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Study Identification Code	CD-14-875
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Study Title	A Randomized, Prospective, Multicenter, Double Blind, Parallel Assignment, Placebo Controlled Bioequivalence Study of Pimecrolimus Cream, 1% and Elidel® (Pimecrolimus) Cream, 1% in Patients with Mild to Moderate Atopic Dermatitis
Sponsor	DPT Laboratories, Ltd., an affiliate of Mylan Inc.

DPT Laboratories

Protocol No. CD-14-875
Novella Study No. CT991616

A RANDOMIZED, PROSPECTIVE, MULTICENTER, DOUBLE BLIND, PARALLEL ASSIGNMENT, PLACEBO CONTROLLED BIOEQUIVALENCE STUDY OF PIMECROLIMUS CREAM, 1% AND ELIDEL® (PIMECROLIMUS) CREAM, 1% IN PATIENTS WITH MILD TO MODERATE ATOPIC DERMATITIS

Statistical Analysis Plan

June 29, 2017

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LIST OF SELECTED ABBREVIATIONS

AD	Atopic Dermatitis
ADR	Adverse Drug Reaction
AE	Adverse Event
BSA	Body Surface Area
CFR	Code of Federal Regulations
CRF	Case Report Form
CRO	Contract Research Organization
DMP	Data Management Plan
FDA	Food and Drug Administration
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IGA	Investigator Global Assessment
IP	Investigational Product
IRB	Institutional Review Board
ITT	Intention To Treat
LOCF	Last Observation Carried Forward
mITT	Modified Intention To Treat
OGD	Office of Generic Drugs
PI	Principal Investigator
PP	Per Protocol
SD	Standard Deviation
SAE	Serious Adverse Event
SAS	Statistical Analyzing System
SOP	Standard Operating Procedure

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on protocol version 2.0 as issued on 14 October, 2016.

This document provides additional details concerning the statistical analyses outlined in the protocol and reflects any changes to the protocol from any amendments. This plan will not repeat all the definitions given in the protocol but will provide further details of the summaries and analyses planned therein.

2. STUDY OBJECTIVES

Primary Objective:

- To establish the bioequivalence between test drug (Pimecrolimus Cream, 1%) and reference listed drug (Elidel® (pimecrolimus) Cream 1%) in the treatment of mild to moderate Atopic Dermatitis (AD), using the primary endpoint in the Per Protocol (PP) population, as detailed in FDA Draft Guidance on Pimecrolimus 1% Topical Cream dated March 2012.

Additional Objectives:

- To establish superiority of each active treatment over the placebo using the primary endpoint in the modified intent to treat (mITT) population and Last Observation Carried Forward (LOCF)
- To assess individual signs and symptoms of AD (i.e., erythema, induration/papulation, lichenification and pruritus) in each treatment group
- To compare the safety and tolerability between the test and reference drugs

3. STUDY DESIGN

The study is a randomized, double blind, active and placebo controlled, prospective multicenter, comparative therapeutic equivalence study in which subjects with mild to moderate atopic dermatitis (AD) are randomized in a 1:1:1 allocation to test drug (Pimecrolimus Cream, 1%) or reference listed drug (RLD) (Elidel® (Pimecrolimus) Cream 1%) or placebo (vehicle cream). As per FDA recommendations, this study will be a bioequivalence study with a clinical endpoint in the treatment of mild to moderate AD comparing the test product versus the reference listed drug and vehicle control. A placebo control arm (vehicle of test product) is used to demonstrate that the test product and RLD are active and as a parameter to establish that the study is sufficiently sensitive to detect differences between products. The primary endpoint is the proportion of subjects with treatment success (a grade of clear or almost clear; a score of 0 or 1, within the

treatment area) based on the Investigator's Global Assessment (IGA) of Disease Severity at the end of treatment (study Day 15).

A total of 648 subjects will be included (216 in each active group and 216 in the placebo group). Subjects are non-immunocompromised males and females aged 8 years and above with mild to moderate atopic dermatitis who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

The study duration for each subject would be up to 21 days, with a possible screening period of 14 days and a treatment period of 14 days. The study will include a total of 4 scheduled visits: screening visit (up to -14 days), baseline and randomization visit (day 1), interim visit (day 8 ± 3 days), end of therapy visit (day 15 ± 3 days).

Study kit numbers will be randomly assigned to one of the three treatment arms based on a randomization code list. The statistician will generate the randomization code list; a copy of this list will be shared with the IP handling team. Subjects fulfilling inclusion and exclusion criteria will receive study product from the next available sequential randomized kit which contains one of the three treatment arms. Each study product kit will contain three 100 gram tubes of study cream from the same randomized treatment arm. The kits will be packaged in a block size of 6. Each block will contain 2 kits of each treatment arm (Test: RLD: Placebo=2:2:2).

Efficacy assessments including Signs and Symptoms of Atopic Dermatitis will be scored per body region (head and neck; trunk; upper limbs; lower limbs) by the principal investigator or a qualified person delegated by the investigator at each visit. Pruritus will be assessed by questioning the subject or the subject's guardian regarding the intensity in the 24 hours prior to the visit for the overall condition. Overall Body Surface Area (BSA) Involvement with AD will be assessed and recorded by the investigator or delegate. Investigator's Global Assessment of Disease Severity Scoring will be scored for the investigator's (or delegate's) assessment of the subject's overall condition.

4. HARDWARE AND SOFTWARE

Statistical analysis will be performed following Novella/TKL standard operating procedures and on the Novella computer network. All statistical analysis will be performed using SAS Version 9.3 with program code prepared specifically for the project by qualified Novella statisticians and SAS programmers.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). The summary tables and listings will be formatted using the Times New Roman 9-point font. The RTF output is included in report documents prepared with Microsoft Word and converted to PDF format without typographical change.

Datasets will be created and taken as input to validated SAS programs to generate the report-ready tables, listings, and figures. Each output display will show the names of the data sets and SAS program used to produce it.

5. DATABASE CLOSURE

According to the Data Management Plan, after completion of all data review procedures, validation of the project database, and approval of the data review document by the study sponsor, the clinical database will be locked. Any change to the clinical database after this time will require written authorization, with explanation, by the Sponsor and the Biostatistician.

6. SAMPLE SIZE DETERMINATION

The primary statistical analysis of interest is the proportion of subjects in the PP population with a clinical response of treatment success (at least an Investigator's Global Assessment of Clear or Almost Clear) at study Day 15. Considering the pivotal studies of the Reference Listed Drug, it is assumed that the active test and RLD will have approximate success rates at 21% and the vehicle cream will have an approximate success rate of 9%. A sample size of 184 subjects per group will provide at least 99% power to demonstrate bioequivalence (i.e., the 90% confidence interval (Yates' continuity -corrected) of the absolute difference between the test and reference composite success rates is within a defined equivalence range [-0.20, +0.20]). Assuming the conversion rate from mITT to PP will be about 90%, 205 subjects in each of the groups of the mITT population will provide at least 85% power to demonstrate superiority of active over placebo. Under the above assumptions, the overall global study power to demonstrate bioequivalence and superiority is estimated to be approximately 85%. To allow for about 5% of subjects who may drop out from the study or are otherwise non-evaluable, approximately 648 subjects will be enrolled (216 in each active group and 216 in the placebo group).

