DignitySciences

Protocol number:
DS107G-02

A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II STUDY TO ASSESS THE EFFICACY AND SAFETY OF ORALLY ADMINISTERED DS107G TO PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

Statistical Analysis Plan

FINAL

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SIGNATURE PAGE

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LIST OF ABBREVIATIONS

AD	Atopic Dermatitis
AE	Adverse Event/Adverse Experience
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
BSA	Body Surface Area
CI	Confidence Interval
CRF	Case Report Form
CS	Clinically Significant
DGLA	Dihomo-gamma-linolenic acid
DLQI	Dermatology Life Quality Index
EASI	Eczema Area and Severity Index
ICF	Informed Consent Form
IGE	Investigator's Global Evaluation of Eczema
ITT	Intent-to-treat
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
LOCF	Last Observation Carried Forward
LLN	Lower Limit of Normal
LLT	Lower Level Term
MedDRA ©	Medical Dictionary for Regulatory Activities
NCS	Non-clinically significant
POEM	Patient Oriented Eczema Measure
PP	Per Protocol
PT	Preferred Term
SAE	Serious Adverse Event/Serious Adverse Experience
SAF	Safety Population
SAP	Statistical analysis plan
SCORAD	SCORing of Atopic Dermatitis
SD	Standard Deviation

SOC	System Organ Classification
TEAE	Treatment-Emergent Adverse Event/Adverse Experience
TEWL	Trans Epithelial Water Loss
ULN	Upper Limit of Normal
WHODD	World Health Organisation Drug Dictionnary
VAS	Visual Analog Scale

1 Introduction

All statistical analyses will be performed in accordance with the protocol DS107G-02, dated 22-JUL-2015 (Version 2.2). This statistical analysis plan (SAP) includes a comprehensive and detailed description of the statistical methods and presentation of the data analysis by adding more details to the proposed methods in the protocol. The purpose of the SAP is to define the statistical approaches for the analysis of study data prior to database lock.

2 Study Objectives

Primary objectives: To compare the efficacy of orally administered DS107G capsules versus placebo, in the treatment of adult patients with moderate to severe atopic dermatitis.

Secondary objective: To assess the safety of orally administered DS107G capsules versus placebo, in adult patients with moderate to severe atopic dermatitis.

3 Study Methods

3.1 General Study Design and Plan

Approximately 100 patients with moderate to severe atopic dermatitis will be included in this multicenter, double-blind, placebo controlled, phase IIa study. All subjects will sign an informed consent and undergo screening for study eligibility. Subjects will be randomized (1:1) at baseline visit to either receive oral DS107G 2 g, or placebo once daily for 8 weeks in a fasting state.

Subjects will come to the clinic on 6 occasions: at screening, baseline, week 2, week 4, week 8 (end of treatment/early termination) and week 10 (follow-up). All subjects will exit the study at the Week 10 visit. The primary efficacy variable will be the proportion of patients achieving an IGA of 0 (clear) or 1 (almost clear) and a decrease of at least 2 points in IGA at week 8. Secondary efficacy variables will include IGA at other visits, pruritus (obtained from the SCORAD visual analog scale), EASI, BSA, POEM, DLQI, SCORAD and TEWL (for selected sites only). Safety will be assessed through adverse events, physical examination, vital signs and safety laboratory tests (including pregnancy tests for women of childbearing potential). Pharmacokinetic samples will be obtained at Baseline (Day 0), week 4 and week 8 visits in order to measure total and free DGLA plasma trough levels. A separate plasma sample will be retained for later analysis of total fatty acid profile and interleukin profile.

The study flow chart of all assessment and timing is presented in Figure 1.

Figure 1. Study Flow Chart

Visit	Screening	Baseline	Week 2	Week 4	Week 8 / ET visit	Follow up visit / Week 10
Day	**-30 to -1**	**0**	**14 (± 2)**	**28 (± 2)**	**56 (± 2)**	**70 (±3)**
Informed Consent	X					
Demographics	X					
Medical / Surgical History	X	X				
Ongoing medical history[¥]					X	X
Review Inclusion/Exclusion Criteria	X	X				
Hanifin and Rajka criteria	X					
Assign subject identifier number	X					
Randomization		X				
Concomitant Medications	X	X	X	X	X	X[δ]
Safety labs and inflammation biomarkers: Serum Chemistry (including FSH levels at screening when applicable[¥] and interleukin profile), Coagulation, Hematology, urinalysis	X[Φ]	X		X	X	(X**)[Φ, δ]
Pharmacokinetics (pre-dose blood draw)[††]		X		X	X	
Blood draw for fatty acid profile sample[††,]		X		X	X	
Pregnancy Test (β-hCG if female of childbearing potential)*	X	X	X	X	X	X[δ]
Vital Signs	X	X	X	X	X	X[δ]
Physical Examination	X			X	X	X[δ]
BMI	X	X			X	
Study Drug Administration (on site)[€]		X		X	[§]	
Dispense Study Drug		X	X	X		
Collect Study Drug			X	X	X	
Dispense Subject Compliance Log		X	X	X		
Collect and Review Subject Compliance Log			X	X	X	
Capsule count			X	X	X	
BSA	X	X	X	X	X	X
IGA	X	X	X	X	X	X
EASI assessment		X	X	X	X	X
SCORAD assessment / VAS pruritus assessment		X	X	X	X	X
POEM questionnaire		X	X	X	X	X
DLQI questionnaire		X	X	X	X	X
TEWL (selected sites only)		X	X	X	X	X
Adverse Events[†]		X[†]	X	X	X	X[δ]

¥:: For women greater than 40 and less than 60 years of age who have had a cessation of menses for at least 12 months but less than 24 months

**: Only if clinically significant change from baseline in safety lab results at week 8

*: Serum pregnancy test at screening and week 8 / ET visits, urine test pregnancy for all other visits
††: If a subject took study medication prior to the visit, he/she will be required to come back the following day for PK blood draws.
€: Subjects must be fasting for at least 8 hours before and 60 minutes after drug administration
§: Subjects will be instructed to take their last study drug dose the day preceding week 8 visit.
†: Collection of AE will start after the first study drug administration
Ɣ: Assessment if any ongoing condition has improved since baseline.
Φ: Interleukin profile will not be evaluated at screening and week 10.
δ: In the case the subject ends the study before completion, the subject will also return 2 weeks after the ET visit for safety assessment listed at Week 10.

3.2 Inclusion-Exclusion Criteria and General Study Population

To participate in the study, subjects must meet all the inclusion criteria and none of the exclusion criteria.

3.2.1 Inclusion Criteria

Subjects must meet all of the following criteria to be eligible for this study:

- Male or female subject aged 18 years and older on the day of signing the informed consent form (ICF).
- Clinically confirmed diagnosis of active atopic dermatitis according to Hanifin and Rajka criteria.
- Moderate to severe atopic dermatitis at baseline as defined by an IGA of minimum 3 at baseline visit.
- Atopic dermatitis covering minimum 10% of the body surface area at baseline.
- Body mass index (BMI) is between 18 and 35 kg/m^2 inclusively.
- Female patients of childbearing potential must use adequate contraception or have a sterilized partner for the duration of the study: systemic hormonal contraceptives, intrauterine device or barrier method of contraception in conjunction with spermicide, or agree to sexual abstinence. Hormonal contraceptives must be on a stable dose for at least one month before baseline. Note: Women of non-child bearing potential are:
  - women who have had surgical sterilization (hysterectomy or bilateral oophorectomy or tubal ligation)
  - women greater than 60 years of age
  - women greater than 40 and less than 60 years of age who have had a cessation of menses for at least 12 months and a follicle-stimulating hormone (FSH) test confirming non-childbearing potential (FSH ≥40 mIU/mL) or cessation of menses for at least 24 months without FSH levels confirmed.
- Patients who are able and willing to stop treatment for atopic dermatitis throughout the study (except for allowed emollients).
- Capable and willing to give signed informed consent and the consent must be obtained prior to any study related procedures.

3.2.2 Exclusion Criteria

Subjects must not have the following to be eligible for this study:

- Female patients with positive pregnancy test at screening or Day 0 visit (baseline) or lactating women.
- Any clinically significant controlled or uncontrolled medical condition or laboratory abnormality that would, in the opinion of the investigator, put the patient at undue risk or interfere with interpretation of study results.
- Clinically significant impairment of renal or hepatic function.
- Other skin conditions that might interfere with atopic dermatitis diagnosis and/or evaluation (such as psoriasis or current viral, bacterial and fungal skin infections).
- History of hypersensitivity to any substance in DS107G or placebo capsules.
- Use of biologics 3 months prior to start of treatment/ Day 0 visit (baseline), or 5 half-lives (whichever is longer).
- Use of systemic treatments (other than biologics) that could affect atopic dermatitis less than 4 weeks prior to baseline visit (Day 0), e.g. retinoids, calcineurin inhibitors, methotrexate, cyclosporine, hydroxycarbamide (hydroxyurea), azathioprine and oral/injectable corticosteroids; Intranasal corticosteroids and inhaled corticosteroids for stable medical conditions are allowed.
- Treatment with any experimental drug within 30 days prior to Day 0 visit (baseline), or 5 half lives (whichever is longer).
- Excessive sun exposure, use of tanning booths or other ultraviolet (UV) light sources 4 weeks prior to Day 0 visit (baseline) and/or is planning a trip to sunny climate to use tanning booths or other UV sources between screening and follow-up visits.
- Use of any topical medicated treatment for atopic dermatitis 2 weeks prior to start of treatment/Day 0 visit (baseline), including but not limited to, topical corticosteroids, calcineurin inhibitors, tars, bleach, antimicrobials and bleach baths.
- Use of topical products containing urea, ceramides or hyaluronic acid for 2 weeks prior to Day 0.
- Use of anti-histamines for atopic dermatitis within 2 weeks of baseline.
- Significant uncontrolled cardiovascular (a history of ECG abnormalities that are clinically significant in the opinion of the investigator), neurologic, malignant, psychiatric, respiratory or hypertensive disease, as well as diabetes and arthritis.
- Medical history of chronic infectious disease (e.g., hepatitis B, hepatitis C or infection with human immunodeficiency virus).
- History of clinically significant drug or alcohol abuse in the last year prior to Day 0 (baseline).

3.3 Randomization and Blinding

Approximately 100 patients will be randomized into double-blind treatment groups a 1:1 ratio by an Interactive Web Response System (IWRS) or Interactive Voice Response System (IVRS), as follows:

- Treatment group A: 2 grams DS107G (4 capsules)
- Treatment group B: 2 grams placebo capsules (4 capsules)

A randomization list permuted blocks will be generated by Dignity Sciences or its designee. The randomization schedule with study drug assignments will be generated prior to the start of the study and will be known only to the individuals responsible for labeling the study drug. The IVRS or IWRS will assign a study drug kit number to each subject and the contents will be based on the randomization code.

Each subject will be assigned a patient identifier number during screening that will be used on all patient documentation. The patient identifier number will contain the site number and the patient number assigned in numerical order at the screening visit (e.g.: 02-010 for the tenth patient screened at the site #02). Numbers will be assigned in ascending order starting with 001.

