Protocol No. MC2-01-C3
Novella Study No. NYA14539

STATISTICAL ANALYSIS PLAN

A Randomised, Multicentre, Open-label, Parallel-group Maximal Use Trial, Evaluating the Pharmacokinetic Profile of the Active Ingredients and their Metabolites after Application of MC2-01 Cream Compared with Active Comparator in Subjects with Extensive Psoriasis Vulgaris

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List of Abbreviations and Definitions of Terms

Abbreviation	Definition
ACTH	Adrenocorticotropic hormone
AE	Adverse event
ALP	Alkaline phosphatase
AUC_{0-7}	Area under the time-concentration curve from time zero to 7 hours
AUC_{0-t}	Area under the time-concentration curve from time zero to the last measurable concentration
$AUC_{0-\infty}$	Area under the time-concentration curve from time zero to infinity
BDP	Betamethasone dipropionate
BSA	Body surface area
CAL	Calcipotriene (United States term) / Calcipotriol (European Union term)
C_{max}	Maximum plasma drug concentration
CRO	Contract Research Organisation
ECG	Electrocardiogram
eCRF	Electronic case report form
FDA	Food and Drug Administration
HPA	Hypothalamic-pituitary-adrenal
ICF	Informed consent form
IP	Investigational product
IRB	Institutional Review Board
IWR	Interactive web response
MCV	Mean corpuscular volume
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over the counter
PGA	Physician's Global Assessment
PK	Pharmacokinetics
PTH	Parathyroid hormone
RBC	Red blood cell
SAE	Serious adverse event
SD	Standard deviation
SOP	Standard operating procedure
$T_{1/2}$	Elimination half-life
T_{max}	Time to maximum plasma drug concentration
UPT	Urine pregnancy test
US	United States
WBC	White blood cell

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study Protocol version 3.0 dated December 20, 2017.

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

2. STUDY OBJECTIVES

The primary objective is to evaluate the pharmacokinetic profile of the active ingredients and their main metabolites after application of MC2-01 cream, and compare with the active comparator following once daily topical application under maximum-use conditions in subjects with extensive psoriasis vulgaris.

The secondary objective is to evaluate the effect of MC2-01 cream on the hypothalamic-pituitary-adrenal (HPA) axis and calcium metabolism following once daily topical application under maximum-use conditions in subjects with extensive psoriasis vulgaris.

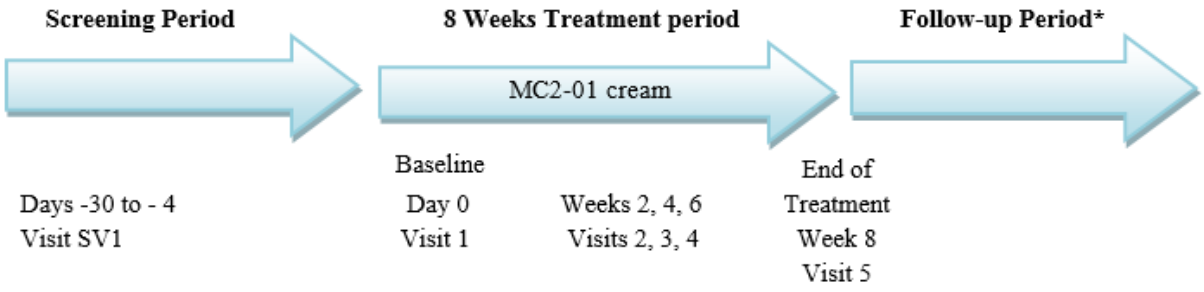
3. STUDY DESIGN

This is a Phase 2, randomised, open-label, parallel-group, multicentre trial in which the investigational product, MC2-01 cream, and CAL/BDP ointment (comparator) are investigated in subjects with clinically diagnosed extensive psoriasis vulgaris of disease severity assessed by Physician's Global Assessment (PGA) of at least moderate (Figure 1). Subjects who meet inclusion/exclusion criteria will be randomly assigned in a 1:1 ratio to receive either MC2-01 cream or the comparator. Subjects assigned to MC2-01 cream will apply 1 dose of trial medication topically once daily for 8 weeks and the subjects assigned to the comparator will apply 1 dose of trial medication topically once daily for 4 weeks.

At Week 4, the pharmacokinetic (PK) profile of calcipotriene (CAL), betamethasone dipropionate (BDP) and their main metabolites MC1080 and betamethasone 17-propionate, respectively, will be assessed for both treatment groups. At Week 8, the PK profile of CAL, BDP and their main metabolites will be assessed for the MC2-01 cream treatment group only. At Week 4 and Week 8, the effect of once-daily use of MC2-01 cream on the HPA axis and calcium metabolism will be evaluated for MC2-01 cream treatment group. Other safety assessments (local skin reactions, AEs, laboratory tests, electrocardiogram (ECG)), vital signs and physical examinations) and efficacy assessments are also performed.

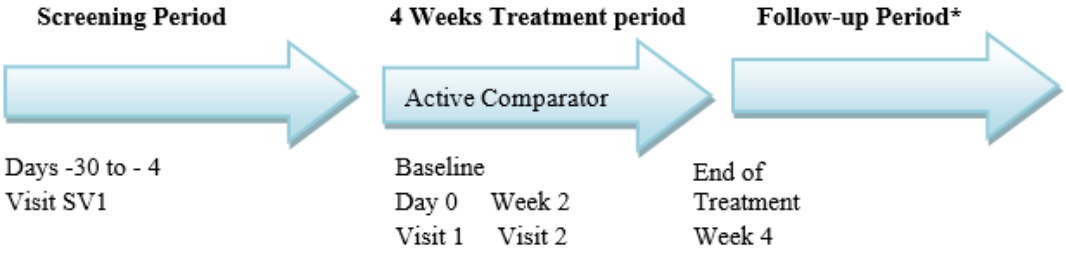
Figure 1: Study Design

Trial Design for Subjects Assigned to the MC2-01 Cream



*Follow-up visits will be required only for subjects who have unresolved AEs or whose calcium levels have not returned to pre-treatment levels at the End of Treatment visit.

Trial Design for Subjects Assigned to the Active Comparator



*Follow-up visits will be required only for subjects who have unresolved AEs at the End of Treatment visit.

4. HARDWARE AND SOFTWARE

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

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

Study data tabulation model (SDTM) data sets and analysis data model (ADaM) data sets will be created and taken as input to validated SAS programs to generate the report-ready tables, listings,

and figures. Each output display will show the names of the data sets and SAS program used to produce it.

5. DATABASE CLOSURE

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

6. SAMPLE SIZE DETERMINATION

The choice of sample size in this trial is not based on statistical considerations, but rather on regulatory considerations with respect to common practice in maximum use studies evaluating pharmacokinetic profiles and evidence of HPA safety. The chosen number of approximately 25 subjects included in the PK population at Week 4 in each treatment arm is considered sufficient to compare the PK properties corresponding to the two treatments.

7. HANDLING OF MISSING DATA

No imputation will be made for missing data.

8. ANALYSIS POPULATIONS

Three analysis populations will be defined for analysis:

- Safety Population: will include all randomized subjects who have been dispensed the trial medication, excluding subjects who return all of the trial medication unopened. The Safety Population will be used for all safety analyses other than evaluation of the HPA-axis.
- HPA population: will include all subjects in the Safety population that are assigned to MC2-01 cream and who show normal HPA function at Baseline (defined as a 30-minute post-stimulation cortisol level ≥18 μg/dL). Since the objective of the analysis is to estimate the risk to subjects with normal HPA function of HPA-axis suppression following treatment, subjects who meet the definition of HPA-axis suppression at Baseline will be excluded from the analysis. The HPA population will be used for the HPA axis suppression analysis.
- Pharmacokinetic (PK) Population: will include all subjects in the Safety population who have received the planned application of treatment at the Week 4 or Week 8 visit, respectively, and have had at least one post-application blood draw for PK assessment at the corresponding visit. The PK Population will be used for the PK analysis.

All safety, HPA and PK analyses will be conducted according to the treatment actually received.

9. DATA CONVENTIONS FOR ANALYSIS

9.1 General Statistical Principles

All statistical processing will be performed using the SAS system (Version 9.3 or higher).

All observed and derived variables (e.g., change from baseline) used in the summaries of analyses will be presented in by-subject listings. Descriptive statistics will be used to provide an overview of the safety and PK results. For categorical parameters, the number and percentage of subjects in each category will be presented. The denominator for percentage will be based on the number of subjects appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include number of observations, mean, standard deviation (SD), median, and range. The PK parameters will be summarised using appropriate descriptive statistics including median, lower and upper quartiles, minimum and maximum. Geometric means and coefficient of variation (CV) will be provided as appropriate.

It is planned that the data from all centers that participate in this protocol will be combined so that an adequate number of subjects will be available for analysis.

No interim analyses are planned.

9.2 Study Day and Baseline

For purpose of the SAP, Day 1 is defined as the date of first application of study drug, which corresponds to Randomization/Visit 1 of the study protocol. Study day is calculated relative to the date of Day 1.

Baseline is defined as the last available measurement prior to first application of study drug. Change from baseline is defined as the post-baseline value minus the baseline value.

10. STATISTICAL EVALUATION

10.1 Subject Disposition

The number and percentage of subjects who are screened, randomized, included in each analysis population, who complete the study, and withdraw from the study (overall and by reason for withdrawal) will be summarized, overall and by treatment group.

A by-subject enrolment and disposition listing will be presented for all randomized subjects.