7. HANDLING OF DROPOUTS AND MISSING DATA

For the analyses of the primary efficacy endpoint, subjects whose condition worsens and require alternate or supplemental therapy for the treatment of their AD during the study should be discontinued, included in the PP population analysis as treatment failures, and provided with effective treatment. Subjects discontinued early for other reasons should be excluded from the PP population, but included in the mITT population, using Last Observation Carried Forward (LOCF). For example, subjects who develop a skin infection in the treated area requiring treatment should be discontinued, excluded from the PP population, but included in the mITT population, using LOCF.

No missing imputations will be done for other non-primary efficacy endpoints or safety endpoints.

8. ANALYSIS POPULATIONS

Four populations will be defined for analysis:

- Safety population: The safety population includes all randomized who received study product.
- Modified ITT (mITT) population: The mITT population includes all randomized subjects who met all inclusion/exclusion criteria, applied at least one dose of assigned product and returned for at least one post-baseline evaluation visit.
- Per Protocol (PP) population: The PP population includes all randomized subjects who met all inclusion/exclusion criteria, applied 75% to 125% of the assigned product for the specified duration of the study, did not miss the scheduled applications for more than 3 consecutive days, and completed the evaluation within the designated visit window (+/- 3 day) with no protocol violations that would affect the treatment evaluation. The subject's compliance will be verified by the use of subject diaries, and the protocol violations that would affect the treatment evaluation.

  Subjects to be included in each population will be determined prior to the unblinding of the study.

The PP and mITT populations will be used for the analyses of efficacy endpoints. The PP population will be the primary population for the primary efficacy bioequivalence analysis. The mITT population will be used for the superiority analysis. The Safety population will be used for the analyses of safety endpoints.

All efficacy analyses will be conducted according to the randomized treatment assignment; all safety analyses will be conducted according to the treatment actually received.

9. DATA CONVENTIONS FOR ANALYSIS

9.1 General Statistical Principles

The purpose of the study is to evaluate the efficacy, safety and tolerability of Pimecrolimus Cream, 1% compared with reference listed drug Elidel® (pimecrolimus) Cream 1% as well as placebo vehicle cream in patients with AD using clinical endpoints. All statistical processing will be performed using the SAS system (Version 9.3).

All observed and derived variables (e.g., change from baseline, treatment success status) used in the summaries of analyses will be presented in by-subject listings. Descriptive statistics will be used to provide an overview of the efficacy and safety results. For categorical parameters, the number and percentage of subjects in each category will be presented. 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 observations, mean, standard deviation (SD), median, and range.

Small study centers with few subjects randomized will be pooled into analysis centers based on geographic locations. The pooling plan will be determined prior to the unblinding of the study.

Baseline value is defined as the last non-missing value prior to the first dose of study drug. Change from baseline is defined as the post-baseline value minus the baseline value.

No adjustments for multiple comparisons are planned. No interim analyses are planned.

9.2 Study Day

Day 1 is defined as the date of first study drug administration or date of randomization for those subjects with missing date of first study drug administration. Study day is calculated relative to the date of Day 1.

10. STATISTICAL EVALUATION

10.1 Subject Disposition

The number and percentage of subjects who are screened, randomized, included in each analysis population, who complete the study, withdraw from the study (overall and by reason for withdrawal), and who are excluded from the PP population (overall and by reason for exclusion) will be summarized using frequencies and percentages by treatment group. The number of subjects who are enrolled and included in each study population will also be summarized for each study center.

A by-subject enrollment and disposition listing will be presented for all randomized subjects. Subjects who are screen failures and subjects who are not randomized will also be presented in a separate listing.

10.2 Protocol Deviation

Protocol deviations will be presented in a by-subject listing, and summarized by treatment group in total per category.

10.3 Demographic and Baseline Characteristics

Demographics and baseline characteristics will be summarized overall and by treatment for the Safety, mITT and PP populations. Statistical comparisons will be performed to detect any baseline differences between test and reference. Continuous variables will be compared using a two-sample t test; categorical variables will be compared using a Fisher's Exact test.

The following demographic and baseline variables will be included:

- Age with mean +/-SD and range

- Age group (<18 years, ≥18 years)
- Sex N and %
- Ethnicity N and %
- Race N and %
- Body weight and height
- IGA
- Signs and symptoms:
    - By body region: erythema, induration/papulation, and lichenification
    - Overall: pruritus
- Percent Body Surface Area (BSA) (%)
- Application site reactions (dryness, burning/stinging, erosion, edema, and pain)
- Dermatological history, including:
    - Dermatologic malignancy (Yes, No)
    - Reason for use of the study products

10.4 Study Drug Exposure and Compliance

Assessments of study drug exposure and compliance will occur at Visit 3 (Day 8) and Visit 4 (Day 15) based on the treatment diary card. The following parameters will be summarized, by Day 8 and Day 15, for each treatment group for the mITT and PP populations:

- Number of days of exposure, defined as the date of last dose of study drug minus date of first dose of study drug plus 1
- Number of expected applications
- Number of applications
- Number of missed applications
- Percentage of compliance based on the investigator's review of subject diary, defined as the number of applications divided by the number of expected applications
- Subject compliance (Yes, No), defined as being 75%-125% in percent compliance

10.5 Prior and Concomitant Medications

Prior (with stop dates prior to Day 1) and concomitant medications (ongoing or with stop dates on or after Day 1) for safety population will be provided separately in by-subject listings. If the medication is ongoing or the stop year is missing, the medication will be considered as received for the remainder of the study.

For the determination of prior vs concomitant medications, the following rules regarding the stop date will be applied:

- If only year was recorded, and it is before Baseline, it is a prior medication; if year is same or after Baseline, it is assumed to be a concomitant medication.

- If day is missing, but month and year are before Baseline, it is a prior medication; if month and year are the same as Baseline, it is assumed to be a concomitant medication; if month and year are after Baseline, it is a concomitant medication.
- If start date is after Baseline, it is a concomitant medication regardless.

Prior and concomitant medications will be summarized separately by treatment, WHO-DD Anatomical-Therapeutic-Chemical (ATC) classification and preferred term (PT).

10.6 Medical History

Past and current medical conditions for all randomized subjects will be provided in a by-subject listing and summarized by treatment group. Dermatological history will be provided in a separate listing.

10.7 Efficacy Endpoints

10.7.1 Primary Efficacy Endpoint

The primary endpoint is the proportion of subjects with treatment success (i.e., a grade of clear or almost clear; a score of 0 or 1, within all treatment areas) at the end of treatment (Day 15) based on the IGA.

IGA Score	Category
0	Clear
1	Almost Clear
2	Mild disease
3	Moderate disease
4	Severe disease

10.7.2 Secondary Efficacy Endpoints

Secondary efficacy endpoints will be the change from baseline to Day 15 in individual signs and symptoms of AD, including:

- Erythema (per body region, i.e., head and neck, trunk, upper limbs, and lower limbs)
- Induration/papulation (per body region)
- Lichenification (per body region)
- Pruritus (overall)

Signs and Symptoms	Category
0	None
1	Mile
2	Moderate

3	Severe

10.8 Efficacy Analyses

10.8.1 Primary Efficacy Analysis

Equivalence Analysis

Therapeutic equivalence of the test product (Pimecrolimus Cream, 1%) to the reference product (Elidel® (pimecrolimus) Cream 1%) will be evaluated using the PP population. If the 90% confidence interval (CI), with Yates' continuity correction of the test - reference difference for the primary endpoint (IGA success proportion) is contained within [-0.20, +0.20], then bioequivalence of the test product to the reference product will be considered to have been demonstrated.