Four patients were randomized under site 6X instead of site 06 (6X-001, 6X-002, 6X-004 and 6X-005). Those 4 patients will be reassigned to site 06 for the presentation and the summarization of the results.

3.4 Study Variables

3.4.1 Demographics and Baseline Characteristics

Age calculated in years is defined as the difference between the informed consent date and the birthdate.

Gender is a code list where 1 equals Male and 2 equals Female.

Height in centimeters measured to the nearest centimeter.

Weight in kilograms (kg) measured to one decimal place.

Body Mass Index (BMI) will be calculated as the weight (kg) divided by the square of height (m) and rounded to one decimal place (kg/m^2).

Race is an integer ranging from 1 to 6, where 1 corresponds to American Indian or Alaska Native, 2 corresponds to Asian, 3 corresponds to Black or African American, 4 corresponds to Native Hawaiian or Other Pacific Islander, 5 corresponds to White, and 6 corresponds to Other.

Ethnicity is code list where 1 corresponds to ‘Hispanic or Latino’ and 2 corresponds to ‘Not Hispanic or Latino’.

Medical History
Medical history will be coded using the Body System Code as the following: Eyes-Ears-Nose-Throat, Respiratory (Asthma/Other), Cardiovascular, Gastrointestinal, Hepatobiliary, Genitourinary/ Renal, Reproductive, Neurological, Endocrine, Hematological, Musculoskeletal, Dermatologic, Extremities, Immunological, Psychiatric, and Allergies.

Medications
Medications will be coded using the Preferred Term from the WHO Drug Dictionary (Sept-2014 B2). If the start and end dates of the medication are prior to the study drug start date then the medication will be coded as prior medication. Otherwise the medication will be considered as concomitant medications.

3.4.2 Efficacy Variables

3.4.2.1 Primary Efficacy Variable
The primary efficacy variable is the **Investigator's Global Assessment (IGA)** of Disease Severity and will be assessed at each visit. The IGA is a global assessment of the current state of the disease. It is a 6-point morphological assessment of overall disease severity and will be determined according to the following definitions:

Score	Grade	Definition
0	Clear	No evidence of disease with the exception of residual pigment changes and/or xerosis
1	Almost clear	Perceptible erythema, papulation/infiltration
2	Mild	Mild erythema, papulation/infiltration
3	Moderate	Moderate erythema, papulation/infiltration
4	Severe	Severe erythema, papulation/infiltration
5	Very Severe	Severe erythema, papulation/infiltration with oozing/crusting

Change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change will be calculated at Week 2, Week 4, Week 8, and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated.

The IGA will be also examined using the following criteria:

- IGA of 0 (clear) or 1 (almost clear) at Week 8;
- at least a 2-point decrease in IGA at Week 8;
- at least a 1-point decrease in IGA at Week 8;
- No Change or Increased from Baseline in IGA at Week 8

3.4.2.2 Secondary Efficacy Variable

Secondary efficacy variables are as follows:

- The **Eczema Area and Severity Index (EASI)** will be assessed at each visit, except screening visit. It quantifies the severity of a subject's atopic dermatitis based on both lesion severity and the percent of BSA affected.

  Four anatomic sites – head, upper extremities, trunk, and lower extremities – are assessed for erythema, induration (papules), excoriation and lichenification as seen on the day of the examination. The severity of each sign is assessed using a 4-point scale: 0 = No symptoms, 1 = Slight, 2 = Moderate, 3 = Marked.

  The area affected by atopic dermatitis within a given anatomic site is estimated as a percentage of the total area of that anatomic site and assigned a numerical value according to the degree of atopic dermatitis involvement as follows: 0 = no involvement, 1 = < 10 %, 2 = 10 to < 30%, 3 = 30 to < 50%, 4 = 50 to < 70%, 5 = 70 to < 90%, 6 = 90 to 100 %.

  The EASI score is obtained by using the formula:

  $$\begin{aligned} EASI = {} & 0.1 * (E_h + I_h + Ex_h + L_h) * A_h + \\ & 0.2 * (E_u + I_u + Ex_u + Ex_u) * A_u + \\ & 0.3 * (E_t + I_t + Ex_t + Ex_t) * A_t + \\ & 0.4 * (E_l + I_l + Ex_l + Ex_l) * A_l \end{aligned}$$

  Where E, I, Ex, L and A denote erythema, induration, excoriation, lichenification and area, respectively, and h, u, t, and l denote head, upper extremities, trunk, and lower extremities, respectively. The EASI score ranges from 0 (no disease) - 72 (maximal disease). The score will be set to missing in case of at least one missing value.

  The change from baseline in EASI at Week 2, Week 4, Week 8, and Week 10 will be calculated as the value at the visit minus the value at Baseline. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated.

- The overall **Body Surface Area (BSA)** affected by AD will be evaluated (from 0 to 100%) at each visit. One patient's palm represents 1% of his/her total BSA. For all study visits except at screening, the BSA of involved skin will be measured with the SCORAD measurement. The change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change from baseline will be calculated at Week 2, Week 4, Week 8 and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated.

- The **SCORing Atopic Dermatitis (SCORAD)** will be measured at each visit, except the screening visit. The SCORAD grading system is a standard tool to assess the AD severity in clinical studies in Europe. Six items (erythema, edema/papulation, oozing/crusts, excoriation, lichenification, and dryness) are selected to evaluate the AD severity. The intensity of each item is graded using a 4-point scale: 0 = No symptoms, 1 = Mild, 2 = Moderate, 3 = Severe.

  The area chosen for grading must be representative (average intensity) for each item. The individual intensity ratings for each item will then be added (ranging from 0-18) and multiplied by 3.5, giving a maximal score of 63.

  The overall BSA affected by AD is evaluated (from 0 to 100%) and divided by 5. One patient's palm represents 1% of his/her total BSA. The maximum is 20.

  Subjective items include loss of sleep and the occurrence of pruritus. These are evaluated by asking patients to indicate on the 10-cm scale (0-10) of the assessment form the point corresponding to the average value for the last three days/nights. The combined maximum score of these two is 20.

  The sum of the above measures represents the SCORAD which can vary from 0 to 103. If the subjective scores of pruritus and loss of sleep are excluded, the SCORAD becomes objective SCORAD (score range 0-83).

  The score will be set to missing if there is at least one missing value. The change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change from baseline will be calculated at Week 2, Week 4, Week 8, and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated.

- The **Visual Analog Scale (VAS) of Pruritus** will be assessed with the SCORAD measurement for all study visits except screening. This will be evaluated by asking subjects to indicate on the 10-cm scale (0-10) of the assessment form the point corresponding to the average value for the last three days/nights. The change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change from baseline will be calculated at Week 2, Week 4, Week 8, and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated.

- The **Patient-Oriented Eczema Measure (POEM)** will be assessed at each visit, except screening visit. The POEM is a self assessment of disease severity by the patient. The following questions are to be rated as: 0=No Days, 1=1-2 Days, 2=3-4 Days, 3=5-6 Days, 4=Everyday.

1. Over the last week, on how many days has your skin been itchy because of your eczema?

2. Over the last week, on how many nights has your sleep been disturbed because of your eczema?

3. Over the last week, on how many days has your skin been bleeding because of your eczema?

4. Over the last week, on how many days has your skin been weeping or oozing clear fluid because of your eczema?

5. Over the last week, on how many days has your skin been cracked because of your eczema?

6. Over the last week, on how many days has your skin been flaking off because of your eczema?

7. Over the last week, on how many days has your skin felt dry or rough because of your eczema?

The POEM score is the sum of the 7 question ratings for a possible total of 28 (more severe eczema). The score will be set to missing if there is at least one missing value. The change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change from baseline will be calculated at Week 2, Week 4, Week 8, and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated

- The **Dermatology Life Quality Index (DLQI)** questionnaire is a simple 10-question validated questionnaire which will be completed at each visit, except screening. The following questions are to be assessed by the patient:

1.	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much (3) A lot (2) A little (1) Not at all (0)	
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much (3) A lot (2) A little (1) Not at all (0)	
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **yard?**	Very much (3) A lot (2) A little (1) Not at all	Not relevant (0)
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much (3) A lot (2) A little (1)	

		Not at all	Not relevant (0)
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much (3) A lot (2) A little (1) Not at all	Not relevant (0)
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much (3) A lot (2) A little (1) Not at all	Not relevant (0)
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes (3) No (0)	
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot (2) A little (1) Not at all (0)	
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much (3) A lot (2) A little (1) Not at all	Not relevant (0)
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much (3) A lot (2) A little (1) Not at all	Not relevant (0)
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much (3) A lot (2) A little (1) Not at all	Not relevant (0)

The DLQI score is the sum of the 10 questions for a possible total of 30 (quality of life is impaired). 'Not relevant" and "Unanswered' questions will be scored as 0. The change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change from baseline will be calculated at Week 2, Week 4, Week 8, and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated

- **Trans epidemal Water Loss (TEWL)**, the clinical severity of AD and associated effect on skin barrier function will be evaluated at each visit, except the screening visit. This evaluation will be performed at selected sites that have demonstrated previous experience with this device.

  At Baseline (Day 0), the investigator will select three representative areas of active AD for each subject; the location of these sites will be recorded. At subsequent visits, TEWL readings for each area of AD will be taken in standard room ambient conditions (22-25˚C, 40-60% relative humidity); the mean of the TEWL measurements will be used for the

analyses. The change from Baseline will be calculated as the value at the visit minus the value at Baseline. The change from baseline will be calculated at Week 2, Week 4, Week 8, and Week 10. Percent change from baseline will also be calculated. In addition, change and percent change from Week 8 to Week 10 will be calculated.

3.4.3 Safety Variables

3.4.3.1 Adverse Events

Treatment-emergent adverse events (TEAEs) are defined as AEs that developed, worsened or became serious after the first dose of study drug during the study, i.e. from the study drug start date to the end of study.

TEAEs will be coded according to Medical Dictionary for Regulatory Activities (MedDRA, version 17.0) terminology. The coding process using MedDRA will be conducted by the data management where lower level term (LLT), the preferred term (PT) and system organ class (SOC) will be assigned to each AE term.

Descriptions of AEs will include the date of onset, the date the AE ended (if it resolved), the severity and seriousness of the AE, the relationship of the AE to study medication, and the outcome. If the onset date of the AE is incomplete or missing and the end date is incomplete or missing, or the end date is after the start of treatment, then the event will be evaluated as a TEAE. If the start date is at the Baseline Visit and the end date is incomplete or missing, then the event will be evaluated as a TEAE. The AE onset will also be shown relative (in number of days) to the day of first dose.

3.4.3.2 Laboratory Safety Variables

Urinalysis, hematology (with differential and coagulation testing), a standard chemistry panel (chemistry includes liver function tests and cholesterol), coagulation, and serum pregnancy test for women of childbearing potential will be collected during the study (see Figure 1. Study Flow Chart for details). The list of laboratory parameters are presented in Table 1 below.

