treat Population)
(Page 5 of 5)

DLQI	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
LS Mean[a]	xx.x	xx.x	xx.x
LS SD[a]	xx.xx	xx.xx	xx.xx
Contrast P-Value vs Vehicle Cream[a]	x.xxx	x.xxx	

[a] P-values and estimates from an ANCOVA with a factor of treatment group and a covariate of baseline DLQI score.
Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.14.1 for the following:

Table 14.2.14.2: Analysis of Secondary Efficacy Endpoint: Change from Baseline in Dermatology Life Quality Index (DLQI) Score (Per-Protocol Population)

Table 14.2.15.1: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score
(Intent-to-Treat Population)
(Page 1 of 3)

NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.15.1: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score
(Intent-to-Treat Population)
(Page 2 of 3)

NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.15.1: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score
(Intent-to-Treat Population)
(Page 3 of 3)

NRS	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.15.1 for the following:
Table 14.2.15.2: Summary of Exploratory Endpoint: Change from Baseline in Fatigue NRS Score (Per-Protocol Population)

Table 14.2.16.1: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score
(Intent-to-Treat Population)
(Page 1 of xx)

<Score Type>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.16.1: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score
(Intent-to-Treat Population)
(Page 2 of xx)

<Score Type>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.16.1: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score
(Intent-to-Treat Population)
(Page 3 of xx)

<Score Type>	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: Missing data imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.16.1 for the following:

Table 14.2.16.2: Summary of Exploratory Endpoint: Change from Baseline in Work Productivity and Activity Impairment (WPAI) Score (Per-Protocol Population)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 1 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 2 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 3 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 4 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 5 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.17.1: Summary of Whole Body Investigator Global Assessment (IGA)
(Intent-to-Treat Population)
(Page 6 of 6)

Whole Body Investigator Global Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data for Week 16 was not imputed.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.17.1 for the following:
Table 14.2.17.2: Summary of Whole Body Investigator Global Assessment (IGA) (Per-Protocol Population)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 1 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx		
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 2 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 3 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 6			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 5 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.18.1: Summary of Intertriginous Area Investigator Global Assessment (I-IGA)
(Intent-to-Treat Population)
(Page 6 of 6)

Intertriginous Area Investigator Global Assessment[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Score of Clear or Almost Clear and a 2-Grade Improvement from Baseline[b]			
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Collected at baseline for subjects with intertriginous area involvement and collected post-baseline for subjects with a severity of at least mild at baseline.
[b] Restricted to subjects with a severity of at least mild at baseline.
Note: Missing data through Week 12 imputed using linear interpolation and last observation carried forward where linear interpolation is not computationally possible. Missing data was not imputed for Week 16.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.18.1 for the following:
Table 14.2.18.2: Summary of Intertriginous Area Investigator Global Assessment (I-IGA) (Per-Protocol Population)

Table 14.3.0.1.1: Summary of Extent of Exposure
(Safety Population)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Number of Doses			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Amount of Drug Applied (g)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Compliant[a]			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] A subject is considered compliant with the dosing regimen if the subject applied at least 80% of the expected doses during the dosing period and did not miss more than 3 consecutive doses.

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

Table 14.3.0.2.1: Summary of Pre-Dose Pharmacokinetic Concentrations
(PK Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.0.2.1: Summary of Pre-Dose Pharmacokinetic Concentrations
(PK Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.0.2.2: Summary of Additional Pharmacokinetic Concentrations
(PK Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
72 hr (3 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
120 hr (5 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
168 hr (7 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
216 hr (9 days)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 1 of 4)

Investigator Local Tolerability Dermal Response	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Baseline			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome			
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 2 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Week 4			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Week 4			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 3 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Week 8			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Week 8			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