The compound hypothesis to be tested is:

$$H_0: P_T - P_R < -0.20 \text{ or } P_T - P_R > 0.20$$

versus

$$H_A: -0.20 \leq P_T - P_R \leq 0.20$$

where P_T = success rate of test treatment and P_R = success rate of reference treatment.

Let

n_T = sample size of test treatment group Tn

cn_T = number of successes in test treatment group Tn

n_R = sample size of reference treatment group Rn

cn_R = number of successes in reference treatment group Rn

$P_T = cn_T / n_T$, $P_R = cn_R / n_R$, and $se = (P_T (1 - P_T) / n_T + P_R (1 - P_R) / n_R)^{½}$.

The 90% CI for the difference in proportions between test and reference will be calculated as follows, using Yates' correction:

$$L = (P_T - P_R) – 1.645\ se – (1/ n_T + 1/ n_R) / 2$$

$$U = (P_T - P_R) + 1.645\ se + (1/ n_T + 1/ n_R) / 2$$

We reject H_0 if $L \geq -0.20$ and $U \leq 0.20$. Rejection of the null hypothesis H_0 supports the conclusion of equivalence of the two products.

Superiority Analysis

As a parameter for determining adequate study sensitivity, the test product and reference product will be compared to placebo with regard to the primary endpoint. Superiority of the test and

reference products against the placebo will be tested using Fisher's exact test in the mITT population with LOCF. The test and reference products should both be superior to placebo at the 5% significance level ($p<0.05$; two-sided) in order to claim adequate study sensitivity.

10.8.2 Secondary Efficacy Analysis

The categorical change from baseline to Day 15 in individual signs and symptoms of AD per body region will be summarized using frequency counts and percentages.

10.8.3 Other Efficacy Analyses

The overall BSA (%), along with the change from baseline values will be summarized using descriptive statistics by treatment group at each visit.

10.9 Safety Analysis

All safety analyses will be based on the Safety Population according to the treatment received. .

10.9.1 Adverse Events

AE terms will be coded using MedDRA dictionary. A treatment-emergent AE (TEAE) is defined as an AE that emerges during and after a certain period of treatment having been absent pre-treatment, or worsen relative to the pre-treatment state. In case of partially recorded dates, similar rules as stated in section 10.5 regarding the start and stop date will be adopted. If relationship to treatment is missing, the event will be conservatively summarized as being related to study drug. If severity is missing, a separate category of missing severity will be included in the summary table, and no imputation of severity will be performed. Through the data cleaning process, all attempts will be made to avoid missing values for relationship and severity.

All AEs will be presented in a by-treatment and by-subject listing, detailing the verbatim term given by the investigator, the preferred term (PT), system organ class (SOC), onset date and time, end date and time, severity, outcome, relationship to study drug, action taken with study drug, other action taken, seriousness and criteria for seriousness. Serious AEs (SAEs) and TEAEs leading to study discontinuation will also be presented in a separate listing.

An overall summary of AEs will be presented by treatment and overall. The summary will include the frequency counts and percentages with:

- Any AE
- Any TEAE
- Any serious TEAE
- Any treatment-related TEAE, including definitely related, probably related, and possibly related

- Any TEAE leading to study drug discontinuation

Fisher's Exact test will also be performed to compare the incidence of the above between test and reference.

Summaries of the incidence of TEAEs will be displayed by treatment according to the following:

- All TEAEs by SOC in alphabetical order and PT in descending order of frequency (the combined frequency in the two active treatments)
- All TEAEs by SOC, PT, and maximum severity (mild, moderate, or severe)
- All TEAEs by SOC, PT, and maximum causality (not related, related) to the study drug

At each level of summarization, a subject will be counted once if he/she reported one or more events. The severity of TEAEs and relationship to study drug will be summarized in a similar manner. For summaries of relationship to study drug, a subject will be classified according to the closest relationship. For summaries of TEAE severity, a subject will be classified according to the highest severity.

10.9.2 Application Site Reactions

Application site reactions including dryness, burning/stinging, erosion, edema, and pain, will be assessed based on Local Irritation Scale (LIS).

Application site reactions	0 None	1 Mild	2 Moderate	3 Severe

Application site reaction scores will be summarized using frequency counts and percentages by visit for each treatment.

10.9.3 Pregnancy Tests

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

10.9.4 Physical Examination

Abnormal physical examination results will be presented in a by-subject listing.

10.9.5 Vital Signs

Vital sign parameters including pulse rate, blood pressure, and body temperature will be summarized using descriptive statistics at Baseline and Visit 4 (Day 15). By-subject listing will be presented.

11. CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

This SAP reflects the analysis plan outlined in the study protocol without significant change.

12. HEADINGS

Each page of the analysis will show the sponsor's name, the investigational product, and the protocol number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

13. ARCHIVING AND RETENTION OF DOCUMENTS

After finalization of the analysis, the following will be archived at Novella Clinical and/or with the study sponsor:

- SAP and any amendments
- All SAS code used in the project for statistical analysis, report tables generation, and analysis data set creation
- Tables, listings and figures as included in the clinical study report
- SAS study data tabulation model (SDTM) and analysis dataset model (ADaM) datasets.

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Table 14.1.1.1.1: Subject Populations

	Pimecrolimus Cream, 1%	Elidel® (Pimecrolimus) Cream, 1%	Placebo	Overall
Number of Subjects Enrolled				XX
Number of Subjects Randomized	XX	XX	XX	XX
Total Safety Population, n(%)	XX	XX	XX	XX
Total Exclusion from Safety Population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for Exclusion from Safety				
No Record of First Dose	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total mITT Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total Exclusion from mITT Population				
Reason for Exclusion from mITT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No Record of First Dose	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No Post-Treatment Data	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Etc.	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total PP Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total Exclusion from PP Population				
Reason for Exclusion from PP	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Enrolled in Error	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)
Non-compliant (Dosing)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Outside Visit Window	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Randomized in Error	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Restricted Medication	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Denominator for percentages is the number of randomized subjects.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.1.1.1.2: Subject Populations by Site

Site Number	Principal Investigator and Location	Enrolled (N)	Included in Safety Population (N)	Included in mITT Population (N)	Included in PP Population (N)
01	XXXXXXXXX	XX	XX	XX	XX
02	XXXXXXXXXX	XX	XX	XX	XX

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DPT Laboratories
Protocol No. CD-14-875

Table 14.1.1.2.1: Summary of Patient Discontinuation/Early Termination from the Study
All Randomized Subjects

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Reason for Discontinuation, n (%)				
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Worsening Signs/Symptoms	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)
Subject Withdrew Consent	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Investigator Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Study Medication Compliance <75% or >125%	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Drug is Unblinded	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnant	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Administrative Reasons	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Denominator for percentages is the number of randomized subjects.