Table 1. Clinical laboratory Testing

Laboratory testing	**Tests included**
Hematology	Basophils, Eosinophils, HCT, HGB, Lymphocytes, MCH, MCV, Monocytes, Neutrophils, platelets, RBC, WBC
Coagulation	APTT, INR, PT
Serum Chemistry	Albumin, Alkaline Phosphatase, ALT, AST, Chloride, Cholesterol (non-fasting), CK, Creatinine (Enzymatic), GGT, Glucose Random, LDH, Potassium, Sodium, Total Bilirubin, Triglycerides, Urea (BUN), Uric Acid β-hCG for females of childbearing potential
Urinalysis	Blood, Glucose, pH, Protein

Laboratory results will be transferred by the laboratory itself. The data will include the visit date and time, the laboratory result type (e.g. hematology), the analyte name, the result, the unit, the reference values, and the abnormal flag.

3.4.3.3 Vital Signs

Vital signs will be assessed at each visit and include systolic and diastolic blood pressure, pulse, oral temperature and respiratory rate. The following variables were created for each vital sign.

- Value at the time specified is the value specified for the parameter on the CRF
- Change from baseline is the value at the time specified minus the value at baseline

3.4.3.4 Physical Examination

The following sites/systems will be included in the Physical examination. Each system will be scored as: Normal, Abnormal Not Clinically Significant, or abnormal clinically significant.

- General appearance
- Dermatological (except atopic dermatitis)
- Head, Eyes, Ears, Nose, Throat (HEENT)

- Respiratory
- Cardiovascular
- Abdominal
- Neurological
- Musculoskeletal
- Lymphatic

3.4.3.5 Total and Free DGLA plasma levels, Total Fatty Profile and Interleukins levels

Total DGLA and free DGLA trough plasma levels will be measured at Baseline, week 4 and week 8. Total fatty profiles and interleukins levels will not be covered in this SAP.

4 Sample Size

The primary endpoint can be translated as a responder analysis where a subject will be classified as Responder if he/she achieves an IGA score of 0 (clear) or 1 (almost clear) at Week 8, considering a 2-point decrease from baseline. A sample size of 45 subjects will have a power of 80% to detect a statistically significant difference of 25% between responders from treated group and from the placebo group, based on a chi-square test and an alpha of 0.05. Based on the literature review, it is expected that the placebo could reach up to 7%, so the minimal proportion expected in the treated group should be at least 32%. Allowing for 10% drop-out, a total of 100 subjects should be enrolled in the study.

5 General Considerations

5.1 Timing of Analyses

The final analysis will be performed on data transferred to the statistician, having been documented as meeting the cleaning and approval requirements of the database lock and after the finalisation and approval of this SAP document.

There is no interim analysis planned for this study.

5.2 Analysis Populations

5.2.1 Intent-to-treat Population

The Intent-to-treat (ITT) population will consist of all randomized subjects. Analysis will be done according to the randomized treatment. This population will be used for all efficacy analyses.

5.2.2 Safety Population

The safety population will be defined as all randomized subjects who received at least one dose of the medication. Analysis will be done according to the actual treatment subjects received.

5.2.3 Per-Protocol Population

The per-protocol (PP) population will include all subjects who received at least one dose of the medication and who had at least one post-baseline evaluation on the primary endpoint of IGA with no significant protocol deviations. Analysis will be done according to the actual treatment subjects received.

Protocol deviation will be listed and summarized. Prior to database lock, significant protocol deviation will be defined and reviewed in a blinded fashion conjointly by the medical director (or delegate) and the statistician. Patients with significant protocol deviations will be excluded from the PP population.

The PP population will be used for all efficacy analyses as supportive analyses.

5.3 Missing Data/Multiple Observations

No imputation will be done for all population and all parameters, except for the primary endpoint. A supportive analysis using the last observation carried forward (LOCF) method will be performed on responder analysis (see section 7.1 for details).

In the event that two values were collected for the same visit, the scheduled assessment value will be retained in the analyses, unless otherwise specified (e.g. lab error). However, all values will be presented in the data listings. Laboratory values of '< X' ou '> X' will be set to 'X' for the analysis.

5.4 Multi-centre Studies

The primary efficacy analysis will be performed with site included in the statistical model as a stratification factor. A sensitivity analysis will also be conducted without site. Analysis on the secondary efficacy endpoints will include information on site. Safety data will be presented with all study sites pooled. Safety analysis will be performed with data from all sites being pooled.

To obtain a sufficient and better-balanced number of subjects among study sites, pooling of study sites will be applied prior to performing the statistical inference and unblinding treatment. Sites without at least 5 subjects in the ITT population will be incorporated into pooled sites as follows:

- All such sites with less than 5 subjects will be ordered from the lowest to the highest in terms of number of ITT subjects. In case of ties, the ordering for tied sites will be determined according to the site identification number (from smallest to largest).
- Sites will be combined beginning at the smallest until the resulting pooled site contains at least 5 ITT subjects. The sites pooled in this way will be considered as a single site in the statistical analyses.
- The process described above will resume for the remaining sites not meeting the criterion of at least 5 subjects. If the final set of pooled site does not meet the criterion of at least 5 ITT subjects, the final set will be pooled with the preceding pooled site.

5.5 Multiple Testing

Since there are only 2 treatment groups involved in this study, no correction for multiplicity will be performed.

6 Summary of Study Data

All continuous variables will be summarised using the following descriptive statistics: n (non-missing sample size), mean, standard deviation (SD), median, inter-quartile range (25th and 75th percentiles), maximum, and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures.

In general, all data will be listed, sorted by treatment group, site and subject, and when appropriate by visit number within subject. All summary tables will be structured with a column for each treatment in the same order (DS107G, Placebo) and will be annotated with the total population size relevant to that table/treatment.

Day 0 is the first day of study medication. In the event that there is more than one value for a given assessment prior to the study drug start date, the value obtained closest to Day 0, before administration of study drug will be considered as the baseline value. The baseline value will be the value nearest to and before the first dose of the study medication.

All statistical tests will be two-sided and will be performed with a significant level of 0.05, unless otherwise specified.

6.1 Subject Disposition

Subject disposition information, including the counts and percentages of subjects screened, screen failed, randomized, and who completed the study will be summarized based on all enrolled subjects (i.e. who signed the informed consent form).

Tables will be created indicating the number of subjects by treatment group in each of the analysis populations and attending each visit. Finally, for each of the analysis populations there will be tables indicating by treatment group the number of days in the study, the percentage of subjects discontinued and the reasons for discontinuation. Overall comparability of subject's discontinuation between the two treatment groups will be tested using a Fisher exact test and overall comparability of the reasons for discontinuation for both treatment groups will be done using an exact Pearson's Chi-Squares test.

Number of days in the study will be calculated as the difference between the date of the last visit (Follow up/Week 10) and the informed consent date plus 1.

6.2 Protocol Deviations

Protocol deviations may include, but are not limited to:

- Visit outside of the visit window
- Missed visit
- Missed/Extra dose(s)
- Study Procedure(s) not done
- Prohibited medication
- Etc.

A listing of all protocol deviations will be presented and documented in the study file. A descriptive summary table of protocol deviation categories by treatment group will be presented.

6.3 Demographic and Baseline Variables

Demographic and baseline variables will be analysed using descriptive statistics.

6.4 Medical History

Medical history will be presented using the frequency and percentage of subject by Body System Code.

6.5 Prior and Concomitant Medications

Medications will be coded to the preferred generic name using the WHO-Drug dictionary (version June 2013 B2). Compound product will be coded to the brand name. Any medications that started and ended prior to the study drug start date will be considered as “Prior” and “Concomitant”, otherwise. A listing of all medications will be produced.

6.6 Exposure and Treatment Compliance

Descriptive statistics will be presented by Treatment group on the extent of exposure and the compliance.

The extent of exposure will be defined as:

Number of days on drug = Date of Week 8/ET Visit – First dose study drug administration date.

Compliance will be calculated as follows:

$$\frac{(\text{Sum of all capsules dispensed}) - (\text{Sum of all capsules returned})}{(4 \times \text{Number of days on drug})} * 100$$

7 Efficacy Analyses

All efficacy variables will be summarized using descriptive statistics by treatment group at each visit.

7.1 Primary Efficacy Analysis

The primary endpoint can be translated as a responder analysis where a subject will be classified as Responder if he/she achieves an IGA score of 0 (clear) or 1 (almost clear) at Week 8, considering a 2-point decrease from baseline. Patients who did not complete the study (i.e. subjects with an early termination visit at Week 8) will be classified as non-responder.

The comparison between groups for the primary endpoint will be done using a Cochran-Mantel–Haenszel (CMH) test where the site will be used as the stratification factor. A sensitivity analysis will also be conducted using a Fisher's exact without Site. Subgroup analyses will also be performed on responders vs. non responders (using CMH test stratified for site) for each subgroup of patients (Very Severe/Severe and Modreate), separately.

The primary efficacy analysis will be done using observed values.A supportive analysis will be conducted using the LOCF method. For subjects who did not complete the study, the last non-missing IGA results (including results collected during the early termination Week 8 visit) will be used.

The analyses will be done using the ITT population and will serve as the primary analysis while the analysis of the primary endpoint using the PP population will be used as a supportive analysis.

7.2 Secondary Efficacy Analyses

The second efficacy endpoints are:

- Change from baseline in IGA at week 2, 4, and 8
- Change from baseline in EASI at week 2, 4, and 8
- Change from baseline in POEM at week 2, 4, and 8
- Change from baseline in DLQI at week 2, 4, and 8
- Change from baseline in SCORAD at week 2, 4, and 8
- Change from baseline in VAS at week 2, 4, and 8
- Change from baseline in BSA at week 2, 4, and 8
- Proportion of patients achieving at least 1-point decrease in IGA at Week 8

All secondary endpoint based on the change from baseline will be assesd using an ANCOVA where the change from baseline will be the dependant variable and including the treatment group and site as fixed effects and baseline value as a covariate. In addition, ANCOVA will also be performed on the change from baseline at week 10 and on the change from Week 8 to Week 10.

All secondary endpoint based on categories will be analysed using a Cochran–Mantel–Haenszel test stratified by site and the p-value from this test will be presented along with frequency and percentage of subjects for each category.

All change and percent change values will be summarized using descriptive statisitics, for each treatment group and visit. Proportion of subjects with no, 1-point, 2-point, 3-point, decrease/increase, will be presented at Week 8.

All statistical analyses will de bone at each visit and using the ITT (primary analysis) and PP (supportive analysis) population. All the analyses will be done using observed values. Results collected during the early termination visit related to Week 8 and Week 10 will not be included. No sensitivity analysis will be done for missing values.

7.3 Exploratory Efficacy Analyses

Change from baseline in TEWL at week 2, 4, and 8 will be analyzed using an ANCOVA as described in section 7.2.

8 Safety Analyses

Safety analysis will be performed based on the safety analysis population. No inferential statistics will be done on safety variables.