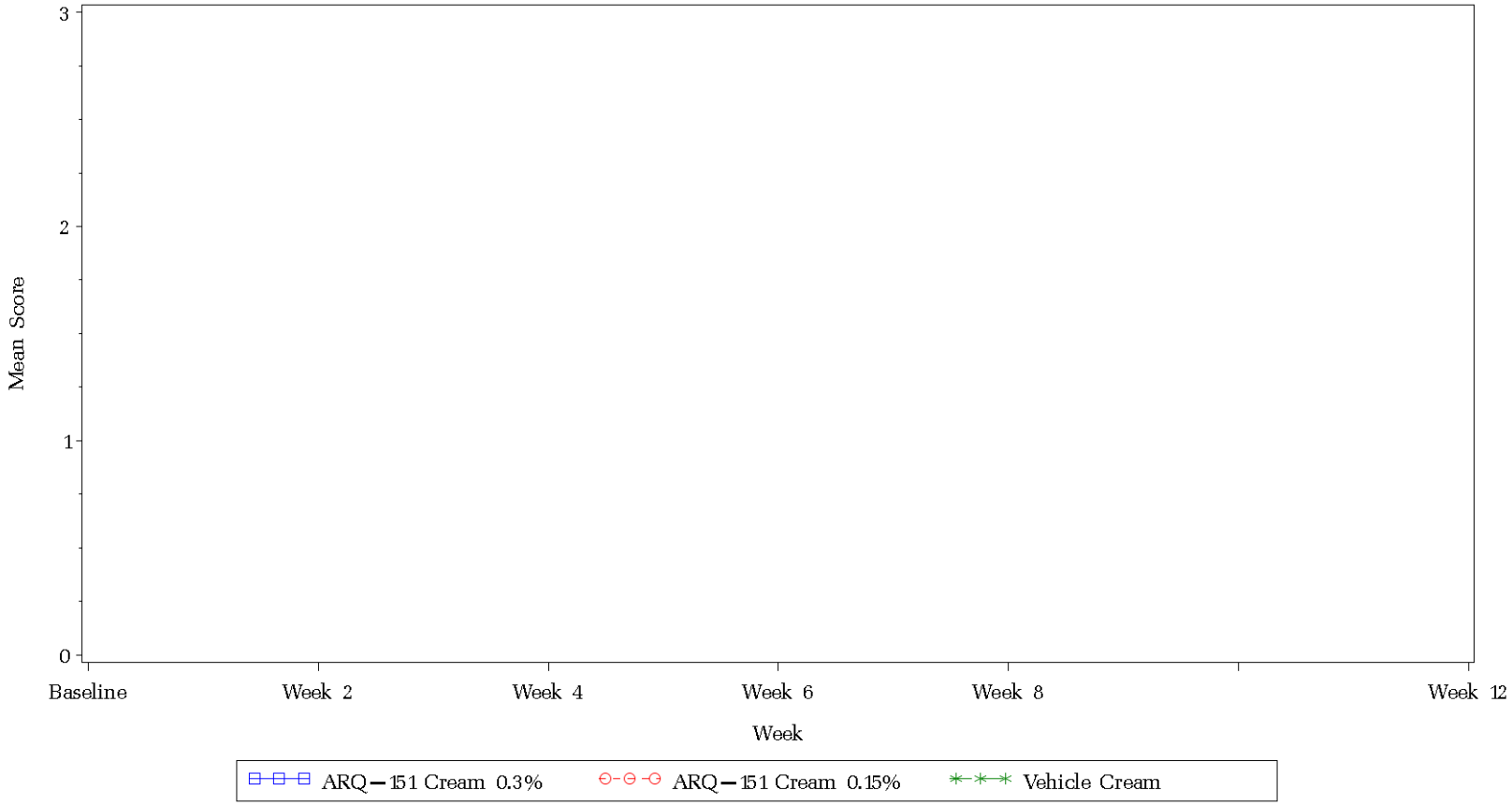
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1: Summary of Local Tolerability
(Safety Population)
(Page 4 of 4)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Investigator Local Tolerability Dermal Response			
Week 12			
n	xx	xx	xx
0 – No evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Minimal Erythema, Barely Perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite Erythema, Readily Visible; Minimal edema or minimal papular response	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%)
Subject Local Tolerability Sensation Following Drug Application			
Week 12			
n	xx	xx	xx
0 – No sensation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Slight warm, tingling sensation; not really bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Definite warm, tingling sensation that is somewhat bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Hot, tingling/stinging sensation that has caused definite discomfort	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Figure 14.3.1.1: Subject Local Tolerability Sensation Following Drug Application
(Safety Population)



Note: 0 (No sensation), 1 (Slight warm, tingling sensation; not really bothersome), 2 (Definite warm, tingling sensation that is somewhat bothersome), 3 (Hot, tingling/stinging sensation that has caused definite discomfort)
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1: Number of Patients with Suicidal Ideation, Suicidal Behavior, and Self-Injurious Behavior without Suicidal Intent Based on the Colombia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population)