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Table 14.1.1.3: Summary of Protocol Deviations
Safety Population

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Protocol Deviation Type, n (%)				
Randomized in Error	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-Compliance	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)
Outside Visit Window	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Restricted Medication	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Etc.	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Table 14.1.2.1.X: Summary of Subject Demographics
[Safety Population][mITT Population][PP Population]

		Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**P Value[1]**
Age (years)	Mean ± SD	XX.X ± XX.XX	XX.X ± XX.XX	XX.X ± XX.XX	0.XXXX
	Minimum, Maximum	XX, XX	XX, XX	XX, XX	
Age Group, n (%)	<18 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
	≥18 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)	Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
	Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)	Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
	Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Race, n (%)	White	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
	Black/African American	XX (XX.X)	XX (XX.X)	XX (XX.X)	
	Native Hawaiian/Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)	
	Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)	
	American Indian/Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)	
	Other [2]	XX (XX.X)	XX (XX.X)	XX (XX.X)	

[1] Statistical comparisons will be performed to detect any baseline differences between test and reference. Continuous variables will be compared using a two-sample t test; categorical variables will be compared using a Fisher's Exact test.
[2] See listing 16.2.4.1 for other races.

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Table 14.1.2.2.X: Summary of Baseline Characteristics
[Safety Population][mITT Population][PP Population]

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Weight (kg)				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Height (cm)				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Erythema by Body Region, n(%)				
Head and Neck				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Continue for Trunk, Upper Limbs, Lower Limbs>				
Induration/Papulation by Body Region, n(%)				
Head and Neck				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc.>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Continue for Trunk, Upper Limbs, Lower Limbs>				

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.1.2.2.X: Summary of Baseline Characteristics
[Safety Population][mITT Population][PP Population]

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Lichenification by Body Region, n(%)				
Head and Neck				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc.>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Continue for Trunk, Upper Limbs, Lower Limbs>				
Overall Pruritus, n(%)				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Percentage of BSA involvement (%)				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
IGA of Disease Severity, n(%)				
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)

[1] See listing 16.2.4.1 for other races.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.1.2.2.X: Summary of Baseline Characteristics
[Safety Population][mITT Population][PP Population]

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Application Site Reaction - Dryness, n(%)				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Application Site Reaction - Burning/Stinging, n(%)				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Application Site Reaction - Erosion, n(%)				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Application Site Reaction - Edema, n(%)				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Table 14.1.2.2.X: Summary of Baseline Characteristics
[Safety Population][mITT Population][PP Population]

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Application site reaction - Pain, n(%)				
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Dermatologic Malignancy, n(%)				
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 Use of this Product, n(%)				
Failed to respond adequately to other topical prescription treatments for AD	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other topical prescription treatments for AD not advisable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Table 14.1.3: Summary of Medical History
by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Pimecrolimus Cream, 1% (N=XX)	Elidel® (Pimecrolimus) Cream, 1% (N=XX)	Placebo (N=XX)
Subjects with any Medical History, n (%)	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more medical history that map to MedDRA (Version 19.1) system organ class or preferred term.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.1.4.1: Summary of Prior Medications
by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term
Safety Population

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream 1% (N=XX)**	**Placebo (N=XX)**
Subjects with any Prior Medication, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Anatomical Therapeutic Chemical Class >>			
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Anatomical Therapeutic Chemical Class >>			
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX

Note: Any medication with stop date prior to Day 1 is a “prior medication” and any medication with stop date on or after Day 1 is a “concomitant medication.” Counts reflect number of subjects in each treatment group reporting one or more prior medication that map to the WHO Drug anatomical therapeutic chemical or preferred term. A subject may be counted once only in each row of the table.

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Table 14.1.4.2: Summary of Concomitant Medications
by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term
Safety Population

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream 1% (N=XX)**	**Placebo (N=XX)**
Subjects with any Concomitant Medication, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Anatomical Therapeutic Chemical Class >>			
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Anatomical Therapeutic Chemical Class >>			
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX

Note: Any medication with stop date prior to Day 1 is a “prior medication” and any medication with stop date on or after Day 1 is a “concomitant medication.” Counts reflect number of subjects in each treatment group reporting one or more concomitant medication that map to the WHO Drug anatomical therapeutic chemical or preferred term. A subject may be counted once only in each row of the table.

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Table 14.1.5.X: Summary of Study Medication Exposure and Compliance
[mITT Population][PP Population]

	Pimecrolimus Cream, 1% (N=XX)		**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**		**Placebo (N=XX)**	
	By Visit 3 (Day 8)	By Visit 4 (Day 15)	By Visit 3 (Day 8)	By Visit 4 (Day 15)	By Visit 3 (Day 8)	By Visit 4 (Day 15)
Percentage of Compliance (%) [1]						
N	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Subject 75%-125% Compliant, n (%)						
N	XX	XX	XX	XX	XX	XX
Yes	XX (XX.X)	XX (XX.X)	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)	XX (XX.X)	XX (XX.X)

[1] Based on the investigator's review of subject diary, defined as the number of applications divided by the number of expected.

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Table 14.2.1: Analysis of Primary Efficacy Outcome
IGA Success Rate on Day 15

	Pimecrolimus Cream, 1%		**Elidel® (Pimecrolimus) Cream, 1%**	**Placebo**
PP Population				
N	XX		XX	XX
IGA Success Rate, n/N (%) [1]	XX/XX (XX.XX)		XX/XX (XX.XX)	XX/XX (XX.XX)
90% Confidence Interval Test – Reference [2]		XX.XX, XX.XX		
mITT Population				
N	XX		XX	XX
IGA Success Rate, n/N (%)	XX/XX (XX.X)		XX/XX (XX.X)	XX/XX (XX.X)
P-value, (Test or Reference) vs. Placebo [3]	0.XXXX		0.XXXX	

[1] IGA success defined as achieving a grade of clear (0) or almost clear (1) on Day 15.
[2] 90% CI calculated with Yates' continuity correction. Equivalence of test to reference is considered to be demonstrated if the 90% CI is contained within [-0.20, +0.20].
[3] P-value calculated with Fisher's Exact Test.

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Table 14.2.2.1.X: Summary of Secondary Efficacy Outcomes by Visit
Individual Signs and Symptoms of Atopic Dermatitis
Erythema by Body Region
[PP Population][mITT Population]

	Pimecrolimus Cream, 1% (N=XX)				Elidel® (Pimecrolimus) Cream, 1% (N=XX)				Placebo (N=XX)			
	Head & Neck	**Trunk**	**Upper Limbs**	**Lower Limbs**	**Head & Neck**	**Trunk**	**Upper Limbs**	**Lower Limbs**	**Head & Neck**	**Trunk**	**Upper Limbs**	**Lower Limbs**
Baseline												
Observed Value, n (%)												
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
0 – None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 – Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 – Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 – Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8												
Observed Value, n (%)												
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
0 – None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 – Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 – Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 – Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change From Baseline, n (%)												
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2 = Worsen by 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 = Worsen by 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
0 = No Change	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
-1 = Improve by 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
-2 = Improve by 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
-3 = Improve by 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Table 14.2.2.1.X: Summary of Secondary Efficacy Outcome by Visit
Individual Signs and Symptoms of Atopic Dermatitis
Erythema by Body Region
[PP Population][mITT Population]

