STATISTICAL ANALYSIS PLAN

Protocol Number:	ARQ-151-202
Study Title:	A Phase 2, Multicenter, Open-Label Extension Study of the Long-Term Safety of ARQ-151 Cream 0.3% in Adult Subjects with Chronic Plaque Psoriasis who have Completed Preceding Study ARQ-151-201 Phase 2 Randomized Controlled Trial (Cohort 1) and non-ARQ-151-201 Subjects (Cohort 2)
Development Phase of Study:	Phase 2
Sponsor:	Arcutis Biotherapeutics, Inc. 2945 Townsgate Road, Suite 110 Westlake Village, CA 91361 USA
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Statistical Analysis Plan based on Protocol Version:	Version 1.0 Amendment 1, 25 March 2019
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Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

SAP Change History

Version	Date	Summary of Changes	Author
1	22 OCT 2020	Original document	[redacted]

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	adverse event(s)
ATC	anatomical therapeutic chemical
cm	centimeters
C-SSRS	Columbia-Suicide Severity Rating Scale
ECG	electrocardiogram
IGA	Investigator Global Assessment
I-IGA	Intertriginous Investigator Global Assessment
kg	kilograms
max	maximum
MedDRA	Medical Dictionary for Regulatory Activities
min	minimum
mPASI	Modified Psoriasis Area Severity Index
mPASI-75	75% reduction from Baseline of Modified Psoriasis Area Severity Index
n	number of observations
N	number of subjects (sample size)
PASI-50	50% reduction from Baseline of Psoriasis Area Severity Index
PASI-75	75% reduction from Baseline of Psoriasis Area Severity Index
PHQ-8	Patient Health Questionnaire Depression Scale
QST	QST Consultations, Ltd.
SAE(s)	serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	standard deviation
SOC	system organ class
TEAE(s)	treatment-emergent adverse event(s)
US	United States
WHO	World Health Organization
WHO-DD	World Health Organization Drug Dictionary

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). IC_{50} 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. The study sponsor is developing a topical formulation of roflumilast for the treatment of chronic plaque psoriasis. Our Phase 2a results suggest that ARQ-151 may be a highly efficacious and well-tolerated topical treatment for psoriasis.

3. STUDY OBJECTIVES

The objective of this study is to assess long-term safety in a multicenter, open-label, 52-week study in subjects treated with ARQ-151 cream 0.3% after completing a 12-week Phase 2b study (ARQ-151-201) Cohort 1 and non ARQ-151-201 subjects (Cohort 2).

4. STUDY DESIGN

4.1 Overall Study Design

This is an open-label, long-term safety study of ARQ-151 cream 0.3% in subjects with chronic plaque psoriasis involving between 0 and 25% BSA. Eligible subjects will enroll into the long-term safety study on the same day as the Week 12 visit for the previous study (ARQ-151-201) for Cohort 1 and on Day 1 for non ARQ-151-201 subjects in Cohort 2. Study medication will be applied by the subjects topically once a day for 52 weeks at home.

A total of up to approximately 300 subjects (Cohort 1) and up to approximately 100 non ARQ-151-201 subjects (Cohort 2) 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. Periodic clinic visits will include assessments for clinical safety, application site reactions evaluated in the clinic using the method of Berger and Bowman (Berger-1982), disease improvement or progression, and investigator global assessment (IGA).

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

This is an open-label single-arm study. Eligible subjects will receive ARQ-151 cream 0.3%.

4.1.3 Blinding

Not applicable.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Safety Endpoints

The primary endpoint will be analysis of safety monitored through application site assessments in the clinic using the method of Berger and Bowman, clinical laboratory testing, 12-lead electrocardiograms (ECGs), Patient Health Questionnaire Depression Scale (PHQ-8), Columbia-Suicide Severity Rating Scale (C-SSRS) and adverse events (AEs). Two primary endpoint analyses are planned:

- Occurrence of treatment emergent AEs (TEAEs)
- Occurrence of Serious Adverse Events (SAEs)

Additionally a set of secondary endpoints will be summarized. These include:

- Changes in PHQ-8, C-SSRS, ECG, clinical laboratory parameters, and vital signs over time.
- Incidence of 5% of weight loss or gain from baseline.
- Incidence of shifts from baseline to last, highest and lowest BMI category.
- Incidence of application site reactions assessed by the investigator.

5.2 Efficacy Endpoints

The secondary endpoints are related to efficacy and will include:

- Proportion (%) of subjects achieving an IGA of clear or almost clear, as observed at Week 4, 12, 24, 36, and 52.
- In subjects who achieve 'Clear' scores for IGA, Intertriginous IGA (I-IGA) (if applicable and Modified Psoriasis Area Severity Index (mPASI)) and stop treatment to all lesions, time to restarting study drug (treatment free interval). Subjects with continual clearance will be censored at their date of last contact.
- The incidence of subjects who stop therapy during the study due to disease clearance on study. Disease clearance is defined as 'Clear' scores for IGA, I-IGA (if applicable and mPASI).
- Proportion (%) of applicable subjects with intertriginous area involvement, 'I-IGA' score of 'Clear' or 'Almost Clear' at Week 4, 12, 24, 36, and 52.
- Proportion (%) of subjects achieving a 75% reduction from Baseline of PASI (PASI-75) at Week 4, 12, 24, 36, and 52. PASI was not specifically collected but will be derived based on already reported information.
- Proportion (%) of subjects achieving a 75% reduction from Baseline of mPASI (mPASI-75) at Week 4, 12, 24, 36, and 52.
- Proportion of subjects (%) with a 2-grade improvement in IGA from Baseline as observed at Weeks 4, 12, 24, 36, 52.
- Proportion of subjects (%) with IGA Success, defined as achievement of an IGA of 'Clear' or 'Almost Clear' plus a 2-grade improvement in IGA from Baseline as observed at Weeks 4, 12, 24, 36, and 52.

- Duration of IGA Success, defined as the time from the first observation of IGA Success to the first subsequent time a subject's disease response does not meet the criteria for IGA Success. The duration of IGA Success for subjects who end treatment in IGA Success will be censored at the last disease assessment date.
- Duration of IGA Clear or Almost Clear, defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's disease response is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last disease assessment date.
- Duration of PASI-50, defined as the time from the first observation of a 50% reduction from Baseline in the PASI to the first subsequent time a subject's PASI score is greater than a 50% reduction from Baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than Baseline will be censored at the last disease assessment date.
- Duration of PASI-75, defined analogously to duration of PASI-50
- Percent change from baseline in PASI score at each disease assessment
- Shift from the baseline IGA score to the last reported IGA score on study
- Frequency of disease recurrence among subjects who stop therapy due to disease clearance. Disease recurrence is defined as any instance where IGA is ≥ 2 or mPASI is greater than 0.
- Time to disease recurrence among subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment
- The incidence of disease control among subjects who restart therapy after having stopped therapy due to disease clearance. Disease control is defined as achieving an IGA score of 0 or 1 subsequent to restarting study therapy.
- Time to disease control among subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.

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.

Descriptive statistics will be used to provide an overview of the safety and efficacy 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 number of subjects (n), mean, standard deviation (SD), median, minimum (min), and maximum (max).

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 outlined herein will be performed by QST Consultations, Ltd. (QST), utilizing 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 described in this SAP.

6.1.2 Baseline Definition

For subjects in Cohort 1, the baseline value for safety and efficacy parameters will be defined as the last observation prior to the first dose of ARQ-151 cream in either the ARQ-151-201 study or this study. Sensitivity analyses of efficacy will be performed where the baseline value for subjects in Cohort 1 is defined as the last observation prior to the first dose of ARQ-151 0.3% cream in this study. For the purpose of these latter analyses, study procedures will not be repeated; the information from the ARQ-151-201 study Week 12 visit will be carried over to the Day 1 visit for this study.

For subjects in Cohort 2, baseline values for efficacy and safety will be defined as the last observation prior to the first dose of ARQ-151 cream 0.3% in this study. Baseline values will most commonly be from Day 1.

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 mapped to the most appropriate visit values based on the midpoints between scheduled visits. 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 4	29	15 to 57
Week 12	85	58 to 127
Week 24	169	128 to 211
Week 36	253	212 to 309
Week 52	365	>= 310

Data collected at early termination and unscheduled visits prior to study day 15 will not be analyzed, with the exception of those identified as baseline values.

For Cohort 1 subjects that were on the ARQ-151 cream 0.15% or ARQ-151 cream 0.3% arm in the Phase 2b Study (ARQ-151-201), efficacy summaries will be presented for the ARQ-151-201 visits as defined in ARQ-151-201 SAP.

For time to event analysis, no visit windowing will be done. The real study day will be used and all assessments will be eligible for analysis.

6.1.4 Adjustments for Covariates

No covariates are planned for this study.

6.1.5 Handling of Dropouts or Missing Data

Missing data will not be imputed.

6.1.6 Interim Analyses and Data Monitoring

No interim inferential 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 with the intention of pooling the data for analysis. Every effort will be made to promote consistency in study execution at each investigational site.

6.1.8 Multiple Comparisons/Multiplicity

No inferential statistical analyses are planned.

6.1.9 Use of an Efficacy Subset of Subjects

No subset of subjects will be used for efficacy.

6.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

6.1.11 Examination of Subgroups

Summaries will be presented for the safety based on previous treatment in ARQ-151-201, and a combined ARQ-151-201 group. Additionally summaries will be presented for a complement set of subjects that did not previously participate in ARQ-151-201.

6.2 Disposition of Subjects

The number of subjects included in the safety population will be summarized by previous treatment group and cohort. The number of subjects enrolled, completed, discontinued (including the reasons for discontinuation), and duration of participation (weeks) will be also be summarized. Duration of participation (weeks) is defined as (last contact date – date of first dose in ARQ-151-202 + 1) / 7.

6.3 Protocol Deviations

All protocol deviations that occur will be documented and reported to Arcutis Biotherapeutics Inc.

6.4 Data Sets Analyzed

6.4.1 Safety Population

All subjects who are enrolled and received at least one confirmed dose of ARQ-151 cream 0.15% or ARQ-151 cream 0.3% study medication in either the Phase 2b Study (ARQ-151-201)

or this extension study. The number of patients included in the safety population will be summarized. All analyses will be performed using the safety population.

6.5 Demographic and Other Baseline Characteristics

All baseline summaries will be done on the safety population.

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

IGA, I-IGA, BSA, PASI, mPASI, Height, and Weight, will be summarized at baseline with descriptive statistics.

Past/coexistent medical history information and physical examination observations and vital signs information for all subjects will be presented in a by-subject listing.

6.6 Prior and Concomitant Medications

Prior and concomitant medication information for all 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.

A by-subject listing of all prior and concomitant medications will be presented.

6.7 Analysis of Efficacy

This study is not intended to assess efficacy, but rather the IGA, I-IGA, PASI and mPASI are included to determine the need for treatment and subsequent re-treatment after treatment course in Study ARQ-151-201 or Study ARQ-151-202. Certain efficacy data and endpoints will, however, be summarized. Descriptive statistics will be used to summarize the assessment of efficacy. IGA scores will be summarized at Baseline and every scheduled visit through end of the study (Day 1 and Weeks 4, 12, 24, 36, and 52). The efficacy variable in this study is success in IGA of disease severity, defined as an IGA of ‘Clear’ or ‘Almost Clear’. The number and percentage of patients who achieve treatment success at the scheduled study visits will be tabulated. The proportion of successes for the secondary variables of IGA, I-IGA, PASI-75 and mPASI-75 will be tabulated in a similar manner.

In subjects who achieve ‘Clear’ scores for IGA, I-IGA (if applicable) and mPASI (if applicable) and stop treatment to all lesions, time to restarting study drug (treatment free interval) will be calculated and analyzed. For Cohort 2 and rollover subjects previously treated with Vehicle Cream, the treatment free interval will be the number of weeks between the end of the initial

treatment in study ARQ-151-202 and the start of the next treatment in study ARQ-151-202 if one should be needed or the end of the subject's participation in study ARQ-151-202. In the event that the subject's participation in the study ends without a second round of treatment, subjects will be censored at last observed disease assessment. For rollover subjects previously treated with ARQ-151 cream 0.3% or ARQ-151 cream 0.15%, the treatment free interval will be the number of days between the last treatment that began in Study ARQ-151-201 and the start of the next treatment in study ARQ-151-202 if one should be needed or the last observed disease assessment in the study ARQ-151-202. Subjects who were lost to follow up will be included using all available information. The duration of IGA success, PASI-50, PASI-75, time to disease recurrence, time to disease control will be calculated in the same manner.

The median time (number of weeks) for duration summaries will be analyzed using the Kaplan–Meier method and will be accompanied with a plot. Patients who discontinue study ARQ-151-202 without achieving the event of interest will be considered censored in the Kaplan–Meier analyses.

6.8 Safety Evaluation

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

6.8.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of applications and total amount of study drug applied. Total amount of study drug will be calculated as the difference between tube weights at dispensation and return. The number and percentage of subjects who are compliant in each treatment group will be summarized. Subjects may not miss more than three consecutive days of dosing and must take at least 80% of expected doses to be considered compliant.

Subjects who were lost to follow up will be included in the total number of applications and total amount of study drug applied summaries, using their last known dose date.

6.8.2 Adverse Events

All TEAEs that occur during the study will be recorded and coded based on the MedDRA dictionary, version 21.1. TEAEs are defined as AEs with an onset on or after the date of the first study drug application in this study.

TEAEs will be summarized by treatment group, the number of subjects reporting a TEAE, system organ class (SOC), preferred name, severity, relationship to study drug (causality), and

seriousness. When summarizing AEs by severity and relationship, each subject will be counted once within an SOC or a preferred term by using the event with the highest severity and strongest relationship within each classification. Summaries of post active treatment emergent AEs (PATEAE) will also be presented. PATEAEs are defined as any AE that occurs after the first dose of ARQ-151 cream in either study.

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

Listings will be presented for all AEs as well as for SAEs, and AEs leading to discontinuation from the study or death.

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, listings of SAEs and subjects who prematurely discontinue from the study due to adverse events will also be provided.

6.8.3 Clinical Laboratory Evaluation

Routine blood chemistries and urinalysis will be obtained throughout the study and the results summarized by parameter at baseline andscheduled ARQ-151-202 study visits.

All clinical laboratory test results and their change from baseline will be summarized along with time point of collection.

Additionally, shifts tables will be provided describing out-of-normal range shifts for clinical laboratory results.

6.8.4 Other Observations Related to Safety

6.8.4.1 12-Lead Electrocardiogram Measurements

Electrocardiograms (ECGs) will be tabulated at baseline and scheduled ARQ-151-202 study visits.

6.8.4.2 Vital Signs

Vital signs will be tabulated at baseline and scheduled ARQ-151-202 study visits. Additionally, a shift table will be used to summarize incidence of subjects who gain or lose >5% and >10% body weight over the course of the study. Any subject who gained or lost >5% body weight will be summarized in a listing with subject reported reason for weight loss (intentional, unintentional).

The incidence of shifts from baseline to last, highest, and lowest BMI category (underweight (BMI < 18.5), normal weight (18.5 ≤ BMI < 25), overweight (25 ≤ BMI < 30), obese (30 ≤ BMI) will be presented in shift tables.

6.8.4.3 Physical Examination

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

6.8.4.4 Local Tolerance Assessments

For the Investigator's assessment the numeric application site reaction scores will be summarized individually by using the number and percentage of subjects by visit.

6.8.4.5 Patient Health Questionnaire Depression Scale

PHQ-8 data will be analyzed by a shift in state of severity using the following scoring system:

Score	Result
0 to 4	None – Minimal Depression
5 to 9	Mild Depression
10 to 14	Moderate Depression
15 to 19	Moderately Severe Depression
20 to 24	Severe Depression

6.8.4.6 Columbia-Suicide Severity Rating Scale

The C-SSRS will be analyzed per the C-SSRS Scoring and Data Analysis Guide.

6.8.4.7 Prior and Concomitant Medication

Prior and concomitant medication information for all 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.

7. DETERMINATION OF SAMPLE SIZE

A sample size of approximately 300 subjects is planned for Cohort 1 and up to approximately 100 subjects in Cohort 2 is planned for the study. This sample size will provide a sufficient population size to evaluate the long-term safety of ARQ-151 cream 0.3%.

8. CHANGES IN THE PLANNED ANALYSES

The definition of baseline for Cohort 1 was changed to: the baseline value for safety and efficacy parameters (excluding laboratory and vital signs values) will be defined as the last observation prior to the first dose of ARQ-151 cream in either the ARQ-151-201 study or this study. Sensitivity analyses of IGA and PASI efficacy will be performed where the baseline value for subjects in Cohort 1 is defined as the last observation prior to the first dose of ARQ-151 0.3% cream in this study. For the purpose of these latter analyses, study procedures will not be repeated; the information from the ARQ-151-201 study Week 12 visit will be carried over to the Day 1 visit for this study.

Week 4 was added to the following secondary endpoints.

- Proportion (%) of subjects achieving an IGA of clear or almost clear
- Proportion (%) of applicable subjects with intertriginous area involvement, ‘I-IGA’ score of ‘Clear’ or ‘Almost Clear’
- Proportion (%) of subjects achieving a 75% reduction from Baseline of mPASI (mPASI-75)

The following secondary endpoints were added to the analyses.

- Incidence of shifts from baseline to last, highest and lowest BMI category.
- The incidence of subjects who stop therapy during the study due to disease clearance on study. Disease clearance is defined as ‘Clear’ scores for IGA, I-IGA (if applicable and mPASI).

- Proportion (%) of subjects achieving a 75% reduction from Baseline of PASI (PASI-75) at Week 4, 12, 24, 36, and 52. PASI was not specifically collected but will be derived based on already reported information.
- Proportion (%) of subjects achieving a 75% reduction from Baseline of mPASI (mPASI-75) at Week 4, 12, 24, 36, and 52.
- Proportion of subjects (%) with a 2-grade improvement in IGA from Baseline as observed at Weeks 4, 12, 24, 36, 52.
- Proportion of subjects (%) with IGA Success, defined as achievement of an IGA of 'Clear' or 'Almost Clear' plus a 2-grade improvement in IGA from Baseline as observed at Weeks 4, 12, 24, 36, and 52.
- Duration of IGA Success, defined as the time from the first observation of IGA Success to the first subsequent time a subject's disease response does not meet the criteria for IGA Success. The duration of IGA Success for subjects who end treatment in IGA Success will be censored at the last disease assessment date.
- Duration of IGA Clear or Almost Clear, defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's disease response is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last disease assessment date.
- Duration of PASI-50, defined as the time from the first observation of a 50% reduction from Baseline in the PASI to the first subsequent time a subject's PASI score is greater than a 50% reduction from Baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than Baseline will be censored at the last disease assessment date.
- Duration of PASI-75, defined analogously to duration of PASI-50
- Percent change from baseline in PASI score at each disease assessment
- Shift from the baseline IGA score to the last reported IGA score on study
- Frequency of disease recurrence among subjects who stop therapy due to disease clearance. Disease recurrence is defined as any instance where IGA is ≥ 2 or mPASI is greater than 0.
- Time to disease recurrence among subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the

first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment

- The incidence of disease control among subjects who restart therapy after having stopped therapy due to disease clearance. Disease control is defined as achieving an IGA score of 0 or 1 subsequent to restarting study therapy.
- Time to disease control among subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.

9. REFERENCES

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10. INDEX OF PLANNED TABLES

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Table 14.0.1.1: Summary of Subject Enrollment and Evaluability
(Enrolled Subjects: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3%	ARQ-151-201: Roflumilast Cream 0.15%	ARQ-151-201: Vehicle Cream	Total
Number of Subjects Enrolled	xx	xx	xx	xx
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.0.1.2: Summary of Subject Enrollment and Evaluability
(Enrolled Subjects: Cohort 2)

	Roflumilast Cream 0.3%
Number of Subjects Enrolled	xx
Number of Subjects Excluded from the Safety Population	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)

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

Table 14.0.1.3: Summary of Subject Enrollment and Evaluability
(Enrolled Subjects)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total
Number of Subjects Enrolled	xx	xx	xx
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.0.2.1: Summary of Subject Completion/Discontinuation
(Safety Subjects: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Completed Study				
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation				
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Duration of Participation (Weeks)[b]				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] See Listing 16.2.1.2 for other discontinuation reasons.
[b] Duration of participation (weeks) is defined as (last contact date – date of first dose in ARQ-151-202 + 1) / 7
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2.2: Summary of Subject Completion/Discontinuation
(Safety Subjects: Cohort 2)

	Roflumilast Cream 0.3% (N=xx)
Completed Study	
Yes	xx (xx.x%)
No	xx (xx.x%)
Reason for Discontinuation	
Adverse Event	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)
Pregnancy	xx (xx.x%)
Protocol Deviation	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)
Physician Decision	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)
Other[a]	xx (xx.x%)
Duration of Participation (Weeks)[b]	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] See Listing 16.2.1.2 for other discontinuation reasons.
[b] Duration of participation (weeks) is defined as (last contact date – date of first dose + 1) / 7
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2.3: Summary of Subject Completion/Discontinuation
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Duration of Participation (Weeks)[b]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] See Listing 16.2.1.2 for other discontinuation reasons.
[b] Duration of participation (weeks) is defined as (last contact date – date of first dose in ARQ-151-202 + 1) / 7
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1.1: Summary of Subject Demographics
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Age (years)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Sex				
n	xx	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity				
n	xx	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race				
n	xx	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of all other races.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1.2: Summary of Subject Demographics
(Safety Population: Cohort 2)

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

[a] See Listing 16.2.4.1 for a complete list of all other races.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1.3: Summary of Subject Demographics
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of all other races.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1.1: Primary Summary of Subject Baseline Characteristics
(Safety Population: Cohort 1)
(Page 1 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Investigator Global Assessment				
n	xx	xx	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intertriginous Investigator Global Assessment [a]				
n	xx	xx	xx	xx
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Body Surface Area (%) Affected				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Table 14.1.2.1.1: Primary Summary of Subject Baseline Characteristics
(Safety Population: Cohort 1)
(Page 2 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Psoriasis Area Severity Index				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Modified Psoriasis Area Severity Index				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Duration of Psoriasis (Years)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1.1: Primary Summary of Subject Baseline Characteristics
(Safety Population: Cohort 1)
(Page 3 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Height (cm)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Weight (kg)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1.2: Sensitivity Summary of Subject Baseline Characteristics
(Safety Population: Cohort 1)
(Page 1 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Investigator Global Assessment				
n	xx	xx	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intertriginous Investigator Global Assessment [a]				
n	xx	xx	xx	xx
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Body Surface Area (%) Affected				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Summary of Subject Baseline Characteristics
(Safety Population: Cohort 1)
(Page 2 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Psoriasis Area Severity Index				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Modified Psoriasis Area Severity Index				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Duration of Psoriasis (Years)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1.2: Sensitivity Summary of Subject Baseline Characteristics
(Safety Population: Cohort 1)
(Page 3 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Height (cm)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Weight (kg)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.2: Summary of Subject Baseline Characteristics
(Safety Population: Cohort 2)
(Page 1 of 3)

	Roflumilast Cream 0.3% (N=xx)
Investigator Global Assessment	
n	xx
0 - Clear	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)
2 - Mild	xx (xx.x%)
3 - Moderate	xx (xx.x%)
4 - Severe	xx (xx.x%)
Intertriginous Investigator Global Assessment [a]	
n	xx
1 - Almost Clear	xx (xx.x%)
2 - Mild	xx (xx.x%)
3 - Moderate	xx (xx.x%)
4 - Severe	xx (xx.x%)
Body Surface Area (%) Affected	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.