Adverse Events

Treatment-emergent AEs (TEAEs) will be summarized by the number of subjects reporting the events, as well as by System Organ Class, Preferred Term, severity, seriousness, and relationship to study medication. A general summary table will be provided with the number of TEAEs, Related TEAEs, Serious TEAEs and Serious Related TEAEs.

For the summary of TEAEs by severity, each patient will be counted only once within a System Organ Class or a Preferred Term by using the TEAEs with the highest intensity within each category for each analysis. For the summary of TEAEs by relationship to study medication, each patient will be counted only once within a System Organ Class or a Preferred Term by using the AEs with the greatest reported relationship within each category. For the summary of AEs by relationship to study medication and severity, each patient will be counted only once within a System Organ Class or a Preferred Term by using (1) the greatest reported relationship followed by (2) the highest reported intensity.

The following tables will be presented:

- TEAEs by SOC/PT;
- Related TEAEs by SOC/PT;
- TEAEs by severity and SOC/PT;
- TEAEs by relationship and SOC/PT;
- TEAEs by relationship/severity and by SOC/PT;
- TEAEs leading to treatment discontinuation by SOC/PT
- Serious TEAEs (SAEs) by SOC/PT;
- Related Serious TEAEs by SOC/PT;

Clinical Laboratory

The clinical laboratory results (including value at visit and change from baseline) will be presented descriptively for each time point. Shift table from baseline to each post-dose time points will be presented.

Vital Signs

The vital signs (including value at visit and change from baseline) will be presented descriptively for each time point.

Total and Free DGLA plasma levels, Total Fatty Profile and Interleukins levels

Relationship between DGLA levels and the severity of disease will be looked at. A scatter plot of Total and Free DGLA concentrations at baseline versus IGA score at Week 8 and versus change from baseline in IGA at Week 8 will be produced by treatment group as well as for both treatment combined. Spearman correlation coefficient will be presented. In addition, change from Baseline in DGLA versus change from baseline in IGA will also be plotted (along with Spearman correlation coefficient) at Week 8 as well as the change from baseline in DGLA at Week 8 versus the change from baseline in IGA at Week 10.

Descriptive statistics of level of DGLA will be presented by treatment, visit and responder status.

The analysis of the total fatty and interleukins data will not be covered in this SAP.

9 Reporting Conventions

P-values will be reported to 3 decimal places. If value is less than 0.001, then it will be shown as "<0.001". The mean, SD, Median and inter-quantile will be reported to one decimal place greater than the original data. The minimum and maximum will use the same number of decimal places as the original data.

10 Technical Details

All statistical processing will be performed using SAS® software, Version 9.2, or higher.

11 Summary of Changes to the Protocol

Additional analyses (not included in the protocol) were added in the statistical analysis plan.

- Total and Free DGLA plasma level in relation with IGA results
- Respondeur analysis controlling for the information on IGA at Baseline
- Comparability of the discontinuation rates and of the reasons for discontinuation for both treatment groups

12 References

No applicable.

13 Mock Tables, Listings and Figures

All tables, listings and figures (TLF) will be generated through SAS.

The title will be unique for each TLF and self-explanatory. The header section will comprise of the Sponsor's name, the protocol number, the TLF number, the TLF title, the analysis population, and the page number (Page X of Y). The footer section of the table will include the date and time of the execution of the program, and the name of the program. All necessary footnotes will be provided to add clarity to the TLF.

The font will be "Courier New", 8-9 points, or similar. The orientation will be landscape with 1 inch margins. The tables and figures will be placed under Appendix 14 in the Clinical Study Report while the listings will be placed in the Appendix 16.

The following sections display the expected TLFs. All efforts were made to create representative mock TLFs, however, these may change depending on the format and layout of the data, without changing the purpose of the presentation. In the event a major change to a TLF is required, this will be discussed within the study team and necessary documentation will be created.

13.1 Mock Tables

The list of tables is presented in the table below followed by the actual mock tables.

Table Number	Title	Population
	Study Conduct Tables	
14.1.1	Summary of Subject Enrollment and Disposition	All
14.1.2	Summary of Visits Completed	SAF/ITT/PP
14.1.3	Summary of Study Completion	SAF/ITT/PP
14.1.4	Summary of Protocol Deviations	SAF
14.1.5.1/.2/.3	Summary of Subject Demographics and Baseline Characteristics	SAF/ITT/PP
14.1.6	Summary of Medical History	SAF
14.1.7.1/.2/.3	Summary of Study Drug Exposure and Compliance	SAF/ITT/PP

Table Number	Title	Population
	Efficacy Tables	
14.2.1.1.1	Summary of Investigator's Global Assessment – Responder Analysis at Week 8	ITT
14.2.1.1.2	Summary of Investigator's Global Assessment – Responder Analysis at Week 8	PP
14.2.1.1.3	Summary of Investigator's Global Assessment – Responder Analysis at Week 8 – Supportive Analysis (LOCF)	ITT
14.2.1.1.4	Summary of Investigator's Global Assessment – Responder Analysis at Week 8 - Supportive Analysis (LOCF)	PP
14.2.1.2.1	Summary of Investigator's Global Assessment – Actual, Change and Percent Change from Baseline	ITT
14.2.1.2.2	Summary of Investigator's Global Assessment – Actual, Change and Percent Change from Baseline	PP
14.2.1.3.1	Summary of Investigator's Global Assessment – Proportion of Subjects with at least 1-point decrease, and with no or increase/decrease at Week 8	ITT
14.2.1.3.2	Summary of Investigator's Global Assessment – Proportion of Subjects with at least 1-point decrease, and with no or increase/decrease at Week 8	PP
14.2.2.1	Summary of Eczema Area and Severity Index – Actual, Change, and Percent Change from Baseline	ITT
14.2.2.2	Summary of Eczema Area and Severity Index – Actual, Change, and Percent Change from Baseline	PP
14.2.3.1	Summary of Patient-Oriented Eczema Measure – Actual, Change, and Percent Change from Baseline	ITT
14.2.3.2	Summary of Patient-Oriented Eczema Measure – Actual, Change, and Percent Change from Baseline	PP
14.2.4.1	Summary of Dermatology Quality of Life Index – Actual, Change, and Percent Change from Baseline	ITT
14.2.4.2	Summary of Dermatology Quality of Life Index – Actual, Change, and Percent Change from Baseline	PP
14.2.5.1	Summary of Summary of SCORing Atopic Dermatitis – Actual, Change, and Percent Change from Baseline	ITT
14.2.5.2	Summary of Summary of SCORing Atopic Dermatitis – Actual, Change, and Percent Change from Baseline	PP
14.2.6.1	Summary of Visual Analog Scale of Pruritus – Actual, Change, and Percent Change from Baseline	ITT
14.2.6.2	Summary of Visual Analog Scale of Pruritus – Actual, Change, and Percent Change from Baseline	PP
14.2.7.1	Summary of Body Surface Area – Actual, Change, and Percent Change from Baseline	ITT
14.2.7.2	Summary of Body Surface Area – Actual, Change, and Percent Change from Baseline	PP
14.2.8.1	Summary of Trans epidemal Water Loss – Actual, Change, and Percent Change from Baseline	ITT
14.2.8.2	Summary of Trans epidemal Water Loss – Actual, Change, and Percent Change from Baseline	PP
14.2.9.1	Summary of Total DGLA Concentrations – Actual and Change from Baseline by IGA results	ITT
14.2.9.2	Summary of Free DGLA Concentrations – Actual and Change from Baseline by IGA results	ITT
	Safety Tables	
14.3.1.1	Overall Summary of Adverse Events	SAF
14.3.1.2	Summary of Treatment-Emergent Adverse Events	SAF
14.3.1.3	Summary of Related Treatment-Emergent Adverse Events	SAF
14.3.1.4	Summary of Treatment-Emergent Adverse Events by Severity	SAF
14.3.1.5	Summary of Treatment-Emergent Adverse Events by Relationship	SAF
14.3.1.6	Summary of Treatment-Emergent Adverse Events by Relationship and Severity	SAF
14.3.1.7	Summary of Treatment-Emergent Adverse Events leading to treatment discontinuation	SAF

Table Number	Title	Population
14.3.1.8	Summary of Serious Treatment-Emergent Adverse Events	SAF
14.3.1.9	Summary of Related Serious Treatment-Emergent Adverse Events	SAF
14.3.4.1.1	Summary of Clinical Safety Laboratory Results – Serum Chemistry	SAF
14.3.4.1.2	Shift Table Clinical Laboratory – Serum Chemistry	SAF
14.3.4.2.1	Summary of Clinical Laboratory – Hematology	SAF
14.3.4.2.2	Shift Table Clinical Laboratory – Hematology	SAF
14.3.4.3.1	Summary of Clinical Laboratory – Urinalysis (Continuous)	SAF
14.3.4.3.2	Shift Table Clinical Laboratory – Urinalysis (Continuous)	SAF
14.3.4.3.3	Summary of Clinical Laboratory – Urinalysis (Categorical)	SAF
14.3.5	Summary of Vital Signs	SAF

Table 14.1.1
Summary of Subject Enrollment and Disposition
(All Subjects)

		Treatement Group		
Parameter	Statistic	DS107G	Placebo	Total
Number of Subjects Screened	N			xx
Number of Subjects Screen Failed	N			xx
Number of Subjects Randomized	N	xx	xx	xx
Number of Subjects in Safety Population[1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects in the Intent-to-Treat Population[1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects in the Per Protocol Population[1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

1 Percentages are based on the number of randomized subjects.
Note(s): The Safety (SAF) population includes all randomized subjects who received at least one dose of the medication, according to treatment received.
The Intent-To-Treat (ITT) population includes all randomized subjects, according to the randomized treatment.
The Per Protocol (PP) population includes all subjects who received at least one dose of the medication and who had at least one post-baseline evaluation on the primary endpoint of IGA with no significant protocol deviations.

Program: t14_1_1.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.2
Summary of Visits Completed

Parameter	Statistic	Treatement Group		Total
		DS107G	Placebo	
Number of Subjects in Safety Population[1]	N	xx	xx	xx
Screening	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 8/ET	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Follow up/Week 10	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects in Intent-to-treat Population[2]	N	xx	xx	xx
Screening	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 8/ET	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Follow up/Week 10	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects in Per Protocol Population[3]	N	xx	xx	xx
Screening	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 8/ET	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Follow up/Week 10	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

1 Percentages are based on the number of subjects in the safety population.
2 Percentages are based on the number of subjects in the intent-to-treat population.
3 Percentages are based on the number of subjects in the per protocol population.

Program: t14_1_2.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.3
Summary of Study Completion

Parameter	Statistic	Treatement Group: DS107G	Treatement Group: Placebo	Total
Number of Subjects in Safety Population	N	xx	xx	xx
Completed the study[1]				
Yes	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[5]	x.xxx		
Primary Reason for Discontinuation[4]				
Withdrawal by subject	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol violation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse event or SAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician decision	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study terminated by sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[6]	x.xxx		
Number of days in study	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

1 Percentages are based on the number of subjects in the safety population.
2 Percentages are based on the number of subjects in the intent-to-treat population.
3 Percentages are based on the number of subjects in the per protocol population.
4 Percentages are based on the number of subjects who discontinued within each population.
5 p-value from Fisher Exact test
6 p-value from a Pearson's Chi-Square test (using exact statement)
Note(s): Number of days in the study is calculated as the difference between the date of the last visit (Follow up/Week 10) and the informed consent date plus 1.