10.2 Protocol Deviation

Protocol deviations will be presented in a by-subject listing.

10.3 Demographic and Baseline Characteristics

Demographics, baseline characteristics will be summarized overall and by treatment for the Safety, HPA and PK populations. The following demographic and baseline variables will be included:

- Age (years)
- Gender
- Race
- Ethnicity
- Fitzpatrick Skin Type
- Weight (kg)
- Height (cm)
- Baseline HPA Axis Suppression Status (MC2-01 cream group only)
- Baseline PGA
- Baseline Total BSA (%)
- Duration of psoriasis in years (calculated as year of baseline minus year of first psoriasis diagnosis)

10.4 Study Drug Exposure and Accountability

Subjects will record the date of each trial medication application in the subject diary. The kit number, and corresponding date dispensed and returned will be collected.

The weight of the returned kits will also be collected.

The following parameters of study medication exposure will be summarized by treatment group and by study period, i.e., from day 1 to Week 4 (both groups) and from day 1 to Week 8 (MC2-01 cream group), for the Safety Population:

- Total number of days of exposure to the study drug, defined as the date of last application of study drug during the period minus date of first application plus one. The last application is the in-clinic dosing at Week 4 visit (Day 1 to Week 4 period) and Week 8 visit (Day 1 to Week 8 period).
- Total number of missed doses during each study period per subject diary
- Total number of applications during each study period, defined as the total number of doses required minus total number of doses missed. Total number of required doses is defined as total number of days of exposure minus any days of investigator approved stop (if applicable)
- Total weight of trial medication used (g) during each study period, defined as the summation of amount of drug used for all dispensed kits. Amount of drug used per kit is defined as the difference in weight between the returned and dispensed kits, where weight

of dispensed kits is a unit value. Amount of drug used for sealed and unreturned kits will be assumed to be 0.0 g

- Amount of drug used per week (g/per week), defined as the total amount of drug used divided by total number of days of exposure to the study drug multiplied by 7

10.5 Prior and Concomitant Medications

Prior (with stop dates prior to Day 1) and concomitant medications (ongoing or with stop dates on or after Day 1) for all randomised subjects will be provided in a by-subject listing. Concomitant medications will be summarized by WHO-DDE Anatomical-Therapeutic-Chemical (ATC) classification and preferred term (PT) for each treatment for Safety population.

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

- If only year was recorded, and it is before Day 1, it is a prior medication; if year is same or after Day 1, it is assumed to be a concomitant medication.
- If day is missing, but month and year are before Day 1, it is a prior medication; if month and year are the same or after Day 1, it is assumed to be a concomitant medication.
- If start date is after Day 1, it is a concomitant medication regardless.

Psoriasis treatment history will be displayed in a by-subject listing.

10.6 Concurrent Procedures

All concurrent procedures will be provided in a by subject listing for all randomized subjects.

10.7 Medical History

Past and current medical conditions will be coded using MedDRA dictionary (version 20.0). Medical history for all randomized subjects will be provided in a by-subject listing.

10.8 Safety Analysis

10.8.1 Safety Endpoints

Primary safety endpoints include:

- HPA-axis suppression

  HPA-axis function will be assessed in a challenge test with an intravenous dose of adrenocorticotropic hormone (ACTH) (Cosyntropin). **Normal HPA function** is, based on the Cosyntropin US Packing Insert (USPI) (revision May 2018), defined as a 30-minute post-stimulation cortisol level ≥18 μg/dL.

Conversely, **HPA-axis suppression** is defined as 30-minute post-stimulation cortisol level <18 μg/dL.

HPA-axis function status will be considered as missing if post-stimulation serum cortisol level is missing.

- Changes in calcium metabolism endpoints from 24-hour urinalysis, including
    - Albumin-corrected serum calcium
    - 24 hours urinary calcium excretion
    - Ratio of urinary calcium to creatinine

Other safety endpoints include:

- Adverse events (AEs)
- Local Skin Reaction (LSR) Assessment
    - Investigator assessed signs: erythema, scaling, edema, atrophy, vesicles and erosion/ulceration; vesicles, and erosion/ulceration
    - Subject assessed symptoms: burning or pain
- Laboratory parameters
    - Hematology: hemoglobin, hematocrit, red blood cell (RBC) count, mean corpuscular volume (MCV), white blood cell (WBC) count, including differential count and platelet count.
    - Serum biochemistry: cortisol, urea, glucose, creatinine, calcium, albumin, calcium (albumin corrected), sodium, potassium, chloride, calcium, phosphate, alkaline phosphatase (ALP), plasma parathyroid hormone (PTH), 25-OH Vitamin D (Visit 1 only)
    - 24-hour urinalysis: calcium, phosphate, creatinine, volume, total calcium excretion, total phosphate excretion, total creatinine excretion, urinary calcium:creatinine ratio, urinary phosphate:creatinine ratio
- Vital signs (blood pressure, pulse rate)
- Standard 12-lead electrocardiogram (ECG) (MC2-01 cream subjects only)
- Physical examination (PE)

10.8.2 Analyses of Safety Endpoints

10.8.2.1 HPA-axis Suppression

The number and proportion of subjects with HPA-axis suppression at Week 4 will be summarised for the HPA population. Subjects with HPA-axis suppression at Week 4, was as described in the

protocol, contacted to discontinue use of MC2-01 cream. Subjects with HPA-axis suppression at Week 8 will be summarised overall and separately by HPA-axis suppression status at Week 4.

An additional analysis of the number and proportion of subjects with HPA-axis suppression will be summarised based on the test laboratory normal reference range established for the analytical method used by the test laboratory in the trial for the ACTH challenge test.

- In this analysis HPA suppression is defined as a 30-minute post-stimulation cortisol level < 14 µg/dl (test laboratory normal reference range of 14 to 36 µg/dl for the 30-minute post-stimulation cortisol level). This analysis will be performed among MC2-01 cream subjects whose Baseline cortisol level is ≥ 14 µg/dl

All HPA-axis function test results (baseline, Week 4, Week 8, and Follow-up) will be presented in a by-subject listing for the Safety population.

10.8.2.2 Calcium Metabolism Endpoints

All calcium metabolism data will be presented in a by-subject listing for the following parameters:

- Albumin-corrected serum calcium
- 24 hours urinary calcium excretion
- Ratio of urinary calcium to creatinine

Observed values and changes from baseline to Week 4 and Week 8 will be summarized using descriptive statistics for subjects in the Safety population assigned to MC2-01 cream.

10.8.2.3 Adverse Events

AE terms will be coded using MedDRA dictionary (version 20.0). A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication (Day 1). If relationship to study medication is missing, the event will be conservatively summarized as being related to study drug. If intensity is missing, a separate category of missing intensity will be included in the summary table, and no imputation of severity will be performed. Through the data cleaning process, all attempts will be made to avoid missing values for relationship and severity.

All AEs will be presented in a by-subject listing, detailing the verbatim term given by the investigator, the PT, SOC, whether or not related to Cosyntropin or study procedure, location of AE to treatment area, start date, stop date, intensity, outcome, relationship to study medication (definitely, probably, possibly, and not related), action taken with study medication, action taken to treat the AE, seriousness and criteria for seriousness. For subjects assigned to MC2-01 cream, all TEAEs will be assigned to the Week 1-4 (starting from Day 1 to 28) or post-Week 4 period (starting from Day 29 and after) based on onset dates. Serious AEs and AEs leading to study drug discontinuation will be presented in a separate listing.

An overall summary of AEs will be presented by treatment and by period (MC2-01 group only). The summary will include the total number of events, frequency counts and percentages with:

- Any AE
- Any TEAE
- Any serious TEAE
- Any treatment-related TEAE
- Any TEAE leading to study drug discontinuation

Summaries of the incidence of TEAEs will be displayed by treatment and by period (MC2-01 group only) according to the following:

- All TEAEs by PT in descending order of frequency (the combined frequency of both treatments)
- All TEAEs by SOC, PT, and maximum severity (mild, moderate, or severe)
- All TEAEs by SOC, PT, and maximum relationship (recorded as 'definitely', 'probably', and 'possibly') to the study drug

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

10.8.2.4 Local Skin Reaction (LSR) Assessment

LSR assessments by investigator and subject will be summarized using frequency counts and percentages by treatment and visit. By-subject listings will be provided.

10.8.2.5 Safety Laboratory Parameters

Clinical laboratory (hematology, biochemistry and urinalysis) results will be presented in by-subject listings. Abnormal laboratory findings will be flagged and presented in a separate listing.

Absolute values, changes from baseline, and relative changes from baseline (defined as ratio of the post-baseline vs baseline value) will be summarized using descriptive statistics (means, medians, standard deviations, ranges, and coefficient of variations) by treatment and by visit. Shift tables using extended normal ranges (baseline to Week 4 and most extreme post-baseline value up to Week 4 for both arms) will also be provided.

Urine pregnancy test will be presented in a by-subject listing for subjects with childbearing potential.

10.8.2.6 Vital Signs

Vital signs data will be presented in a by-subject listing. Observed values and changes from baseline will be summarized using descriptive statistics by treatment and visit.

10.8.2.7 Electrocardiograms (ECG)

ECG data will be presented in a by-subject listing, with flagging of abnormal results.

10.8.3 Physical Examination (PE)

Physical examination results will be present in a by-subject listing.

10.9 Pharmacokinetics Analysis

All analyses of pharmacokinetics (PK) will be based on the PK population.