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

Table 14.1.2.2: Summary of Subject Baseline Characteristics
(Safety Population: Cohort 2)
(Page 2 of 3)

	Roflumilast Cream 0.3% (N=xx)
Psoriasis Area Severity Index	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Modified Psoriasis Area Sevierty Index	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Duration of Psoriasis (Years)	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.

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

Table 14.1.2.2: Summary of Subject Baseline Characteristics
(Safety Population: Cohort 2)
(Page 3 of 3)

	Roflumilast Cream 0.3% (N=xx)
Height (cm)	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Weight (kg)	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.

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

Table 14.1.2.3: Summary of Subject Baseline Characteristics
(Safety Population)
(Page 1 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Investigator Global Assessment			
n	xx	xx	xx
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intertriginous Investigator Global Assessment [a]			
n	xx	xx	xx
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%)
Body Surface Area (%) Affected			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Table 14.1.2.3: Summary of Subject Baseline Characteristics
(Safety Population)
(Page 2 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Psoriasis Area Severity Index			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Modified Psoriasis Area Severity Index			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Duration of Psoriasis (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

[a] Collected for subjects with intertriginous involvement. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.3: Summary of Subject Baseline Characteristics
(Safety Population)
(Page 3 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=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. Subjects reporting Clear or no intertriginous area involvement are included in denominator for percentages.
Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.3.1: Summary of Concomitant Medications by ATC Level 2 Term and Standard Medication Name
(Safety Population: Cohort 1)
(Page 1 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
ATC Level 2 Term[a] Standard Medication Name	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Standard Medication Name	xx (xx.x%)	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 Drug Dictionary. At each level of summarization (ATC Level 2 Term or Standard Medication Name) subjects are counted once.

Note: WHO Drug Dictionary (Version xx).

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

Table 14.1.3.2: Summary of Concomitant Medications by ATC Level 2 Term and Standard Medication Name
(Safety Population: Cohort 2)
(Page 1 of xx)

ATC Level 2 Term[a] Standard Medication Name	Roflumilast Cream 0.3% (N=xx)
ATC Level 2 Term	xx (xx.x%)
Standard Medication Name	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more concomitant medications that map to the WHO Drug Dictionary. At each level of summarization (ATC Level 2 Term or Standard Medication Name) subjects are counted once.
Note: WHO Drug Dictionary (Version xx).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.3.3: Summary of Concomitant Medications by ATC Level 2 Term and Standard Medication Name
(Safety Population)
(Page 1 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%		
ATC Level 2 Term[a] Standard Medication Name	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Standard Medication 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 Drug Dictionary. At each level of summarization (ATC Level 2 Term or Standard Medication Name) subjects are counted once.
Note: WHO Drug Dictionary (Version xx).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 1 of 11)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 2 of 11)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 2				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 3 of 11)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 4				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
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Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 6				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
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Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 8				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 6 of 11)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 12				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
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Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
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Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
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Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 24				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
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Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.1: Primary Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 11 of 11)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Sensitivity Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 1 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Sensitivity Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 2 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Sensitivity Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 3 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Sensitivity Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 4 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 24				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Sensitivity Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 5 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.2: Sensitivity Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)
(Page 6 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.3: Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)
(Page 1 of 6)

Investigator Global Assessment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Baseline	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.3: Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)
(Page 2 of 6)

Investigator Global Assessment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Week 4	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.3: Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)
(Page 3 of 6)

Investigator Global Assessment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.3: Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)
(Page 4 of 6)

Investigator Global Assessment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Week 24	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.3: Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)
(Page 5 of 6)

Investigator Global Assessment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.3: Summary of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)
(Page 6 of 6)

Investigator Global Assessment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Week 52	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.4: Summary of Investigator Global Assessment (IGA)
(Safety Population)
(Page 1 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Baseline[a]			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.4: Summary of Investigator Global Assessment (IGA)
(Safety Population)
(Page 2 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 4			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.4: Summary of Investigator Global Assessment (IGA)
(Safety Population)
(Page 3 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 12			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.4: Summary of Investigator Global Assessment (IGA)
(Safety Population)
(Page 4 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 24			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.4: Summary of Investigator Global Assessment (IGA)
(Safety Population)
(Page 5 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1.4: Summary of Investigator Global Assessment (IGA)
(Safety Population)
(Page 6 of 6)

Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 52			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear Plus 2-Grade Improvement from Baseline			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.2.1: Shift Table of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)

		Last Reported IGA				
ARQ-151-201: Roflumilast Cream 0.3% (N=xx)						
	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Last Reported IGA				
ARQ-151-201: Roflumilast Cream 0.15% (N=xx)						
	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Last Reported IGA				
ARQ-151-201: Vehicle Cream (N=xx)						
	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Last Reported IGA				
Total (N=xx)						
	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.2.2: Sensitivity Shift Table of Investigator Global Assessment (IGA)
(Safety Population: Cohort 1)

		Last Reported IGA				
ARQ-151-201: **Roflumilast Cream 0.3% (N=xx)**	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Last Reported IGA				
ARQ-151-201: **Roflumilast Cream 0.15% (N=xx)**	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Last Reported IGA				
ARQ-151-201: **Vehicle Cream (N=xx)**	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Last Reported IGA				
Total (N=xx)	Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
	0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to entry in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.2.3: Shift Table of Investigator Global Assessment (IGA)
(Safety Population: Cohort 2)

Roflumilast Cream 0.3% (N=xx)	Last Reported IGA				
Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.2.1.2.4: Shift Table of Investigator Global Assessment (IGA)
(Safety Population)

ARQ-151-201: Roflumilast Cream (N=xx)	Last Reported IGA				
Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Last Reported IGA				
Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total (N=xx)	Last Reported IGA				
Baseline IGA	0 - Clear	1 - Almost Clear	2 - Mild	3 - Moderate	4 - Severe
0 - Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Primary Summary of Intrigenous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)
(Page 1 of 6)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
ARQ-151-201 Week 2				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Primary Summary of Intrigenous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)
(Page 2 of 6)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 4				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
ARQ-151-201 Week 6				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Primary Summary of Intrigenous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)
(Page 3 of 6)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 8				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
ARQ-151-201 Week 12				
n	xx	xx	NA	xx
0 - Clear	xx (xx%)	xx (xx%)		xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)		xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)		xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)		xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)		xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Primary Summary of Intrigenous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Week 12				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Primary Summary of Intrigenous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)
(Page 5 of 6)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 24				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Week 36				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Primary Summary of Intrigenous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast Cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2: Sensitivity Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)
(Page 1 of 3)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Week 4				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2: Sensitivity Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)
(Page 2 of 3)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Week 24				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2: Sensitivity Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Week 52				
n	xx	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3: Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 2)
(Page 1 of 3)

Intertriginous Investigator Global Assessment	Roflumilast Cream 0.3% (N=xx)
Baseline[a]	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Week 4	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)

[a] Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3: Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 2)
(Page 2 of 3)

Intertriginous Investigator Global Assessment	Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
Week 24	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)

[a] Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3: Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 2)
(Page 3 of 3)

Intertriginous Investigator Global Assessment	Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)
Week 52	
n	xx
0 - Clear	xx (xx%)
1 - Almost Clear	xx (xx%)
2 - Mild	xx (xx%)
3 - Moderate	xx (xx%)
4 - Severe	xx (xx%)
Score of Clear or Almost Clear	
Success	xx (xx%)
Failure	xx (xx%)

[a] Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4: Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population)
(Page 1 of 3)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Baseline[a]			
n	xx	xx	xx
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Week 4			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4: Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population: Cohort 1)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 12			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Week 24			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4: Summary of Intertriginous Investigator Global Assessment (I-IGA)
(Safety Population)
(Page 3 of 3)

Intertriginous Investigator Global Assessment	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
Week 52			
n	xx	xx	xx
0 - Clear	xx (xx%)	xx (xx%)	xx (xx%)
1 - Almost Clear	xx (xx%)	xx (xx%)	xx (xx%)
2 - Mild	xx (xx%)	xx (xx%)	xx (xx%)
3 - Moderate	xx (xx%)	xx (xx%)	xx (xx%)
4 - Severe	xx (xx%)	xx (xx%)	xx (xx%)
Score of Clear or Almost Clear			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study. Collected for subjects with intertriginous involvement. Subjects reporting no intertriginous area involvement are included in denominator for percentages.
Note: Collected post-baseline for subjects with a severity of at least mild. No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 1 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 2 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 2				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 3 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 4				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 4 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 6				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 5 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 8				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 6 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 12				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Primary Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 7 of 11)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx.x
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to the programmer:Repeat this page for Week 12, 24, 36 and 52.

Table 14.2.3.2: Sensitivity Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 1 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2: Sensitivity Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 2 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx.x
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2: Sensitivity Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 3 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx.x
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2: Sensitivity Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 4 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 24				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2: Sensitivity Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 5 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2: Sensitivity Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 1)
(Page 6 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%			
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
PASI-50				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.3: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 2)
(Page 1 of 6)

Psoriasis Area and Severity Index	Roflumilast Cream 0.3% (N=xx)
Baseline	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx

Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.3: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 2)
(Page 2 of 6)

Psoriasis Area and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 4	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
PASI-50	
Success	xx (xx%)
Failure	xx (xx%)
PASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.3: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 2)
(Page 3 of 6)

Psoriasis Area and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
PASI-50	
Success	xx (xx%)
Failure	xx (xx%)
PASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.3: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 2)
(Page 4 of 6)

Psoriasis Area and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 24	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
PASI-50	
Success	xx (xx%)
Failure	xx (xx%)
PASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.3: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 2)
(Page 5 of 6)

Psoriasis Area and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
PASI-50	
Success	xx (xx%)
Failure	xx (xx%)
PASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.3: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population: Cohort 2)
(Page 6 of 6)

Psoriasis Area and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 52	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
PASI-50	
Success	xx (xx%)
Failure	xx (xx%)
PASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population)
(Page 1 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%		
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Baseline[a]			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population)
(Page 2 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%		
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx.x
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
PASI-50			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population)
(Page 3 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%		
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx.x
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
PASI-50			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population)
(Page 4 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%		
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 24			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
PASI-50			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population)
(Page 5 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%		
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
PASI-50			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.4: Summary of Psoriasis Area and Severity Index (PASI)
(Safety Population)
(Page 6 of 6)

	ARQ-151-202: Roflumilast Cream 0.3%		
Psoriasis Area and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 52			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
PASI-50			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)
PASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. PASI-50 is defined as a 50% reduction from baseline of PASI. PASI-75 is defined as a 75% reduction from Baseline of PASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Primary Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 1 of 10)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
ARQ-151-201 Week 2				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.xx	xx.xx		xx.xx
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx
SD	xx.xx	xx.xx		xx.xx
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.xx	xx.xx		xx.xx
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Primary Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 2 of 10)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 4				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Primary Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 3 of 10)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 6				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Primary Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 4 of 10)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 8				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Primary Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 5 of 10)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
ARQ-151-201 Week 12				
n	xx	xx	NA	xx
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
Change from Baseline				
Mean	xx	xx		xx.x
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max	xx to xx	xx to xx		xx to xx
Percent Change from Baseline				
Mean	xx	xx		xx
SD	xx.x	xx.x		xx.x
Median	xx	xx		xx
Min. to Max.	xx to xx	xx to xx		xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)		xx (xx%)
Failure	xx (xx%)	xx (xx%)		xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Primary Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 6 of 10)

Modified Psoriasis and Severity Index	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx.x
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to the programmer:Repeat this page for Week 12, 24, 36 and 52.

Table 14.2.4.2: Sensitivity Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 1 of 5)

Modified Psoriasis and Severity Index	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline[a]				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 4				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.2: Sensitivity Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 2 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx.x
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.2: Sensitivity Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 3 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 24				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.2: Sensitivity Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 4 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.2: Sensitivity Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 1)
(Page 5 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%			
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline				
Mean	xx	xx	xx	xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
mPASI-75				
Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.3: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 2)
(Page 1 of 5)

Modified Psoriasis and Severity Index	Roflumilast Cream 0.3% (N=xx)
Baseline	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Week 4	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
mPASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.3: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 2)
(Page 2 of 5)

Modified Psoriasis and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
mPASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.3: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 2)
(Page 3 of 5)

Modified Psoriasis and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 24	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
mPASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.3: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 2)
(Page 4 of 5)

Modified Psoriasis and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
mPASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.3: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population: Cohort 2)
(Page 5 of 5)

Modified Psoriasis and Severity Index	Roflumilast Cream 0.3% (N=xx)
Week 52	
n	xx
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max	xx to xx
Percent Change from Baseline	
Mean	xx
SD	xx.x
Median	xx
Min. to Max.	xx to xx
mPASI-75	
Success	xx (xx%)
Failure	xx (xx%)

Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population)
(Page 1 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%		
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Baseline[a]			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.xx	xx.xx	xx.xx
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population)
(Page 2 of 5)

Modified Psoriasis and Severity Index	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 4			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx.x
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population)
(Page 2 of 5)

Modified Psoriasis and Severity Index	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: AR Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 12			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx.x
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population)
(Page 3 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%		
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 24			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population)
(Page 4 of 5)

	ARQ-151-202: Roflumilast Cream 0.3%		
Modified Psoriasis and Severity Index	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Summary of Modified Psoriasis and Severity Index (mPASI)
(Safety Population)
(Page 5 of 5)

Modified Psoriasis and Severity Index	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 52			
n	xx	xx	xx
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max	xx to xx	xx to xx	xx to xx
Percent Change from Baseline			
Mean	xx	xx	xx
SD	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min. to Max.	xx to xx	xx to xx	xx to xx
mPASI-75			
Success	xx (xx%)	xx (xx%)	xx (xx%)
Failure	xx (xx%)	xx (xx%)	xx (xx%)

[a] Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
Note: No imputation of missing values. mPASI-75 is defined as a 75% reduction from baseline of mPASI.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Summary of Duration of Treatment Free Interval and Investigator Global Assessment (IGA) Success
(Safety Population: Cohort 1)

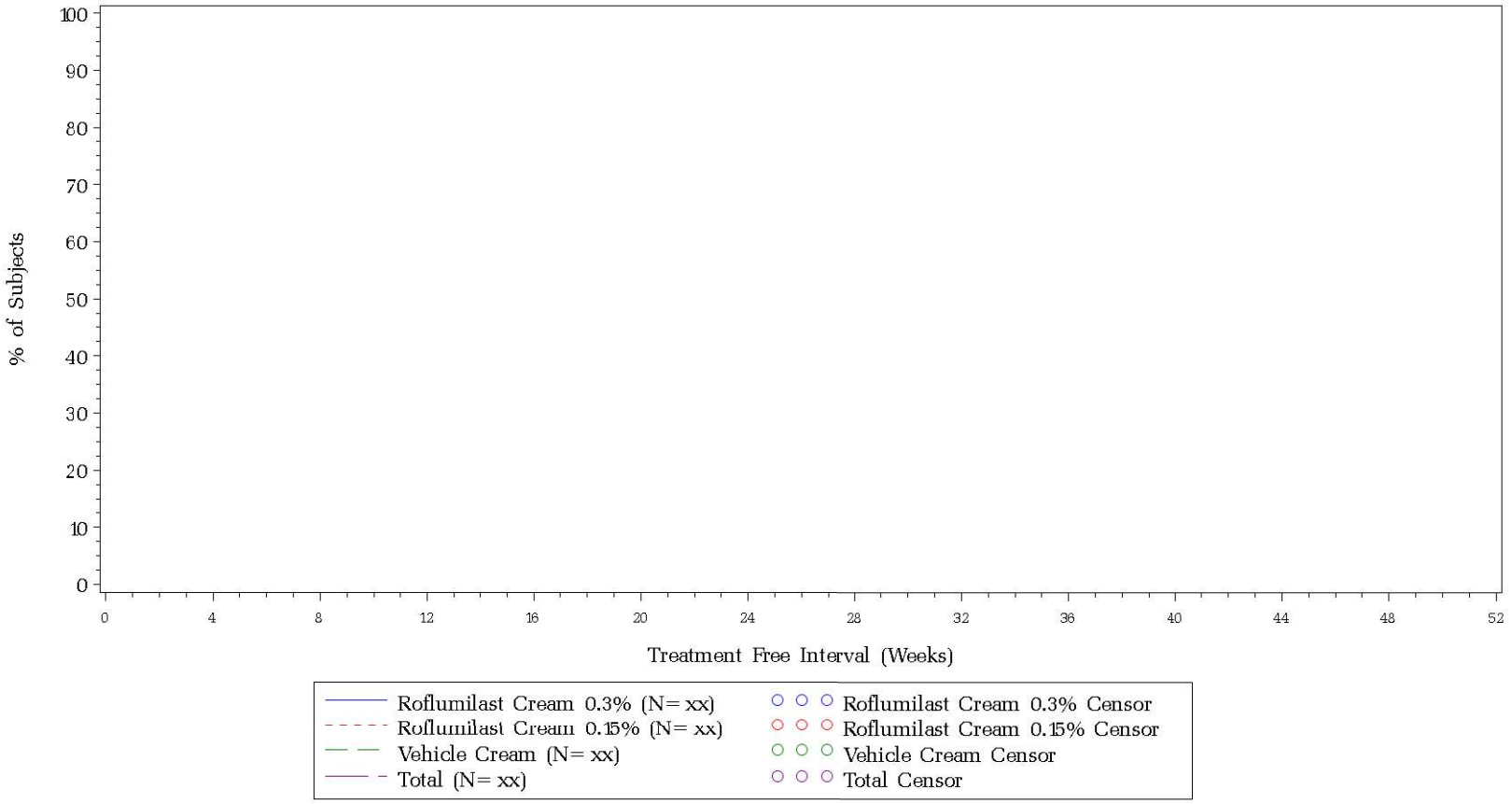
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Number of Subjects who Achieved Disease Clearance and Stopped Treatment	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Treatment Free Interval (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Resumed Treatment	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects With IGA Success	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Duration of IGA Success (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Disease clearance is defined as Clear scores for IGA, I-IGA (if applicable) and mPASI (if applicable).
Treatment free interval is defined as time to re-starting study drug for subjects who achieved disease clearance and stopped treatment to all lesions. Subjects not re-starting study drug before ending participation in the study were censored at the day of the last observed disease assessment.
IGA success defined as achievement of an IGA of Clear or Almost Clear plus a 2-grade improvement in IGA. Duration of IGA success is defined as the time from first observation of IGA success to the first subsequent time a subject's disease response does not meet the criteria for IGA success. Subjects with a continued success at end of participation in the study were censored at the day of the last observed disease assessment.

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

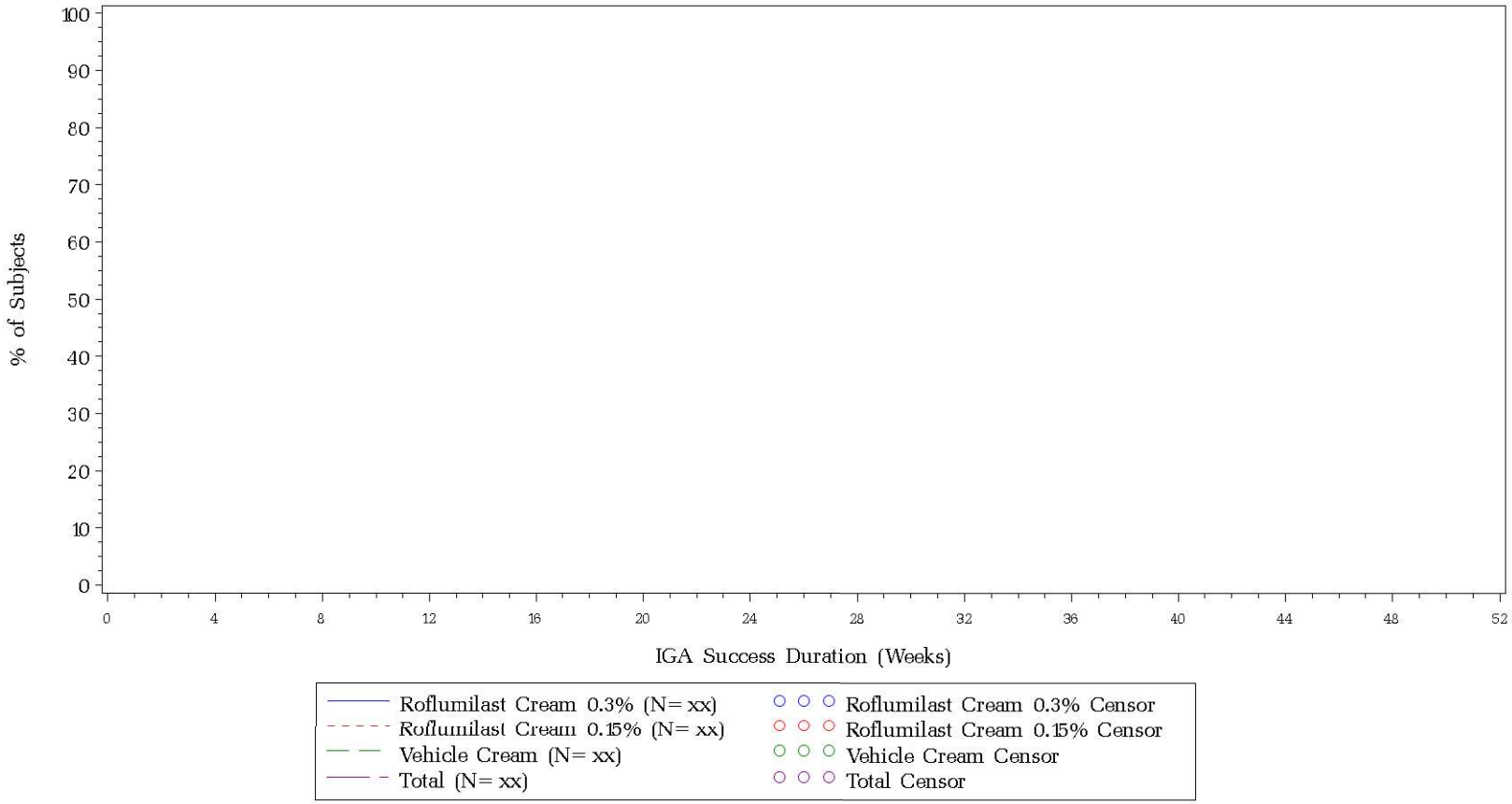
Figure 14.2.5.1.1: Kaplan-Meier Plot of Treatment Free Interval (Weeks)
(Safety Population: Cohort 1)



Note: Treatment free interval is defined as time to re-starting study drug for subjects who achieved Clear scores for IGA, I-IGA (if applicable) and mPASI (if applicable), and stopped treatment to all lesions. Subjects not re-starting study drug before ending participation in the study were censored at the day of the last observed disease assessment.