Events during treatment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Suicidal Ideation (1-5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1) Wish to be dead	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2) Non-specific active suicidal thoughts	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3) Active suicidal ideation with any methods (not plan) without intent to act	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4) Active suicidal ideation with some intent to act, without specific plan	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5) Active suicidal ideation with specific plan and intent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior (6-10)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6) Preparatory acts or behavior	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
7) Aborted attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
8) Interrupted attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
9) Non-fatal suicide attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
10) Completed suicide	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation or Behavior (1-10)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Self-injurious behavior without suicidal intent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Number of Patients with Suicide-Related Treatment-Emergent Events Based on the Colombia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population)

Treatment-emergent (TE) Events	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
TE suicidal ideation (1-5) compared to recent history [a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TE serious suicidal ideation (0-3 to 4-5) compared to recent history [b]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Emergence of serious suicidal ideation (0 to 4-5) compared to recent history[c]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Improvement in suicidal ideation at endpoint compared with baseline[d]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Emergence of suicidal behavior (6-10) compared to all prior history [e]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] N=Number of enrolled patients with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the comparison period is non-missing and <5.
[b] N=Number of enrolled patients with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the comparison period is 0-3.
[c] N=Number of enrolled patients with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the comparison period is 0.
[d] N=Number of enrolled patients whose suicidal ideation score is non-missing and >0 just prior to treatment.
[e] N=number of enrolled patients with with at least one post-baseline C-SSRS assessment and who did not have suicidal behavior (6-10) prior to treatment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.1: Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)

PHQ-8 Assessment	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx		
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4			
n	xx	xx	xx
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
n	xx	xx	xx
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12			
n	xx	xx	xx
None – Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.3.2: Shift Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)
(Page 1 of 3)

PHQ-8 for (ARQ-151 Cream 0.3%)

	Week 4				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 8				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 12				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: None = Minimal Depression (0 to 4); Mild = Mild Depression (5 to 9); Moderate = Moderate Depression (10 to 14);
Moderately Severe = Moderately Severe Depression (15 to 19); Severe = Severe Depression (20 to 24).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.2: Shift Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)
(Page 2 of 3)

PHQ-8 for (ARQ-151 Cream 0.15%)	Week 4				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 8				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 12				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: None = Minimal Depression (0 to 4); Mild = Mild Depression (5 to 9); Moderate = Moderate Depression (10 to 14);
Moderately Severe = Moderately Severe Depression (15 to 19); Severe = Severe Depression (20 to 24).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.2: Shift Summary of PHQ-8 Assessments by Treatment Group
(Safety Population)
(Page 3 of 3)

PHQ-8 for (Vehicle Cream)

	Week 4				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 8				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Week 12				
Baseline	None	Mild	Moderate	Moderately Severe	Severe
None	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%)
Moderate	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%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: None = Minimal Depression (0 to 4); Mild = Mild Depression (5 to 9); Moderate = Moderate Depression (10 to 14);
Moderately Severe = Moderately Severe Depression (15 to 19); Severe = Severe Depression (20 to 24).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.1: Overall Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Subjects with any TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of TEAEs	xx	xx	xx
Subjects with any Related TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related TEAEs	xx	xx	xx
Subjects with any Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx
Subjects with any Related Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related Serious TEAEs	xx	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Drug due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity By Subject			
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject			
Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.4.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.3: Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.4: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.5: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.6: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)

	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Subjects with any Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx
Subjects with any Related Serious TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related Serious TEAEs	xx	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Drug due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study due to TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity By Subject			
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject			
Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.4.7: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.8: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: Treatment-emergent adverse events are those with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.9: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Total	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version 21.1). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

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

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

Table 14.3.1.5.1.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.5.1.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Repeat Table 14.3.1.5.1.1: Summary of Chemistry Laboratory Results

For the following tables:
Table 14.3.1.5.1.2: Summary of Hematology Laboratory Results (Safety Population)
Table 14.3.1.5.1.3: Summary of Quantitative Urinalysis Laboratory Results (Safety Population)

Table 14.3.1.5.2.1: Shift Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of x)

<Test name> (<units>)	ARQ-151 Cream 0.3% (N=xx)			ARQ-151 Cream 0.15% (N=xx)			Vehicle Cream (N=xx)		
	Week 4			Week 4			Week 4		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	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%)
WNL	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%)
ANL	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 12			Week 12			Week 12		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	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%)
WNL	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%)
ANL	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%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.5.2.1: Shift Summary of Chemistry Laboratory Results