Program: t14_1_3.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.3
Summary of Study Completion

Parameters	Statistic	Treatement Group: DS107G	Treatement Group: Placebo	Total
Number of Subjects in Intent-to-treat Population	N	xx	xx	xx
Completed the study[2]				
Yes	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[5]	x.xxx		
Primary Reason for Discontinuation[4]				
Withdrawal by subject	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol violation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse event or SAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician decision	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study terminated by sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[6]	x.xxx		
Number of days in study	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

1 Percentages are based on the number of subjects in the safety population.
2 Percentages are based on the number of subjects in the intent-to-treat population.
3 Percentages are based on the number of subjects in the per protocol population.
4 Percentages are based on the number of subjects who discontinued within each population.
5 p-value from Fisher Exact test
6 p-value from a Pearson's Chi-Square test (using exact statement)
Note(s): Number of days in the study is calculated as the difference between the date of the last visit (Follow up/Week 10) and the informed consent date plus 1.

Program: t14_1_3.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.3
Summary of Study Completion

Parameters	Statistic	Treatement Group: DS107G	Treatement Group: Placebo	Total
Number of Subjects in Per Protocol Population	N	xx	xx	xx
Completed the study[3]				
Yes	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[5]	x.xxx		
Primary Reason for Discontinuation[4]				
Withdrawal by subject	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol violation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse event or SAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician decision	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study terminated by sponsor	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[6]	x.xxx		
Number of days in study	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

1 Percentages are based on the number of subjects in the safety population.
2 Percentages are based on the number of subjects in the intent-to-treat population.
3 Percentages are based on the number of subjects in the per protocol population.
4 Percentages are based on the number of subjects who discontinued within each population.
5 p-value from Fisher Exact test
6 p-value from a Pearson's Chi-Square test (using exact statement)
Note(s): Number of days in the study is calculated as the difference between the date of the last visit (Follow up/Week 10) and the informed consent date plus 1.

Program: t14_1_3.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.4
Summary of Protocol Deviations
(Safety Population)

Deviations	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Washout period not respected	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missed dose(s)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Extra dose(s)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fasting period not respected	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Randomization error	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study product not kept within temperature range	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study visit not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Visit performed out of window	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Procedure(s) done but not required by the protocol	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time window/order/of events for study procedure not respected	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study procedure(s) not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prohibithed Medications	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note(s): n = Number of subjects. Each subject is counted only once within each deviation.

Program: t14_1_4.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.5.1
Summary of Subject Demographics and Baseline Characteristics
(Safety Population)

Characteristic	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Sex	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female				
Age (years)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Race				
American Indian/Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity				
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Program: t14_1_5_1.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.5.1
Summary of Subject Demographics and Baseline Characteristics
(Safety Population)

Characteristic	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Height (cm)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Weight (kg)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
BMI (kg/m2)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

Program: t14_1_5_1.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.1.5.2 Summary of Subject Demographics and Baseline Characteristics (Intent-to-Treat Population)

Table 14.1.5.3 Summary of Subject Demographics and Baseline Characteristics (Per Protocol Population)

Table 14.1.6
Summary of Medical History
(Safety Population)

Body System	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Eyes-Ears-Nose-Throat	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Respiratory - Asthma	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Respiratory - Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cardiovascular	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gastrointestinal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hepatobiliary	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Genitourinary/Renal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reproductive	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neurological	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Endocrinal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hematological	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Musculoskeletal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dermatological	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Extremities	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Immunological	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Psychiatric	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Allergies	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Program: t14_1_6.SAS, Generated on DDMMMYYY HH:MM

Table 14.1.7.1
Summary of Study Drug Exposure and Compliance
(Safety Population)

Parameters	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Number of days on drug	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Compliance (%)	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

Note(s): Number of days on drug is defined as (Date of Week 8/ET Visit – First dose of study drug administration date)
Compliance is defined as 100*[(Sum of all capsules dispensed) - (Sum of all capsules returned)]/[4 x Number of days on drug]

Program: t14_1_7_1.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.1.7.2 Summary of Study Drug Exposure and Compliance (Intent-to-Treat Population)

Table 14.1.7.3 Summary of Study Drug Exposure and Compliance (Per Protocol Population)

Table 14.2.1.1.1
Summary of Investigator's Global Assessment – Responder Analysis at Week 8
(Intent-to-Treat Population)

Parameter	Statistic	Treatement Group: DS107G (N=XX)	Placebo (N=XX)	Total (N=XX)
IGA Score				
Baseline				
3 – Moderate	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 – Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5 – Very Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 8				
0 – Clear	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 – Almost Clear	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 – Mild	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 – Moderate	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 – Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5 – Very Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Responders[1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Responders	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[2]	x.xxx		
	p-value[3]	x.xxx		
Week 8 – Very Severe/Severe[4]				
0 – Clear	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 – Almost Clear	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 – Mild	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 – Moderate	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 – Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5 – Very Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Responders[1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Responders	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[2]	x.xxx		

Week 8 - Moderate[4]				
0 - Clear	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 - Almost Clear	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 - Mild	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 - Moderate	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 - Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5 - Very Severe	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Responders[1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Responders	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[2]	x.xxx		

1 Subject is classified as Responder if he/she achieves an IGA score of 0 (clear) or 1 (almost clear) at Week 8
2 p-value from a Cochran-Mantel-Haenszel test with site included as a stratification factor
3 p-value from a Fisher Exact test (data from all sites combined)
4 IGA score at baseline visit.

Program: t14_2_1_1_1.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.2.1.1.2 Summary of Investigator's Global Assessment – Responder Analysis at Week 8 (Per Protocol Population)

Table 14.2.1.1.3 Summary of Investigator's Global Assessment – Responder Analysis at Week 8 (Intent-to-Treat Population) Supportive Analysis (LOCF)

Table 14.2.1.1.4 Summary of Investigator's Global Assessment – Responder Analysis at Week 8 (Per Protocol Population) Supportive Analysis (LOCF)

Table 14.2.1.2.1
Summary of Investigator's Global Assessment – Actual, Change and Percent Change from Baseline
(Intent-to-Treat Population)

Parameter	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
IGA Score				
Baseline	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Week 2				
Actual	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Change from Baseline	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
	LSMEANS[1]	xx.x	xx.x	
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	
	p-value[1]			
Percent Change from Baseline	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

NOTE: Results at Week 4, Week 8, and Week 10 will also be presented as well as the change from Week 8 to Week 10.

1 LSMEANs and p-value from an ANCOVA on the change from baseline. The model includes Treatment group, Site as fixed effects and the baseline value as the covariate.
Note(s): Baseline is the result measured at Baseline Visit.
Program: t14_2_1_2_1.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.2.1.2.2	Summary of Investigator's Global Assessment – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.2.1	Summary of Eczema Area and Severity Index – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.2.2	Summary of Eczema Area and Severity Index – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.3.1	Summary of Patient-Oriented Eczema Measure – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.3.2	Summary of Patient-Oriented Eczema Measure – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.4.1	Summary of Dermatology Quality of Life Index – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.4.2	Summary of Dermatology Quality of Life Index – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.5.1	Summary of Summary of SCORing Atopic Dermatitis – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.5.2	Summary of Summary of SCORing Atopic Dermatitis – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.6.1	Summary of Visual Analog Scale of Pruritus – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.6.2	Summary of Visual Analog Scale of Pruritus – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.7.1	Summary of Body Surface Area – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.7.2	Summary of Body Surface Area – Actual, Change, and Percent Change from Baseline (Per Protocol Population)
Table 14.2.8.1	Summary of Trans epidemal Water Loss – Actual, Change, and Percent Change from Baseline (Intent-to-Treat Population)
Table 14.2.8.2	Summary of Trans epidemal Water Loss – Actual, Change, and Percent Change from Baseline (Per Protocol Population)

Table 14.2.1.3.1
Summary of Investigator's Global Assessment – Proportion of Subjects with
at least 1-point decrease, and with no change or increase/decrease at Week 8 and Week 10
(Intent-to-Treat Population)

Parameter	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
IGA Score				
Week 8				
At least a 1-point decrease from baseline in IGA				
Yes	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[1]	x.xxx		
Change from Baseline in IGA				
3-point decrease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2-point decrease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1-point decrease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No change	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1-point increase	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2-point increase	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3-point increase	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 10				
At least a 1-point decrease from baseline in IGA				
Yes	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	p-value[1]	x.xxx		
Change from Baseline in IGA				
3-point decrease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2-point decrease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1-point decrease	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No change	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1-point increase	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2-point increase	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3-point increase	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

1 p-value from a Cochran-Mantel-Haenszel test with site included as a stratification factor
Note(s): Baseline is the result measured at Baseline Visit.

Program: t14_2_1_3_1.SAS, Generated on DDMMMYYY HH:MM

Similar table will be provided for

Table 14.2.1.3.2 Summary of Investigator's Global Assessment – Proportion of Subjects with at least 1-point decrease, and with no change or increase/decrease at Week 8 and Week 10 (Per Protocol Population)

Table 14.2.9.1
Summary of Total DGLA Concentrations – Actual and Change from Baseline by IGA results
(Intent-to-Treat Population)

		Treatement Group					
		DS107G (N=XX)		Placebo (N=XX)		Total (N=XX)	
Parameter		IGA Responder status[1]					
Total DGLA	Statistic	Responder	Non Responder	Responder	Non Responder	Responder	Non Responder
Baseline	n		xx		xx		xx
	Mean		xx.x		xx.x		xx.x
	SD		xx.x		xx.x		xx.x
	Median		xx.x		xx.x		xx.x
	Min, Max		xx, xx		xx, xx		xx, xx
	Interquartile		xx, xx		xx, xx		xx, xx
Week 4							
Actual	n	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Change from Baseline	n	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

NOTE: Results at Week 8 will also be presented as well as the change from Week 8 for DGLA result by IGA results at Week 10.

[1]IGA resuls for the corresponding visit
Note(s): Baseline is the nearest value to and before the first dose of the study medication.