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

Figure 14.2.5.1.2: Kaplan-Meier Plot of Duration of Investigator Global Assessment (IGA) Success (Weeks)
(Safety Population: Cohort 1)



Note: IGA success defined as achievement of an IGA of Clear or Almost Clear plus a 2-grade improvement in IGA. Duration of IGA success is defined as the time from first observation of IGA success to the first subsequent time a subject's disease response does not meet the criteria for IGA success. Subjects with a continued success at end of participation in the study were censored at the day of the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2: Summary of Duration of Treatment Free Interval and Investigator Global Assessment (IGA) Success
(Safety Population: Cohort 2)

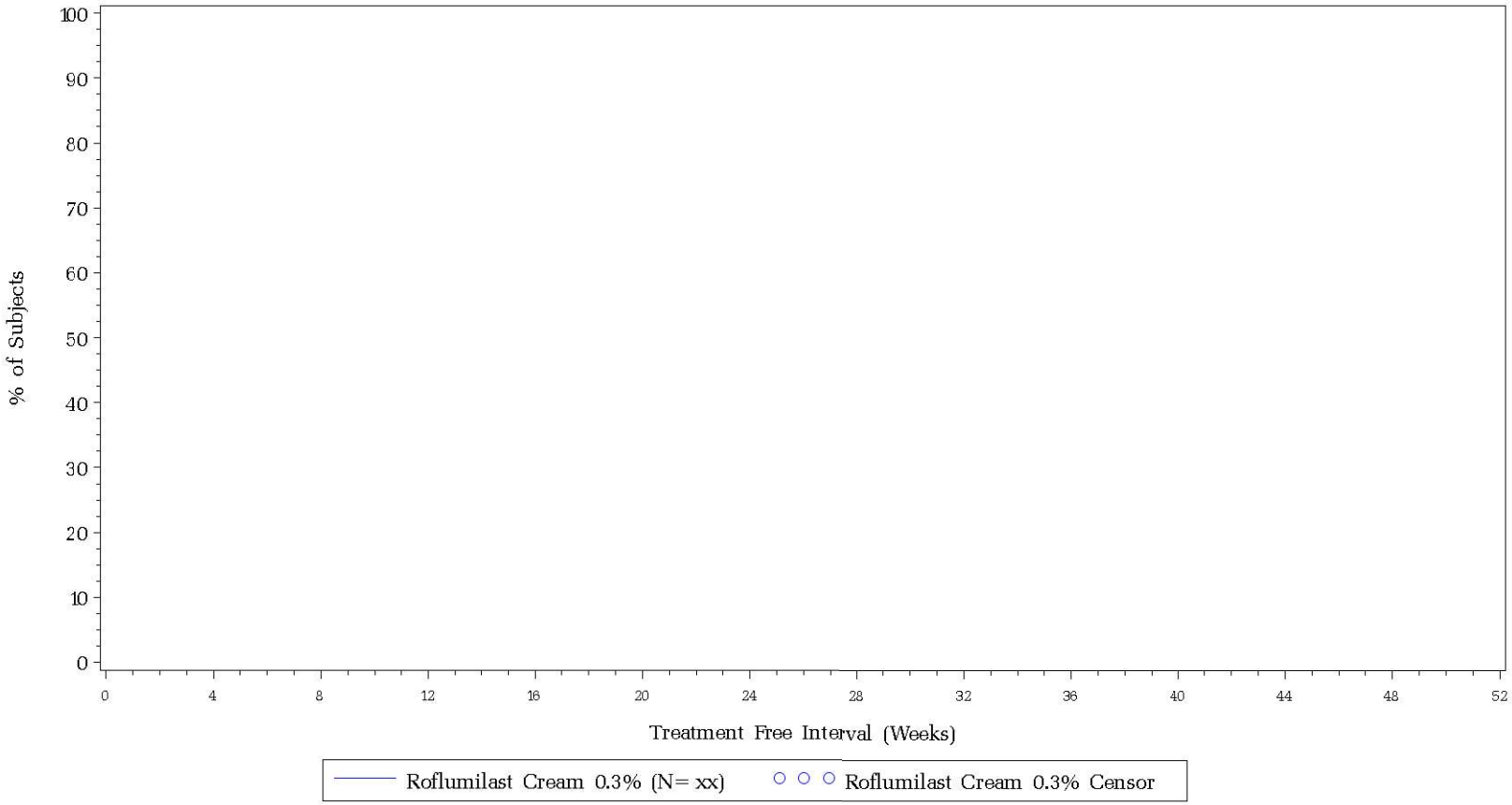
	Roflumilast Cream 0.3% (N=xx)
Number of Subjects who Achieved Disease Clearance and Stopped Treatment	xx (xx%)
Treatment Free Interval (Weeks)	
n	xx
Median[a]	xx
Resumed Treatment	xx (xx%)
Censored	xx (xx%)
Number of Subjects With IGA Success	xx (xx%)
Duration of IGA Success (Weeks)	
n	xx
Median[a]	xx
Disease Recurrence	xx (xx%)
Censored	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Disease clearance is defined as Clear scores for IGA, I-IGA (if applicable) and mPASI (if applicable).
Treatment free interval is defined as time to re-starting study drug for subjects who achieved disease clearance and stopped treatment to all lesions. Subjects not re-starting study drug before ending participation in the study were censored at the day of the last observed disease assessment.
IGA success defined as achievement of an IGA of Clear or Almost Clear plus a 2-grade improvement in IGA. Duration of IGA success is defined as the time from first observation of IGA success to the first subsequent time a subject's disease response does not meet the criteria for IGA success. Subjects with a continued success at end of participation in the study were censored at the day of the last observed disease assessment.

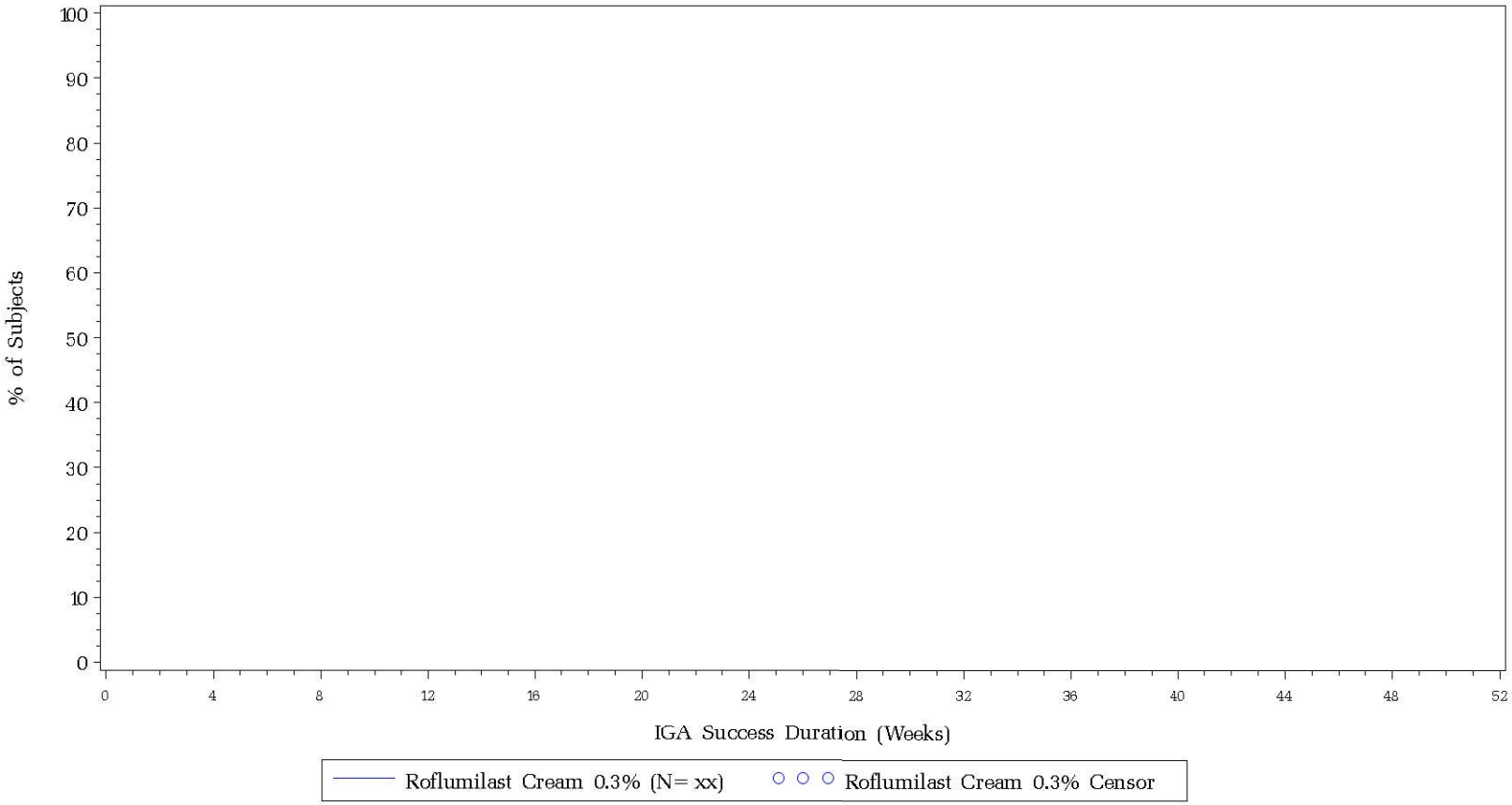
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.5.2.1: Kaplan-Meier Plot of Treatment Free Interval (Weeks)
(Safety Population: Cohort 2)



Note: Treatment free interval is defined as time to re-starting study drug for subjects who achieved Clear scores for IGA, I-IGA (if applicable) and mPASI (if applicable), and stopped treatment to all lesions. Subjects not re-starting study drug before ending participation in the study were censored at the day of the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.5.2.2: Kaplan-Meier Plot of Duration of Investigator Global Assessment (IGA) Success (Weeks)
(Safety Population: Cohort 2)



Note: IGA success defined as achievement of an IGA of Clear or Almost Clear plus a 2-grade improvement in IGA. Duration of IGA success is defined as the time from first observation of IGA success to the first subsequent time a subject's disease response does not meet the criteria for IGA success. Subjects with a continued success at end of participation in the study were censored at the day of the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.3: Summary of Duration of Treatment Free Interval and Investigator Global Assessment (IGA) Success
(Safety Population)

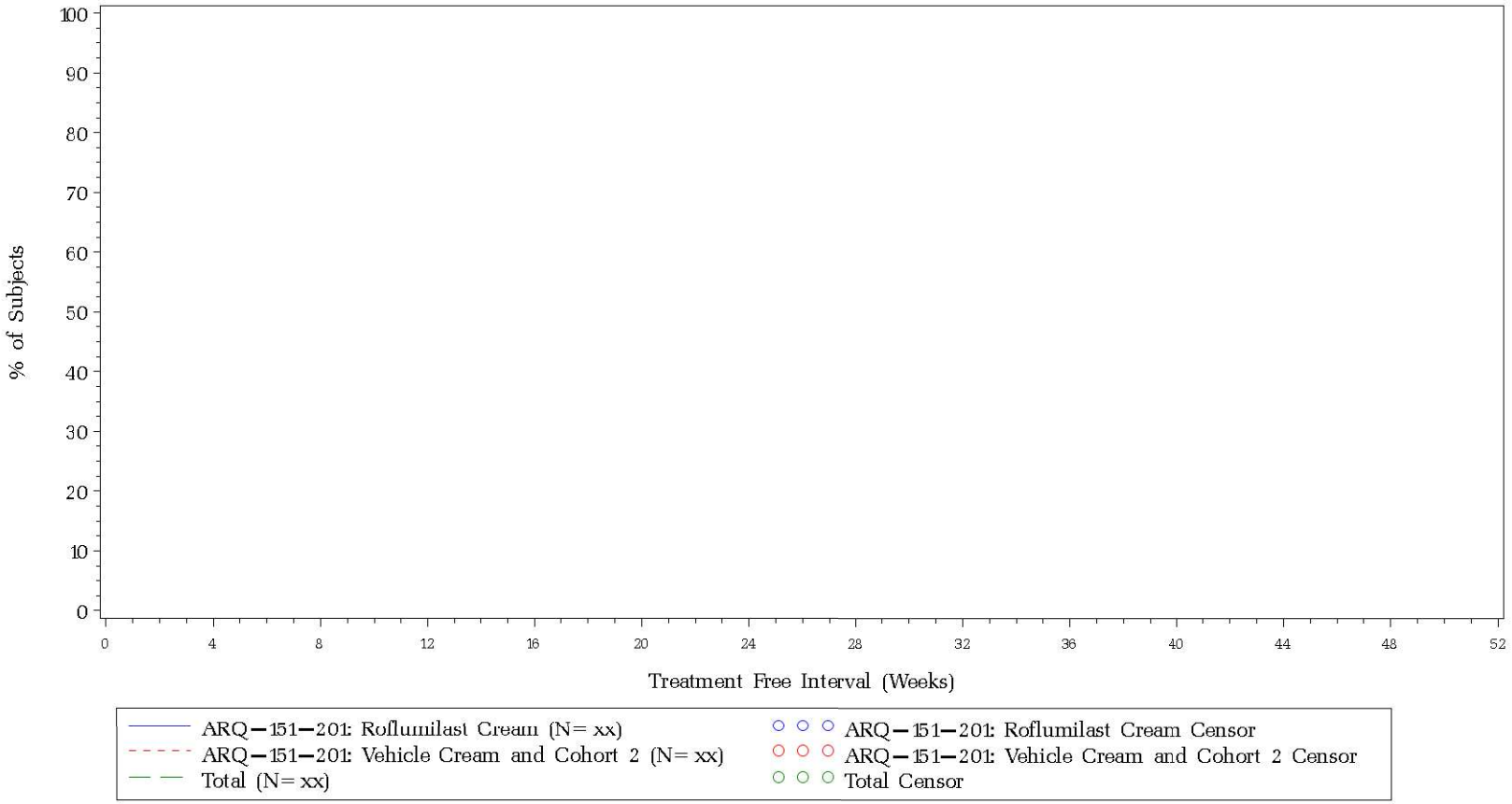
	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Number of Subjects who Achieved Disease Clearance and Stopped Treatment	xx (xx%)	xx (xx%)	xx (xx%)
Treatment Free Interval (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Resumed Treatment	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects With IGA Success	xx (xx%)	xx (xx%)	xx (xx%)
Duration of IGA Success (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Disease clearance is defined as Clear scores for IGA, I-IGA (if applicable) and mPASI (if applicable).
Treatment free interval is defined as time to re-starting study drug for subjects who achieved disease clearance and stopped treatment to all lesions. Subjects not re-starting study drug before ending participation in the study were censored at the day of the last observed disease assessment.
IGA success defined as achievement of an IGA of Clear or Almost Clear plus a 2-grade improvement in IGA. Duration of IGA success is defined as the time from first observation of IGA success to the first subsequent time a subject's disease response does not meet the criteria for IGA success. Subjects with a continued success at end of participation in the study were censored at the day of the last observed disease assessment.

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

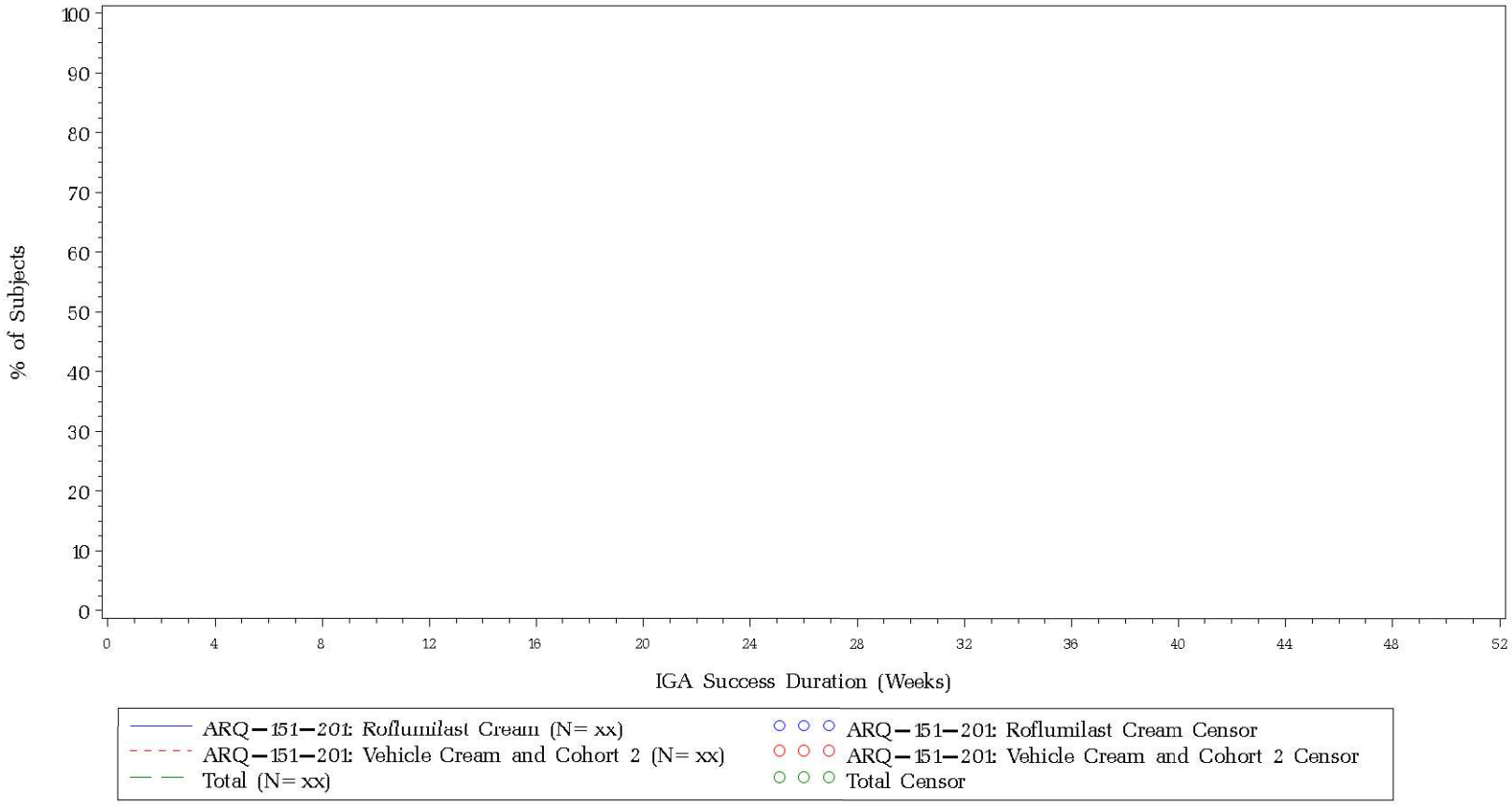
Figure 14.2.5.3.1: Kaplan-Meier Plot of Treatment Free Interval (Weeks)
(Safety Population)



Note: Treatment free interval is defined as time to re-starting study drug for subjects who achieved Clear scores for IGA, I-IGA (if applicable) and mPASI (if applicable), and stopped treatment to all lesions. Subjects not re-starting study drug before ending participation in the study were censored at the day of the last observed disease assessment.