All available concentration results will be summarised using appropriate descriptive statistics (number of subjects, number of quantifiable concentrations, median, lower and upper quartiles, minimum, maximum) for active ingredients (BDP and CAL) and for their major metabolites. A listing for sample date/times as well as derived sampling time deviations will be provided. Median and individual concentration versus time curves will be plotted (linear and semi-log plots). Nominal sample collection times will be used in determining concentration descriptive statistics and plotting median concentration versus time profiles.

All analyte concentrations below the lower limit of quantification (BLOQ) will be reported as the lower limit of quantification (LLoQ) and will be treated as LLoQ in descriptive statistics and plasma concentration-time profiles.

10.9.1 Analysis of Pharmacokinetic Parameters

Plasma PK parameters shown below (AUC_{0-t}, $AUC_{0-\infty}$, AUC_{0-7}, C_{max}, T_{max}, and $T_{½}$) will be calculated at Week 4 in subjects randomized to comparator and MC2-01 groups and Week 8 in subjects randomized to MC2-01 cream only.

For a given analyte, the PK parameters AUC_{0-t}, $AUC_{0-\infty}$, T_{max}, and $T_{½}$ will be calculated if data allow. AUC_{0-7} and C_{max} will be calculated using standard formulas inserting the lower limit of quantification (LLoQ) for non-quantifiable levels of the analyte; therefore, AUC_{0-7} will be an upper limit in case at least one time point shows a non-quantifiable level of the analyte, and C_{max} will be an upper limit in case all time points show non-quantifiable levels of the analyte.

C_{max}	Maximum plasma drug concentration. BLOQ Concentrations will be treated as LLoQ for this calculation

T_{max}	Time to maximum plasma drug concentration. If the maximum concentration value occurs at more than one time point, T_{max} is defined as the first time point with this value
AUC_{0-7}	Area under the time-concentration curve from time zero to 7 hours, as calculated by the linear trapezoidal method. BLOQ Concentrations will be treated as LLoQ for this calculation
AUC_{0-t}	Area under the time-concentration curve from time zero to the last quantifiable concentration
$AUC_{0-\infty}$	Area under the time-concentration curve from time zero to infinity, calculated as $AUC_{0-t} + C_{tf}/\lambda z$, where C_{tf} is the last concentration ≥ LoQ. $AUC_{0-\infty}$ will be calculated only if λz can be calculated.
$T_{½}$	Elimination half-life, calculated as $\ln(2)/ \lambda z$. $T_{½}$ will not be calculated if λz cannot be determined
Λz	Elimination (terminal phase) rate constant, calculated as the slope of the terminal phase linear regression line of the log-scale concentration over the time points corresponding to the elimination phase of the concentration-time profiles. The elimination rate constant, λz, will not be calculated if the elimination phase of the log-linear concentration-time profile cannot be fit with an appropriate regression line. The time points corresponding to a subject's elimination phase will be identified by visually examining the log-scale concentration-time profile. A minimum of three points, not including C_{max}, in which there is a relatively straight downward trend in concentration when plotted on a log scale, and the adjusted R^2 value for the fitted line must be at least 0.9 is required for the determination of λz. As an additional confirmation of the suitability of λz, the log-linear profile, which includes the regression line through the terminal points, will be checked via visual inspection, to determine whether the regression appropriately represents the terminal slope.

PK parameters will be listed and summarized using descriptive statistics (n, median, lower and upper quartiles, minimum and maximum) where appropriate. Geometric means and geometric CV will be calculated for AUC_{0-t}, $AUC_{0-\infty}$, AUC_{0-7}, and C_{max} as appropriate. An exception to this is T_{max} and $T_{½}$ where only median, minimum, and maximum will be presented.

Assessment of systemic exposure (Week 4)

Assessment of relative systemic exposure in the two treatment arms will be performed for AUC_{0-7} and C_{max} at Week 4. If any of the post-dose time point shows a non quantifiable level of the analyte, the calculated PK parameters will be considered left censored. In particular, AUC_{0-7} will be considered censored if at least one post-dose concentration is below LLOQ. C_{max} will be considered censored if all post-dose values are below LLOQ. To account for the censored data, the SAS PROC LIFEREG procedure will be used on log-transformed PK parameters with treatment group as a fixed effect. Geometric mean ratio and associated 90% confidence interval (CI) (back-transformed from the estimates) will be presented.

10.10 Analysis of Other Endpoints

10.10.1Physician Global Assessment of Psoriasis Severity (PGA)

PGA will be summarised using frequency counts and percentages for each treatment at Week 4 (all subjects) and at Week 8 (subjects assigned to MC2-01 cream). The proportion of subjects with treatment success, defined as a minimum 2-point decrease from Baseline in the PGA will also be summarized.

10.10.2Body Surface Area Involvement of Psoriasis (BSA)

BSA results will be presented in a by-subject listing.

10.10.3Psoriasis Treatment Convenience Scale (PTCS)

The PTCS consists of 6 disease-specific, self-report questions with a recall period of 1 week and rated on a 1-10 scale.

1. How easy was the treatment to apply to the skin?
2. How greasy was the treatment when applying it to the skin?
3. How moisturised did your skin feel after applying the treatment?
4. How greasy did your skin feel after applying the treatment?
5. How much did treating your skin disrupt your daily routine?
6. Overall, how satisfied were you with the medical treatment?

Each of the questions and the sum of the first 5 questions of PTCS will be summarized using descriptive statistics by treatment for Week 4. Sum of the first 5 question will be further compared between MC2-01 cream and the active comparator using a mixed effect model with treatment as a systematic effect and study site as a random effect. Treatment difference (MC2-01 cream minus active comparator) along with 95% CI will be reported.

11. CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

The 30 minutes ACTH test using the ACTH analogue tetracosactide to stimulate cortisol secretion from the adrenals is an effective test for the assessment of the HPA axis in subjects with pituitary

disease. Diagnostic criteria for adrenal insufficiency have traditionally relied both on the absolute level of cortisol 30 minutes after injection of tetracosactide as well as a requirement of an absolute increase in cortisol during the test. The diagnostic criteria used in the MC2-01-C3 protocol was based on the USPI dated February 2012 (1) for Cosyntropin in which there were specific requirements to plasma cortisol both concerning the level of increase as well as the 30 minutes value according to the original description of the test (2) when testing morning samples. The diagnostic value of an absolute increase in cortisol has, however, been challenged. Several studies, e.g.(3, 4) have shown that calculation of the increment cortisol increase is of no diagnostic value, and careful reviews (5, 6) have strongly warned against this parameter as a diagnostic criterion. As a consequence, both expert guidelines from the Endocrine Society (7) as well as the recently updated (May 2018) USPI for Cosyntropin (8) recommends the 30 minutes cortisol value as the sole diagnostic criterion for the diagnosis of adrenal insufficiency with a limit for adrenal supression of plasma cortisol < 18 µg/dl (500 nmol). This criterion is used in the evaluation of the data obtained in MC2-01-C3 trial. Furthermore, the plasma cortisol from the ACTH challenge test is measure by mass spectrometry. Mass spectrometry assays of cortisols are without any of the positive bias that plaque most cortisol immunoassays (9) and consequently limit for adrenal supression of plasma cortisol is below 14 µg/dl (390 nmol/l) according to laboratory report from the manufacturer (Quest Diagnostics) of this test. For this reason, this lower limit for plasma cortisol of 14 µg/dl (390 nmol/l) will also be used in the evaluation of the data obtained in MC2-01-C3 trial.

1. FDA. Cosyntropin USPI Sandoz. 2012.

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3. Patel SR, Selby C, Jeffcoate WJ. The short Synacthen test in acute hospital admissions. Clin Endocrinol (Oxf). 1991;35(3):259-61.

4. Widmer IE, Puder JJ, Konig C, Pargger H, Zerkowski HR, Girard J, et al. Cortisol response in relation to the severity of stress and illness. J Clin Endocrinol Metab. 2005;90(8):4579-86.

5. Clark PM, Neylon I, Raggatt PR, Sheppard MC, Stewart PM. Defining the normal cortisol response to the short Synacthen test: implications for the investigation of hypothalamic-pituitary disorders. Clin Endocrinol (Oxf). 1998;49(3):287-92.

6. Arafah BM. Hypothalamic pituitary adrenal function during critical illness: limitations of current assessment methods. J Clin Endocrinol Metab. 2006;91(10):3725-45.

7. Bornstein SR, Allolio B, Arlt W, Barthel A, Don-Wauchope A, Hammer GD, et al. Diagnosis and Treatment of Primary Adrenal Insufficiency: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016;101(2):364-89.

8. FDA. Cosyntropin USPI Sandoz. May 2018.

9. El-Farhan N, Pickett A, Ducroq D, Bailey C, Mitchem K, Morgan N, et al. Method-specific serum cortisol responses to the adrenocorticotrophin test: comparison of and five automated immunoassays. Clin Endocrinol (Oxf). 2013;78(5):673-80.