For the following tables:
Table 14.3.1.5.2.2: Shift Summary of Hematology Laboratory Results (Safety Population)
Table 14.3.1.5.2.3: Shift Summary of Quantitative Urinalysis Laboratory Results (Safety Population)

Table 14.3.1.6.1: Summary of Electrocardiogram (ECG) Parameters
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.6.1: Summary of Electrocardiogram (ECG) Parameters
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.6.2: Shift Summary of Overall Electrocardiogram (ECG) Assessments
(Safety Population)
(Page 1 of x)

Overall ECG Assessment		ARQ-151 Cream 0.3% (N=xx)		ARQ-151 Cream 0.15% (N=xx)		Vehicle Cream (N=xx)	
		Week 4		Week 4		Week 4	
	Baseline	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 12		Week 12		Week 12	
	Baseline	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 2			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 3 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 8			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 12			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.1: Summary of Vital Signs
(Safety Population)
(Page 4 of xx)

<Parameter> (<units>)	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

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

Table 14.3.1.7.2: Summary of Change in Body Weight Compared to Baseline
(Safety Population)
(Page 1 of 2)

Change in Body Weight Compared to Baseline[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 4			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Percentages may sum to over 100% due to the possibility of being included in more than one category.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.7.2: Summary of Change in Body Weight Compared to Baseline
(Safety Population)
(Page 2 of 2)

Change in Body Weight Compared to Baseline[a]	ARQ-151 Cream 0.3% (N=xx)	ARQ-151 Cream 0.15% (N=xx)	Vehicle Cream (N=xx)
Week 16			
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Percentages may sum to over 100% due to the possibility of being included in more than one category.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

S: Subject A: Age/Sex E: Eval	F: Date of First Dose of Drug L: Date of Last Dose of Drug	Primary Reason for Study Completion/Discontinuation	Date of Completion/Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxx xxxx xxxxxxxx xxxxx	xxxxxxxxxx xxxx

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

Note to programmer: concatenate 'Describe' text onto Primary Reason where applicable.

Listing 16.2.1.2: Discontinued Subjects
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	F: Date of First Dose of Drug L: Date of Last Dose of Drug	Primary Reason for Study Completion/Discontinuation	Date of Completion/Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxxx xx xxxxxxxxxxxxxx	xxxxxxxxxx xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xxxxxxxxx xxxx xxxxxxxx xxxxx	xxxxxxxxxx xxxx

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

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

Subject	Age/Sex	Eval	Criterion Category	Criterion Identifier	Description
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx xxxxx xxxxxxxxxxx xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxxx xxx xxxxxxxx xxxx
			xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx xxxxxxx x xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxxx xxx xxxxxxxx xxxxxx xxxxxxx x xxxxxxxxx xxxxx xxx
			xxxxxxxxx	xx	xxxxxxxx xxxx xxxxxx xxxx xxxxxxxxxxxx xxxxxx xxxxxxxxx xxxxxxxxx xxx xxxxxxxx xxxxx xx xxxx xxxx xx xxx xx xxxx xxxx xxx xxxxx xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	x	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx
			xxxxxxxxx	xx	xxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xx x xxxxxxxx xx xxx xxxxxxxx xxx xxxxx xxxxxxxxx xxxx

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

Listing sorted by Subject, Criterion Category, and Criterion Identifier.

Listing 16.2.2.2: Protocol Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Protocol Deviation
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx xxxxxxxxxxx xxxxxx xxxxxxxx xxxxxxxxxx xx xxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx x xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxxx xxxxx xxx xxxxxxxx xxxx xxxxxx xxxx xxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx xxxx xxxx x xxxxx xx x xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx x xxxxxx xxxxxxxx xxxxxxxxxx xx xxx xxxxxxxx xxxx xxxxxx xxxx xxxxxxx

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

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

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

Listing sorted by Subject, and Population.