	Pimecrolimus Cream, 1% (N=XX)				**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**				**Placebo (N=XX)**			
	Head & Neck	**Trunk**	**Upper Limbs**	**Lower Limbs**	**Head & Neck**	**Trunk**	**Upper Limbs**	**Lower Limbs**	**Head & Neck**	**Trunk**	**Upper Limbs**	**Lower Limbs**
Day 15												
Observed Value, n (%)												
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
0 – None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 – Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 – Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 – Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change From Baseline, n (%)												
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2 = Worsen by 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 = Worsen by 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
0 = No Change	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
-1 = Improve by 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
-2 = Improve by 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
-3 = Improve by 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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<Repeat for >

Table 14.2.2.2.X: Summary of Secondary Efficacy Outcomes by Visit
Individual Signs and Symptoms of Atopic Dermatitis
Induration/Papulation by Body Region
[PP Population][mITT Population]

Table 14.2.2.3.X: Summary of Secondary Efficacy Outcomes by Visit
Individual Signs and Symptoms of Atopic Dermatitis
Lichenification by Body Region
[PP Population][mITT Population]

Table 14.2.2.4.X: Summary of Secondary Efficacy Outcomes by Visit
Individual Signs and Symptoms of Atopic Dermatitis
Overall Pruritus
[PP Population][mITT Population]

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**
Baseline			
Observed Value, n (%)			
N	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
Day 8			
Observed Value, n (%)			
N	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
Change From Baseline, n (%)			
N	XX	XX	XX
2 = Worsen by 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 = Worsen by 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
0 = No Change	XX (XX.X)	XX (XX.X)	XX (XX.X)
-1 = Improve by 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
-2 = Improve by 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
-3 = Improve by 3	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Table 14.2.2.4.X: Summary of Secondary Efficacy Outcomes by Visit
Individual Signs and Symptoms of Atopic Dermatitis
Overall Pruritus
[PP Population][mITT Population]

	Pimecrolimus Cream, 1% (N=XX)	**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**	**Placebo (N=XX)**
Day 15			
Observed Value, n (%)			
N	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
Change From Baseline, n (%)			
N	XX	XX	XX
2 = Worsen by 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 = Worsen by 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
0 = No Change	XX (XX.X)	XX (XX.X)	XX (XX.X)
-1 = Improve by 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
-2 = Improve by 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
-3 = Improve by 3	XX (XX.X)	XX (XX.X)	XX (XX.X)

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.2.3.X: Summary of Overall Body Surface Area by Visit
[PP Population][mITT Population]

	Pimecrolimus Cream, 1% (N=XX)		Elidel® (Pimecrolimus) Cream 1% (N=XX)		Placebo (N=XX)	
	Observed Value	**Change from Baseline**	**Observed Value**	**Change from Baseline**	**Observed Value**	**Change from Baseline**
Baseline						
N	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Minimum, Maximum	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Day 8						
N	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Day 15						
N	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X

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Table 14.3.1.1: Overall Summary of Adverse Events
All Randomized

Description	Pimecrolimus Cream, 1% (N=XX)	Elidel® (Pimecrolimus) Cream 1% (N=XX)	Placebo (N=XX)	Overall (N=XX)	P Value[2]
Patients Randomized, n (%)					
Patients with at Least One Treatment-emergent AE (TEAE) [1]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Discontinued Study Drug Due to TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
TEAEs Reported, n (%)					
Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Definite Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Probably Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Possibly Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Missing Relationship	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX
Serious AE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXX

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA (Version XX). A subject may be counted once only in each row of the table.
[1] TEAEs are defined as AEs with an onset date on or after the date of the first applications of study medication.
[2] Fisher's Exact test will be performed to compare the incidence of the above between test and reference

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Table 14.3.1.2: Summary of Treatment-emergent Adverse Events
by System Organ Class and Preferred Term in Descending Frequency
Safety Population

System Organ Class Preferred Term	Pimecrolimus Cream, 1% (N=XX)	Elidel® (Pimecrolimus) Cream 1% (N=XX)	Placebo (N=XX)
Subjects with any TEAE, n (%)	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA (Version 19.1) system organ class or preferred term. A subject may be counted once only in each row of the table.

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<Programming Note: sort by SOC in alphabetical order and PT in descending order of the combined frequency in the two active treatments>

Table 14.3.1.3: Summary of Treatment-emergent Adverse Events
by System Organ Class, Preferred Term, and Maximum Severity
Safety Population

System Organ Class Preferred Term	Severity	Pimecrolimus Cream, 1% (N=XX)	Elidel® (Pimecrolimus) Cream 1% (N=XX)	Placebo (N=XX)
Subjects with any TEAE, n (%)	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA (Version 19.1) system organ class or preferred term. A subject may be counted only once at the highest severity.

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Table 14.3.1.4: Summary of Treatment-emergent Adverse Events
by System Organ Class, Preferred Term, and Maximum Causality
Safety Population

System Organ Class Preferred Term	Causality Assessment[1]	Pimecrolimus Cream, 1% (N=XX)	Elidel® (Pimecrolimus) Cream 1% (N=XX)	Placebo (N=XX)
Subjects with any TEAE, n (%)	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA (Version 19.1) system organ class or preferred term. A subject may be counted only once at the highest causality.
[1] Related includes definitely related, probably related, and possibly related events. If relationship to treatment is missing, the event will be conservatively summarized as being related to study drug

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Table 14.3.2: Summary of Application Site Reactions
Safety Population

	Pimecrolimus Cream, 1% (N=XX)			**Elidel® (Pimecrolimus) Cream 1% (N=XX)**			**Placebo (N=XX)**		
	Baseline	**Day 8**	**Day 15**	**Baseline**	**Day 8**	**Day 15**	**Baseline**	**Day 8**	**Day 15**
Dryness, n(%)									
N	XX	XX	XX	XX	XX	XX	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stinging/burning, n(%)									
N	XX	XX	XX	XX	XX	XX	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Erosion, n(%)									
N	XX	XX	XX	XX	XX	XX	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Table 14.3.2: Summary of Application Site Reactions
Safety Population

	Pimecrolimus Cream, 1% (N=XX)			**Elidel® (Pimecrolimus) Cream 1% (N=XX)**			**Placebo (N=XX)**		
	Baseline	**Day 8**	**Day 15**	**Baseline**	**Day 8**	**Day 15**	**Baseline**	**Day 8**	**Day 15**
Edema, n(%)									
N	XX	XX	XX	XX	XX	XX	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pain, n(%)									
N	XX	XX	XX	XX	XX	XX	XX	XX	XX
0 – None	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Table 14.3.3: Summary of Vital Signs by Visit
Safety Population

	Pimecrolimus Cream, 1% (N=XX)		**Elidel® (Pimecrolimus) Cream, 1% (N=XX)**		**Placebo (N=XX)**	
	Observed Value	**Change from Baseline**	**Observed Value**	**Change from Baseline**	**Observed Value**	**Change from Baseline**
Body Temperature (ºF)						
Baseline						
N	XX		XX		XX	
Mean (SD)	XX (XX.X)		XX (XX.X)		XX (XX.X)	
Median	XX (XX.X)		XX (XX.X)		XX (XX.X)	
Minimum, Maximum	XX, XX		XX, XX		XX, XX	
Day 15						
N	XX	XX	XX	XX	XX	XX
Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