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

Figure 14.2.5.3.2: Kaplan-Meier Plot of Duration of Investigator Global Assessment (IGA) Success (Weeks)
(Safety Population)



Note: IGA success defined as achievement of an IGA of Clear or Almost Clear plus a 2-grade improvement in IGA. Duration of IGA success is defined as the time from first observation of IGA success to the first subsequent time a subject's disease response does not meet the criteria for IGA success. Subjects with a continued success at end of participation in the study were censored at the day of the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Disease Recurrence
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Total Number of Instances of Disease Recurrence Following Clearance				
n	xx	xx	xx	xx
0	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4+	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Instances of Disease Recurrence Following Clearance Through Week 24[a]				
n	xx	xx	xx	xx
0	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4+	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Instances of Disease Recurrence Following Clearance Through Week 52[a]				
n	xx	xx	xx	xx
0	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
2	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
3	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
4+	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Percentages calculated out of total number of subjects who participated in study through the respective visit.
Note: Disease clearance defined as an IGA of Clear and mPASI of 0.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.2: Summary of Disease Recurrence
(Safety Population: Cohort 2)

	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)
Total Number of Instances of Disease Recurrence Following Clearance	
n	xx
0	xx (xx%)
1	xx (xx%)
2	xx (xx%)
3	xx (xx%)
4+	xx (xx%)
Number of Instances of Disease Recurrence Following Clearance Through Week 24[a]	
n	xx
0	xx (xx%)
1	xx (xx%)
2	xx (xx%)
3	xx (xx%)
4+	xx (xx%)
Number of Instances of Disease Recurrence Following Clearance Through Week 52[a]	
n	xx
0	xx (xx%)
1	xx (xx%)
2	xx (xx%)
3	xx (xx%)
4+	xx (xx%)

[a] Percentages calculated out of total number of subjects who participated in study through the respective visit.
Note: Disease clearance defined as an IGA of Clear and mPASI of 0.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.3: Summary of Disease Recurrence
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Total Number of Instances of Disease Recurrence Following Clearance			
n	xx	xx	xx
0	xx (xx%)	xx (xx%)	xx (xx%)
1	xx (xx%)	xx (xx%)	xx (xx%)
2	xx (xx%)	xx (xx%)	xx (xx%)
3	xx (xx%)	xx (xx%)	xx (xx%)
4+	xx (xx%)	xx (xx%)	xx (xx%)
Number of Instances of Disease Recurrence Following Clearance Through Week 24[a]			
n	xx	xx	xx
0	xx (xx%)	xx (xx%)	xx (xx%)
1	xx (xx%)	xx (xx%)	xx (xx%)
2	xx (xx%)	xx (xx%)	xx (xx%)
3	xx (xx%)	xx (xx%)	xx (xx%)
4+	xx (xx%)	xx (xx%)	xx (xx%)
Number of Instances of Disease Recurrence Following Clearance Through Week 24[a]			
n	xx	xx	xx
0	xx (xx%)	xx (xx%)	xx (xx%)
1	xx (xx%)	xx (xx%)	xx (xx%)
2	xx (xx%)	xx (xx%)	xx (xx%)
3	xx (xx%)	xx (xx%)	xx (xx%)
4+	xx (xx%)	xx (xx%)	xx (xx%)

[a] Percentages calculated out of total number of subjects who participated in study through the respective visit.
Note: Disease clearance defined as an IGA of Clear and mPASI of 0.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Duration of Investigator Global Assessment (IGA) of Clear or Almost Clear
(Safety Population: Cohort 1)

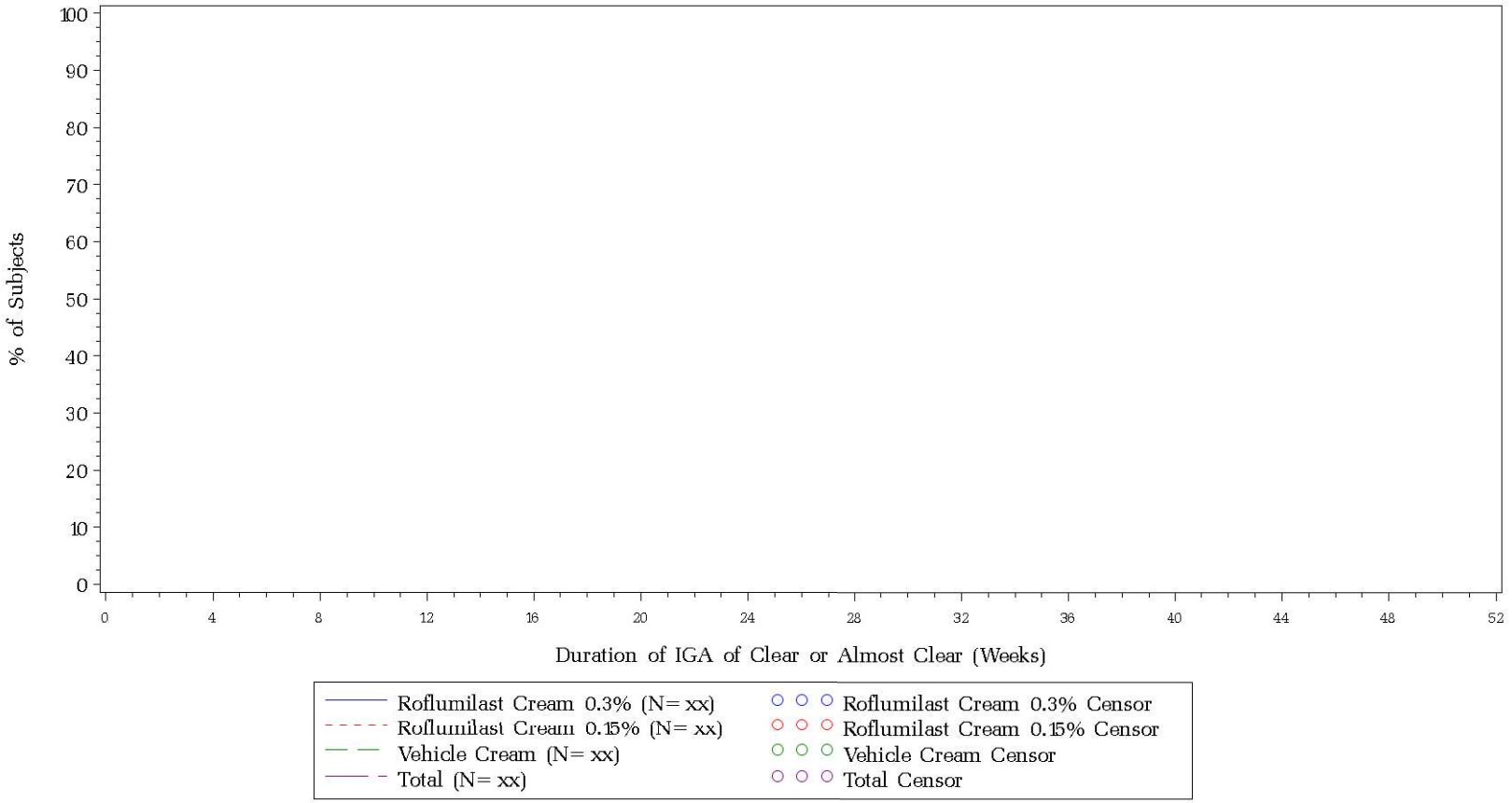
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Duration of IGA of Clear or Almost Clear (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of IGA of Clear or Almost Clear is defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's IGA is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last IGA date.

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

Figure 14.2.7.1: Kaplan-Meier Plot of Duration of Investigator Global Assessment (IGA) of Clear or Almost Clear (Weeks)
(Safety Population: Cohort 1)



Note: Duration of IGA of Clear or Almost Clear is defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's IGA is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last IGA date.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.2: Summary of Duration of Investigator Global Assessment (IGA) of Clear or Almost Clear
(Safety Population: Cohort 2)

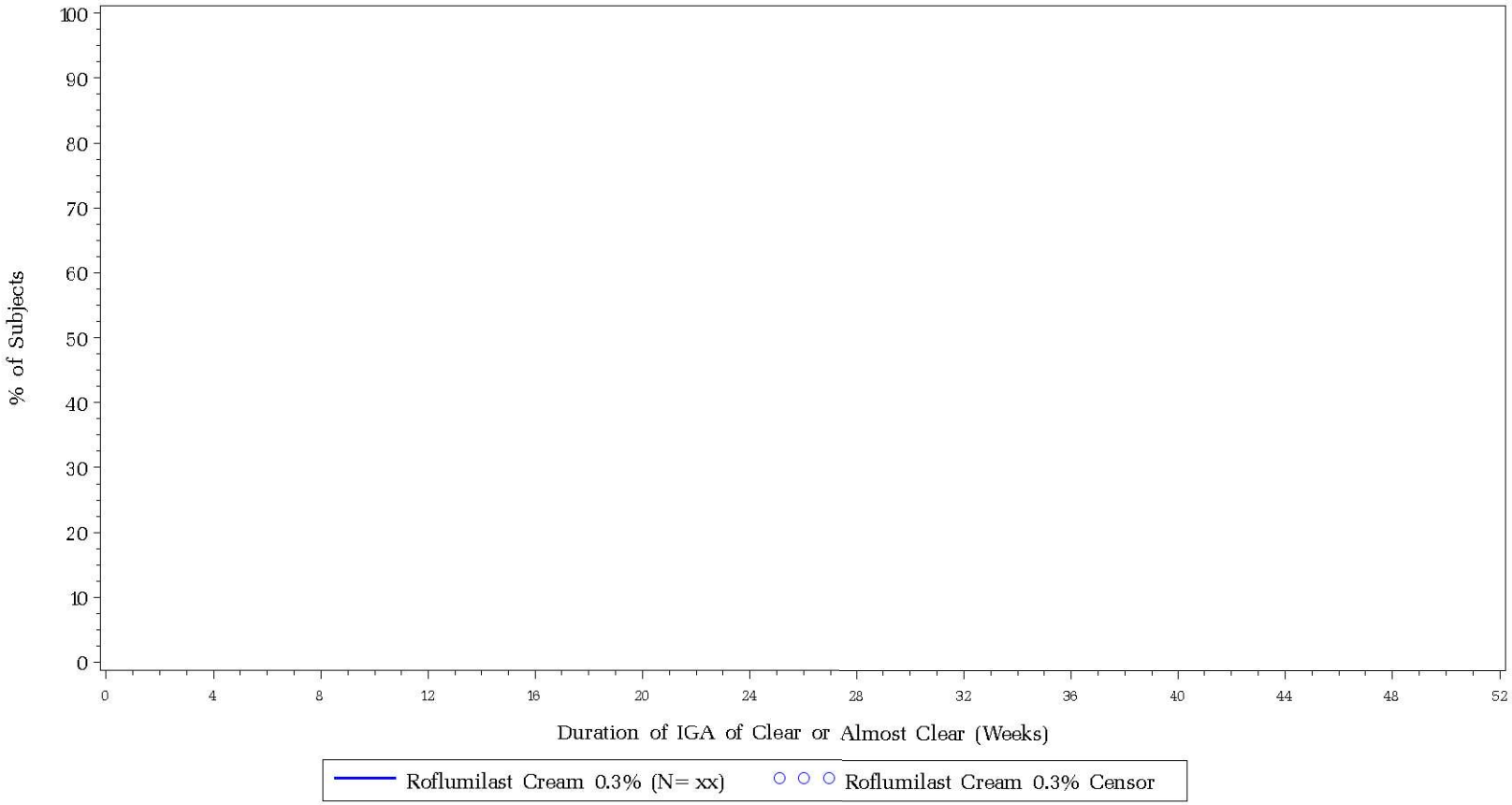
	Roflumilast Cream 0.3% (N=xx)
Duration of IGA of Clear or Almost Clear (Weeks)	
n	xx
Median[a]	xx
Disease Recurrence	xx (xx%)
Censored	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of IGA of Clear or Almost Clear is defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's IGA is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last IGA date.

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

Figure 14.2.7.2: Kaplan-Meier Plot of Duration of Investigator Global Assessment (IGA) of Clear or Almost Clear (Weeks)
(Safety Population: Cohort 2)



Note: Duration of IGA of Clear or Almost Clear is defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's IGA is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last IGA date.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.3: Summary of Duration of Investigator Global Assessment (IGA) of Clear or Almost Clear
(Safety Population)

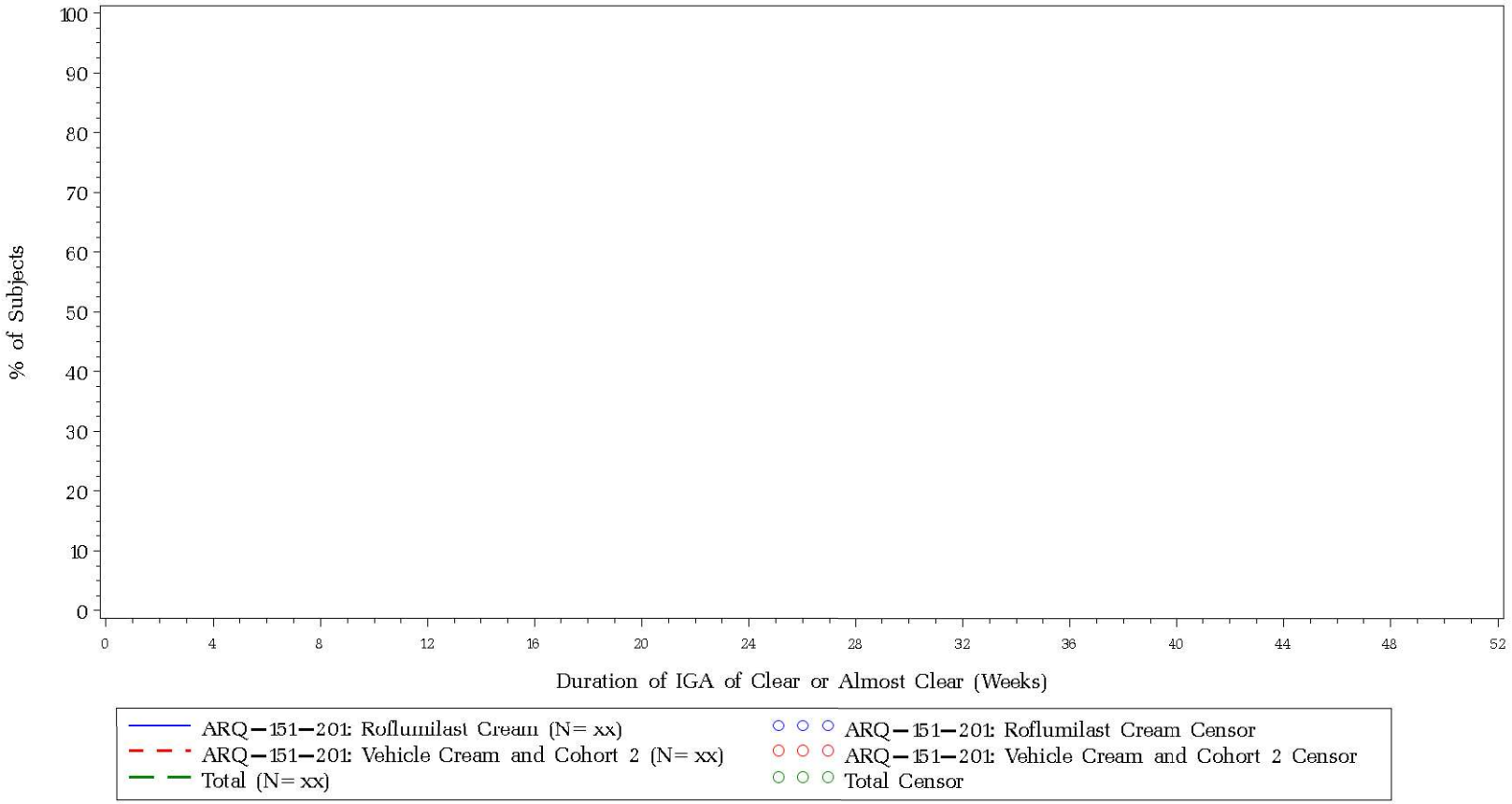
	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Duration of IGA of Clear or Almost Clear (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of IGA of Clear or Almost Clear is defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's IGA is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last IGA date.

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

Figure 14.2.7.3: Kaplan-Meier Plot of Duration of Investigator Global Assessment (IGA) of Clear or Almost Clear (Weeks)
(Safety Population)



Note: Duration of IGA of Clear or Almost Clear is defined as the time from the first observation of IGA Clear or Almost Clear to the first subsequent time a subject's IGA is not Clear or Almost Clear. The duration of IGA Clear or Almost Clear for subjects who end treatment with IGA Clear or Almost Clear will be censored at the last IGA date.

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

Table 14.2.8.1.1: Primary Summary of Duration of PASI-50
(Safety Population: Cohort 1)

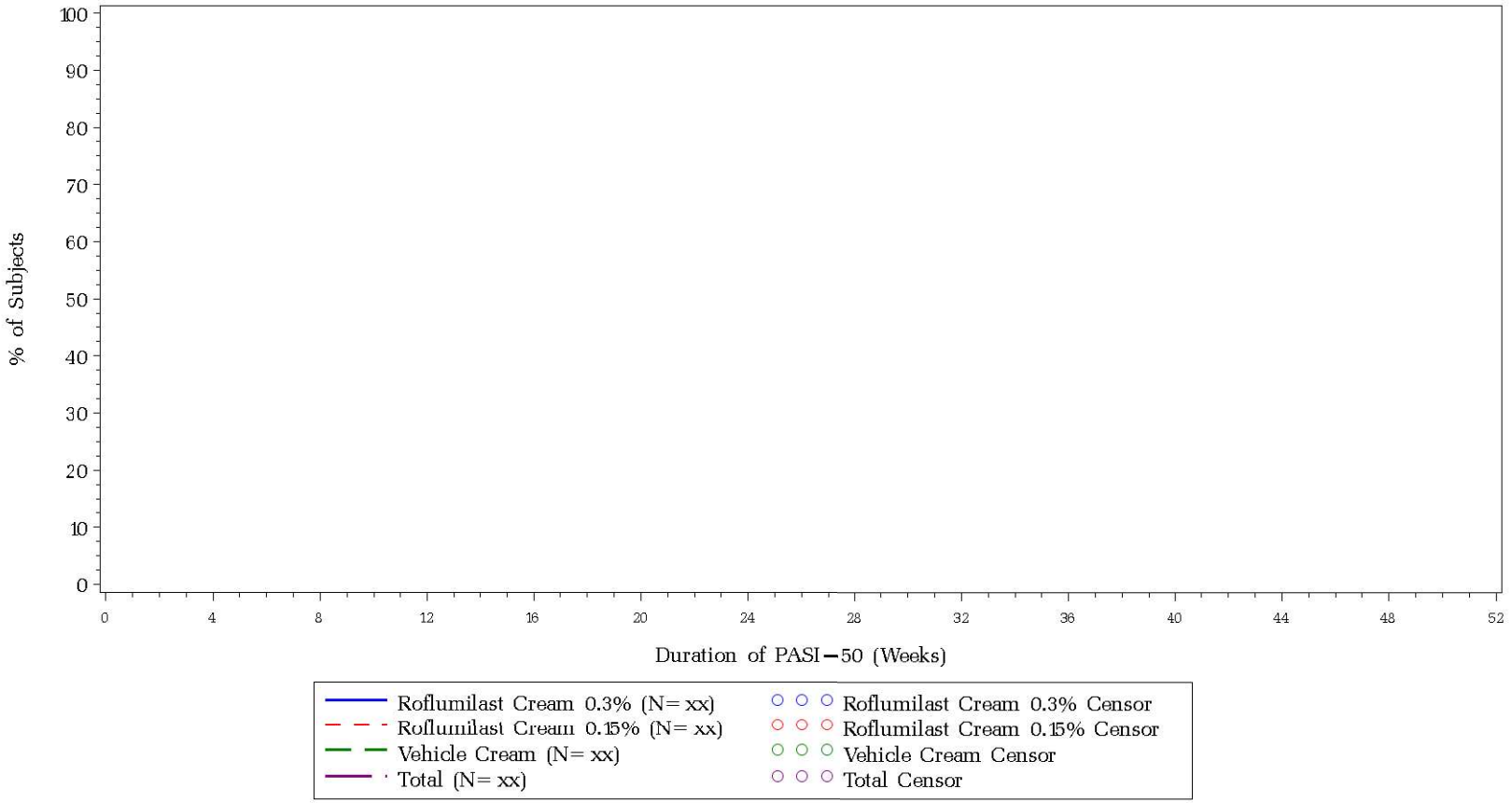
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Duration of PASI-50 (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Figure 14.2.8.1.1: Primary Kaplan-Meier Plot of Duration of PASI-50
(Safety Population: Cohort 1)



Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1.2: Sensitivity Summary of Duration of PASI-50
(Safety Population: Cohort 1)

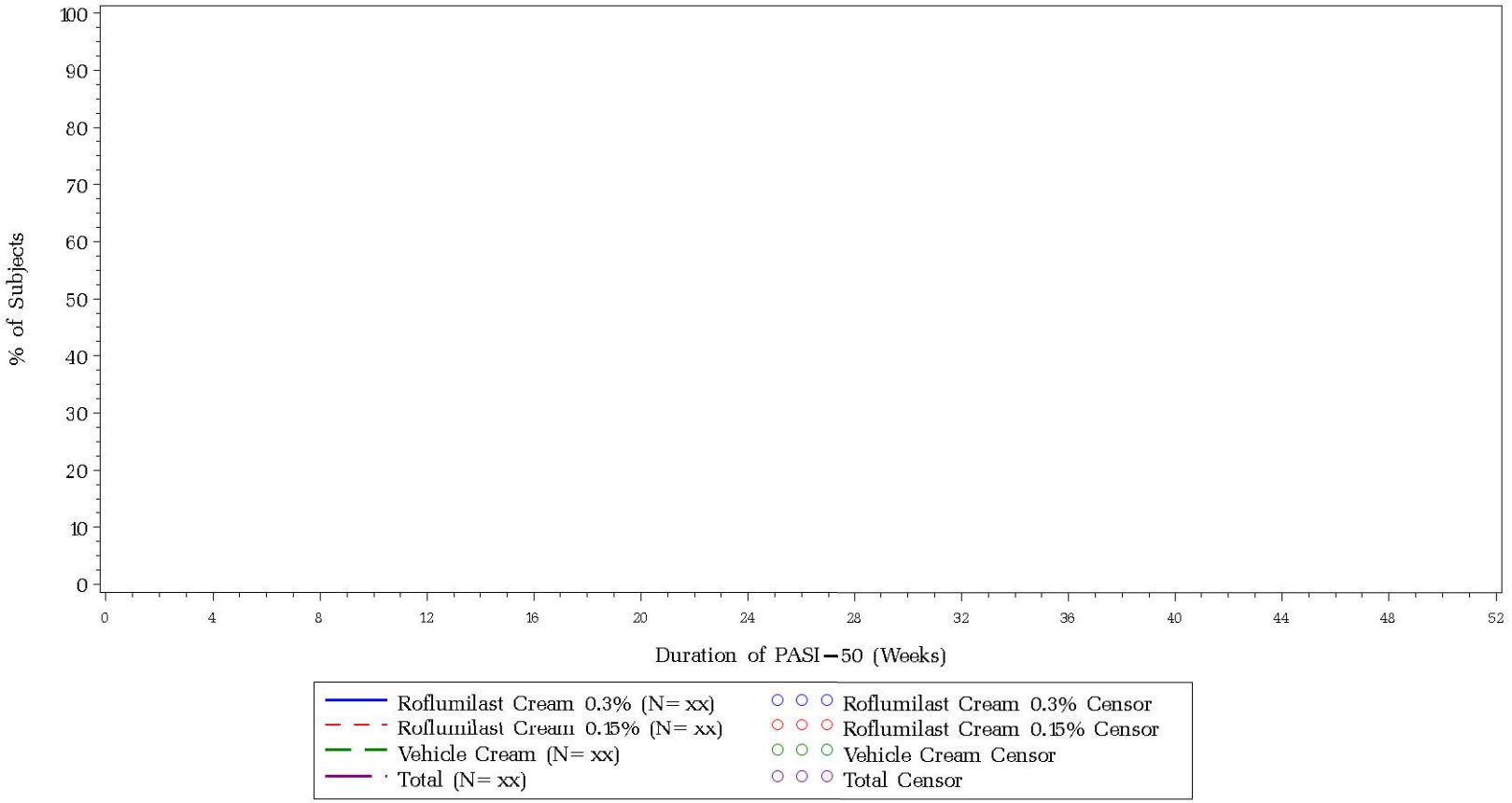
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Duration of PASI-50 (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.