12. HEADINGS

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

13. ARCHIVING AND RETENTION OF DOCUMENTS

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

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

14. OUTLINE OF PROPOSED TABLES, FIGURES AND LISTINGS

Summary Tables

14.1	**Summary of Disposition, Demographic, and Exposure Tables**
14.1.1.1	Summary of Subject Disposition
14.1.2.1	Summary of Subject Demographics and Baseline Characteristics; Safety Population
14.1.2.2	Summary of Subject Demographics and Baseline Characteristics; HPA Population
14.1.2.3	Summary of Subject Demographics and Baseline Characteristics; PK Population
14.1.3	Summary of Extent of Exposure and Compliance; Safety Population
14.1.4	Summary of Concomitant Medications by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term; Safety Population
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Table 14.1.1: Summary of Subject Disposition

	MC2-01 Cream	**Active Comparator**	**Overall**
Number of Subjects Screened			XX
Number of Subjects Randomized	XX	XX	XX
Number of Subjects in Safety Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects in HPA Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects in PK Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects Completing the Study, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects Discontinued, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for Discontinuation, n (%)			
Investigator discretion	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unacceptable adverse events	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exclusion criteria	XX (XX.X)	XX (XX.X)	XX (XX.X)
HPA axis suppression at Visit 1/Day 0	XX (XX.X)	XX (XX.X)	XX (XX.X)
Albumin corrected serum calcium above upper limit at Visit 1/Day 0	XX (XX.X)	XX (XX.X)	XX (XX.X)
Trial suspended by Sponsor	XX (XX.X)	XX (XX.X)	XX (XX.X)
Voluntary withdrawal	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other reasons	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

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Table 14.1.2.X: Summary of Subject Demographics and Baseline Characteristics
[Safety Population] [HPA Population] [PK Population]

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**	**Overall (N=XX)**
Age (years)			
N	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Sex, n(%)			
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Race, n(%)			
White	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other [1]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n(%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] See listing 16.2.4.1 for other races.
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Table 14.1.2.X: Summary of Subject Demographics and Baseline Characteristics
[Safety Population] [HPA Population] [PK Population]

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**	**Overall (N=XX)**
Fitzpatrick Skin Type, n(%)			
I	XX (XX.X)	XX (XX.X)	XX (XX.X)
II	XX (XX.X)	XX (XX.X)	XX (XX.X)
III	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc.>			
Height (cm)			
N	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Weight (kg)			
N	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX

Note: Height and weight can be self-reported.
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Table 14.1.2.X: Summary of Subject Demographics and Baseline Characteristics
[Safety Population] [HPA Population] [PK Population]

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**	**Overall (N=XX)**
Baseline HPA Axis Suppression Status, n(%)			
Yes	XX (XX.X)	--	--
No	XX (XX.X)	--	--
Unknown	XX (XX.X)	--	--
Baseline PGA (Scalp, Trunk and/or Limbs), n(%)			
0 – Clear	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Almost clear	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
4 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
Baseline Total BSA (%)	XX	XX	XX
N	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Mean (SD)	XX.X	XX.X	XX.X
Median	XX, XX	XX, XX	XX, XX
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX	XX	XX
Duration of Psoriasis (years) [2]			
N	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX

[2] Calculated as year of baseline minus year of first psoriasis diagnosis

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Table 14.1.3: Summary of Extent of Exposure and Compliance
Safety Population

	Day 1 to Week 8	Day 1 to Week 4	
	MC2-01 Cream (N=XX)	**MC2-01 Cream (N=XX)**	**Active Comparator (N=XX)**
Total Number of Days of Exposure[1]			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Total Number of Missed Doses			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Total Number of Doses Applied[2]			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX

[1] Total number of days of exposure is defined as the date of last application of study drug minus date of first application plus one. The last application is the in-clinic dosing at Week 4 visit (Day 1 to Week 4 period) and Week 8 visit (for Day 1 to Week 8 period).
[2] Total number of doses applied= total number of doses required – total number of missed doses. Total number of doses required = total number of days of exposure – any days of investigator approved stop.

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Table 14.1.3: Summary of Extent of Exposure and Compliance
Safety Population

	Day 1 to Week 8	Day 1 to Week 4	
	MC2-01 Cream (N=XX)	**MC2-01 Cream (N=XX)**	**Active Comparator (N=XX)**
Total Amount of Drug Used (g)[3]			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Amount of Drug Used per Week (g/per week)[4]			
N	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX

[3] Total amount of drug used (g) is defined as the summation of amount of drug used per kit for all returned kits. Amount of drug used per kit is the difference in weight between the returned and dispensed kits. Amount of drug used for sealed and unreturned kits will be assumed to be 0.0 g.
[4] Amount of drug used per week (g/per week) is defined as the total amount of drug used divided by total number of days of exposure to the study drug multiplied by 7.

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Table 14.1.4: Summary of Concomitant Medications
by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term
Safety Population

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**
Subjects with any Concomitant Medication, n (%)	XX (XX.X)	XX (XX.X)
<< Anatomical Therapeutic Chemical Class >>		
<< Medication Preferred Term >>	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX
<< Anatomical Therapeutic Chemical Class >>		
<< Medication Preferred Term >>	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX

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

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Table 14.2.1.X: Summary of Plasma Concentration of [CAL, BDP, MC1080, Betamethasone 17-propionate] (ng/mL) by Time Point
PK Population
[MC2-01 Cream] [Active Compartor]

Time Point	N	N_{quant}	Median	Lower, Upper Quartiles	Minimum, Maximum
Baseline					
Pre-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
Visit 2/Week 2					
Pre-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
Visit 3/Week 4					
Pre-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
0.5 hours post-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
1 hour post-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
2 hours post-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
3 hours post-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
5 hours post-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
7 hours post-dose	XX	XX	XX.X	XX.X, XX.X	XX.X, XX.X
Visit 5/Week 8					
<include all time points>					

Note: Concentration below the limit of quantitation (< XX.X ng/mL) are reported as the lower limit of quantification (LLoQ) for calculating summary statistics.
N_{quant}: number of samples in the N population with quantifiable levels of analyte;

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Table 14.2.2.X: Summary of [CAL, BDP, MC1080, Betamethasone 17-propionate] (ng/mL) Pharmacokinetics Parameters
PK Population

	N	Median	Lower Quartile, Upper Quartile	Minimum, Maximum
Week 4				
MC2-01 Cream (N=XX)				
C_{max} (ng/mL)	XX	XXX.X	XXX, XXX	XXX, XXX
T_{max} (h)	XX	XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
AUC_{0-7} (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
AUC_{0-t} (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
$AUC_{0-\infty}$ (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
$T_{1/2}$ (h)	XX	XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
Active Comparator (N=XX)				
C_{max} (ng/mL)	XX	XXX.X	XXX, XXX	XXX, XXX
T_{max} (h)	XX	XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
AUC_{0-7} (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
AUC_{0-t} (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
$AUC_{0-\infty}$(ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
$T_{1/2}$ (h)	XX	XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
Week 8				
MC2-01 Cream (N=XX)				
C_{max} (ng/mL)	XX	XXX.X	XXX, XXX	XXX, XXX
T_{max} (h)	XX	XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
AUC_{0-7} (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
AUC_{0-t} (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
$AUC_{0-\infty}$ (ng*h/mL)	XX	XXXX	XXX, XXX	XXX, XXX
$T_{1/2}$ (h)	XX	XXX.X	XXX.X, XXX.X	XXX.X, XXX.X

Table 14.2.3.X: Assessment of Relative Systemic Exposure of [CAL, BDP, MC1080, Betamethasone 17-propionate] (ng/mL) at Week 4
PK Population

		Natural Log-Scale Difference[1]		Geometric Mean Ratio (GMR) [2]	
	N	**Estimate**	**90% CI**	**Estimate**	**90% CI**
Cmax (ng/mL)	XX	X.XXX	X.XXX, X.XXX	X.XXX	X.XXX, X.XXX
AUC_{0-7} (ng*h/mL)	XX	X.XXX	X.XXX, X.XXX	X.XXX	X.XXX, X.XXX

[1] Difference and the associated 90% CI (confidence interval), are estimated by using an analysis of variance model for censored data including treatment group, using log-transformed PK parameters.
[2] Geometric Mean ratio (GMR) and the associated 90% CI are back transformed point estimate and the associated 90% CI.

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Table 14.2.4.1 Summary of HPA-Axis Suppression (Based on Cosyntropin US Packing Insert)
HPA Population

	MC2-01 Cream (N=XX)
HPA-Axis Suppression, n / N (%)	
Visit 3/ Week 4	XX/XX (XX.X)
Visit 5/ Week 8	XX/XX (XX.X)
HPA-Axis Suppressed at Week 4	XX/XX (XX.X)
HPA-Axis Not Suppressed at Week 4	XX/XX (XX.X)

Note: HPA-axis suppression is defined as a 30-minute post-stimulation cortisol level <18 µg/dL
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[Programming note: Denominator for Visit 5/Week 8 (Week 4 HPA-Axis Suppressed) row is subjects with HPA-Axis Suppressed at Week 8; denominator for Visit 5/Week 8 (Week 4 HPA-Axis Not Suppressed) row is subjects with HPA-Axis Suppressed at Week 8]

Table 14.2.4.2 Summary of HPA-Axis Suppression (Based on Lab Reference Range)
MC2-01 Cream Subjects with Baseline Cortisol Level ≥ 14 µg/dl

	MC2-01 Cream (N=XX)
HPA-Axis Suppression, n / N (%)	
Visit 3/ Week 4	XX/XX (XX.X)
Visit 5/ Week 8	XX/XX (XX.X)
HPA-Axis Suppressed at Week 4	XX/XX (XX.X)
HPA-Axis Not Suppressed at Week 4	XX/XX (XX.X)

Note: HPA-axis suppression is defined as a 30-minute post-stimulation cortisol level <14 µg/dL
Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