<*Continue for* **Systolic Blood Pressure (mmHg), Diastolic Blood Pressure (mmHg), and Pulse Rate (bpm***)*>

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Data Listing 16.1: Subject Enrollment and Randomization
All Randomized Subjects

Subject Number	Date and Time of Informed Consent/Assent	Satisfy All I/E Criteria?	Randomization Date	Randomized Kit Number	Randomized Treatment	Actual Treatment
XX-XXXX	YYYY-MM-DDTHH:MM	No: Inclusion XX	YYYY-MM-DD	XXXX	Pimecrolimus Cream, 1%	Pimecrolimus Cream, 1%
XX-XXXX	YYYY-MM-DDTHH:MM	Yes	YYYY-MM-DD	XXXX	Elidel® (Pimecrolimus) Cream 1%	Elidel® (Pimecrolimus) Cream 1%
XX-XXXX	YYYY-MM-DDTHH:MM	Yes	YYYY-MM-DD	XXXX	Placebo	Placebo

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Data Listing 16.2.1.1: Screen Failures
All Screen Failure Subjects

Subject Number	Date and Time of Informed Consent/Assent	Date of Screening	Age (Years)	Sex	Race	Ethnicity	Primary Reason for Screen Failure
XX-XXXX	YYYY-MM-DDTHH:MM	YYYY-MM-DD	XX	X	XXXXXXXX	XXXXXXXX	I/E criteria not met: Inclusion 2
XX-XXXX	YYYY-MM-DDTHH:MM	YYYY-MM-DD	XX	X	XXXXXXXX	XXXXXXXX	Other: XXXXXXX
XX-XXXX	YYYY-MM-DDTHH:MM	YYYY-MM-DD	XX	X	XXXXXXXX	XXXXXXXX	XXXXXXXXXXX
XX-XXXX	YYYY-MM-DDTHH:MM	YYYY-MM-DD	XX	X	XXXXXXXX	XXXXXXXX	XXXXXXXXXXX
XX-XXXX	YYYY-MM-DDTHH:MM	YYYY-MM-DD	XX	X	XXXXXXXX	XXXXXXXX	XXXXXXXXXXX

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Data Listing 16.2.1.2: Subject Disposition
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Date (Day) and Time of [1]			Completion Status / Discontinuation Reason	Reason for Unblinding
	First Treatment (Baseline)	Last Visit	Unblinding		
XX-XXXX	YYYY-MM-DD (XX)	YYYY-MM-DD (XX)THH:MM	N/A	Completed	
XX-XXXX	YYYY-MM-DD (XX)	YYYY-MM-DD (XX)THH:MM	N/A	Lost to Follow-up	
XX-XXXX	YYYY-MM-DD (XX)	YYYY-MM-DD (XX)THH:MM	N/A	XXXXXXX	
XX-XXXX	YYYY-MM-DD (XX)	YYYY-MM-DD (XX)THH:MM	YYYY-MM-DD (XX)	XXXXXXX	XXXXXX

[1] Day is date minus Baseline date plus 1.

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Data Listing 16.2.2: Protocol Deviations
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Deviations/Violations Done by	Category	Date of Deviation	Reason(s) for Deviation/Violations
XX-XXXX	Investigator	Major	YYYY-MM-DD	XXXXXXXXX
XX-XXXX	Subject	Minor	YYYY-MM-DD	XXXXXXXXX

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Data Listing 16.2.3: Population Inclusion
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Safety Population	mITT Population	PP Population	Reason for Exclusion from mITT Population	Reason for Exclusion from PP Population
XX-XXXX	Yes	Yes	No	NA	Not compliant with the treatment regimen
XX-XXXX	Yes	Yes	No	NA	No Day 15 IGA evaluation within the designated visit window
XX-XXXX	Yes	No	No	Did not return for post-baseline visit	--
XX-XXXX	Yes	No	No	Not meeting all inclusion/exclusion criteria	--

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Data Listing 16.2.4.1: Demographics and Baseline Characteristics
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Age (Years)	Sex	Ethnicity	Race	BSA Involvement (%)	IGA	Weight (kg)	Height (cm)
XX-XXXX	XX.X	X	XXXXXXXX	XXXXXX	XX.X	2 – Mild	XX.X	XX.X
XX-XXXX	XX.X	X	XXXXX	Other: XXXXX	XX.X	3 – Moderate	XX.X	XX.X

Note: BSA = Body Surface Area; IGA = Investigator's Global Assessment

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Data Listing 16.2.4.2.1: Medical History
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Diagnosis and/or Procedure	System Organ Class	Preferred Term	Onset Date	Resolution Date
XX-XXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXX-XX-XX	XXXX-XX-XX
	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXX-XX-XX	Ongoing
	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXX-XX-XX	XXXX-XX-XX
XX-XXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXX-XX-XX	XXXX-XX-XX
XX-XXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXX-XX-XX	XXXX-XX-XX

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Data Listing 16.2.4.2.2: Dermatologial History and Diagnosis of AD
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Dermatologic malignancy?	Reason for Use of Study Products[1]	Dermatological Exams	Hanifin and Rajka Criteria	
				Major	Minor
XX-XXXX	Y	Inadequate prior response	XXXXXX XXXXXXXXX	XXXXXX XXXXXXXX XXXXXXXXXXXXXXXXXXX	XXXXXX XXXXXXXXXXXXXXXX XXXXXXX
XX-XXXX	N	Cannot use other topicals	XXXXXX	XXXXXX XXXXXXXX XXXXXXXXXXXXXXXXXX	XXXXXX XXXXXXXXXXXXXXXX XXXXXXX

[1] Inadequate prior response = failed to respond adequately to other topical prescription treatments for AD; Cannot use other topicals = it is not advisable for the subject to use other topical prescription treatments?

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<Programming note: concatenate and present all recorded reasons for use of study proudcts, derm exam results, and major and minor criteria >

Data Listing 16.2.4.3.1: Prior Medications
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication	Dosage / Units	Frequency / Route	Start Date (Day) – Stop Date (Day) [1]
XX-XXXX	XXXXXXXX (XXXXXXXX) / XXXXXXXX	Adverse Event	XXXX / XXXX	XXXX / XXXX	YYYY-MM-DD(X)- YYYY-MM-DD(X)
	XXXXXXXX (XXXXXXXX) / XXXXXXXX	Medical History	XXXX / XXXX	XXXX / XXXX	YYYY-MM-DD(X)- Ongoing

[1] Day is date of visit minus Baseline/Day 1 date plus 1.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Data Listing 16.2.4.3.2: Concomitant Medications
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication	MH/AE SOC/ PT	Dosage / Units	Frequency / Route	Start Date (Day) – Stop Date (Day) [1]
XX-XXXX	XXXXXXXX (XXXXXXXX) / XXXXXXXX	Adverse Event	XXXXXX	XXXX / XXXX	XXXX / XXXX	YYYY-MM-DD(X)- YYYY-MM-DD(X)
	XXXXXXXX (XXXXXXXX) / XXXXXXXX	Medical History	XXXX	XXXX / XXXX	XXXX / XXXX	YYYY-MM-DD(X)- Ongoing

[1] Day is date of visit minus Baseline/Day 1 date plus 1.