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

Figure 14.2.8.1.2: Sensitivity Kaplan-Meier Plot of Duration of PASI-50
(Safety Population: Cohort 1)



Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to entrance into the ARQ-151-202 study.

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

Table 14.2.8.2: Summary of Duration of PASI-50
(Safety Population: Cohort 2)

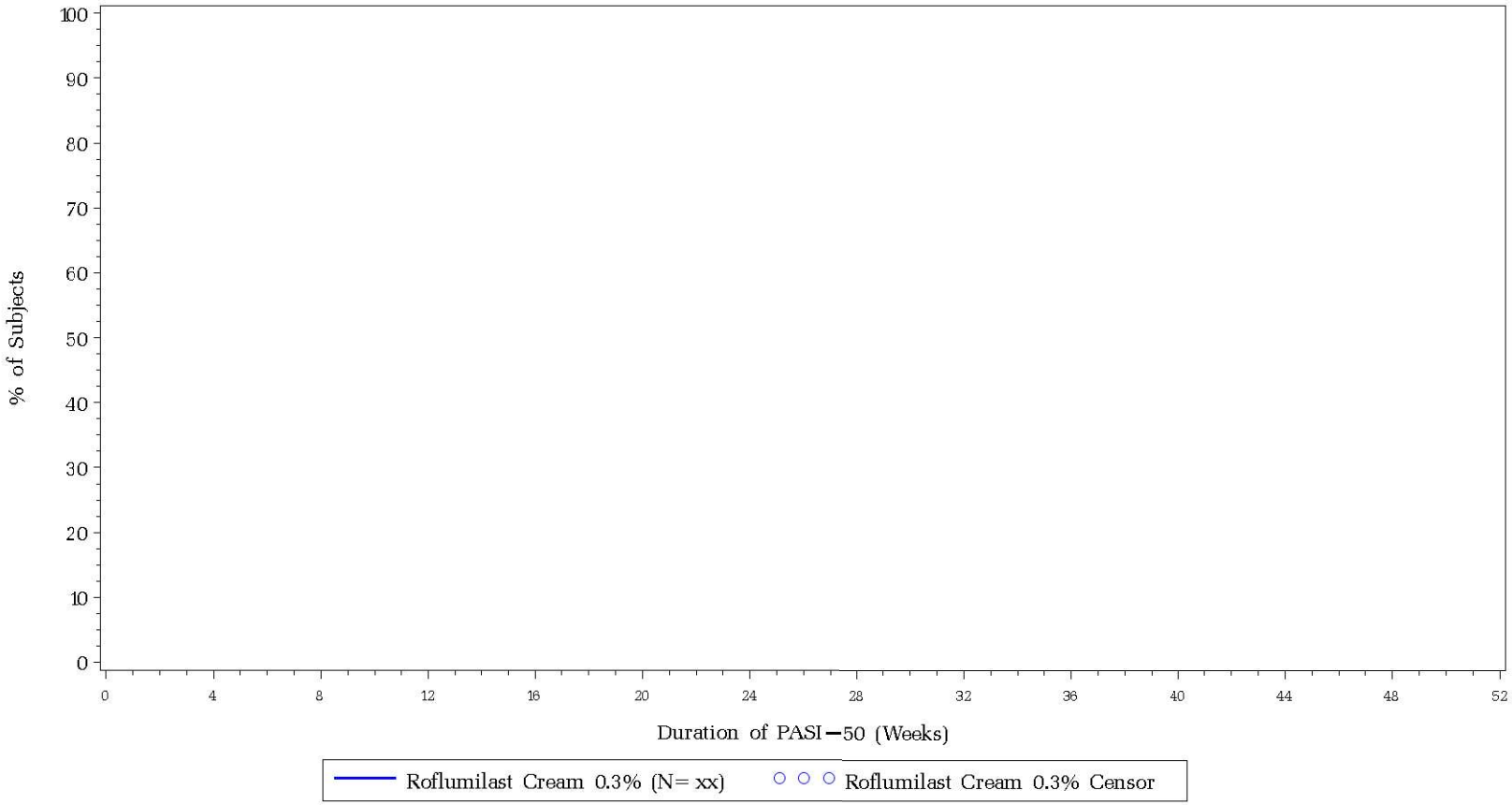
	Roflumilast Cream 0.3% (N=xx)
Duration of PASI-50 (Weeks)	
n	xx
Median[a]	xx
Disease Recurrence	xx (xx%)
Censored	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.

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

Figure 14.2.8.2: Kaplan-Meier Plot of Duration of PASI-50
(Safety Population: Cohort 2)



Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.3: Summary of Duration of PASI-50
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Duration of PASI-50 (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)

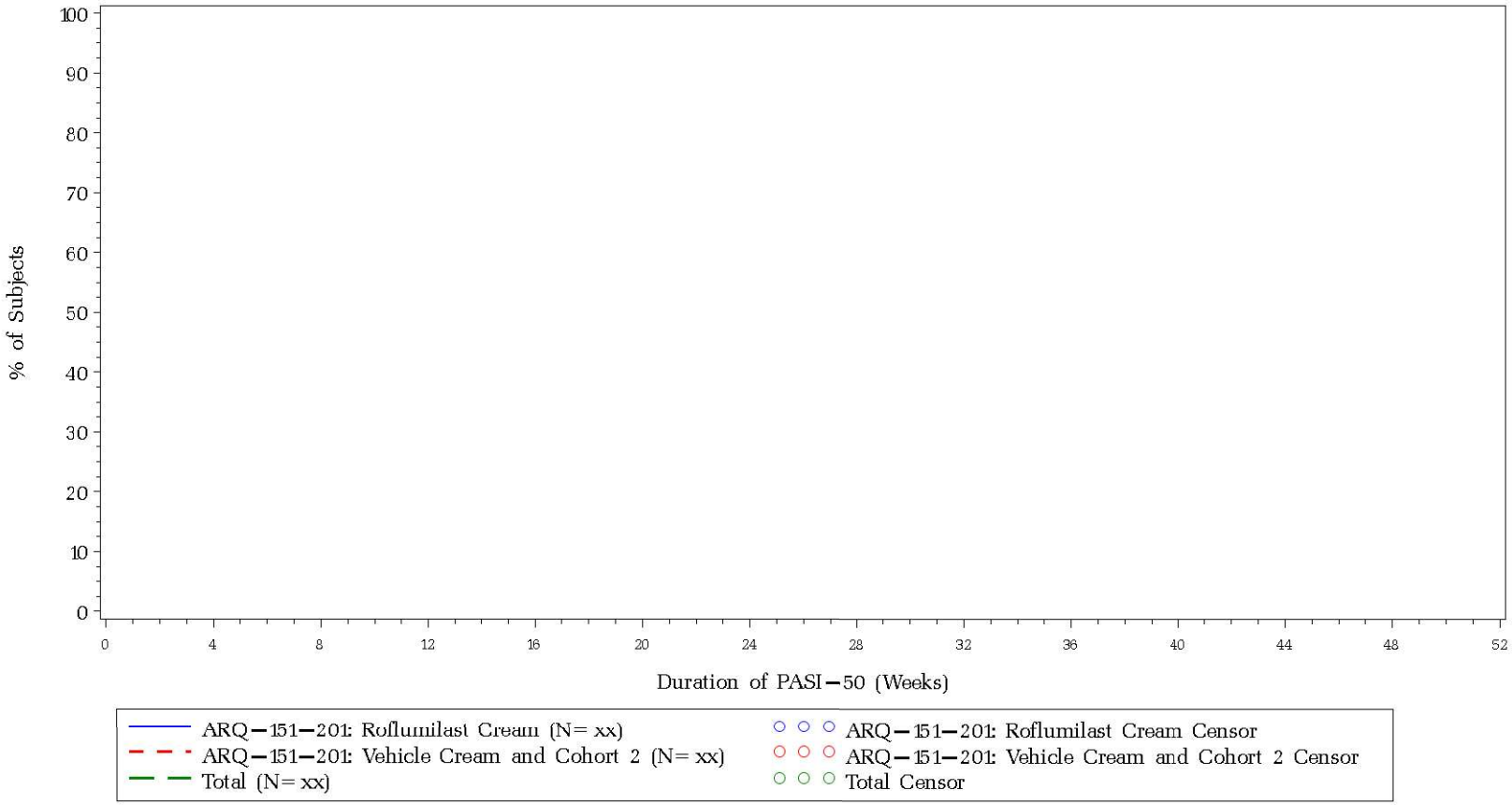
[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.

Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Figure 14.2.8.3: Kaplan-Meier Plot of Duration of PASI-50
(Safety Population)



Note: Duration of PASI-50 is defined as the time from the first observation of a 50% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 50% reduction from baseline. The duration of PASI-50 for subjects who end treatment with PASI score at least 50% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Table 14.2.9.1: Summary of Duration of PASI-75
(Safety Population: Cohort 1)

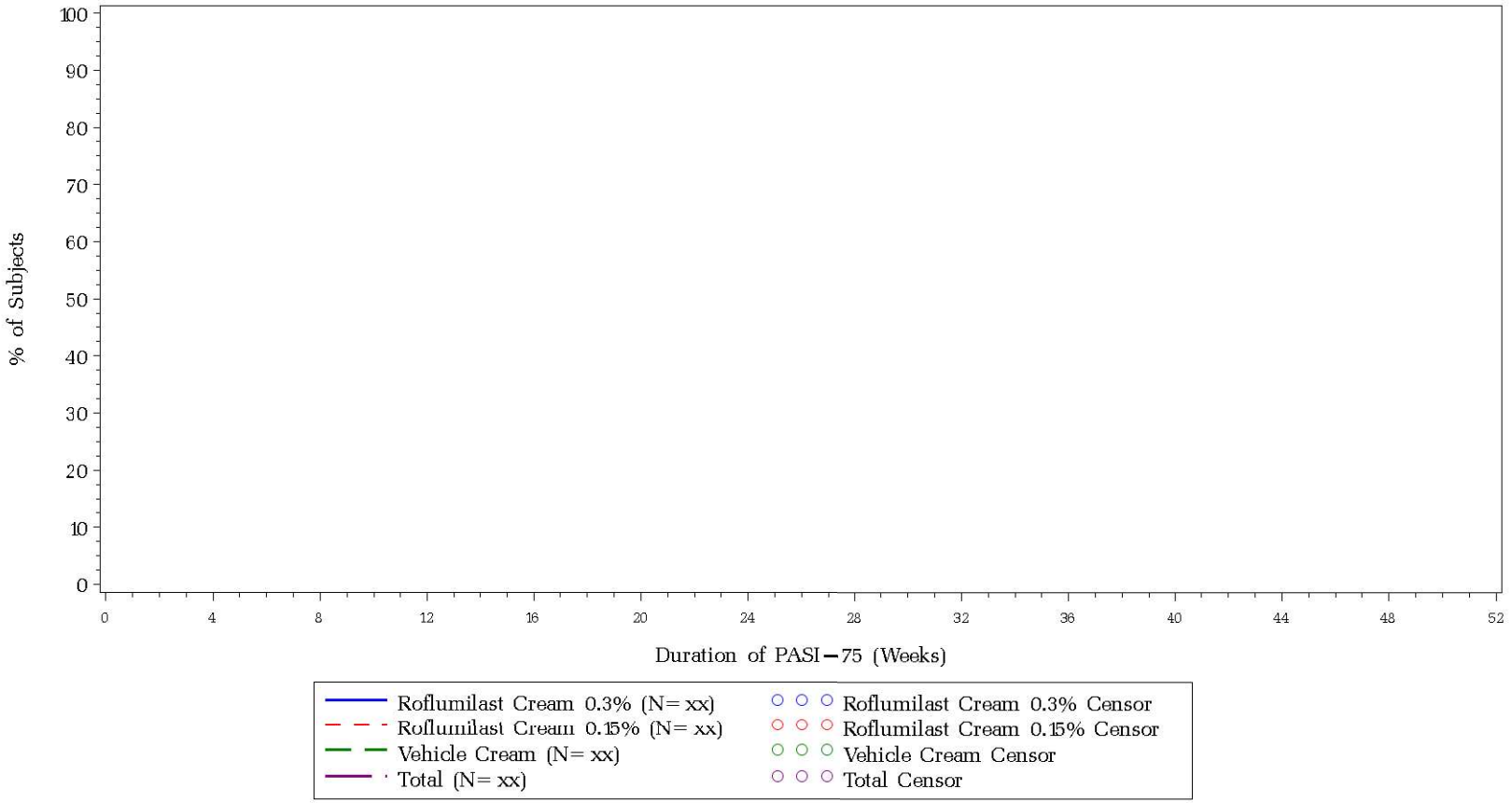
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Duration of PASI-75 (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-75 is defined as the time from the first observation of a 75% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 75% reduction from baseline. The duration of PASI-75 for subjects who end treatment with PASI score at least 75% less than baseline will be censored at the last disease assessment date.

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

Figure 14.2.9.1: Kaplan-Meier Plot of Duration of PASI-75
(Safety Population: Cohort 1)



Note: Duration of PASI-75 is defined as the time from the first observation of a 75% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 75% reduction from baseline. The duration of PASI-75 for subjects who end treatment with PASI score at least 75% less than baseline will be censored at the last disease assessment date.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.2: Summary of Duration of PASI-75
(Safety Population: Cohort 2)

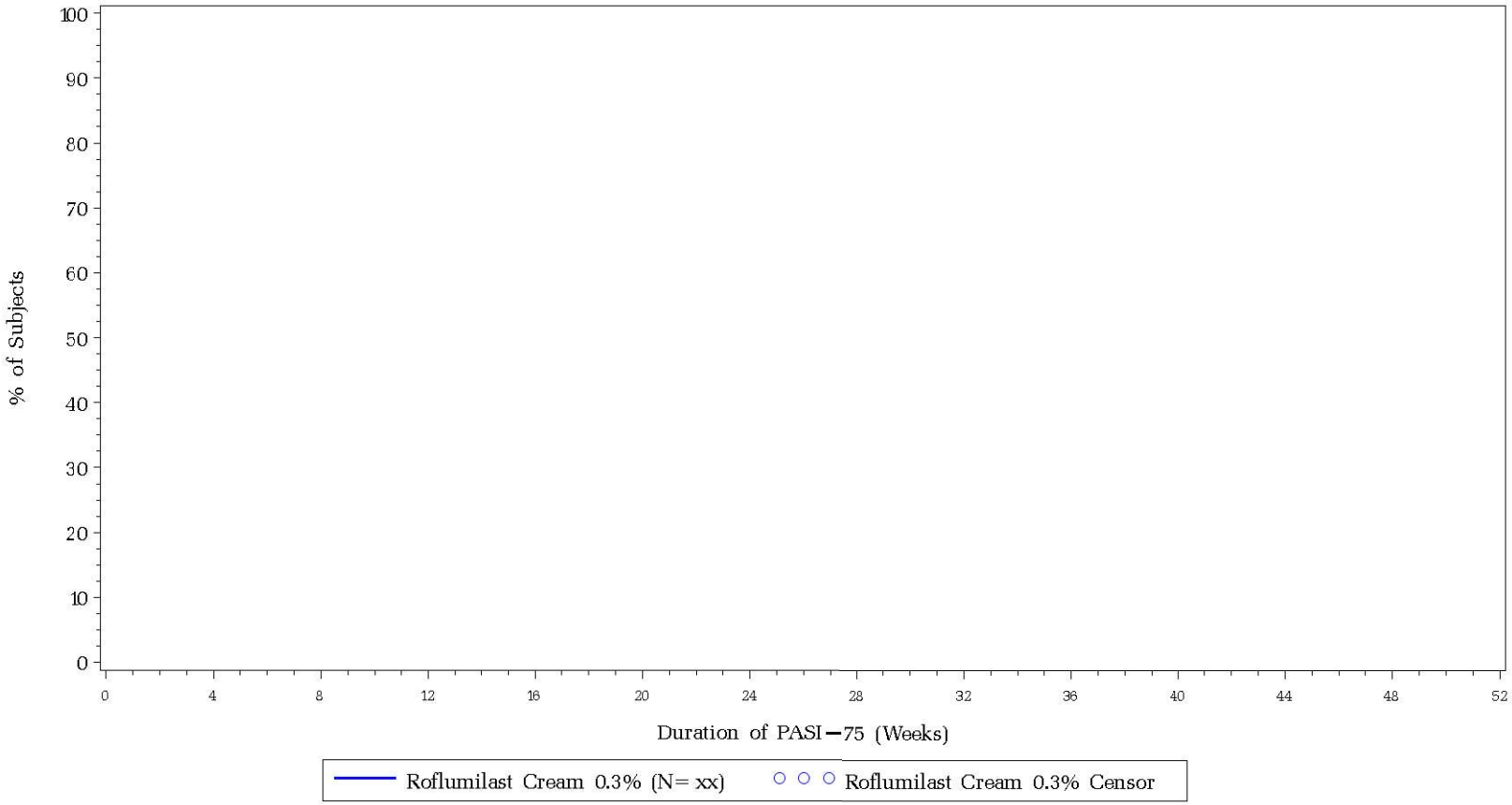
	Roflumilast Cream 0.3% (N=xx)
Duration of PASI-75 (Weeks)	
n	xx
Median[a]	xx
Disease Recurrence	xx (xx%)
Censored	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-75 is defined as the time from the first observation of a 75% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 75% reduction from baseline. The duration of PASI-75 for subjects who end treatment with PASI score at least 75% less than baseline will be censored at the last disease assessment date.

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

Figure 14.2.9.2: Kaplan-Meier Plot of Duration of PASI-75
(Safety Population: Cohort 2)



Note: Duration of PASI-75 is defined as the time from the first observation of a 75% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 75% reduction from baseline. The duration of PASI-75 for subjects who end treatment with PASI score at least 75% less than baseline will be censored at the last disease assessment date.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.3: Summary of Duration of PASI-75
(Safety Population)

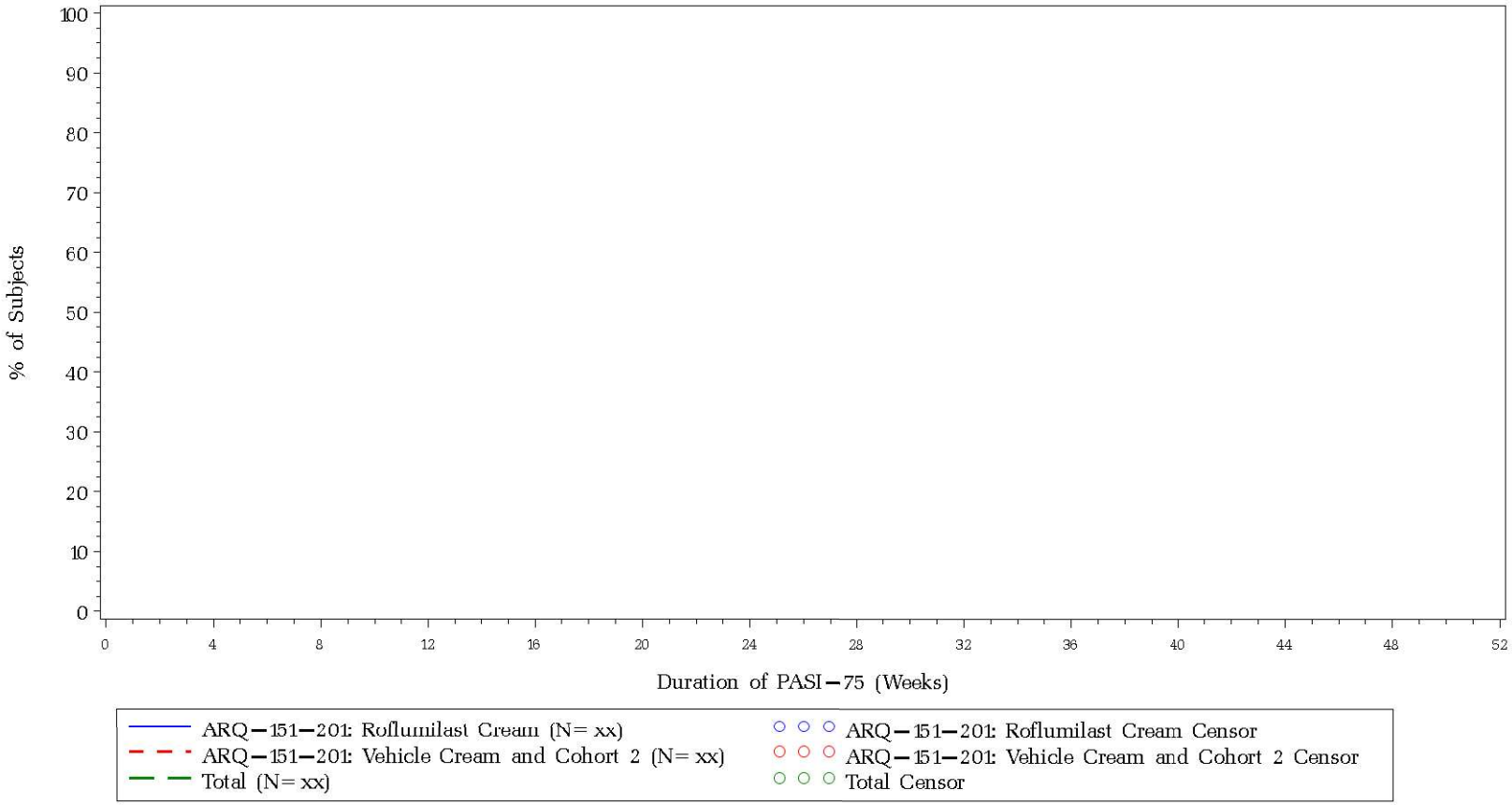
	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Duration of PASI-75 (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Duration of PASI-75 is defined as the time from the first observation of a 75% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 75% reduction from baseline. The duration of PASI-75 for subjects who end treatment with PASI score at least 75% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Figure 14.2.9.3: Kaplan-Meier Plot of Duration of PASI-75
(Safety Population)



Note: Duration of PASI-75 is defined as the time from the first observation of a 75% reduction from baseline in the Psoriasis Area and Severity Index (PASI) to the first subsequent time a subjects's PASI score is greater than a 75% reduction from baseline. The duration of PASI-75 for subjects who end treatment with PASI score at least 75% less than baseline will be censored at the last disease assessment date.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.