[Programming note: Denominator for Visit 5/Week 8 (Week 4 HPA-Axis Suppressed) row is subjects with HPA-Axis Suppressed at Week 8; denominator for Visit 5/Week 8 (Week 4 HPA-Axis Not Suppressed) row is subjects with HPA-Axis Suppressed at Week 8]

Table 14.2.5 Summary of Calcium Metabolism
HPA Population

	MC2-01 Cream (N=XX)	
	Observed Value	**Change from Baseline**
Albumin-Corrected Serum Calcium (unit)		
Baseline		
N	XX	--
Mean (SD)	XX.X (XX.X)	--
Median	XX.X	--
Q1, Q3	XX, XX	--
Minimum, Maximum	XX, XX	--
Visit 3/Week 4		
N	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX
Visit 5/Week 8		
N	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X
Q1, Q3	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX

<Continue for: **24 Hours Urinary Calcium Excretion (unit)** and **Ratio of Urinary Calcium to Creatinine**>

Table 14.2.6: Summary of Physician's Global Assessment (PGA)
Safety Population

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**
Baseline		
Observed Value, n (%)		
N	XX	XX
0 – Clear	XX (XX.X)	XX (XX.X)
1 – Almost clear	XX (XX.X)	XX (XX.X)
2 – Mild	XX (XX.X)	XX (XX.X)
3 – Moderate	XX (XX.X)	XX (XX.X)
4 – Severe	XX (XX.X)	XX (XX.X)
Visit 3/Week 4		
Observed Value, n (%)		
N	XX	XX
0 – Clear	XX (XX.X)	XX (XX.X)
<Etc.>	XX (XX.X)	XX (XX.X)
Change From Baseline, n (%)		
N	XX	XX
2 = Worsen by 2	XX (XX.X)	XX (XX.X)
1 = Worsen by 1	XX (XX.X)	XX (XX.X)
0 = No Change	XX (XX.X)	XX (XX.X)
-1 = Improve by 1	XX (XX.X)	XX (XX.X)
-2 = Improve by 2	XX (XX.X)	XX (XX.X)
-3 = Improve by 3	XX (XX.X)	XX (XX.X)
PGA Treatment Success [1]	XX (XX.X)	XX (XX.X)

[1] PGA success is defined as a minimum 2-point decrease from Baseline in the PGA.

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

Table 14.2.6: Summary of Physician's Global Assessment (PGA)
Safety Population

	MC2-01 Cream (N=XX)	Active Comparator (N=XX)
Visit 5/Week 8		
Observed Value, n (%)		
N	XX	--
0 – Clear	XX (XX.X)	--
<Etc.>	XX (XX.X)	--
Change From Baseline, n (%)		
N	XX	--
2 = Worsen by 2	XX (XX.X)	--
1 = Worsen by 1	XX (XX.X)	--
0 = No Change	XX (XX.X)	--
-1 = Improve by 1	XX (XX.X)	--
-2 = Improve by 2	XX (XX.X)	--
-3 = Improve by 3	XX (XX.X)	--
PGA Treatment Success [1]	XX (XX.X)	--

[1] PGA success is defined as a minimum 2-point decrease from Baseline in the PGA.

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

Table 14.2.7: Summary of Psoriasis Treatment Convenience Score (PTCS) at Week 4
Safety Population

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**
Total Score (Sum of Q1 to Q5)		
N	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X
Minimum, Maximum	XX.X, XX.X	XX.X, XX.X
Linear Mixed Effect Model[1]		
LSM (SE)	XX.X(XX.X)	XX.X(XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X
LSM Difference (MC2-01 Cream - Active Comparator) (SE)	XX.X (XX.X)	
LSM Difference, 95% CI	XX.X, XX.X	
Q1: How easy was the treatment to apply to the skin?		
N	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X
Minimum, Maximum	XX.X, XX.X	XX.X, XX.X

<<Continue for Q2: How greasy was the treatment when applying it to the skin?
Q3: How moisturized did your skin feel after applying the treatment?
Q4: How greasy did your skin feel after applying the treatment?
Q5: How much did treating your skin disrupt your daily routine?
Q6: Overall, how satisfied were you with the medical treatment?>>

SE = Standard error; LSM = Least square means; CI = Confidence interval
[1] The linear mixed effect model includes as a systematic effect and study site as a random effect.

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

Table 14.3.1.1: Overall Summary of Adverse Events
Safety Population

	Weeks 1 – 4 [1]		Post Week 4 [2]
	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**	**MC2-01 Cream (N=XX)**
Adverse Events			
Number of Events	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Treatment-Emergent Adverse Events (TEAEs)			
Number of Events	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Treatment-Related TEAEs			
Number of Events	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious AEs (All)			
Number of Events	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious TEAEs			
Number of Events	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
AEs Leading to Study Drug Discontinuation			
Number of Events	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect number of subjects reporting one or more adverse events that map to MedDRA 20.0. A subject will be counted once only within each AE category. TEAEs include all AEs starting or worsening after the first dose of study drug.

Generated on XX/XX/XX:XXXX by SMYAE / Uses: XXXX / Reference: Data Listing XXXX

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

System Organ Class Preferred Term	Weeks 1 – 4 [1] MC2-01 Cream (N=XX)	Weeks 1 – 4 [1] Active Comparator (N=XX)	Post Week 4 [2] MC2-01 Cream (N=XX)
Subjects with any TEAE, n (%)	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted once only in each row of the table.
[1] Includes TEAEs with an onset date on or before Week 4 visit.
[2] Includes TEAEs with an onset date after Week 4 visit.

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

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

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

System Organ Class Preferred Term	Severity	Weeks 1 – 4 [1] MC2-01 Cream (N=XX)	Weeks 1 – 4 [1] Active Comparator (N=XX)	Post Week 4 [2] MC2-01 Cream (N=XX)
Subjects with any TEAE, n (%)	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
		XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest severity. AEs are categorized by onset date.

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

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

System Organ Class Preferred Term	Causality Assessment[1]	Weeks 1 – 4 [1] MC2-01 Cream (N=XX)	Weeks 1 – 4 [1] Active Comparator (N=XX)	Post Week 4 [2] MC2-01 Cream (N=XX)
Subjects with any TEAE, n (%)	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest severity. AEs are categorized by onset date.

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

Table 14.3.2.1.X: Summary of Clinical Laboratory Results by Treatment and Visit
[Biochemistry][Hematology]
Safety Population
[Lab Tests Name (Units)]

	MC2-01 Cream (N=XX)			Active Comparator (N=XX)		
	Observed Value	**CFBL**	**Relative CFBL**	**Observed Value**	**CFBL**	**Relative CFBL**
Baseline						
N	XX			XX		
Mean (SD)	XX.X (XX.X)			XX.X (XX.X)		
Median	XX.X			XX.X		
CV (%)	XX.X			XX.X		
Q1, Q3	XX.X, XX.X			XX.X, XX.X		
Minimum, Maximum	XX.X, XX.X			XX.X, XX.X		
Visit 3/Week 4						
N	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	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
CV (%)	XX.X	-	-	XX.X	-	-
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Minimum, Maximum	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Visit 5/Week 8						
N	XX	XX	XX	--	--	--
<Etc.>						

CFBL=Change from baseline; CV = Coefficient of Variation.
Note: Relative CFBL is defined as ratio of the post-baseline vs baseline value

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

<Programming Note: Serum biochemistry tests include: cortisol, urea, glucose, creatinine, calcium, albumin, calcium (albumin corrected), sodium, potassium, chloride, calcium, phosphate, alkaline phosphatase (ALP), plasma parathyroid hormone (PTH). Hematology tests include: hemoglobin, hematocrit, red blood cell (RBC) count, mean corpuscular volume (MCV), white blood cell (WBC) count. Page break after each lab parameter.>

Table 14.3.2.2.X: Clinical Laboratory Results, Shifts from Baseline
[Biochemistry][Hematology]
Safety Population
[Lab Tests Name (Units)]

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**
Baseline - > Visit 3/Week 4, n (%)		
Low -> Normal	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)
Normal -> Missing	XX (XX.X)	XX (XX.X)
Missing -> Low	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>		
Baseline - > Most Extreme Post-Baseline Value up to Visit 3/Week 4, n (%)		
Low -> Normal	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)
Normal -> Missing	XX (XX.X)	XX (XX.X)
Missing -> Low	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>		

Note: Denominator is number of subjects with available baseline and post-baseline visit.