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Data Listing 16.2.5.1: Study Drug Administration and Compliance
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Visit	Date of First Dose Administration(AM/PM)/ Date of Last Dose Administration(AM/PM)	Study Drug Administration Stopped?	Reason Stopped	Date (Day) of Decision[1]	Number of Recorded Doses	Number of Expected Doses	Percentage of Compliance (%)
XX-XXXX	Day 8	YYYY-MM-DD (AM)/ YYYY-MM-DD (XX)	No	NA	NA	XX	XX	XX.X
	Day 15	YYYY-MM-DD (PM)/ YYYY-MM-DD (XX)	Yes	XXXXXXX	YYYY-MM-DD (XX)	XX	XX	XX.X
XX-XXXX	Day 8	YYYY-MM-DD (AM)/ YYYY-MM-DD (XX)	No	NA	NA	XX	XX	XX.X
	Day 15	YYYY-MM-DD (PM)/ YYYY-MM-DD (XX)	Yes	XXXXXXX	YYYY-MM-DD(XX)	XX	XX	XX.X

[1] Day is date of visit minus Baseline date plus 1.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Data Listing 16.2.5.2: Subject Treatment Diary Card
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Medication Application Date (Day)[1]	Medication Applied		Reason if Medication not Applied	Comments or Feeling of Discomfort Due to Medication
		AM	PM		
XX-XXXX	YYYY-MM-DD (1)	Y	N	XXXXXXX	XXXXX
	YYYY-MM-DD (XX)	Y	Y	NA	NA

[1] Day is date minus Baseline date plus 1.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Data Listing 16.2.5.3: Study Drug Accountability
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

			Used Drug Tubes		Unused/Partially Used Drug Tubes					
Subject Number	**Visit**	**Date (Day)[1]**	**Collected?**	**Number Used**	**Collected?**	**Number Partially Used**	**Number unused**	**All Tubes Returned?/ Reason if Not**	**Study Drug Re-dispensed?/ Reason if Not**	**Dispensing Date**
XX-XXXX	Day 8	YYYY-MM-DD (XX)	Y	X	N	0	0	No/ XXXXXXX	Yes/ NA	YYYY-MM-DD
	Day 15	YYYY-MM-DD (XX)	N	0	Y	X	X	Yes/ NA	No/ XXXXX	NA

[1] Day is date minus Baseline date plus 1.

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Data Listing 16.2.6.1: Investigator's Global Assessment (IGA)
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

					Observed		LOCF[4]		
Subject Number	**Visit**	**Date (Day) [1]**	**Was IGA Performed?**	**Reason if not Performed**	**Overall IGA[2]**	**Change from Baseline[3]**	**Overall IGA**	**Change from Baseline**	**IGA Success on Day 15**
XX-XXXX	Screening	YYYY-MM-DD (XX)	Yes	NA	2 – Mild	-	-	-	-
	Baseline/Day 1	YYYY-MM-DD (XX)	Yes	NA	2 – Mild	-	-	-	-
	Day 8	YYYY-MM-DD (XX)	Yes	NA	1 – Almost Clear	-1	-	-	-
	Day 15	YYYY-MM-DD (XX)	Yes	NA	XXXXXX	X	XXXXXX	X	Y

Note: Baseline is the last available measurement prior to first application of study medication. LOCF=Last Observation Carried Forward
[1] Day is date of visit minus Baseline date plus 1.
[2] Based on a 5-point scale of 0 (Clear) to 4 (Severe Disease).
[3] Indication: 2 = Worsen by 2 Points; 1 = Worsen by 1 Point; 0 = No Change; -1 = Improve by 1 Point; -2 = Improve by 2 Points; -3 = Improve by 3 Points
[4] LOCF results only present at Day 15

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Data Listing 16.2.6.2: Individual Signs and Symptoms of AD
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

			Erythema				**Induration/Papulation**				**Lichenification**				
Subject Number	**Visit**	**Date (Day) [1]**	Head & Neck	Trunk	Upper Limbs	Lower Limbs	Head & Neck	Trunk	Upper Limbs	Lower Limbs	Head & Neck	Trunk	Upper Limbs	Lower Limbs	**Overall Pruritus**
XX-XXXX	Screening	YYYY-MM-DD (XX)	1	X	X	X	X	X	X	X	X	X	X	X	X
	Baseline/Day 1	YYYY-MM-DD (XX)	3	X	X	X	X	X	X	X	X	X	X	X	X
	Day 8	YYYY-MM-DD (XX)	X	X	X	X	X	X	X	X	X	X	X	X	X
	Day 15	YYYY-MM-DD (XX)	X	X	X	X	X	X	X	X	X	X	X	X	X

Note: 0=None, 1=Mild, 2=Moderate, 3= Severe
[1] Day is date minus Baseline date plus 1.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Data Listing 16.2.6.3: Body Surface Area (BSA) Assessment
All Randomized Subjects
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Visit	Date (Day) [1]	Was BSA Assessment Performed?	Reason if not Performed	Percentage of BSA Involvement (%)	Change from Baseline[2]
XX-XXXX	Screening	YYYY-MM-DD (XX)	Yes	NA	XX.X	-
	Baseline/Day 1	YYYY-MM-DD (XX)	Yes	NA	XX.X	-
	Day 8	YYYY-MM-DD (XX)	No	XXXXXX	XX.X	XX.X
	Day 15	YYYY-MM-DD (XX)	Yes	NA	XX.X	XX.X

Note: Baseline is the last available measurement prior to first application of study medication.
[1] Day is date of visit minus Baseline date plus 1.
[2] Calculated as post-Baseline minus Baseline.

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Data Listing 16.2.7.1: Adverse Events
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term)	SAE? SAE Criteria	Treatment-emergent? [1] Onset Date (Day) – End Date (Day) [2]	Outcome	Severity	Causality Assessment	Action Taken / Other Action Taken
XX-XXXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes: XXXXX	Yes / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	Mild	Definitely Related	XXXXXXXX / XXXXXXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	No	No / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX / XXXXXXXX
XX-XXXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	No	XXX / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX / XXXXXXXX

[1] Treatment-emergent AEs (TEAEs) are defined as AEs with an onset date on or after the first application of study medication.
[2] Day is date minus Baseline/Day 1 date plus 1.

Generated on XX/XX/XX:XXXX by LSTAE / Uses: AE

Data Listing 16.2.7.2: Serious Adverse Events
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	SAE Criteria	Treatment-emergent? [1] Onset Date (Day) – End Date (Day) [2]	Outcome	Severity	Causality Assessment	Action Taken / Other Action Taken
XX-XXXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	XXXXX	Yes / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	Mild	Definitely Related	XXXXXXXX / XXXXXXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	XXXXX	No / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX / XXXXXXXX
XX-XXXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	XXXXX	XXX / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX / XXXXXXXX

[1] Treatment-emergent AEs (TEAEs) are defined as AEs with an onset date on or after the first application of study medication.
[2] Day is date minus Baseline/Day 1 date plus 1.