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

Table 14.2.10.1: Summary of Time to Disease Recurrence
(Safety Population: Cohort 1)

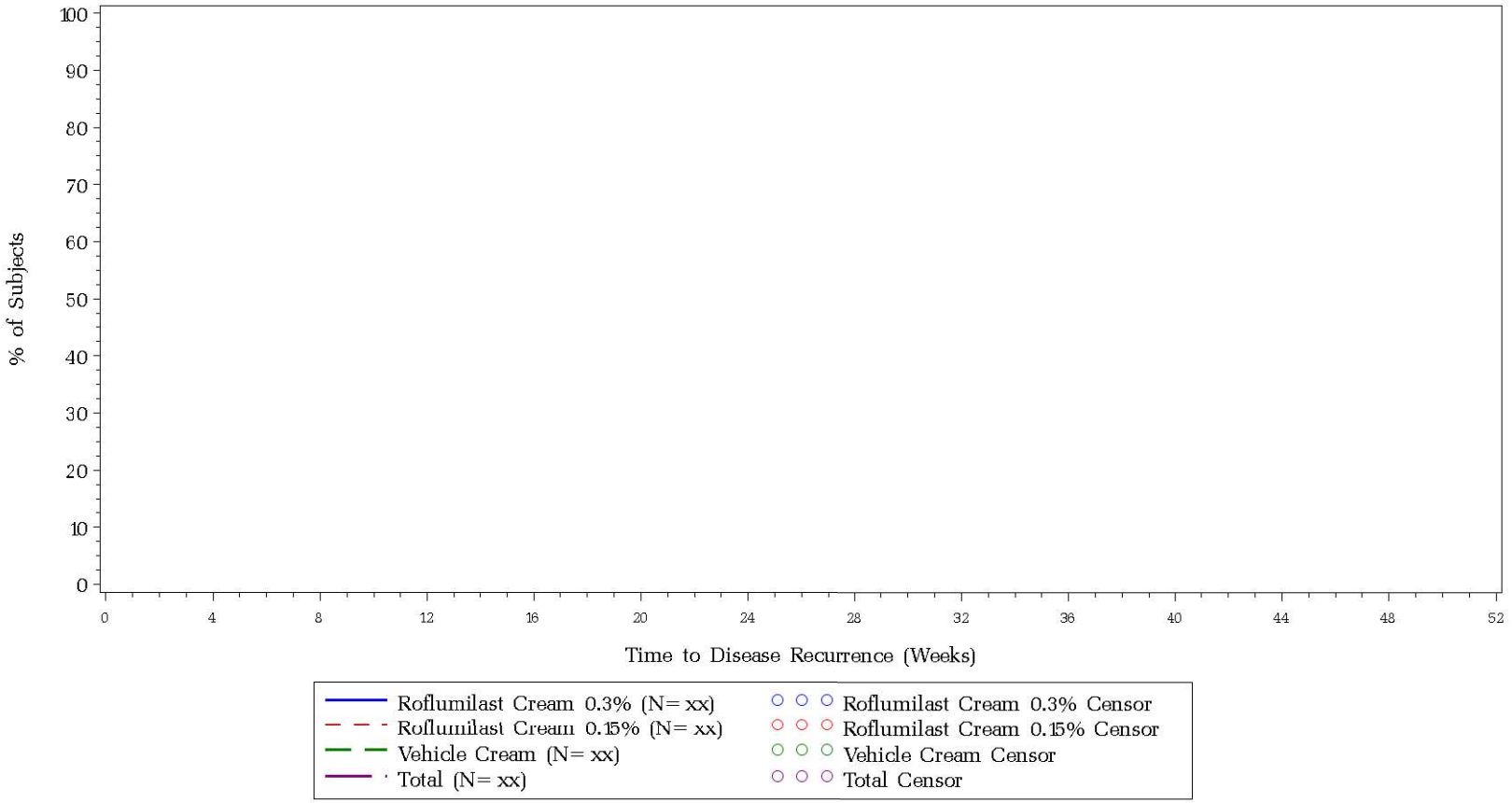
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Time to Disease Recurrence (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Restricted to subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment.

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

Figure 14.2.10.1: Kaplan-Meier Plot of Time to Disease Recurrence
(Safety Population: Cohort 1)



Note: Restricted to subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.10.2: Summary of Time to Disease Recurrence
(Safety Population: Cohort 2)

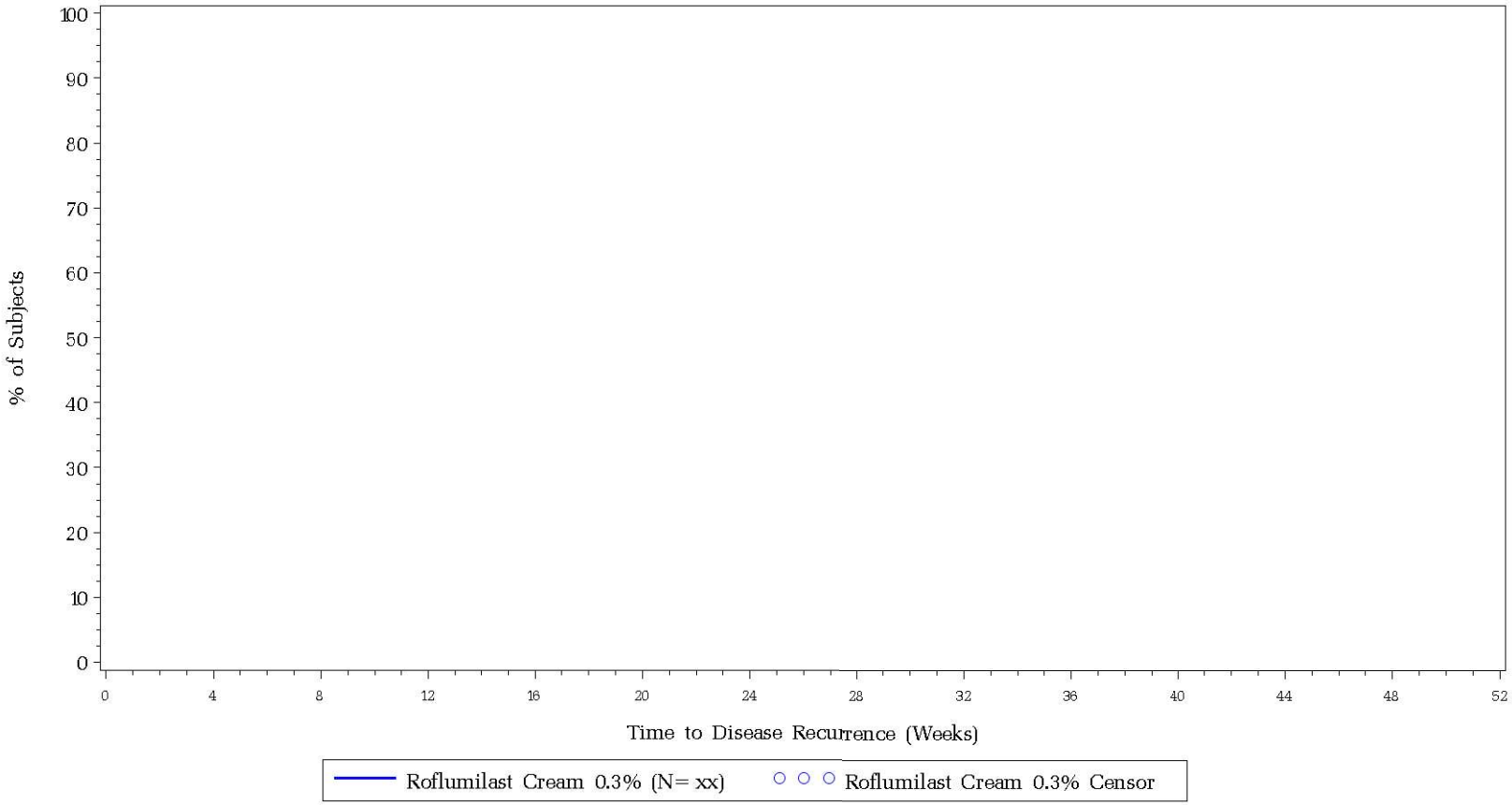
	Roflumilast Cream 0.3% (N=xx)
Duration of PASI-75 (Weeks)	
n	xx
Median[a]	xx
Disease Recurrence	xx (xx%)
Censored	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Restricted to subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment.

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

Figure 14.2.10.2: Kaplan-Meier Plot of Time to Disease Recurrence
(Safety Population: Cohort 2)



Note: Restricted to subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.10.3: Summary of Time to Disease Recurrence
(Safety Population)

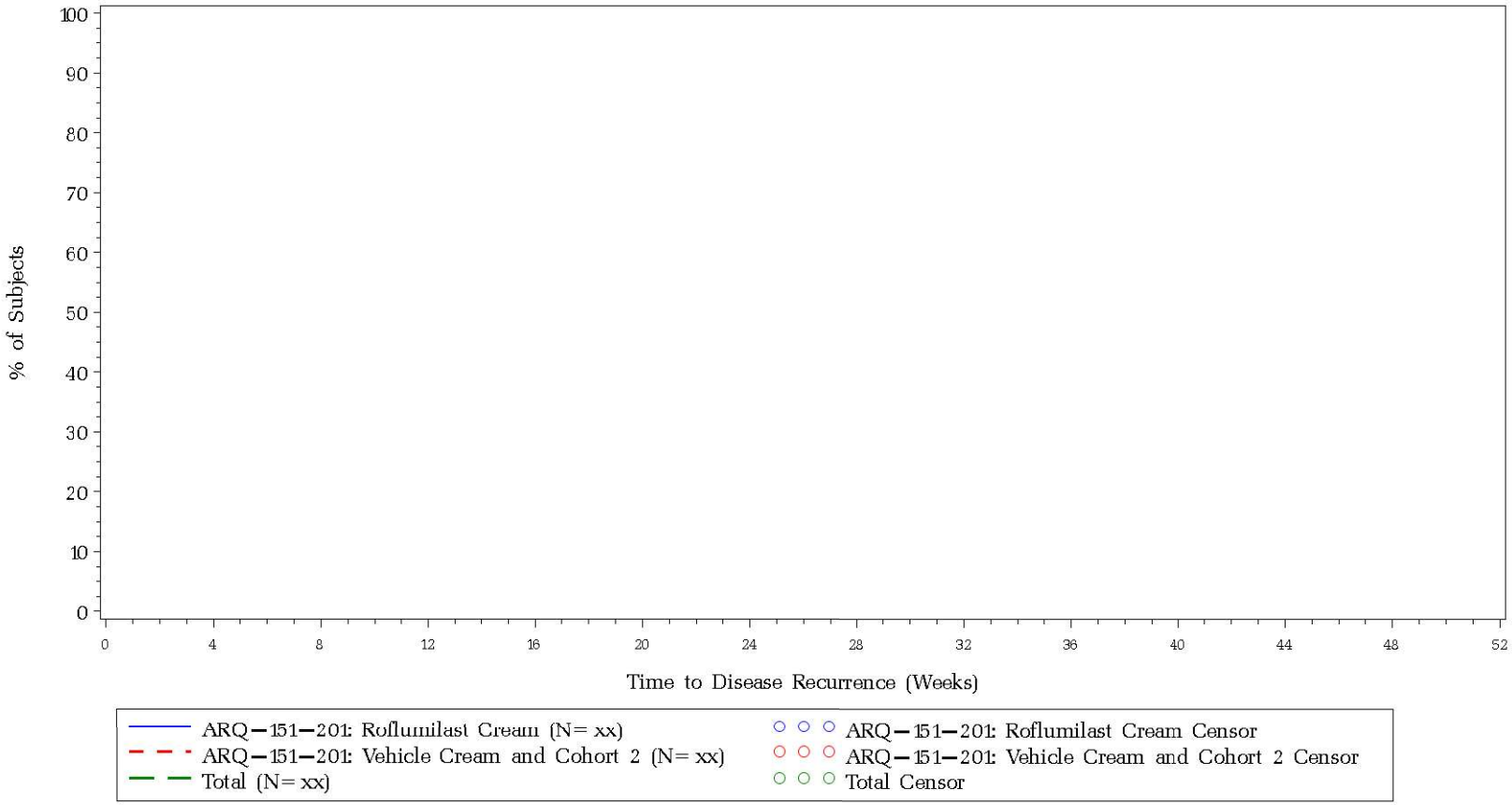
	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Duration of PASI-75 (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Disease Recurrence	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Restricted to subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment.

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

Figure 14.2.10.3: Kaplan-Meier Plot of Time to Disease Recurrence
(Safety Population)



Note: Restricted to subjects who stop therapy due to disease clearance. Time to disease recurrence is defined as the time from the last dose of ARQ-151 to the first observation of an IGA score of 2 or greater. The time to disease recurrence among subjects with clearance at the end of the study observation period will be censored at the last observed disease assessment.

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

Table 14.2.11.1: Summary of Disease Control
(Safety Population: Cohort 1)

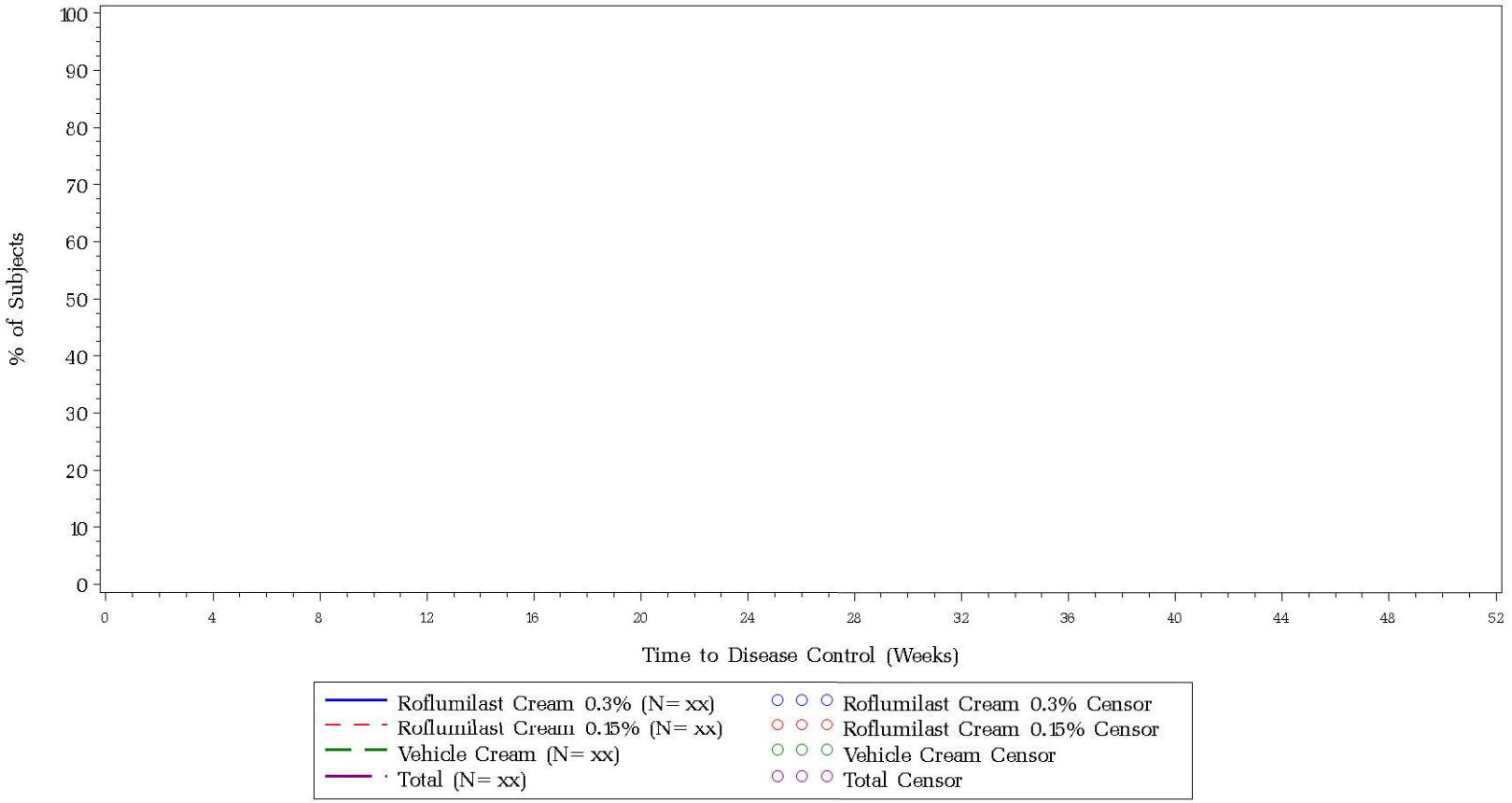
	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Time to Disease Control (Weeks)				
n	xx	xx	xx	xx
Median[a]	xx	xx	xx	xx
Disease Control	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Restricted to subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of Clear or Almost Clear. The time to disease control among subjects who do not achieve an IGA score of Clear or Almost Clear by the end of the study observation period will be censored at the last observed disease assessment.

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

Figure 14.2.11.1: Kaplan-Meier Plot of Time to Disease Control
(Safety Population: Cohort 1)



Note: Restricted to subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.2: Summary of Disease Control
(Safety Population: Cohort 2)

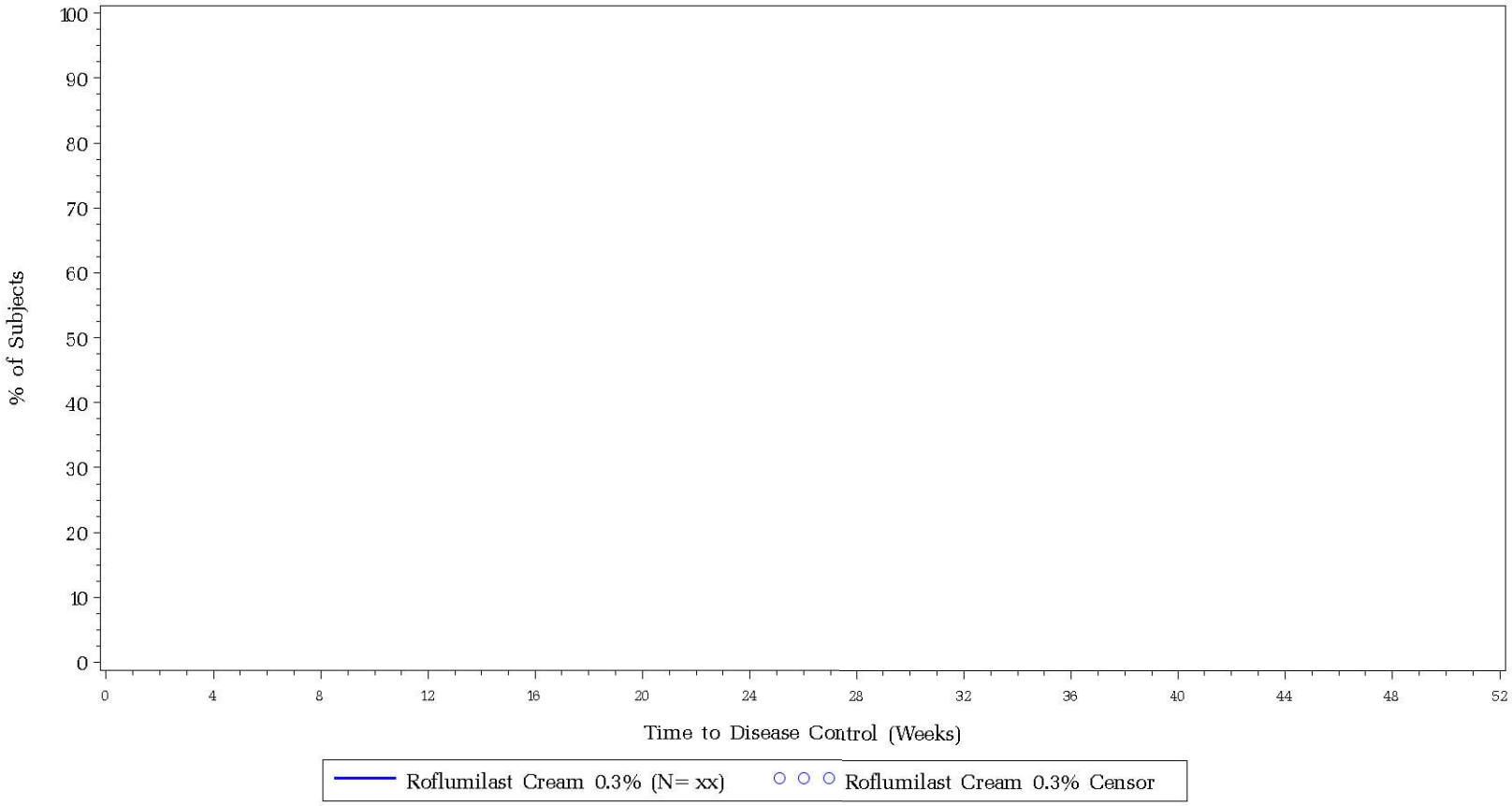
	Roflumilast Cream 0.3% (N=xx)
Time to Disease Control (Weeks)	
n	xx
Median[a]	xx
Disease Control	xx (xx%)
Censored	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Restricted to subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.