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

Table 14.3.3: Summary of Vital Signs by Treatment and Visit
Safety Population
[Pulse Rate (bpm)][Systolic Blood Pressure (mmHg)][Diastolic Blood Pressure (mmHg)]

	MC2-01 Cream (N=XX)		Active Comparator (N=XX)	
	Observed Value	**Change from Baseline**	**Observed Value**	**Change from Baseline**
Baseline				
N	XX		XX	
Mean (SD)	XX (XX.X)		XX (XX.X)	
Median	XX (XX.X)		XX (XX.X)	
Q1, Q3	XX, XX		XX, XX	
Minimum, Maximum	XX, XX		XX, XX	
Visit 2/Week 2				
N	XX	XX	XX	XX
Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Q1, Q3	XX, XX	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Visit 3/Week 4				
N	XX	XX	XX	XX
Mean (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Median	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Q1, Q3	XX, XX	XX, XX	XX, XX	XX, XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

<<Continue for all visits>>

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

Table 14.3.4: Summary of Investigator Assessed Local Skin Reactions (LSR)
Safety Population

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**
Baseline		
Perilesional Signs		
Erythema, n(%)		
N	XX	XX
0 – Absent	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)
<<Continue for Scaling, Edema, Atrophy, Vesicles, Erosion/Ulceration>>		
Lesional Signs		
Vesicles, n(%)		
N	XX	XX
0 – None	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)
<<Continue Erosion/Ulceration>>		
<<Continue for all visits>>		

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

Table 14.3.5: Summary of Subject Assessed Local Skin Reactions (LSR)
Safety Population

	MC2-01 Cream (N=XX)	**Active Comparator (N=XX)**
Baseline		
Burning or Pain, n(%)		
N	XX	XX
0 – Absent	XX (XX.X)	XX (XX.X)
1 – Mild	XX (XX.X)	XX (XX.X)
2 – Moderate	XX (XX.X)	XX (XX.X)
3 – Severe	XX (XX.X)	XX (XX.X)

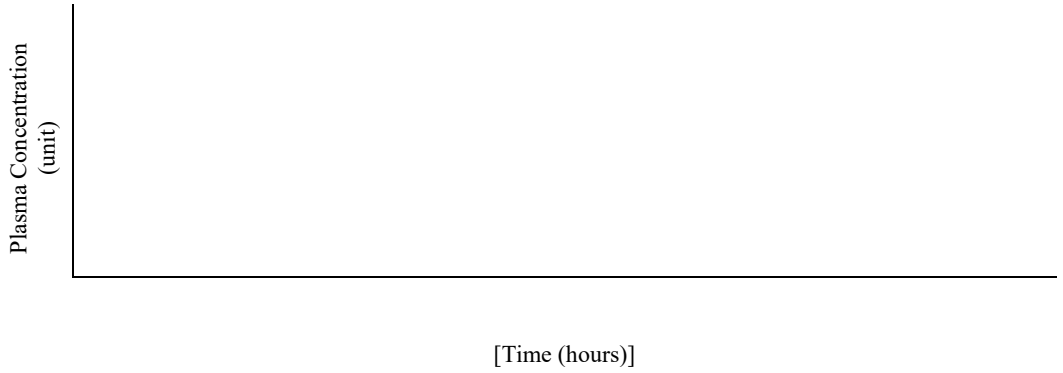
<<Continue for all visits>>

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

Figure 14.4.1.1.X.Y: [CAL, BDP, MC1080, Betamethasone 17-propionate] Concentration (Median) by Time Point, Linear Scale

[Week 4 Serial PK Sampling] [Week 8 Serial PK Sampling]

PK Population



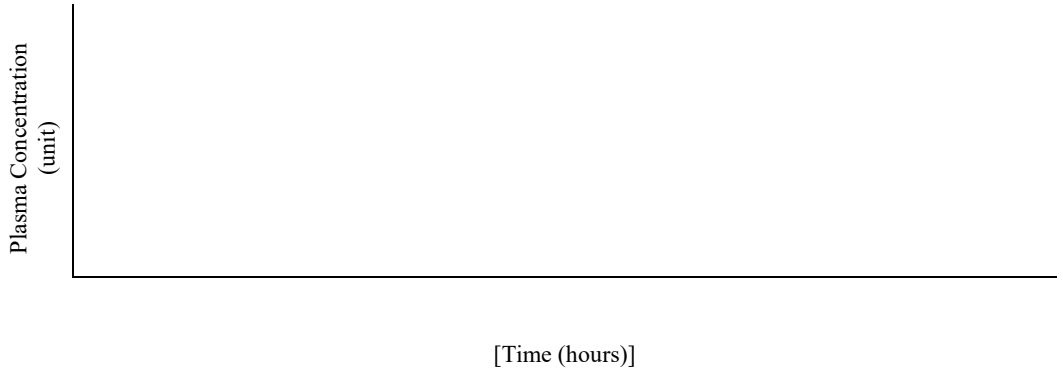
Note: Nominal sample collection times used in this figure. Concentrations below the limit of quantitation are reported as lower limit of quantification (LLOQ=XXXX).

Generated on XX/XX/XX XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference:
[Programming Note: include all time points pre-dose (0), 0.5, 1, 2, 3, 5, 7 Hour. The plot will include 2 lines (MC2-01 Cream and Active Comparator) at Week 4, 1 line (MC2-01 Cream) at Week 8.]

Figure 14.4.1.2.X.Y: [CAL, BDP, MC1080, Betamethasone 17-propionate] Concentration (Median) by Time Point, Semi-Log Scale

[Week 4 Serial PK Sampling] [Week 8 Serial PK Sampling]

PK Population



Note: Nominal sample collection times used in this figure. Concentrations below the limit of quantitation are reported as lower limit of quantification (LLOQ=XXXX).

Generated on XX/XX/XX XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference:
[Programming Note: include all time points pre-dose (0), 0.5, 1, 2, 3, 5, 7 Hour. The plot will include 2 lines (MC2-01 Cream and Active Comparator) at Week 4, 1 line (MC2-01 Cream) at Week 8.]

Figure 14.4.2.1.X.Y: Individual [CAL, BDP, MC1080, Betamethasone 17-propionate] Concentration (Median) by Time Point, Linear Scale

[Week 4 Serial PK Sampling] [Week 8 Serial PK Sampling]

PK Population

[MC2-01 Cream] [Active Comparator]

Subject: XXXX

Note: Actual sample collection times used in this figure.

Generated on XX/XX/XX XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference:
[Programming Note: include all time points pre-dose (0), 0.5, 1, 2, 3, 5, 7 Hour.]

Figure 14.4.2.2.X.Y: Individual [CAL, BDP, MC1080, Betamethasone 17-propionate] Concentration (Median) by Time Point, Semi-Log Scale

[Week 4 Serial PK Sampling] [Week 8 Serial PK Sampling]

PK Population

[MC2-01 Cream] [Active Comparator]

Subject: XXXX

Note: Actual sample collection times used in this figure.

Generated on XX/XX/XX XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference:
[Programming Note: include all time points pre-dose (0), 0.5, 1, 2, 3, 5, 7 Hour.]

Data Listing 16.1.7: Subject Enrollment and Randomization
All Randomized Subjects

Subject Number	Date of Informed Consent	Require Washout Period?/ Exclusion Criteria	Washout Start Date	Satisfy All I/E Criteria?	Randomization Date	Randomization Number	Randomized Treatment	Actual Treatment
XX-XXX	DDMMMYYYY	Yes / Exclusion X	DDMMYYYY	No: Inclusion XX	DDMMMYYYY	XXXX	MC2-01 Cream	MC2-01 Cream
XX-XXX	DDMMMYYYY	No	--	Yes	DDMMMYYYY	XXXX	Active Comparator	Active Comparator
XX-XXX	DDMMMYYYY	No	--	Yes	DDMMMYYYY	XXXX	MC2-01 Cream	Not Treated

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

Data Listing 16.2.1.1: Screen Failures
All Screen Failure Subjects

Subject Number	Date of Informed Consent	Date of Screening	Birth Month/Year	Age (Years)	Sex	Primary Reason for Screen Failure
XX-XXX	DDMMMYYYY	DDMMMYYYY	MMMYYYY	XX	X	I/E criteria not met: Inclusion 2
XX-XXX	DDMMMYYYY	DDMMMYYYY	MMMYYYY	XX	X	Other: XXXXXXX
XX-XXX	DDMMMYYYY	DDMMMYYYY	MMMYYYY	XX	X	XXXXXXXXXXX
XX-XXX	DDMMMYYYY	DDMMMYYYY	MMMYYYY	XX	X	XXXXXXXXXXX
XX-XXX	DDMMMYYYY	DDMMMYYYY	MMMYYYY	XX	X	XXXXXXXXXXX

Data Listing 16.2.1.2: Subject Disposition
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

	Date (Day) of [1]						
Subject Number	**Screening**	**Randomization**	**First Dose**	**Last Dose**	**Last Visit**	**Last Contact**	**Completion Status / Discontinuation Reason**
XX-XXX	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	XXXXX
XX-XXX	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	XXXXX
001-001	19JUN2017(-10)	29JUN2017(1)	29JUN2017(1)	--	06JUL2017(8)	--	Completed

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.2: Protocol Deviation
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Category	Major/Minor	Protocol Deviation
XX-XXX	XXXX	Minor	XXXXXXXXXXXX
	XXXXX	Major	XXXX

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

<Programming Note: The format of protocol deviation listing depends on the actual protocol deviation report form layout. Additional columns may be added, such as "Reference" "Type". If site deviation or deviation for SF subjects are also available, include those at the very end of this listing.>

Data Listing 16.2.3: Population Datasets
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	In Safety Population?	In HPA Population?	In PK Population?	Reason for Exclusion from Safety Population	Reason for Exclusion from HPA Population	Reason for Exclusion from PK Population
XX-XXX	Yes	Yes	No	NA	NA	XXX
XX-XXX	No	No	No	XXX	XXX	XXX
XX-XXX	XXX	XXX	XXX	NA	NA	NA

Data Listing 16.2.4.1: Demographics and Baseline Characteristics
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Age (years)	Sex	Race	Ethnicity	Weight (kg)	Height (cm)	Fitzpatrick Skin Type	HPA-axis Suppression Status[1]	PGA	Total BSA (%)	Duration of Psoriasis (years)
XX-XXX	XX	M	Asian	NH	XXX	XXX	X	Yes	X	XX.X	XX.X
XX-XXX	XX	F	White	H	XXX	XXX	X	No	X	XX.X	XX.X

Note: PGA = Physician's Global Assessment; BSA = Body Surface Area. NH=Not Hispanic or Latino; H=Hispanic or Latino
[1] HPA-axis suppression status is only assessed among subjects assigned to MC2-01 cream.