Generated on XX/XX/XX:XXXX by LSTAE / Uses: AE

Data Listing 16.2.7.3: Adverse Events Leading to Study Drug Discontinuation
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	SAE? SAE Criteria	Treatment-emergent? [1] Onset Date (Day) – End Date (Day) [2]	Outcome	Severity	Causality Assessment	Other Action Taken
XX-XXXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes: XXXXX	Yes / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	Mild	Definitely Related	XXXXXXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	No	No / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
XX-XXXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	No	XXX / YYYY-MM-DD (XX) – YYYY-MM-DD (XX)	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX

[1] Treatment-emergent AEs (TEAEs) are defined as AEs with an onset date on or after the first application of study medication.
[2] Day is date minus Baseline/Day 1 date plus 1.

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Data Listing 16.2.7.4: Scoring of Local Application Site Reactions
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Visit	Date (Day) [1]	Was the Scoring Performed?	Reason not Performed	Dryness	Stinging/ Burning	Erosion	Edema	Pain
XX-XXXX	Screening	YYYY-MM-DD (XX)	Yes	NA	1 – Mild	XXXX	XXXX	XXXX	XXXX
	Baseline/Day 1	YYYY-MM-DD (XX)	Yes	NA	XXXX	XXXX	XXXX	XXXX	XXXX
	Day 8	YYYY-MM-DD (XX)	Yes	NA	XXXX	XXXX	XXXX	XXXX	XXXX
	Day 15	YYYY-MM-DD (XX)	Yes	NA	XXXX	XXXX	XXXX	XXXX	XXXX

[1] Day is date of visit minus Baseline date plus 1.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

16.2.8.1: Urine Pregnancy Test
All Randomized Female Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Childbearing Potential	Visit	Date of Test (Day)[1]	Result
XX-XXXX	Abstinence	Baseline/Day 1	YYYY-MM-DD (XX)	Negative
		Day 15	YYYY-MM-DD (XX)	Negative
XX-XXXX	XXXXXXX	Baseline/Day 1	YYYY-MM-DD (XX)	Negative
		Day 15	YYYY-MM-DD (XX)	Negative

[1]Day is date minus Baseline/Day 1 date plus 1.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.2: Vital Signs
All Randomized Subjects
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Visit	Date (Day) [1]	Assessment Performed?	Height (cm)	Weight (kg)	Body Temperature (ºF)		SBP (mmHg)		DBP (mmHg)		Pulse Rate (bpm)	
						Observed	CFBL	Observed	CFBL	Observed	CFBL	Observed	CFBL
XX-XXXX	Screening	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	--	xx.x	--	xx.x	--	xx.x	--
	Baseline/Day 1	YYYY-MM-DD (XX)	N:XXXX	xx.x	xx.x	xx.x **(CS)**	--	xx.x	--	xx.x	--	xx.x	--
	Day 8	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 15	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	xx.x	xx.x **(CS)**	xx.x	xx.x	xx.x	xx.x	xx.x
XX-XXXX	Screening	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	--	xx.x	--	xx.x	--	xx.x	--
	Baseline/Day 1	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	--	xx.x	--	xx.x	--	xx.x	--
	Day 8	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 15	YYYY-MM-DD (XX)	Y	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Note: CS=Clinically Significant; SBP=Systolic blood pressure; DBP=Diastolic blood pressure; CFBL= change from baseline
[1] Day is date of visit minus Baseline date plus 1.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

<programming note: include CS in bold for CS observations >

Data Listing 16.2.8.3: Physical Examination
Randomized Subjects with Abnormal Results
Actual Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Visit	Date (Day) [1]	Organ/System	Comment
XX-XXXX	Screening	YYYY-MM-DD (XX)	Head	XXXXXXXXXX
			Eyes	XXXXX
	Baseline/Day 1	YYYY-MM-DD (XX)	Eyes	XXXXXXXXXX
XX-XXXX	XXXX	YYYY-MM-DD (XX)	NA	XXXXX
	XXXX	YYYY-MM-DD (XX)	Head	XXXXX

[1] Day is date of visit minus Baseline date plus 1.

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16.2.9: General Comments
Randomized Treatment: [Pimecrolimus Cream, 1%][Elidel® (Pimecrolimus) Cream 1%][Placebo]

Subject Number	Reference	Comment
XX-XXXX	eCRF Page XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	eCRF Page XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XX-XXXX	eCRF Page XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	eCRF Page XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

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Certificate Of Completion

Envelope Id: 64D898E58F71424D8C9E3689337E9547
Status: Completed
Subject: Please DocuSign: DPT_CD-14-875_SAP_Final.pdf
Source Envelope:
Document Pages: 68
Signatures: 3
Envelope Originator:
Supplemental Document Pages: 0
Initials: 0
Ivelisse Rivera
Certificate Pages: 5
AutoNav: Enabled
Payments: 0
1700 Perimeter Park Drive
EnvelopeId Stamping: Disabled
Morrisville, NC 27560
Time Zone: (UTC-08:00) Pacific Time (US & Canada)
Ivelisse.Rivera@novellaclinical.com
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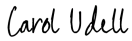
Carol Udell Carol.Udell@novellaclinical.com Security Level: Email, Account Authentication (Required)	 Signature ID: CE741CD0-FE97-41EC-A29C-B39E84B183BB Using IP Address: 65.205.190.115 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 6/29/2017 7:53:08 AM Viewed: 6/29/2017 7:56:12 AM Signed: 6/29/2017 7:56:42 AM
Electronic Record and Signature Disclosure: Accepted: 6/29/2017 6:05:59 AM ID: 23a67abb-661c-48d7-a3b0-5cd8fbe94ff5		
Katrin Beckmann katrin.beckmann@mylan.com Security Level: Email, Account Authentication (Required)	 Signature ID: 57B7C204-8BC8-4782-AF97-02CCDE55D6D2 Using IP Address: 129.35.202.236 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 6/29/2017 7:56:46 AM Viewed: 6/30/2017 1:51:15 AM Signed: 6/30/2017 2:15:07 AM
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Kathleen Ocasio Kathleen.Ocasio@dptlabs.com Security Level: Email, Account Authentication (Required)	 Signature ID: FFE08E0F-E0E3-411F-89EF-D4D82881E090 Using IP Address: 67.86.42.245 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 6/30/2017 2:15:11 AM Resent: 6/30/2017 5:34:01 AM Resent: 6/30/2017 5:59:52 AM Resent: 7/6/2017 8:05:31 AM Viewed: 6/30/2017 6:37:50 AM Signed: 7/7/2017 6:38:00 AM
Electronic Record and Signature Disclosure: Accepted: 6/30/2017 6:37:50 AM ID: c4951be6-83ed-40c1-adfb-38d49d6344c2		

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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	7/7/2017 6:38:05 AM
Certified Delivered	Security Checked	7/7/2017 6:38:05 AM
Signing Complete	Security Checked	7/7/2017 6:38:05 AM
Completed	Security Checked	7/7/2017 6:38:05 AM

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Browsers (for SENDERS):	Internet Explorer 6.0? or above
Browsers (for SIGNERS):	Internet Explorer 6.0?, Mozilla FireFox 1.0, NetScape 7.2 (or above)
Email:	Access to a valid email account
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	•Allow per session cookies •Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection

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