Program: t14_2_9_1.SAS, Generated on DDMMMYYY HH:MM

Similar table will be provided for

Table 14.2.9.2 Summary of Free DGLA Concentrations – Actual and Change from Baseline by IGA results (Intent-to-treat Population)

Table 14.3.1.1
Overall Summary of Adverse Events
(Safety Population)

Parameter	Statistic[1]	Treatement Group DS107G (N=XX)	Placebo (N=XX)	Total (N=XX)
Number of Subjects with Treatment-Emergent Adverse Events	n(%) E	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Number of Subjects with Related Treatment-Emergent Adverse Events	n(%) E	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Number of Subjects with Serious Treatment-Emergent Adverse Events	n(%) E	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Number of Subjects with Related Serious Treatment-Emergent Adverse Events	n(%) E	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Number of Subjects with Treatment-Emergent Adverse Events leading to treatment discontinuation	n(%) E	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx

1 n=number of subjects; E=number of events
Note(s): Adverse events are coded using MedDRA dictionary (version 17.0)

Program: t14_3_1_1.SAS, Generated on DDMMMYYY HH:MM

Table 14.3.1.2
Summary of Treatment-Emergent Adverse Events
(Safety Population)

System Organ Class Preferred Term	Statistic	Treatement Group DS107G (N=XX)	 Placebo (N=XX)	 Total (N=XX)
Number of subjects with at least one TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				

Note(s): Adverse events are coded using MedDRA dictionary (version 17.0). Subjects experiencing the same adverse event multiple times within the same system organ class are counted only once for that system organ class. Similarly, subjects experiencing the same adverse event multiple times within the same preferred term are counted only once. Adverse events are sorted alphabetically by system organ class and within each system organ class, the preferred terms are presented by decreasing order of total frequency.

Program: t14_3_1_2.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.3.1.3 Summary of Related Treatment-Emergent Adverse Events (Safety Population)

Table 14.3.1.7 Summary of Treatment-Emergent Adverse Events leading to treatment discontinuation (Safety Populaiton)

Table 14.3.1.8 Summary of Serious Treatment-Emergent Adverse Events (Safety Population)

Table 14.3.1.9 Summary of Related Serious Treatment-Emergent Adverse Events (Safety Population)

Table 14.3.1.4
Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)

System Organ Class Preferred Term	Statistic	Treatement Group					
		DS107G (N=XX)			Placebo (N=XX)		
		Mild	Moderate	Severe	Mild	Moderate	Severe
Number of subjects with at least one TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.							

Note(s): Adverse events are coded using MedDRA dictionary (version 17.0). Subjects experiencing the same adverse event multiple times within the same system organ class are counted only once according to the highest severity for that system organ class. Similarly, subjects experiencing the same adverse event multiple times within the same preferred term are counted only once according to the highest severity. Adverse events are sorted alphabetically by system organ class and within each system organ class, the preferred terms are presented by decreasing order of total frequency.

Program: t14_3_1_4.SAS, Generated on DDMMMYYY HH:MM

Table 14.3.1.5
Summary of Treatment-Emergent Adverse Events by Relationship
(Safety Population)

System Organ Class Preferred Term	Statistic	Treatement Group			
		DS107G (N=XX)		Placebo (N=XX)	
		Related	Not Related	Related	Not Related
Number of subjects with at least one TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.					

Note(s): Adverse events are coded using MedDRA dictionary (version 17.0). Subjects experiencing the same adverse event multiple times within the same system organ class are counted only once according to the greatest reported relationship for that system organ class. Similarly, subjects experiencing the same adverse event multiple times within the same preferred term are counted only once according to the greatest reported relationship. Adverse events are sorted alphabetically by system organ class and within each system organ class, the preferred terms are presented by decreasing order of total frequency.

Program: t14_3_1_5.SAS, Generated on DDMMMYYY HH:MM

Table 14.3.1.6
Summary of Treatment-Emergent Adverse Events by Relationship and Severity
(Safety Population)

System Organ Class Preferred Term	Statistic	Treatement Group DS107G (N=XX) Mild Related	Mild Not Related	Moderate Related	Moderate Not Related	Severe Related	Severe Not Related
Number of subjects with at least one TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.							

Note(s): Adverse events are coded using MedDRA dictionary (version 17.0). Subjects experiencing the same adverse event multiple times within the same system organ class are counted only once Term by using (1) the greatest reported relationship followed by (2) the highest reported intensity for that system organ class. Similarly, subjects experiencing the same adverse event multiple times within the same preferred term are counted only once Term by using (1) the greatest reported relationship followed by (2) the highest reported intensity. Adverse events are sorted alphabetically by system organ class and within each system organ class, the preferred terms are presented by decreasing order of total frequency.

Program: t14_3_1_6.SAS, Generated on DDMMMYYY HH:MM

Table 14.3.1.6
Summary of Treatment-Emergent Adverse Events by Relationship and Severity
(Safety Population)

System Organ Class Preferred Term	Statistic	Treatement Group					
		Placebo (N=XX)					
		Mild		Moderate		Severe	
		Related	Not Related	Related	Not Related	Related	Not Related
Number of subjects with at least one TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.							

Note(s): Adverse events are coded using MedDRA dictionary (version 17.0). Subjects experiencing the same adverse event multiple times within the same system organ class are counted only once Term by using (1) the greatest reported relationship followed by (2) the highest reported intensity for that system organ class. Similarly, subjects experiencing the same adverse event multiple times within the same preferred term are counted only once Term by using (1) the greatest reported relationship followed by (2) the highest reported intensity. Adverse events are sorted alphabetically by system organ class and within each system organ class, the preferred terms are presented by decreasing order of total frequency.

Program: t14_3_1_6.SAS, Generated on DDMMMYYY HH:MM

Table 14.3.4.1.1
Summary of Clinical Laboratory - Serum Chemistry
(Safety Population)

Parameter	Statistic	Treatement Group: DS107G (N=XX)	Placebo (N=XX)	Total (N=XX)
ALT (IU/L)				
Screening	n	xx	xx	xx
Actual	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Baseline				
Actual	n	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Week 4				
Actual	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Change from Baseline	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

NOTES: Results at Week 8 will also be presented. See Table 1 for details on parameters to be presented

Note(s): Baseline is the nearest value to and before the first dose of the study medication.

Program: t14_3_4_1_1.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.4.2.1 Summary of Clinical Laboratory – Hematology (Safety Population)

Table 14.4.3.1 Summary of Clinical Laboratory – Urinalysis (Continuous) (Safety Population)

Table 14.3.4.1.2
Shift Table Clinical Laboratory – Serum Chemistry
(Safety Population)

			Treatement Group					
			DS107G (N=XX)			Placebo (N=XX)		
	Post-Baseline Laboratory Evaluation	Statistic	Baseline Laboratory Evaluation			Baseline Laboratory Evaluation		
Parameter			Low	Normal	High	Low	Normal	High
ALT (IU/L)								
Week 4	Low	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 8	Low	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

NOTE: See Table 1 for details on parameters to be presented.

Note(s): Baseline is the nearest value to and before the first dose of the study medication.

Program: t14_3_4_1_2.SAS, Generated on DDMMMYYY HH:MM

Similar tables will be provided for

Table 14.4.2.2 Shift Table Clinical Laboratory – Hematology (Safety Population)

Table 14.4.3.2 Shift Table Clinical Laboratory – Urinalysis (Continuous) (Safety Population)

Table 14.3.4.3.3
Summary of Clinical Laboratory – Urinalysis (Categorical)
(Safety Population)

Parameter	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Bilirubin				
Screening				
Positive	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline				
Positive	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4				
Positive	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 8				
Positive	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

NOTE: See Table 1 for details on parameters to be presented.

Program: t14_3_4_3_3.SAS, Generated on DDMMMYYY HH:MM

Table 14.3.5
Summary of Vital Signs
(Safety Population)

Parameter	Statistic	Treatement Group: DS107G (N=XX)	Treatement Group: Placebo (N=XX)	Total (N=XX)
Systolic Blood Pressure (mmHg)				
Screening	n	xx	xx	xx
Actual	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Baseline				
Actual	n	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Week 2				
Actual	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx
Change from Baseline	n	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	Interquartile	xx, xx	xx, xx	xx, xx

NOTES: Results at Week 4 and Week 8 will also be presented. All parameters (systolic/diastolic blood pressure, pulse, oral temperature and respiratory rate) all be presented.

Note(s): Baseline is the nearest value to and before the first dose of the study medication.

Program: t14_3_5.SAS, Generated on DDMMMYYY HH:MM

13.2 Mock Listings

The list of listings is presented in the table below followed by the actual mock listings. In all listings will appear the subject identification and the population indicator. They will be sorted by treatment group, study site, subject, and visit (when applicable).

Listing Number	Title	Population
	Study Conduct Listings	
16.2.1.1.1	Subject Disposition	Screen Failures
16.2.1.1.2	Subject Disposition	Enrolled
16.2.1.2	Subject Visits	Enrolled
16.2.2	Protocol Deviations	Enrolled
16.2.3	Analysis Populations	Enrolled
16.2.4.1	Demographics and Baseline Characteristics	Enrolled
16.2.4.2	Medical History	Enrolled
16.2.4.3	Prior and Concomitant Medications	Enrolled
16.2.4.4	Other Procedures	Enrolled
16.2.4.5	Emollient	Enrolled
16.2.5.1	Study Drug Administration	Enrolled
16.2.5.2	Drug Accountability	Enrolled
16.2.5.3	Subject Compliance Log	Enrolled
16.2.5.4	Study Drug Exposure and Compliance	Enrolled
16.2.5.5	Total and Free DGLA plasma concentrations	Enrolled
	Efficacy Listings	
16.2.6.1	Investigator's Global Assessment	Enrolled
16.2.6.2	Eczema Area and Severity Index	Enrolled
16.2.6.3	Patient-Oriented Eczema Measure	Enrolled
16.2.6.4	Dermatology Quality of Life Index	Enrolled
16.2.6.5	SCORing Atopic Dermatitis	Enrolled
16.2.6.6	Trans epidemal Water Loss	Enrolled
	Safety Listings / Other Listings	
16.2.7	Adverse Events	Enrolled
16.2.8.1	Clinical Laboratory	Enrolled
16.2.8.2	Clinical Laboratory – Abnormal Results	Enrolled
16.2.9	Vital Signs	Enrolled
16.2.10	Physical Examination	Enrolled
16.2.11	Additional Information	Enrolled

Lisintg 16.2.1.1.1
Subject Disposition
(Screen Failed Subjects)

Site ID	Subject ID	Signature ICF	Meet All Inclusion/Exclusion Criteria	Criteria Not Meet

Program: L16_2_1_1_1.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.1.1.2
Subject Disposition
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Signature ICF	Randomization Date	Randomization Number	Completed the study?	Date of Completion/ Discontinuation	Primary Reason for Discontinuation

Program: L16_2_1_1_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.1.2
Subject Visits
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Screening	Baseline	Week 2	Week 4	Week 8/ET	Follow up/Week 10

Program: L16_2_1_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.2
Protocol Deviations
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Date Reported	Category	Deviation	Impact

Program: L16_2_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.3
Analysis Population
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Intent-to-Treat Population	Safety Populaiton	Per Protocol Population	Reason not included in Intent-to-treat Population/ Safety Population/ Per Protocol Population

Program: L16_2_3.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.4.1
Demographic and Baseline Characteristics
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	DOB	Age (years)	Gender	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m2)

Program: L16_2_4_1.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.4.2
Medical History
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Body System	Medical/Surgical term	Onset Date	Ongoing	Resolution Date	Improved from Baseline at Week 8 Visit	Improved from Baseline at Week 10 Visit

Program: L16_2_4_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.4.3
Prior and Concomitant Medications
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Medication/ ATC Classification	Indication	Dose/ Freq/ Route	Start Date	Ongoing	Stop Date	Prior or Concomitant

Note(s): Medications are coded using WHO-Drug dictionary (version June 2013 B2).