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

Subject	Eval	B: Date of Birth S: Sex	D: Date/Time of Informed Consent A: Age at Consent	R: Race E: Ethnicity	C: Childbearing Potential B: Birth Control Method	P: Did the Subject Consent to Photography? D: Date of Photography Consent
xxxxxx	xxxxxxxx	B: xxxxxxxxxx S: xxxx	D: xxxx-xx-xxTxx:xx:xx A: xx	R: xxxxx xx xxxxxxx E: xxx xxxxxxxx xx	C: xx B:	P: xxx D: xxxxxxxxxx
xxxxxx	xxxxxxxx	B: xxxxxxxxxx S: xxxxxx	D: xxxx-xx-xxTxx:xx:xx A: xx	R: xxxxx E: xxx xxxxxxxx xx	C: xxx B: xxxxxxxxxx xxxxxxxx	P: xx D:
xxxxxx	xxxxxxxx	B: xxxxxxxxxx S: xxxxxx	D: xxxx-xx-xxTxx:xx:xx A: xx	R: xxxxx E: xxx xxxxxxxx xx	C: xxx B: xxxx xxxxxxxxxxxxx	P: xxx D: xxxxxxxxxx

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

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

MedDRA System Organ Class	MedDRA Preferred Term	Condition/Surgery Verbatim Term
x xxx xxxxx	xxxx xxx xxxxx	xxxx xxxxxxxxxx xx xxxxxx
		xxxxx xxx xxxxxx xx
xxxx x xxxxxxxxx	xxxxxxx xxxxxxxxxxxx	xxxx xxxxxx xxxxxxxxxx xx xxxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx xxxxxxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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

Subject	Age/Sex	Eval	Condition/Surgery Verbatim Term	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Onset Date E: End Date
xxxxxx	xxxx	xxxxxxxx	xxxxxx xxxxxxx (xxxxxxxx xxxxx)	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx
			xxxxxxxx xxxxxxxxxx	P: xxxxxxx xxxxxxxx S: xxxxxx xxxxxxxxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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

ATC Level 2 Term	Preferred Name	Medication Name	I: Indication R: Route
xxxxxx xxxxxx xx xxx	xxxxxxxxxx	xxxxxxxxxx	I: xxxxxxx xxxxxxxx R: xxxx
	xxxxxxx x	xxxxxx	I: xxxxxxx xxxxxxxx xxxxxxxxxxxx R: xxxx
	xxxxxxxxx	xxxxxxxxx	I: xxxxxxx xxxxxxxx xxxx xxxxx xxxxxxxx R: xxxx

Note: Preferred Name and ATC Level 2 Term map to the WHO-DD (Version March 1, 2018).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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

Subject	Age/Sex	Eval	M: Medication Name P: Preferred Name A: ATC Level 2 Term I: Indication	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	D: Dose U: Units F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx	D: xx U: xx F: xxxx R:xxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx	D: xxxxx U: xx F: xx R:xxxx
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx	D: xxx U: xx F: xx R:xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: Preferred Name and ATC Level 2 Term map to the WHO-DD (Version March 1, 2018).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route. If ongoing, include 'Ongoing' in place of End Date. Concatenate Topical Area Treated onto route where applicable.

Listing 16.2.4.4.1: Unique Therapies and Procedures Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Procedure/Therapy Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, MedDRA Preferred Term, and Procedure/Therapy Verbatim Term.

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

S: Subject A: Age/Sex E: Eval	Procedure/Therapy Verbatim Term	I: Indication A: Anatomical Area	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Start Date E: End Date
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxx xxxxxxx (xxxxxxxx xxxxx)	I: xxxxxxxxxx A: xxxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx
	xxxxxx xxxxxxx xxxxxxx	I: xxxxxxxxxx xxxxx A:	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxx xxxxxxxxxxxxx	I: xxxxxxxxxx xxxxx A: xxxx xxx xxxxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxxxxxxxxx E: xxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Procedure/Therapy, Indication. If ongoing, include 'Ongoing' in place of End Date.

Listing 16.2.4.5: Physical Examination
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Visit	Date	Body System Assessed	Finding	Abnormal Finding Specification
S: xxxxxx A: xxxx E: xxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxx	Heart Lungs Skin (Other than Psoriasis) <Other, specify>	xxxxxxxxxx xxxxx xxxxxxx xxxxxxxx xxxx xxx xx	xxxxxxx xxxxx xxxxxxxxxxx xxx xxxxxx
	xxxxxxxxxxx	xxxxxxxxxx	Heart Lungs Skin (Other than Psoriasis)	xxxxxxxx xxxxx xxxxxxx xxxxxxxx	
	xxxx xx	xxxxxxxxxx	Heart Lungs Skin (Other than Psoriasis)	xxxxxxxx xxxxx xxxxxxx xxxxxxxx	
S: xxxxxx A: xxxx E: xxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxx	Heart Lungs Skin (Other than Psoriasis)	xxxxxxxxxx xxxxxxxxx xx xxxx xxxxxxxx	 xxxxxx
	xxxxxxxxxxx	xxxxxxxxxx	Heart Lungs Skin (Other than Psoriasis)	xxxxxx xxxxx xxxxxxx xxxxxxxxxx	
	xxxx xx	xxxxxxxxxx	Heart Lungs Skin (Other than Psoriasis)	xxxxxxxx xxxxx xxxxxxx xxxxxxxx	

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

Listing sorted by Subject, Visit, Date, Body System Assessed.