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

Data Listing 16.2.4.2: Prior and Concomitant Medication
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	**Category**	**WHO Preferred Term (Verbatim Term) / ATC Classification**	**Topical treatment within 2 cm of treatment area?/ Indication Dose(Frequency)/Unit /Route**	**Administered for AE #/ MH #**	**Start Date (Day)-Stop Date (Day)**
XX-XXX	Prior	XXXXXX (xxxxx)/ XXXXXX	Yes/XXX XX/XXX/XXXX	NA/1	DDMMMYYYY (XX) – DDMMMYYYY (XX)
XX-XXX	Concomitant	XXXXXX (xxxxx)/ XXXXXX	No/XXX XX/XXX/XXXX	NA/NA	DDMMMYYYY (XX) – Ongoing

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

<Programming Note: List medication in ascending start date for each subject.>

Data Listing 16.2.4.3: Concurrent Procedures
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Preferred Term/ System Organ Class/ Procedure	Inside treatment area?/ Diagnosis/Body Location	Administered for AE #/ MH #	Procedure Start Date (Day)-Stop Date (Day)
XX-XXX	XXXXXXXX/ XXXXX/ XXXXXX	Yes/ XXXX/XXXXXXX	1/NA	DDMMMYYYY (XX) – DDMMMYYYY (XX)
XX-XXX	XXXXXXXX/ XXXXX/ XXXXXX	No/ XXXX/XXXXXXX	NA/NA	DDMMMYYYY (XX) – DDMMMYYYY (XX)

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

<Programming Note: List medication in ascending start date for each subject.>

Data Listing 16.2.4.4: Medical or Surgical History
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	MH #	Diagnosis / Procedure	System Organ Class	Preferred Term	Ongoing?
XX-XXX	1	XXXX	XXXXX	XXXXXX	No
XX-XXX	1	XXXX	XXXXX	XXXXXX	Yes

Data Listing 16.2.4.5: Psoriasis Treatment History
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Year of First Diagnosis of Psoriasis	Previous Treatment
XX-XXX	YYYY	TNF-a inhibitors
XX-XXX	YYYY	Topical: retinoids

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

Data Listing 16.2.5.1: Study Drug Administration and Compliance
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day)[1]	Apply Study Drug Once Daily Since Last Visit?	Number of Missed Applications	Approved Stop Date (Day) [1]	Reason Missed
XX-XXX	Visit 2/Week 2	DDMMMYYYY(XX)	Y	XX	NA	NA
	Visit 3/Week 4	DDMMMYYYY(XX)	Y	XX	NA	NA
	Visit 4/Week 6	DDMMMYYYY(XX)	Y	XX	NA	NA
	Visit 5/Week 8	DDMMMYYYY(XX)	N	XX	DDMMMYYYY(XX)	XXXXXXXXXXX
XX-XXX	Visit 2/Week 2	DDMMMYYYY(XX)	Y	XX	NA	NA
	Visit 3/Week 4	DDMMMYYYY(XX)	Y	XX	NA	NA
	Visit 4/Week 6	DDMMMYYYY(XX)	N	XX	NA	NA
	Visit 5/Week 8	DDMMMYYYY(XX)	N	XX	DDMMMYYYY(XX)	XXXXXXX

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.5.2: Study Drug Accountability
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Kit Number	Date (Day) Dispensed [1]	Tube Number	Tube Retuned?	Date (Day) Returned [1]	Tube Sealed?	Return Weight (g)
XX-XXX	Visit 1/Day 1	XXXXXXX	DDMMMYYYY(XX)	1	Yes	DDMMMYYYY(XX)	XX	XX.X
				2	No	DDMMMYYYY(XX)	-	-
	Visit 2/Week 2	XXXXXXX	DDMMMYYYY(XX)	1	Yes	DDMMMYYYY(XX)	XX	XX.X
				2	Redispensed	-	-	-
	Visit 3/Week 4	XXXXXXX	DDMMMYYYY(XX)	1	XXXX	DDMMMYYYY(XX)	XX	XX.X
				2	XXXX	DDMMMYYYY(XX)	XX	XX.X
XX-XXX	Visit 1/Day 1	XXXXXXX	DDMMMYYYY(XX)	1	Redispensed	DDMMMYYYY(XX)	XX	XX.X
				2	No	DDMMMYYYY(XX)	XX	XX.X
	Visit 2/Week 2	XXXXXXX	DDMMMYYYY(XX)	1	Yes	DDMMMYYYY(XX)	XX	XX.X
				2	Redispensed	DDMMMYYYY(XX)	XX	XX.X

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.5.3.1: Overall Study Drug Exposure and Compliance, Day 1 to Week 4 Period
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Total Number of Days of Exposure[1]	Total Number of Expected Doses[2]	Total Number of Missed Doses	Total Number of Applied Doses[3]	Total Amount of Drug Used (g)[4]	Amount of Drug Used per week (g/per week)[5]
XX-XXX	XX	XX	XX	XX	XX.X	XX.X
XX-XXX	XX	XX	XX	XX	XX.X	XX.X

[1] Total number of days of exposure to the study drug is defined as the date of last application of study drug minus date of first application plus one. Last application is applied in-clinic at Week 4 visit.
[2] Total number of expected doses is defined as total number of days of exposure minus any days of investigator approved stop (if applicable)
[3] Total number of doses applied, defined as the total number of doses required minus total number of doses missed.
[4] Total amount of drug used (g), defined as the summation of amount of drug used per kit for all dispensed kits.
[5] Amount of drug used per week (g/per week), defined as the total amount of drug used divided by total number of days of exposure to the study drug multiplied by 7.

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

Data Listing 16.2.5.3.2: Overall Study Drug Exposure and Compliance, Day 1 to Week 8 Period
All Randomized Subjects
[MC2-01 Cream]

Subject Number	Total Number of Days of Exposure[1]	Total Number of Expected Doses[2]	Total Number of Missed Doses	Total Number of Applied Doses[3]	Total Amount of Drug Used (g)[4]	Amount of Drug Used per week (g/per week)[5]
XX-XXX	XX	XX	XX	XX	XX.X	XX.X
XX-XXX	XX	XX	XX	XX	XX.X	XX.X

[1] Total number of days of exposure to the study drug is defined as the date of last application of study drug minus date of first application plus one. Last application is applied in-clinic at Week 8 visit.
[2] Total number of expected doses is defined as total number of days of exposure minus any days of investigator approved stop (if applicable)
[3] Total number of doses applied, defined as the total number of doses required minus total number of doses missed.
[4] Total amount of drug used (g), defined as the summation of amount of drug used per kit for all dispensed kits.
[5] Amount of drug used per week (g/per week), defined as the total amount of drug used divided by total number of days of exposure to the study drug multiplied by 7.

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

Data Listing 16.2.5.4.1: Subject Treatment Diary Card
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Date (Day)[1]	Study Drug Applied?	Reason if Medication not Applied
XX-XXX	DDMMMYYYY (1)	Y	-
	DDMMMYYYY (XX)	Y	-
	DDMMMYYYY (XX)	N	XXXXXXX

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.5.4.2: Subject Food Diary
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Time Point	Date (Day)[1]	Number of Servings of Calcium-rich Foods	Reason Not Done
XX-XXX	Visit 1/Day 1	Day -3	DDMMMYYYY (-3)	X	NA
		Day -2	DDMMMYYYY (-2)	X	NA
		Day -1	DDMMMYYYY (-1)	X	XXXXXXX
		Collection Day	DDMMMYYYY (1)		

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Listing 16.2.6.1: Plasma Concentration Sample Date and Time and Plasma Concentrations
PK Population
[MC2-01 Cream] [Active Comparator]

Subject	Visit	Dosing Date and Time	PK Time Point	Sample Collection Date and Time (Day)	Elapsed Time (hours)	CAL (unit)	BDP (unit)	MC1080 (unit)	Betamethasone 17-propionate (unit)
XX-XXX	Baseline	--	--	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
	Visit 2/ Week 2	DDMMYYYYTXX:XX	Pre-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
	Visit 3/ Week 4	DDMMYYYYTXX:XX	Pre-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			0.5 hour post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			1 hour post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			2 hours post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			3 hours post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			5 hours post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			7 hours post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			<etc.>						
	Visit 5/ Week 8	DDMMYYYYTXX:XX	Pre-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			0.5 hour post-dose	DDMMYYYYTXX:XX (XX)	XX.X	XX.X	XX.X	XX.X	XX.X
			<etc.>						

Listing 16.2.6.2.X: [CAL, BDP, MC1080, Betamethasone 17-propionate] Derived Pharmacokinetics Parameters
PK Population
[MC2-01 Cream] [Active Comparator]

Subject	Visit	C_{max} (ng/mL)	T_{max} (h)	AUC_{0-7} (ng*h/mL)	AUC_{0-t} (ng*h/mL)	$AUC_{0-\infty}$ (ng*h/mL)	$T_{1/2}$ (h)
XXX-XXX	Week 4	XXXX	XXXX	XX.XX	XXXXX	XXXXX	XXXX
	Week 8	XXXX	XXXX	XX.XX	XXXXX	XXXXX	XXXX

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

[Programming Note: Week 8 only applies to MC2-01 Cream subjects]

Data Listing 16.2.6.3: Physician's Global Assessment of Disease Severity (PGA) – Scalp, Trunk and/or Limbs
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	PGA	Change from Baseline	Treatment Success?[2]
XX-XXX	Screening	DDMMMYYYY(XX)	3 – Moderate	--	--
	Visit 1/Day 1	DDMMMYYYY(XX)	3 – Moderate	--	--
	Visit 2/Week 2	DDMMMYYYY(XX)	2 – Mild	-1	N
	Visit 3/Week 4	DDMMMYYYY(XX)	2 – Mild	-1	N
	Visit 4/Week 6	DDMMMYYYY(XX)	1 – Almost clear	-2	Y
	Visit 5/Week 8	DDMMMYYYY(XX)	1 – Almost clear	-2	Y

[1] Study day is calculated relative to date of first application of study drug (Day 1).
[2] PGA success is defined as a minimum 2-point decrease from Baseline in the PGA.