Program: L16_2_4_3.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.4.4
Other Procedures
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Procedure	Indication	Start Date	Ongoing	Stop Date	Prior or Concomitant

Program: L16_2_4_4.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.4.5
Emollient
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Emollient Name	Start Date	Ongoing	Stop Date	Prior or Concomitant

Program: L16_2_4_5.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.5.1
Study Drug Admnistration
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Was Study Drug Administered?	If no, Reason	Administration Date	Administration Time

Program: L16_2_5_1.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.5.2
Drug Accountability
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Date Dispensed	Batch Number	Capsules Dispensed	Date returned	Capsules Returned	Comments

Program: L16_2_5_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.5.3
Subject Compliance Log
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Missing doses since last visit?	If Yes, Number of missed doses	Comment

Program: L16_2_5_3.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.5.4
Study Drug Exposure and Compliance
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Number of days on drug	Compliance (%)

Program: L16_2_5_4.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.5.5
Total and Free DGLA plasma concentrations
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Analyte	Visit	Result

Program: L16_2_5_5.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.1
Investigator's Global Assessment
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Assessment

Program: L16_2_6_1.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.2 (Part 1)
Eczema Area and Severity Index
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Erythema			
				Head	Upper Extremities	Trunk	Lower Extremities

Program: L16_2_6_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.2 (Part 2)
Eczema Area and Severity Index
(Enrolled Subjects)

				Induration			
Treatment Group	Site ID	Subject ID	Visit	Head	Upper Extremities	Trunk	Lower Extremities

Program: L16_2_6_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.2 (Part 3)
Eczema Area and Severity Index
(Enrolled Subjects)

				Excoriation			
Treatment Group	Site ID	Subject ID	Visit	Head	Upper Extremities	Trunk	Lower Extremities

Program: L16_2_6_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.2 (Part 4)
Eczema Area and Severity Index
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Lichenification				EASI Score
				Head	Upper Extremities	Trunk	Lower Extremities	

Program: L16_2_6_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.3
Patient-Oriented Eczema Measure
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Q1	Q2	Q3	Q4	Q5	Q6	Q7	POEM Score

Program: L16_2_6_3.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.4 (Part 1)
Dermatology Quality of Life Index
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Q1	Q2	Q3	Q4	Q5	Q6

Program: L16_2_6_4.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.4 (Part 2)
Dermatology Quality of Life Index
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Q7	Q7A	Q8	Q9	Q10	DLQI Score

Program: L16_2_6_4.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.5 (Part 1)
SCORing Atopic Dermatitis
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Erythema Intensity	Edema/Papulation Intensity	Oozing/Crust Intensity	Excoriation Intensity	Lichenification Intensity	Dryness Intensity	Total Intensity

Program: L16_2_6_5.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.5 (Part 2)
SCORing Atopic Dermatitis
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Extent Area involved (BSA)	Pruritus VAS Symptom Score	Sleep loss VAS Symptom Score	Objective SCORAD	SCORAD

Program: L16_2_6_5.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.6.6
Trans Epithelial Water Loss
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Area	Represented Area	Measurement (g/m2h)	Control Area	Control Measurement (g/m2h)

Program: L16_2_6_6.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.7
Adverse Events
(Enrolled Subjects)

Treatment Group	Subject ID	System Organ Class/ Preferred Term/ Verbatim	Onset Date	End Date	Onset Day	Dur.	Severity/ Relationship/ Outcome	Action Taken Drug	Action Taken Subject	SAE

Note(s): Adverse events are coded using MedDRA dictionary (version 17.0). *Treatment-Emergent Adverse Event. Dur.=Duration. Severity: Mild; Mod.= Moderate; Sev.=Severe. Relationship: Rel.=Related; Not Rel.=Not Related. Outcome: Rec/Res= Recovered/Resolved; Rec/Res. Seq= Recovered/Resolved with Sequelae; Recing/Resing= Recovering/Resolving; NotRec/NotRes= Not Recovered/ NotResolved; Unk=Unknown. Action Taken Drug: NotChg=Dose not changed; Inter.=Treatment interrupted; Withdr.=Treatment Withdrawn; NA=Not applicable; Unk.=Unknown; Oth.=Other. Action Taken Subject: NotReq=Not required; TrtUsed.=Treatment used; Withdr.=Subject Withdrawn; Unk.=Unknown; Oth.=Other.

Program: L16_2_7.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.8.1
Clinical Laboratory
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Category	Laboratory Test (units)	Normal Range	Result

Note(s): (L)=Below normal range; (H)=Above normal range

Program: L16_2_8_1.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.8.2
Clinical Laboratory – Abnormal Results
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Category	Laboratory Test (units)	Normal Range	Result

Note(s): (L)=Below normal range; (H)=Above normal range

Program: L16_2_8_2.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.9
Vital Signs
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Parameter (units)	Result

Program: L16_2_9.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.10
Physical Examination
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Visit	Body System	Results	Description of Abnormality

Program: L16_2_10.SAS, Generated on DDMMMYYY HH:MM

Lisintg 16.2.10
Physical Examination
(Enrolled Subjects)

Treatment Group	Site ID	Subject ID	Was there any additional information	Visit	Form	Comments/Clarifications

Program: L16_2_11.SAS, Generated on DDMMMYYY HH:MM

13.3 Mock Figures

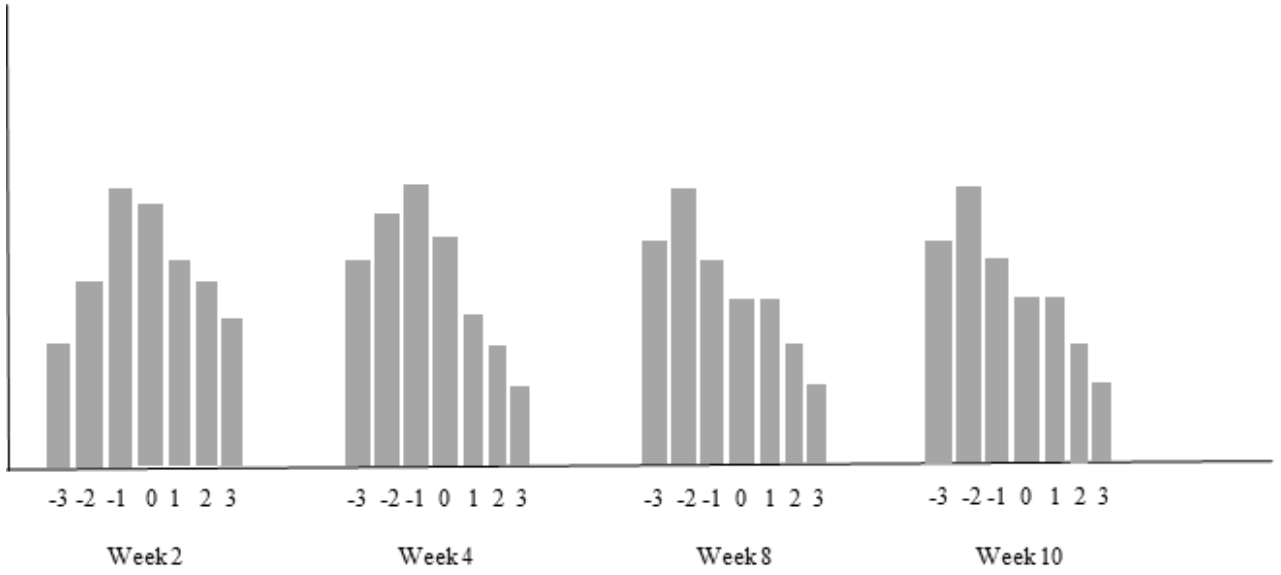
The list of Figures is presented in the table below followed by the actual mock.

Figure Number	Title	Population
14.2.1.1.1	Bar Chart of the Number of Subjects on the Change from Baseline in IGA during study	ITT
14.2.1.1.2	Bar Chart of the Number of Subjects on the Change from Baseline in IGA during study	PP
14.2.1.2.1	Mean Change from baseline in IGA during study	ITT
14.2.1.2.2	Mean Change from baseline in IGA during study	PP
14.2.1.3.1	Mean Percent Change from baseline in IGA during study	ITT
14.2.1.3.2	Mean Percent Change from baseline in IGA during study	PP
14.2.2.1.1	Mean Change from baseline in EASI during study	ITT
14.2.2.1.2	Mean Change from baseline in EASI during study	PP
14.2.2.2.1	Mean Percent Change from baseline in EASI during study	ITT
14.2.2.2.2	Mean Percent Change from baseline in EASI during study	PP
14.2.3.1.1	Mean Change from baseline in POEM during study	ITT
14.2.3.1.2	Mean Change from baseline in POEM during study	PP
14.2.3.2.1	Mean Percent Change from baseline in POEM during study	ITT
14.2.3.2.2	Mean Percent Change from baseline in POEM during study	PP
14.2.4.1.1	Mean Change from baseline in DLQI during study	ITT
14.2.4.1.2	Mean Change from baseline in DLQI during study	PP
14.2.4.2.1	Mean Percent Change from baseline in DLQI during study	ITT
14.2.4.2.2	Mean Percent Change from baseline in DLQI during study	PP
14.2.5.1.1	Mean Change from baseline in SCORAD during study	ITT
14.2.5.1.2	Mean Change from baseline in SCORAD during study	PP
14.2.5.2.1	Mean Percent Change from baseline in SCORAD during study	ITT
14.2.5.2.2	Mean Percent Change from baseline in SCORAD during study	PP
14.2.6.1.1	Mean Change from baseline in VAS during study	ITT
14.2.6.1.2	Mean Change from baseline in VAS during study	PP
14.2.6.2.1	Mean Percent Change from baseline in VAS during study	ITT
14.2.6.2.2	Mean Percent Change from baseline in VAS during study	PP
14.2.7.1.1	Mean Change from baseline in BSA during study	ITT
14.2.7.1.2	Mean Change from baseline in BSA during study	PP
14.2.7.2.1	Mean Percent Change from baseline in BSA during study	ITT
14.2.7.2.2	Mean Percent Change from baseline in BSA during study	PP

Figure Number	Title	Population
14.2.8.1.1	Mean Change from baseline in TEWL during study	ITT
14.2.8.1.2	Mean Change from baseline in TEWL during study	PP
14.2.8.2.1	Mean Percent Change from baseline in TEWL during study	ITT
14.2.8.2.2	Mean Percent Change from baseline in TEWL during study	PP
14.2.9.1	Scatter Plot of Total DGLA concentrations at Baseline versus IGA score at Week 8	ITT
14.2.9.2	Scatter Plot of Free DGLA concentrations at Baseline versus IGA score at Week 8	ITT
14.2.10.1	Scatter Plot of Change from Baseline Total DGLA concentrations at Week 8versus IGA score at Week 8	ITT
14.2.10.2	Scatter Plot of Change from Baseine Free DGLA concentrations at Week 8 versus IGA score at Week 8	ITT
14.2.11.1	Scatter Plot of Change from Baseline Total DGLA concentrations at Week 8 versus IGA score at Week 10	ITT
14.2.11.2	Scatter Plot of Change from Baseline Free DGLA concentrations at Week 8 versus IGA score at Week 10	ITT