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

Subject	Age/Sex	Eval	Visit	Visit Date	Study Day[1]	Within Visit Window	Days Out of Window[2]
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	xxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx to xxxxxxxxxx	x	xxx	
			xxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx	
			xxxxxxxx	xxxxxxxxxx	x	xxx	
			xxxx x	xxxxxxxxxx	xx	xxx	

[1] Day is calculated as date – baseline date for dates prior to baseline visit. Otherwise, day is calculated as date – baseline date + 1 for dates on or after baseline visit.
[2] Populated only for post baseline visits that are planned and out of window.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Visit Date.

Listing 16.2.5.2: Drug Accountability
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Kit Number	Date Dispensed	Date Returned	Tube ID	Dispensed Weight (g)	Returned Weight (g)
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
			xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
			xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
			xxxxx	xxxxxxxxxx	xxxxxxxxxx	x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x
						x	xx.x	xx.x

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

Listing sorted by Subject, Kit Number, Date Dispensed, Date Returned, and Tube ID.

Listing 16.2.5.3: Study Drug Application
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date/Time of Study Drug Application	Study Drug Applied in Clinic?	Pre-Dose Weight (g)	Post-Dose Weight (g)	Reason Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xx			xxx xxx xxxxx
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxTxxxx	xx			xxx xxx xxxxx
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	
			xxxxx	xxxxxTxxxx	xxx	xx.x	xx.x	

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

Listing sorted by Subject, Date/Time of Study Drug Application, Visit.

Listing 16.2.5.4: Dosing Compliance
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	D: Date of First Dose R: Date of Last Dose	Number of Days of Exposure	Calculated[1] Number of Doses	Amount of Study Drug Used (g)	Maximum Number of Missed Consecutive Doses	Percent Compliant	Compliant?[2]
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxxxxxxxxx R: xxxxxxxxxxx	xx	xx	xxxx	x	xxx	xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxxxxxxxxx R: xxxxxxxxxxx	xx	xx	xxxx	x	xxx	xx
S: xxxxxx A: xxxx E: xxxxxxxxx	D: xxxxxxxxxxx R: xxxxxxxxxxx	xx	xx	xxxx		xxxx	xxx

[1] The total number of doses was calculated from the date of first dose and the date of last known dose minus the missed doses plus additional dose deviations.
[2] A subject was considered compliant with the dosing regimen if the subject applied at least 80% of the expected doses during the study drug application period and did not miss more than 3 consecutive doses.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.5.5: Dosing Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Dose	Date of Dosing Deviation	Number of Doses Applied
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x
				xxxxxxxxxx	x
				xxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x
				xxxxxxxxxx	x
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	x
				xxxxxxxxxx	x

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

Listing sorted by Subject, and Date of Dosing Deviation.

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

S: Subject A: Age/Sex E: Eval	Visit	Date of Assessment	Whole Body Investigator Global Assessment Score	Does the Subject have Intertriginous Area involvement?	Intertriginous Investigator Global Assessment Score	Evaluator Initials
S: xxxxxx A: xxxx E: xxxxxxxx	SCREENING	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	BASELINE	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 2	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 4	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 6	xxxxxxxxxx	x x xxxxxxxx	xxx	x x xxxxxxxx	xxx
	WEEK 8	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 12	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 16	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
S: xxxxxx A: xxxx E: xxxxxxxx	SCREENING	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	BASELINE	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	WEEK 2	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	WEEK 4	xxxxxxxxxx	x x xxxxxxxx	xx		x-x
	WEEK 6	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 8	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 12	xxxxxxxxxx	x x xxxxxxxx	xx		xxx
	WEEK 16	xxxxxxxxxx	x x xxxxxxxx	xx		xxx

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

Listing sorted by Subject, Visit, and Date of Assessment.