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

Figure 14.2.11.2: Kaplan-Meier Plot of Time to Disease Control
(Safety Population: Cohort 2)



Note: Restricted to subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.3: Summary of Disease Control
(Safety Population)

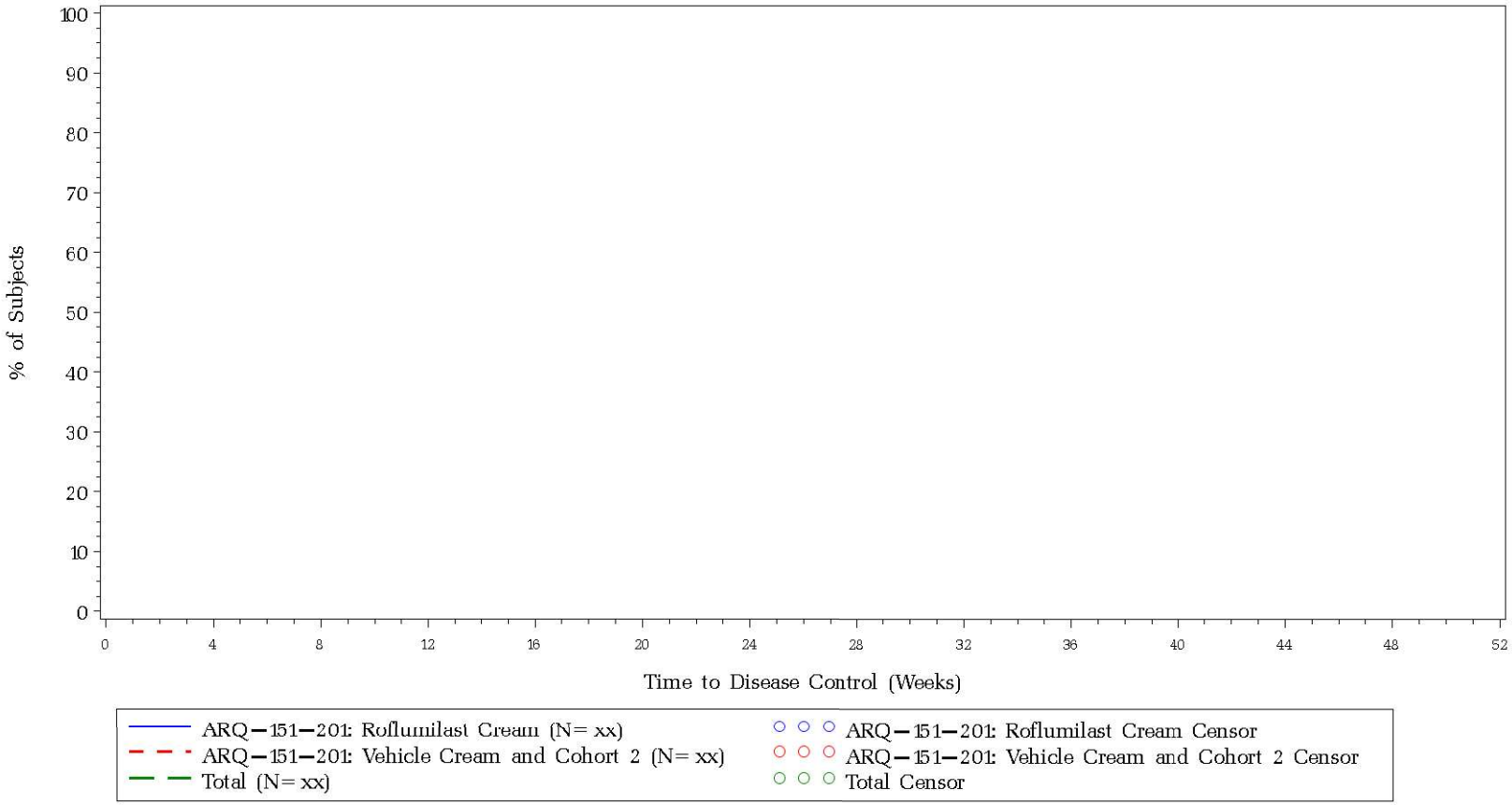
	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Time to Disease Control (Weeks)			
n	xx	xx	xx
Median[a]	xx	xx	xx
Disease Control	xx (xx%)	xx (xx%)	xx (xx%)
Censored	xx (xx%)	xx (xx%)	xx (xx%)

[a] Median determined using the Kaplan-Meier method.

Note: Restricted to subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.

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

Figure 14.2.11.3: Kaplan-Meier Plot of Time to Disease Control
(Safety Population)



Note: Restricted to subjects who restart therapy after having stopped therapy due to disease clearance. Time to disease control is the time from the restart of therapy to the first reported IGA score of 0 or 1. The time to disease control among subjects who do not achieve an IGA score of 0 or 1 by the end of the study observation period will be censored at the last observed disease assessment.

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

Table 14.3.0.1.1: Summary of Extent of Exposure
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Number of Applications				
N	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Amount of Drug Used (g)				
N	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Completed >= 80% of Expected Doses	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Completed < 80% of Expected Doses	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Compliant[a]	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Compliant	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

[a] A subject was considered compliant with the dosing regimen if the subject did not miss more than 3 consecutive days dosing and applied >= 80% of expected doses while participating in the study.
Note: Lost to Follow-Up subjects were included using all available information.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.0.1.2: Summary of Extent of Exposure
(Safety Population: Cohort 2)

	Roflumilast Cream 0.3% (N=xx)
Number of Applications	
N	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Amount of Drug Used (g)	
N	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Completed >= 80% of Expected Doses	xx (xx%)
Completed < 80% of Expected Doses	xx (xx%)
Compliant[a]	xx (xx%)
Not Compliant	xx (xx%)

[a] A subject was considered compliant with the dosing regimen if the subject did not miss more than 3 consecutive days dosing and applied >= 80% of expected doses while participating in the study.
Note: Lost to Follow-Up subjects were included using all available information.

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

Table 14.3.0.1.3: Summary of Extent of Exposure
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Number of Applications			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Amount of Drug Used (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
Completed >= 80% of Expected Doses	xx (xx%)	xx (xx%)	xx (xx%)
Completed < 80% of Expected Doses	xx (xx%)	xx (xx%)	xx (xx%)
Compliant[a]	xx (xx%)	xx (xx%)	xx (xx%)
Not Compliant	xx (xx%)	xx (xx%)	xx (xx%)

[a] A subject was considered compliant with the dosing regimen if the subject did not miss more than 3 consecutive days dosing and applied >= 80% of expected doses while participating in the study.
Note: Lost to Follow-Up subjects were included using all available information.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.1: Summary of Local Tolerability
(Safety Population: Cohort 1)
(Page 1 of 3)

Investigator Local Tolerability Dermal Response	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline				
n	xx	xx	xx	xx
0 - no evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - definite edema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)	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%)	xx (xx.x%)
Week 4				
n	xx	xx	xx	xx
0 - no evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - definite edema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)	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%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.1: Summary of Local Tolerability
(Safety Population: Cohort 1)
(Page 2 of 3)

Investigator Local Tolerability Dermal Response	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
0 - no evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - definite edema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)	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%)	xx (xx.x%)
Week 24				
n	xx	xx	xx	xx
0 - no evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - definite edema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)	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%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.1: Summary of Local Tolerability
(Safety Population: Cohort 1)
(Page 3 of 3)

Investigator Local Tolerability Dermal Response	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
0 - no evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - definite edema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)	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%)	xx (xx.x%)
Week 52				
n	xx	xx	xx	xx
0 - no evidence of irritation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 - definite edema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)	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%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2: Summary of Local Tolerability
(Safety Population: Cohort 2)
(Page 1 of 3)

Investigator Local Tolerability Dermal Response	Roflumilast Cream 0.3% (N=xx)
Baseline	
n	xx
0 - no evidence of irritation	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)
4 - definite edema	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)
7 - strong reaction spreading beyond application site	xx (xx.x%)
Week 4	
n	xx
0 - no evidence of irritation	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)
4 - definite edema	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)
7 - strong reaction spreading beyond application site	xx (xx.x%)

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

Investigator Local Tolerability Dermal Response	Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
0 - no evidence of irritation	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)
4 - definite edema	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)
7 - strong reaction spreading beyond application site	xx (xx.x%)
Week 24	
n	xx
0 - no evidence of irritation	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)
4 - definite edema	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)
7 - strong reaction spreading beyond application site	xx (xx.x%)

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

Table 14.3.1.1.2: Summary of Local Tolerability
(Safety Population: Cohort 2)
(Page 3 of 3)

Investigator Local Tolerability Dermal Response	Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
0 - no evidence of irritation	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)
4 - definite edema	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)
7 - strong reaction spreading beyond application site	xx (xx.x%)
Week 52	
n	xx
0 - no evidence of irritation	xx (xx.x%)
1 - minimal erythema, barely perceptible	xx (xx.x%)
2 - definite erythema, readily visible; minimal edema or minimal popular response	xx (xx.x%)
3 - erythema and papules	xx (xx.x%)
4 - definite edema	xx (xx.x%)
5 - erythema, edema and papules	xx (xx.x%)
6 - vesicular eruption	xx (xx.x%)
7 - strong reaction spreading beyond application site	xx (xx.x%)

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

Table 14.3.1.1.3: Summary of Local Tolerability
(Safety Population)
(Page 1 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%		
Investigator Local Tolerability Dermal Response	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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 popular 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%)
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 popular 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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.3: Summary of Local Tolerability
(Safety Population)
(Page 2 of 3)

	ARQ-151-202: Roflumilast Cream 0.3%		
Investigator Local Tolerability Dermal Response	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
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 popular 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%)
Week 24			
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 popular 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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.3: Summary of Local Tolerability
(Safety Population)
(Page 3 of 3)

Investigator Local Tolerability Dermal Response	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
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 popular 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%)
Week 52			
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 popular 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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1: Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8)
(Safety Population: Cohort 1)
(Page 1 of 2)

Patient Health Questionnaire Depression Scale	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline				
n	xx	xx	xx	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4				
n	xx	xx	xx	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12				
n	xx	xx	xx	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1: Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8)
(Safety Population: Cohort 1)
(Page 2 of 2)

Patient Health Questionnaire Depression Scale	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 24				
n	xx	xx	xx	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 36				
n	xx	xx	xx	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 52				
n	xx	xx	xx	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.2: Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8)
(Safety Population: Cohort 2)
(Page 1 of 2)

Patient Health Questionnaire Depression Scale	Roflumilast Cream 0.3% (N=xx)
Baseline	
n	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)
Week 4	
n	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)
Week 12	
n	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8)
(Safety Population: Cohort 2)
(Page 2 of 2)

Patient Health Questionnaire Depression Scale	Roflumilast Cream 0.3% (N=xx)
Week 24	
n	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)
Week 36	
n	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)
Week 52	
n	xx
None - Minimal Depression (0 to 4)	xx (xx.x%)
Mild Depression (5 to 9)	xx (xx.x%)
Moderate Depression (10 to 14)	xx (xx.x%)
Moderately Severe Depression (15 to 19)	xx (xx.x%)
Severe Depression (20 to 24)	xx (xx.x%)

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

Table 14.3.1.2.3: Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8)
(Safety Population)
(Page 1 of 2)

Patient Health Questionnaire Depression Scale	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Baseline			
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 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 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 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 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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.3: Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8)
(Safety Population)
(Page 2 of 2)

Patient Health Questionnaire Depression Scale	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 24			
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 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 36			
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 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 52			
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 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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.1: Shift Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8) by Treatment Group
(Safety Population: Cohort 1)
(Page 1 of 8)

PHQ-8 for (ARQ-151-201: Roflumilast 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 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%)

	Week 24				
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).
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

PHQ-8 for (ARQ-151-201: Roflumilast Cream 0.3%)

	Week 36				
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 52				
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).
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to Programmer - Repeat for each treatment group (ARQ-151-201: Roflumilast Cream 0.15%; ARQ-151-201: Vehicle Cream; Total)

Table 14.3.1.3.2: Shift Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8) by Treatment Group
(Safety Population: Cohort 2)
(Page 1 of 2)

PHQ-8 for (Roflumilast 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 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%)

	Week 24				
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 Patient Health Questionnaire Depression Scale Assessments (PHQ-8) by Treatment Group
(Safety Population: Cohort 2)

PHQ-8 for (Roflumilast Cream 0.3%)

	Week 36				
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 52				
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)

Note to Programmer - Do not repeat for any other treatements.

Table 14.3.1.3.3: Shift Summary of Patient Health Questionnaire Depression Scale Assessments (PHQ-8) by Treatment Group
(Safety Population)
(Page 1 of 6)

PHQ-8 for (ARQ-151-201: Roflumilast 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 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%)

	Week 24				
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).
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

PHQ-8 for (ARQ-151-201: Roflumilast Cream)

	Week 36				
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 52				
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).
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to Programmer - Repeat for each treatment group (ARQ-151-201: Vehicle Cream and Cohort 2; Total)

Table 14.3.1.4.1.1: Number of Patients with Suicidal Ideation, Suicidal Behavior, and Self-Inurious Behavior without Suicidal Intent Based on the Columbia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
Events During Treatment	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Suicidal Ideation (1-5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1) Wish to be dead	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2) Non-specific active suicidal thoughts	xx (xx.x%)	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%)	xx (xx.x%)
4) Active suicidal ideation with some intent to act, without specific plan	xx (xx.x%)	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%)	xx (xx.x%)
Suicidal Behavior (6-10)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
6) Preparatory acts or behavior	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
7) Aborted attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
8) Interrupted attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
9) Non-fatal suicide attempt	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
10) Completed Suicide	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation or Behavior (1-10)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Self-injurious behavior without suicidal intent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.4.1.2: Number of Patients with Suicidal Ideation, Suicidal Behavior, and Self-Inurious Behavior without Suicidal Intent Based on the Columbia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population: Cohort 1)

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

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

Table 14.3.1.4.1.3: Number of Patients with Suicidal Ideation, Suicidal Behavior, and Self-Inurious Behavior without Suicidal Intent Based on the Columbia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
Events During Treatment	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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 14.3.1.4.2.1: Number of Patients with Suicidal-Related Treatment-Emergent Events Based on the Columbia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population: Cohort 1)

Treatment-Emergent (TE) Events	ARQ-151-202: Roflumilast Cream 0.3%							
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)		ARQ-151-201: Roflumilast Cream 0.15% (N=xx)		ARQ-151-201: Vehicle Cream (N=xx)		Total (N=xx)	
	N	n[a] (%)	N	n[a] (%)	N	n[a] (%)	N	n[a] (%)
TE suicidal ideation (1-5) compared to recent history [b]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
TE serious suicidal ideation (0-3 to 4-5) compared to recent history [c]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Emergence of serious suicidal ideation (0 to 4-5) compared to recent history [d]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Improvement in suicidal ideation at endpoint compared with baseline [e]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Emergence of suicidal behavior (6-10) compared to all prior history [f]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

Note: Restricted to subjects with at least one post-treatment C-SSRS assessment.
[a] Counts reflect numbers of subjects who experienced the event at least once post-treatment.
[b] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is non-missing and <5.
[c] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is 0-3.
[d] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is 0.
[e] N=Number of subjects whose suicidal ideation score is non-missing and >0 just prior to treatment.
[f] N=Number of subjects 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 14.3.1.4.2.2: Number of Patients with Suicidal-Related Treatment-Emergent Events Based on the Columbia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population: Cohort 2)

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

Note: Restricted to subjects with at least one post-treatment C-SSRS assessment.
[a] Counts reflect numbers of subjects who experienced the event at least once post-treatment.
[b] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is non-missing and <5.
[c] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is 0-3.
[d] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is 0.
[e] N=Number of subjects whose suicidal ideation score is non-missing and >0 just prior to treatment.
[f] N=Number of subjects 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 14.3.1.4.2.3: Number of Patients with Suicidal-Related Treatment-Emergent Events Based on the Columbia-Suicide Severity Rating Scale (C-SSRS) During Treatment
(Safety Population)

Treatment-Emergent (TE) Events	ARQ-151-202: Roflumilast Cream 0.3%					
	ARQ-151-201: Roflumilast Cream (N=xx)		ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)		Total (N=xx)	
	N	n[a] (%)	N	n[a] (%)	N	n[a] (%)
TE suicidal ideation (1-5) compared to recent history[b]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
TE serious suicidal ideation (0-3 to 4-5) compared to recent history[c]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Emergence of serious suicidal ideation (0 to 4-5) compared to recent history[d]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Improvement in suicidal ideation at endpoint compared with baselined[e]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Emergence of suicidal behavior (6-10) compared to all prior history[f]	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

Note: Restricted to subjects with at least one post-treatment C-SSRS assessment.
[a] Counts reflect numbers of subjects who experienced the event at least once post-treatment.
[b] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is non-missing and <5.
[c] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is 0-3.
[d] N=Number of subjects with at least one post-baseline suicidal ideation score and whose maximum C-SSRS suicidal ideation score during the past 6 months is 0.
[e] N=Number of subjects whose suicidal ideation score is non-missing and >0 just prior to treatment.
[f] N=Number of subjects 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 14.3.2.1.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Number (%) of Subjects Reporting At Least One TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of TEAEs	xx	xx	xx	xx
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx	xx
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity by Subject				
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject				
Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.1.1.1.: Summary of Treatment Emergent Adverse Events Characteristics and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.1.1.2: Summary of Post Active Treatment-Emergent Adverse Events Characteristics (Safety Population: Cohort 1)

Table 14.3.2.1.2: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population: Cohort 2)

	Roflumilast Cream 0.3% (N=xx)
Number (%) of Subjects Reporting At Least One TEAE	xx (xx.x%)
Number of TEAEs	xx
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)
Number of Serious TEAEs	xx
Number (%) of Subjects who Died	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	xx (xx.x%)
Maximum Severity by Subject	
Grade 5	xx (xx.x%)
Grade 4	xx (xx.x%)
Grade 3	xx (xx.x%)
Grade 2	xx (xx.x%)
Grade 1	xx (xx.x%)
Maximum Relationship by Subject	
Likely	xx (xx.x%)
Probably	xx (xx.x%)
Possibly	xx (xx.x%)
Unlikely	xx (xx.x%)
Unrelated	xx (xx.x%)

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1.3.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Number (%) of Subjects Reporting At Least One TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of TEAEs	xx	xx	xx
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	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 event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.1.3.1.: Summary of Treatment Emergent Adverse Events Characteristics and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.1.3.2: Summary of Post Active Treatment-Emergent Adverse Events Characteristics (Safety Population)

Table 14.3.2.2.1.1: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population: Cohort 1)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	 ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	 ARQ-151-201: Vehicle Cream (N=xx)	 Total (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: MedDRA dictionary (Version xx)
Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to the programmer: Sort the table by descending total frequency of system organ class and descending total frequency of preferred terms within each system organ class. Sort all remaining AE tables in the same fashion.

Table 14.3.2.2.1.2: Summary of Post Active Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
System Organ Class[a] Preferred Term	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: MedDRA dictionary (Version xx)

Note: Post active treatment-emergent adverse event defined as event with an onset on or after the date of the first dose of active study drug application in either ARQ-151-201 or ARQ-151-202 study.

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

Table 14.3.2.2.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population: Cohort 2)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Roflumilast Cream 0.3% (N=xx)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: MedDRA dictionary (Version xx)
Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.2.3.1: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class[a] Preferred Term	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream (N=xx)	 ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	 Total (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%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: MedDRA dictionary (Version xx)
Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to the programmer: Sort the table by alphabetical order of system organ class and descending total frequency of preferred terms within each system organ class. Sort all remaining AE tables in the same fashion.