Figure 14.2.1.1.1
Bar Chart of the Number of Subjects on the Change from Baseline in IGA during study
(Intent-to-Treat Population)

Treatment: DGLA

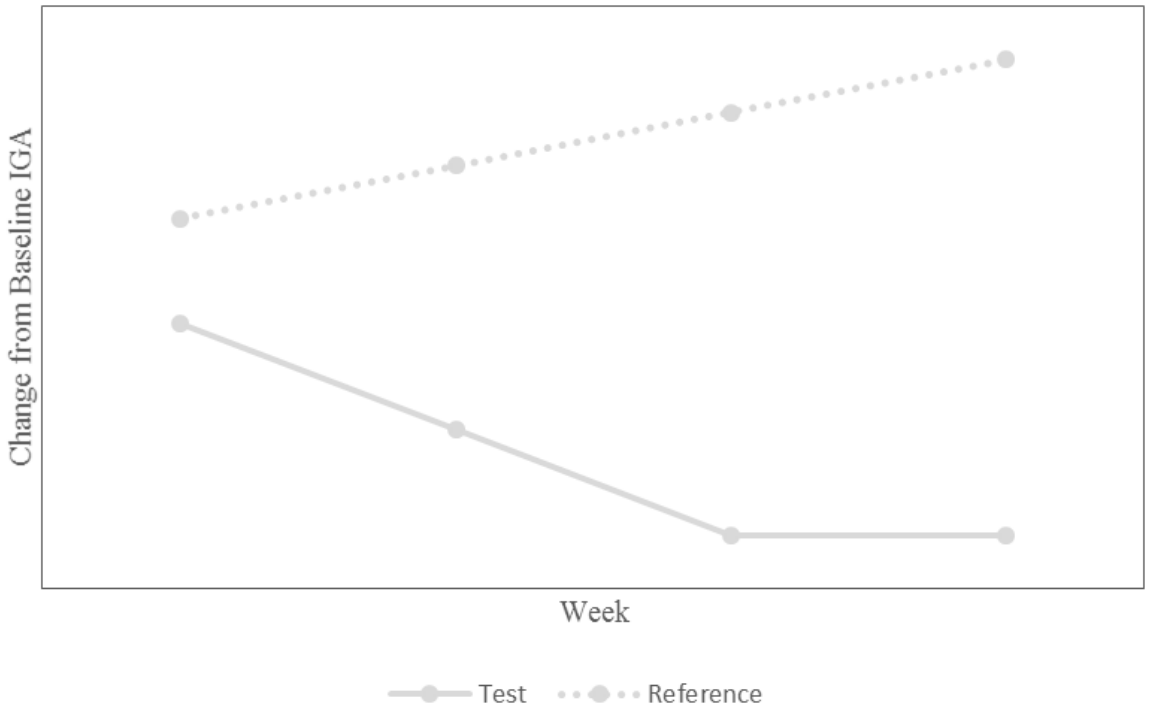


Program: F14_2_1_1_1.SAS, Generated on DDMMMYYY HH:MM

Similar Figure will be provided for

14.2.1.1.2 Bar Chart of the Number of Subjects on the Change from Baseline in IGA during study (Per Protocol Population)

Figure 14.2.1.2.1
Mean Change from baseline in IGA during study
(Intent-to-Treat Population)



Program: F14_2_1_2_1.SAS, Generated on DDMMMYYY HH:MM

Similar Figures will be provided for

14.2.1.2.2 Mean Change from baseline in IGA during study (Per Protocol Population)

14.2.1.3.1 Mean Percent Change from baseline in IGA during study (Intent-to-Treat Population)

14.2.1.3.2 Mean Percent Change from baseline in IGA during study (Per Protocol Population)

14.2.2.1.1 Mean Change from baseline in EASI during study (Intent-to-Treat Population)

14.2.2.1.2 Mean Change from baseline in EASI during study (Per Protocol Population)

14.2.2.2.1 Mean Percent Change from baseline in EASI during study (Intent-to-Treat Population)

14.2.2.2.2 Mean Percent Change from baseline in EASI during study (Per Protocol Population)

14.2.3.1.1 Mean Change from baseline in POEM during study (Intent-to-Treat Population)

14.2.3.1.2 Mean Change from baseline in POEM during study (Per Protocol Population)

14.2.3.2.1 Mean Percent Change from baseline in POEM during study (Intent-to-Treat Population)

14.2.3.2.2 Mean Percent Change from baseline in POEM during study (Per Protocol Population)

14.2.4.1.1 Mean Change from baseline in DLQI during study (Intent-to-Treat Population)

14.2.4.1.2 Mean Change from baseline in DLQI during study (Per Protocol Population)

14.2.4.2.1 Mean Percent Change from baseline in DLQI during study (Intent-to-Treat Population)

14.2.4.2.2 Mean Percent Change from baseline in DLQI during study (Per Protocol Population)

14.2.5.1.1 Mean Change from baseline in SCORAD during study (Intent-to-Treat Population)

14.2.5.1.2 Mean Change from baseline in SCORAD during study (Per Protocol Population)

14.2.5.2.1 Mean Percent Change from baseline in SCORAD during study (Intent-to-Treat Population)

14.2.5.2.2 Mean Percent Change from baseline in SCORAD during study (Per Protocol Population)

14.2.6.1.1 Mean Change from baseline in VAS during study (Intent-to-Treat Population)

14.2.6.1.2 Mean Change from baseline in VAS during study (Per Protocol Population)

14.2.6.2.1 Mean Percent Change from baseline in VAS during study (Intent-to-Treat Population)

14.2.6.2.2 Mean Percent Change from baseline in VAS during study (Per Protocol Population)

14.2.7.1.1 Mean Change from baseline in BSA during study (Intent-to-Treat Population)

14.2.7.1.2 Mean Change from baseline in BSA during study (Per Protocol Population)

14.2.7.2.1 Mean Percent Change from baseline in BSA during study (Intent-to-Treat Population)

14.2.7.2.2 Mean Percent Change from baseline in BSA during study (Per Protocol Population)

14.2.8.1.1 Mean Change from baseline in TEWL during study (Intent-to-Treat Population)

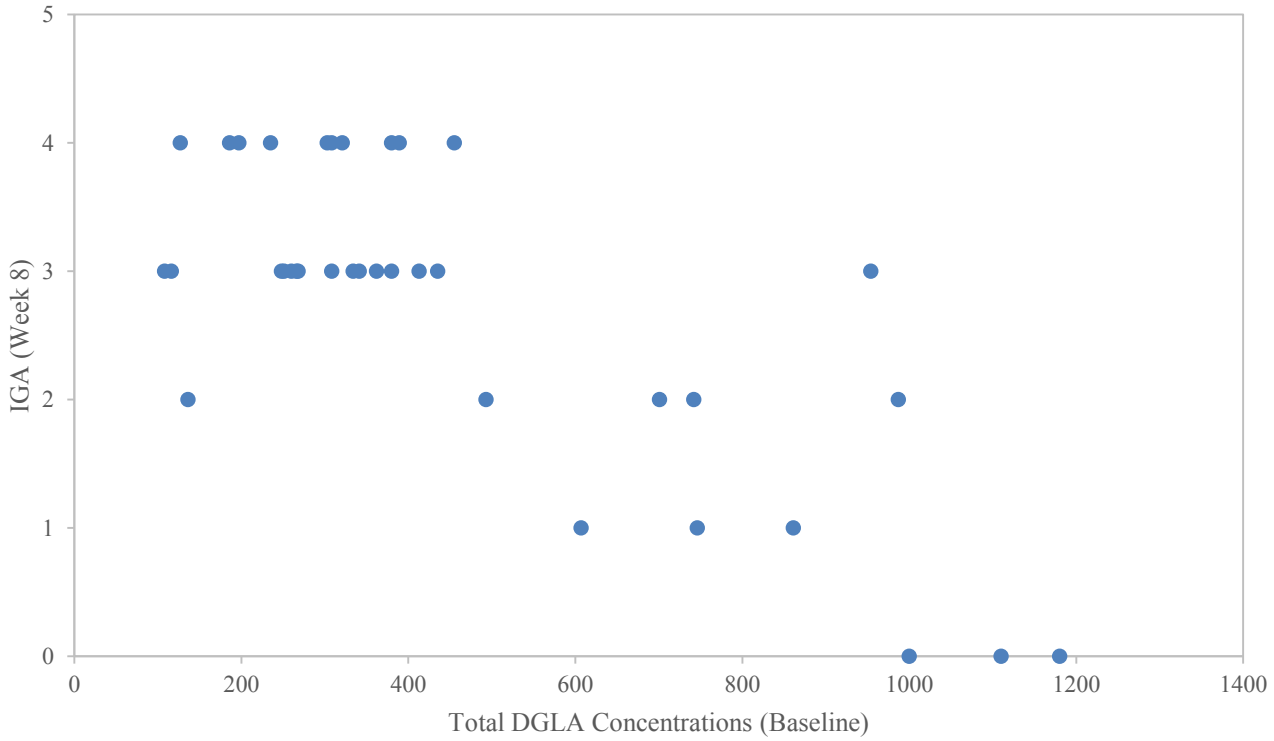
14.2.8.1.2 Mean Change from baseline in TEWL during study (Per Protocol Population)

14.2.8.2.1 Mean Percent Change from baseline in TEWL during study (Intent-to-Treat Population)

14.2.8.2.2 Mean Percent Change from baseline in TEWL during study (Per Protocol Population)

Figure 14.2.9.1
Scatter Plot of Total DGLA concentrations at Baseline versus IGA score at Week 8
(Intent-to-Treat Population)

Treatment: DGLA
Spearman Correlation Coefficient: x.xxx



Program: F14_2_9_1.SAS, Generated on DDMMMYYY HH:MM

Similar Figures will be provided for

14.2.9.2 Scatter Plot of Free DGLA concentrations at Baseline versus IGA score at Week 8 (Intent-to-Treat Population)

14.2.10.1 Scatter Plot of Change from Baseline Total DGLA concentrations at Week 8versus IGA score at Week 8 (Intent-to-Treat Population)

14.2.10.2 Scatter Plot of Change from Baseine Free DGLA concentrations at Week 8 versus IGA score at Week 8 (Intent-to-Treat Population)

14.2.11.1 Scatter Plot of Change fdrom Baseline Total DGLA concentrations at Week 8 versus IGA score at Week 10 (Intent-to-Treat Population)

14.2.11.2 Scatter Plot of Change fdrom Baseline Free DGLA concentrations at Week 8 versus IGA score at Week 10 (Intent-to-Treat Population)