Repeat Table 14.3.2.2.3.1.: Summary of Treatment Emergent Adverse Events by MedDRA System Organ Class and Preferred Term - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.2.3.2: Summary of Post Active Treatment-Emergent Adverse Events System Organ Class and Preferred Term (Safety Population)

Table 14.3.2.3.1.1: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population: Cohort 1)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	ARQ-151-202: Roflumilast Cream 0.3%			
		ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)

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

Repeat Table 14.3.2.3.1.1.: Summary of Treatment Emergent Adverse Events by Severity - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.3.1.2: Summary of Post Active Treatment-Emergent Adverse Events by Severity (Safety Population: Cohort 1)

Table 14.3.2.3.2: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population: Cohort 2)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	Roflumilast Cream 0.3% (N=xx)
System Organ Class	Grade 5	xx (xx.x%)
	Grade 4	xx (xx.x%)
	Grade 3	xx (xx.x%)
	Grade 2	xx (xx.x%)
	Grade 1	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)
	Grade 4	xx (xx.x%)
	Grade 3	xx (xx.x%)
	Grade 2	xx (xx.x%)
	Grade 1	xx (xx.x%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application.
MedDRA dictionary (Version xx)

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

Table 14.3.2.3.3.1: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
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 MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)

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

Repeat Table 14.3.2.3.3.1.: Summary of Treatment Emergent Adverse Events by Severity - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.3.3.2: Summary of Post Active Treatment-Emergent Adverse Events by Severity (Safety Population)

Table 14.3.2.4.1.1: Summary of Treatment-Emergent Adverse Events by Relationship
(Safety Population: Cohort 1)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151-202: Roflumilast Cream 0.3%			
		ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
System Organ Class	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)

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

Repeat Table 14.3.2.4.1.1.: Summary of Treatment Emergent Adverse Events by Relationship - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.4.1.2: Summary of Post Active Treatment-Emergent Adverse Events by Relationship (Safety Population: Cohort 1)

Table 14.3.2.4.2: Summary of Treatment-Emergent Adverse Events by Relationship
(Safety Population: Cohort 2)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Roflumilast Cream 0.3% (N=xx)
System Organ Class	Likely	xx (xx.x%)
	Probably	xx (xx.x%)
	Possibly	xx (xx.x%)
	Unlikely	xx (xx.x%)
	Unrelated	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)
	Probably	xx (xx.x%)
	Possibly	xx (xx.x%)
	Unlikely	xx (xx.x%)
	Unrelated	xx (xx.x%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application.
MedDRA dictionary (Version xx)

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

Table 14.3.2.4.3.1: Summary of Treatment-Emergent Adverse Events by Relationship
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
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%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.4.3.1: Summary of Treatment Emergent Adverse Events by Relationship - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.4.3.2: Summary of Post Active Treatment-Emergent Adverse Events by Relationship (Safety Population)

Table 14.3.2.5.1.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx	xx
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity by Subject				
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject				
Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.5.1.1.: Summary of Treatment Emergent Serious Adverse Events Characteristics - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.5.1.2: Summary of Post Active Treatment-Emergent Serious Adverse Events Characteristics (Safety Population: Cohort 1)

Table 14.3.2.5.2: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population: Cohort 2)

	Roflumilast Cream 0.3% (N=xx)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)
Number of Serious TEAEs	xx
Number (%) of Subjects who Died	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	xx (xx.x%)
Maximum Severity by Subject	
Grade 5	xx (xx.x%)
Grade 4	xx (xx.x%)
Grade 3	xx (xx.x%)
Grade 2	xx (xx.x%)
Grade 1	xx (xx.x%)
Maximum Relationship by Subject	
Likely	xx (xx.x%)
Probably	xx (xx.x%)
Possibly	xx (xx.x%)
Unlikely	xx (xx.x%)
Unrelated	xx (xx.x%)

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.5.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)

	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx	xx
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	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 event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.5.3.1.: Summary of Treatment Emergent Serious Adverse Events Characteristics - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.5.3.2: Summary of Post Active Treatment-Emergent Serious Adverse Events Characteristics (Safety Population)

Table 14.3.2.6.1.1: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population: Cohort 1)
(Page 1 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
System Organ Class[a] Preferred Term	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: MedDRA dictionary (Version xx)

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.

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

Repeat Table 14.3.2.6.1.1.: Summary of Treatment Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term- and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.6.1.2: Summary of Post Active Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population: Cohort 1)

Table 14.3.2.6.2: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population: Cohort 2)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Roflumilast Cream 0.3% (N=xx)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)

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

Table 14.3.2.6.3.1: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream (N=xx)	 ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	 Total (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%)

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

Note: MedDRA dictionary (Version xx)

Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.

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

Repeat Table 14.3.2.6.3.1: Summary of Treatment Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term- and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.6.3.2: Summary of Post Active Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Table 14.3.2.7.1.1: Summary of Treatment-Emergent Serious Adverse Events by Severity
(Safety Population: Cohort 1)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Vehicle Cream (N=xx)	ARQ-151-202: Roflumilast Cream 0.3% Total (N=xx)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)

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

Repeat Table 14.3.2.7.1.1.: Summary of Treatment Emergent Serious Adverse Events by Severity- and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.7.1.2: Summary of Post Active Treatment-Emergent Serious Adverse Events by Severity (Safety Population: Cohort 1)

Table 14.3.2.7.2: Summary of Treatment-Emergent Serious Adverse Events by Severity
(Safety Population: Cohort 2)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	Roflumilast Cream 0.3% (N=xx)
System Organ Class	Grade 5	xx (xx.x%)
	Grade 4	xx (xx.x%)
	Grade 3	xx (xx.x%)
	Grade 2	xx (xx.x%)
	Grade 1	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)
	Grade 4	xx (xx.x%)
	Grade 3	xx (xx.x%)
	Grade 2	xx (xx.x%)
	Grade 1	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more serious adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application.
MedDRA dictionary (Version xx)

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

Table 14.3.2.7.3.1: Summary of Treatment-Emergent Serious Adverse Events by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
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 serious adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.7.3.1: Summary of Treatment Emergent Serious Adverse Events by Severity- and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.7.3.2: Summary of Post Active Treatment-Emergent Serious Adverse Events by Severity (Safety Population)

Table 14.3.2.8.1.1: Summary of Treatment-Emergent Serious Adverse Events by Relationship
(Safety Population: Cohort 1)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
System Organ Class	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Probably	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Possibly	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)

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

Repeat Table 14.3.2.8.1.1.: Summary of Treatment Emergent Serious Adverse Events by Relationship - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.8.1.2: Summary of Post Active Treatment-Emergent Serious Adverse Events by Relationship (Safety Population: Cohort 1)

Table 14.3.2.8.2: Summary of Treatment-Emergent Serious Adverse Events by Relationship
(Safety Population: Cohort 2)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Roflumilast Cream 0.3% (N=xx)
System Organ Class	Likely	xx (xx.x%)
	Probably	xx (xx.x%)
	Possibly	xx (xx.x%)
	Unlikely	xx (xx.x%)
	Unrelated	xx (xx.x%)
Preferred Term	Likely	xx (xx.x%)
	Probably	xx (xx.x%)
	Possibly	xx (xx.x%)
	Unlikely	xx (xx.x%)
	Unrelated	xx (xx.x%)

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

Table 14.3.2.8.3.1: Summary of Treatment-Emergent Serious Adverse Events by Relationship
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-202: Roflumilast Cream 0.3% ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
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%)

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

Note: Treatment-emergent adverse event defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.
MedDRA dictionary (Version xx)
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.2.8.3.1.: Summary of Treatment Emergent Serious Adverse Events by Relationship - and update footnote to:

Note: Post active treatment-emergent adverse event defined as event with an onset date on or after the date of first dose of active study drug in either ARQ-151-201 or ARQ-151-202.:

For the following tables:

Table 14.3.2.8.3.2: Summary of Post Active Treatment-Emergent Serious Adverse Events by Relationship (Safety Subjects)

Table 14.3.3.1.1.1: Summary of Chemistry Laboratory Results
(Safety Population: Cohort 1)
(Page 1 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 4				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1.1.1: Summary of Chemistry Laboratory Results
(Safety Population: Cohort 1)

	ARQ-151-202: Roflumilast Cream 0.3%			
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 24				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1.1.1: Summary of Chemistry Laboratory Results
(Safety Population: Cohort 1)
(Page 3 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 52				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.3.1.1.1: Summary of Chemistry Laboratory Results

For the following tables:

Table 14.3.3.1.2.1: Summary of Hematology Laboratory Results (Safety Population: Cohort 1)
Table 14.3.3.1.3.1: Summary of Urinalysis Laboratory Results (Safety Population: Cohort 1)

Table 14.3.3.1.1.2: Summary of Chemistry Laboratory Results
(Safety Population: Cohort 2)
(Page 1 of xx)

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

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

Table 14.3.3.1.1.2: Summary of Chemistry Laboratory Results
(Safety Population: Cohort 2)
(Page 2 of xx)

<Parameter> (<units>)	Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Week 24	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

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

Table 14.3.3.1.1.2: Summary of Chemistry Laboratory Results
(Safety Population: Cohort 2)
(Page 3 of xx)

<Parameter> (<units>)	Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Week 52	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

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

Repeat Table 14.3.3.1.1.2: Summary of Chemistry Laboratory Results

For the following tables:

Table 14.3.3.1.2.2: Summary of Hematology Laboratory Results (Safety Population: Cohort 2)
Table 14.3.3.1.3.2: Summary of Urinalysis Laboratory Results (Safety Population: Cohort 2)

Table 14.3.3.1.1.3: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1.1.3: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 2 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%		
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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
Week 24			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1.1.3: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 3 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%		
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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 52			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.3.1.1.3: Summary of Chemistry Laboratory Results

For the following tables:

Table 14.3.3.1.2.3: Summary of Hematology Laboratory Results (Safety Population)
Table 14.3.3.1.3.3: Summary of Urinalysis Laboratory Results (Safety Population)

Table 14.3.3.2.1.1: Shift Summary of Chemistry Lab Results
(Safety Population: Cohort 1)
(Page 1 of x)

<Test Name> (<units>)

	Week 4					
	Roflumilast Cream 0.3% (N=xx)			Roflumilast Cream 0.15% (N=xx)		
Baseline	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%)
WNL	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%)

	Vehicle Cream (N=xx)			Total (N=xx)		
Baseline	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%)
WNL	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%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to Programmer: Repeat for Visits: Week 12, Week 24, Week 36, Week 52

Repeat table 14.3.3.2.1.1 Shift Summary of Chemistry Lab Results

For the following tables:

Table 14.3.3.2.2.1: Shift Summary of Hematology Laboratory Results (Safety Population: Cohort 1)
Table 14.3.3.2.3.1: Shift Summary of Quantitative Urinalysis Laboratory Results (Safety Population: Cohort 1)

Table 14.3.3.2.1.2: Shift Summary of Chemistry Lab Results
(Safety Population: Cohort 2)
(Page 1 of x)

<Test Name> (<units>)	Week 4		
	Roflumilast Cream 0.3% (N=xx)		
Baseline	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note to Programmer: Repeat for Visits: Week 12, Week 24, Week 36, Week 52

Repeat table 14.3.3.2.1.2 Shift Summary of Chemistry Lab Results

For the following tables:

Table 14.3.3.2.2.2: Shift Summary of Hematology Laboratory Results (Safety Population: Cohort 2)
Table 14.3.3.2.3.2: Shift Summary of Quantitative Urinalysis Laboratory Results (Safety Population: Cohort 2)

Table 14.3.3.2.1.3: Shift Summary of Chemistry Lab Results
(Safety Population)
(Page 1 of x)

<Test Name> (<units>)

	Week 4					
	ARQ-151-201: Roflumilast Cream (N=xx)			ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)		
Baseline	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%)
WNL	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%)

	Total (N=xx)		
Baseline	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note to Programmer: Repeat for Visits: Week 12, Week 24, Week 36, Week 52

Repeat table 14.3.3.2.1.3 Shift Summary of Chemistry Lab Results

For the following tables:

Table 14.3.3.2.2.3: Shift Summary of Hematology Laboratory Results (Safety Population)
Table 14.3.3.2.3.3: Shift Summary of Quantitative Urinalysis Laboratory Results (Safety Population)

Table 14.3.4.1: Summary of Electrocardiogram (ECG) Parameters
(Safety Population: Cohort 1)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 24				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.4.1: Summary of Electrocardiogram (ECG) Parameters
(Safety Population: Cohort 1)
(Page 2 of xx)

<Parameter> (<units>)	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.4.2: Summary of Electrocardiogram (ECG) Parameters
(Safety Population: Cohort 2)
(Page 1 of xx)

<Parameter> (<units>)	Roflumilast Cream 0.3% (N=xx)
Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Week 24	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

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

Table 14.3.4.2: Summary of Electrocardiogram (ECG) Parameters
(Safety Population: Cohort 2)
(Page 2 of xx)

<Parameter> (<units>)	Roflumilast Cream 0.3% (N=xx)
Week 52	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

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

Table 14.3.4.3: Summary of Electrocardiogram (ECG) Parameters
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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 24			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.4.3: Summary of Electrocardiogram (ECG) Parameters
(Safety Population)
(Page 2 of xx)

<Parameter> (<units>)		ARQ-151-202: Roflumilast Cream 0.3%		
		ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 52				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.1.1: Summary of Vital Signs
(Safety Population: Cohort 1)
(Page 1 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 4				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.1.1: Summary of Vital Signs
(Safety Population: Cohort 1)
(Page 2 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 12				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 24				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.1.1: Summary of Vital Signs
(Safety Population: Cohort 1)
(Page 3 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%			
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Week 52				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.1.2: Summary of Vital Signs
(Safety Population: Cohort 2)
(Page 1 of xx)

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

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

Table 14.3.5.1.2: Summary of Vital Signs
(Safety Population: Cohort 2)
(Page 2 of xx)

<Parameter> (<units>)	Roflumilast Cream 0.3% (N=xx)
Week 12	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Week 24	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

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

Table 14.3.5.1.2: Summary of Vital Signs
(Safety Population: Cohort 2)
(Page 3 of xx)

<Parameter> (<units>)	Roflumilast Cream 0.3% (N=xx)
Week 36	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Week 52	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Change from Baseline	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx

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

Table 14.3.5.1.3: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

<Parameter> (<units>)	ARQ-151-202: Roflumilast Cream 0.3%		
	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.1.3: Summary of Vital Signs
(Safety Population)
(Page 2 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%		
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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
Week 24			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.1.3: Summary of Vital Signs
(Safety Population)
(Page 3 of xx)

	ARQ-151-202: Roflumilast Cream 0.3%		
<Parameter> (<units>)	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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 52			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.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: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.2.1: Summary of Change in Body Weight Compared to Baseline
(Safety Population: Cohort 1)
(Page 1 of 2)

	ARQ-151-202: Roflumilast Cream 0.3%			
Change in Body Weight Compared to Baseline	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 4				
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12				
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 24				
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.2.1: Summary of Change in Body Weight Compared to Baseline
(Safety Population: Cohort 1)
(Page 2 of 2)

Change in Body Weight Compared to Baseline	ARQ-151-202: Roflumilast Cream 0.3%			
	ARQ-151-201: Roflumilast Cream 0.3% (N=xx)	ARQ-151-201: Roflumilast Cream 0.15% (N=xx)	ARQ-151-201: Vehicle Cream (N=xx)	Total (N=xx)
Week 36				
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 52				
Lost >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.2.2: Summary of Change in Body Weight Compared to Baseline
(Safety Population: Cohort 2)
(Page 1 of 2)

Change in Body Weight Compared to Baseline	Roflumilast Cream 0.3% (N=xx)
Week 4	
Lost >5% Body Weight	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)
Week 12	
Lost >5% Body Weight	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)
Week 24	
Lost >5% Body Weight	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)
Week 36	
Lost >5% Body Weight	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)

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

Table 14.3.5.2.2: Summary of Change in Body Weight Compared to Baseline
(Safety Population: Cohort 2)
(Page 2 of 2)

Change in Body Weight Compared to Baseline	Roflumilast Cream 0.3% (N=xx)
Week 52	
Lost >5% Body Weight	xx (xx.x%)
Lost >10% Body Weight	xx (xx.x%)
Maintained Body Weight	xx (xx.x%)
Gained >5% Body Weight	xx (xx.x%)
Gained >10% Body Weight	xx (xx.x%)

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

Table 14.3.5.2.3: Summary of Change in Body Weight Compared to Baseline
(Safety Population)
(Page 1 of 2)

	ARQ-151-202: Roflumilast Cream 0.3%		
Change in Body Weight Compared to Baseline	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (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 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%)
Week 24			
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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.2.3: Summary of Change in Body Weight Compared to Baseline
(Safety Population)
(Page 2 of 2)

	ARQ-151-202: Roflumilast Cream 0.3%		
Change in Body Weight Compared to Baseline	ARQ-151-201: Roflumilast Cream (N=xx)	ARQ-151-201: Vehicle Cream and Cohort 2 (N=xx)	Total (N=xx)
Week 36			
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 52			
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%)

Note: Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.5.3.1: Shift Summary of Body Mass Index (BMI) Results
(Safety Population: Cohort 1)
(Page 1 of 2)

Body Mass Index	**Last BMI Record**							
	Roflumilast Cream 0.3% (N=xx)				Roflumilast Cream 0.15% (N=xx)			
Baseline	Under	Normal	Over	Obese	Under	Normal	Over	Obese
Under	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Over	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Obese	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Vehicle Cream (N=xx)				Total (N=xx)			
Baseline	Under	Normal	Over	Obese	Under	Normal	Over	Obese
Under	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Over	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Obese	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note To Programmer: Repeat this page, with Highest BMI Record and Lowest BMI Record

Table 14.3.5.3.2: Shift Summary of Body Mass Index (BMI) Results
(Safety Population: Cohort 2)

Body Mass Index	**Roflumilast Cream 0.3% (N=xx)**							
	Lowest BMI Record				Highest BMI Record			
Baseline	Under	Normal	Over	Obese	Under	Normal	Over	Obese
Under	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Over	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Obese	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Last BMI Record			
Baseline	Under	Normal	Over	Obese
Under	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Over	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Obese	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.5.3.3: Shift Summary of Body Mass Index (BMI) Results
(Safety Population)
(Page 1 of 2)

Body Mass Index

	Last BMI Record							
	ARQ-151-201: Roflumilast Cream (N=xx)				ARQ-151-201: Vehicle Cream (N=xx)			
Baseline	Under	Normal	Over	Obese	Under	Normal	Over	Obese
Under	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Over	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Obese	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

	Total (N=xx)			
Baseline	Under	Normal	Over	Obese
Under	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Over	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Obese	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.
Baseline is defined as the last observation prior to the first dose of Roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Note To Programmer: Repeat this page, with Highest BMI Record and Lowest BMI Record

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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 xxxxxxxxxx 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 xxxxxxxxxxx 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

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

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
xxxxxx	xxxx	Safety	xxx	
xxxxxx	xxxx	Safety	xxx	

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
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:
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
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

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]	Reason Not Done
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	x	xxx		xxxxxxx
			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		xxxxxxxxx xx
			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	Was Dosing Stopped
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	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	xx
	WEEK 16	xxxxxxxxxx	x x xxxxxxxx	xx		xxx	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: Psoriasis Area and Severity Index (PASI)
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date E: Evaluator Initials	P: PASI M: mPASI	Affected Area (% 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	P: xx.x M: x.x	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 - xxxx	x - xxxx	x
	V: BASELINE D: xxxxxxxxxx E: xxx	P: x.x M: x.x	Arms (x%)	x	x	x
			Head (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	P: x.x M: x.x	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	P: x.x M: x.x	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 16.2.6.7: 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 xxxxxxxxxxx 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 16.2.7.1.1: 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 16.2.7.2.1: 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 xxxxxxxxxxx	xxxxx xxxxxxxxx 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 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: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	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: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	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: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	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 or Exeprienced an Adverse Event Resulting in Death
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: 12-lead Electrocardiogram Test Results
Treatment Group
(Page x of xx)

Subject	Age/Sex	Eval	V: Visit D: Date/Time of ECG	ECG Parameter	Result (Units)	ECG Interpetation	Abnormal
xxxxxxxxx	xxxx	xxxxxxxx	V: xxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	xxx - xxx
			D: xxxx-xx-xxTxx:xx:xx	xxxxxxxxxx	xxxx xxxxx xx		
				xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	xxxxxx
				xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	
				xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	
				xxxxxxxxxx	xxxx xxxxx xx		
				xxxxxxxxxx	xxxx xxxxx xx		
				xxxxxxxxxx	xxxx xxxxx xx		
			V: xxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx		
			D: xxxx-xx-xxTxx:xx: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		
				xxxxxxxxxx	xxxx xxxxx xx		
xxxxxxxxx	xxxx	xxxxxxxx	V: xxxxxxxxx	xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	
			D: xxxx-xx-xxTxx:xx:xx	xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	
				xxxxxxxxxx	xxxx xxxxx xx	xxxxxxxxxxxxxxx	
				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 16.2.8.3.1: 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
					Weight	xxx	xx
			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 16.2.8.3.2: Weight Loss/Gain >5%
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Weight(kg)	Baseline Weight(kg)	% Change from Baseline	Reason
xxxxxx	xxxx	xxxxxxxx	xxxx x	xxxxxxxxxx	xxx	xxx	xxx	xxxx xxxxx xxxx xxx xx xxxxxxx xxxx xxxx xx xx
			xxxx x	xxxxxxxxxx	xxx	xxx	xxx	xxxx xxx xxxx xxx xxxxxx x xxxxxx xxxx xxxx xxxx

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

Listing sorted by Subject, Visit, Date.

Certificate Of Completion

Envelope Id: CDEB1B02388C4970A7D23284343C98D6
Status: Completed
Subject: Arcutis ARQ-151-202 Finalized SAP
Source Envelope:
Document Pages: 337
Signatures: 4
Envelope Originator:
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-05:00) Eastern Time (US & Canada)

[redacted]

Record Tracking

Status: Original
10/22/2020 12:23:58 PM

[redacted]

Location: DocuSign

Signer Events	Signature	Timestamp
[redacted]		Sent: 10/22/2020 12:39:01 PM Viewed: 10/23/2020 3:36:38 PM Signed: 10/23/2020 7:58:10 PM

With Signing Authentication via DocuSign password
With Signing Reasons (on each tab):
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Electronic Record and Signature Disclosure:
Accepted: 10/23/2020 3:36:38 PM
ID: a7419f37-d2a5-45b2-904d-cfd5cf1ff84b

[redacted]		Sent: 10/23/2020 7:58:13 PM Viewed: 10/23/2020 8:14:07 PM Signed: 10/23/2020 8:14:29 PM

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Electronic Record and Signature Disclosure:
Accepted: 10/23/2020 8:14:07 PM
ID: 6ff260db-7ba0-4f4a-a0a7-0b3f069a889b

Signer Events	Signature	Timestamp
[redacted]		Sent: 10/23/2020 8:14:32 PM Viewed: 10/25/2020 9:59:44 PM Signed: 10/25/2020 10:00:38 PM
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Editor Delivery Events	Status	Timestamp

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Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	10/25/2020 10:00:42 PM
Certified Delivered	Security Checked	10/26/2020 7:41:01 AM
Signing Complete	Security Checked	10/26/2020 7:42:02 AM
Completed	Security Checked	10/26/2020 7:42:02 AM

Payment Events	Status	Timestamps

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