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

Data Listing 16.2.6.4: Investigator's Assessment of the Body Surface Area (BSA) Involvement of Psoriasis
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	Scalp BSA (%)	Neck, Trunk and/or Limbs BSA (%)	Total BSA (%)
XX-XXX	Screening	DDMMMYYYY(XX)	XX.X	XX.X	XX.X
	Visit 1/Day 1	DDMMMYYYY(XX)	XX.X	XX.X	XX.X
	Visit 3/Week 4	DDMMMYYYY(XX)	XX.X	XX.X	XX.X
	Visit 5/Week 8	DDMMMYYYY(XX)	XX.X	XX.X	XX.X

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.6.5: Investigator and Subject Assessed Local Skin Reaction (LSR)
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	Investigator Assessed								Subject Assessed
			Perilesional Signs					Lesional Signs			
			Erythema	Scaling	Edema	Atrophy	Vesicles	Erosion/ Ulceration	Vesicles	Erosion/ Ulceration	Burning or Pain
XX-XXX	Visit 1/Day 1	DDMMMYYYY(XX)	1=Mild	1=Mild	1=Mild	3=Severe	X	X	X	X	X
	Visit 2/Week 2	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X
	Visit 3/Week 4	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X
	Visit 4/Week 6	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X
	Visit 5/Week 8	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.6.6: Psoriasis Treatment Convenience Scale
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	Q1	Q2	Q3	Q4	Q5	Q6	Total Score of Q1-Q5
XX-XXX	Visit 3/Week 4	DDMMMYYYY(XX)	XX	XX	XX	XX	XX	XX	XX
XX-XXX	Unscheduled	DDMMMYYYY(XX)	XX	XX	XX	XX	XX	XX	XX

Q1 = How easy was the treatment to apply to the skin?; Q2 = How greasy was the treatment when applying it to the skin?; Q3 = How moisturized did your skin feel after applying the treatment?; Q4 = How greasy did your skin feel after applying the treatment?; Q5 = How much did treating your skin disrupt your daily routine?; Q6 = Overall, how satisfied were you with the medical treatment?

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.6.7: ACTH Challenge
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Date (Day) [1]	Cosyntropin Injection Time	Pre-Stimulation		30 Min Post-Stimulation		HPA-Axis Suppression
				Collection Time	Cortisol Level (µg/dL)	Collection Time	Cortisol Level (µg/dL)	
XX-XXX	Visit 1/Day 1	DDMMMYYYY (XX)	HH:MM	HH:MM	XX.X	HH:MM	XX.X	No
	Visit 3/Week 4	DDMMMYYYY (XX)	HH:MM	HH:MM	XX.X	HH:MM	XX.X	No
	Visit 4/Week 8	DDMMMYYYY (XX)	HH:MM	HH:MM	XX.X	HH:MM	XX.X	Yes

[1] Study day is calculated relative to date of first application of study drug (Day 1).

Data Listing 16.2.7.1: Adverse Events
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	AE #	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term)	TEAE? [1] / Period Onset Date (Day) – End Date (Day) [2]	Related to Cosyntropin?/ Related to Study Procedure?	Outcome/ Withdraw due to AE?	SAE: Criteria?/ Severity	Location to Treatment Area/ Relationship to Study Medication	Action Taken / Other Action Taken
XX-XXX	1	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes / 1 DDMMMYYYY(XX) – DDMMMYYYY(XX)	No/No	XXXXXXXX/ Yes	Yes: Hospitalization / Mild	Inside treatment area/ Definitely Related	XXXXXXXX / XXXXXXXX
	2	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	No / NA DDMMMYYYY(XX) – Ongoing	No/Yes	XXXXXXXX/ No	No/ XXXXXXXX	Outside treatment area/ XXXXXXXX	XXXXXXXX / XXXXXXXX
XX-XXX	1	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes / 2 DDMMMYYYY(XX) – DDMMMYYYY(XX)	No/No	XXXXXXXX/ XX	No/ XXXXXXXX	Non-cutaneous/ XXXXXXXX	XXXXXXXX / XXXXXXXX

Period 1=Week 1-4; Period 2=Post Week4.
[1] A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication.
[2] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.7.2: Serious Adverse Events
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	AE #	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term)	TEAE? [1] / Period Onset Date (Day) – End Date (Day) [2]	Related to Cosyntropin?/ Related to Study Procedure?	Outcome/ Withdraw due to AE?	SAE Criteria/ Severity	Location to Treatment Area/ Relationship to Study Medication	Action Taken / Other Action Taken
XX-XXX	1	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes / 1 DDMMMYYYY(XX) – DDMMMYYYY(XX)	No/No	XXXXXXXX/ Yes	Hospitalization / Mild	Inside treatment area/ Definitely Related	XXXXXXXX / XXXXXXXX
XX-XXX	2	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	No / NA DDMMMYYYY(XX) – DDMMMYYYY(XX)	No/No	XXXXXXXX/ No	XXX/ XXXXXXXX	Non-cutaneous/ XXXXXXXX	XXXXXXXX / XXXXXXXX

Period 1=Week 1-4; Period 2=Post Week4.
[1] A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication.
[2] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.7.3: Adverse Events Leading to Study Drug Discontinuation
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	AE #	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term)	TEAE? [1] / Period Onset Date (Day) – End Date (Day) [2]	Related to Cosyntropin?/ Related to Study Procedure?	Outcome/ Withdraw due to AE?	SAE: Criteria?/ Severity	Location to Treatment Area/ Relationship to Study Medication	Other Action Taken
XX-XXX	1	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes / 1 DDMMMYYYY(XX) – DDMMMYYYY(XX)	No/No	XXXXXXXX/ Yes	Yes: Hospitalization / Mild	Inside treatment area/ Definitely Related	XXXXXXXX
	2	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	No / NA DDMMMYYYY(XX) – Ongoing	No/Yes	XXXXXXXX/ No	No/ XXXXXXXX	Outside treatment area/ XXXXXXXX	XXXXXXXX
XX-XXX	1	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Yes / 2 DDMMMYYYY(XX) – DDMMMYYYY(XX)	No/No	XXXXXXXX/ XX	No/ XXXXXXXX	Non-cutaneous/ XXXXXXXX	XXXXXXX

Period 1=Week 1-4; Period 2=Post Week4.
[1] A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication.
[2] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.8.1: Urine Pregnancy Test
All Randomized Female Subjects with Childbearing Potential
[MC2-01 Cream][Active Comparator]

Subject Number	Birth Control Methods	Visit	Date of Test (Day)[1]	Result
XX-XXX	Abstinence	Screening	DDMMMYYYY(XX)	Negative
		Visit 1/Day 0	DDMMMYYYY(XX)	Negative
		Visit 3/Week 4	DDMMMYYYY(XX)	Negative
		Visit 5/Week 8	DDMMMYYYY(XX)	Negative

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.8.2.X: Clinical Laboratory Test
[Biochemistry][Hematology]
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Date (Day) and Time of Sample[1]	Parameter (Unit)	Reference Range	Results	Abnormality	CFBL
XX-XXX	Visit 1/Day 1	DDMMMYYYY (XX)THH:MM	XXXX	XXXX,XXXX	XX.XX		--
			XXXX	XXXX,XXXX	XX.XX	High	--
			XXXX	XXXX,XXXX	XX.XX		XXX.X
	Visit 3/Week 4	DDMMMYYYY (XX)	XXXX	XXXX,XXXX	XX.XX	Low	XXX.X
	Visit 4/Week 8	DDMMMYYYY (XX)	XXXX	XXXX,XXXX	XX.XX		XXX.X

CFBL = Change from Baseline
[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.8.2.3: Clinical Laboratory Test
24 Hour Urinalysis
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Collection Date and Time Start – Stop	Total Volume Collected (mL)	Parameter (Unit)	Reference Range	Results	Abnormality	CFBL
XX-XXX	Visit 1/Day 1	DDMMYYYY(DD)THH:MM-DDMMYYYY(DD)THH:MM	XXXX	XXXX	XXXX,XXXX	XX.XX		--
				XXXX	XXXX,XXXX	XX.XX	High	--
				XXXX	XXXX,XXXX	XX.XX		XXX.X
	Visit 3/Week 4			XXXX	XXXX,XXXX	XX.XX	Low	XXX.X
	Visit 4/Week 8			XXXX	XXXX,XXXX	XX.XX		XXX.X

CFBL = Change from Baseline
[1] Study day is calculated relative to date of first application of study drug (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX
[Programming Note: Week 4 and Week 8 only applies to MC2-01 Cream subjects]

Data Listing 16.2.8.3: Laboratory Values Outside of Normal Range
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Date (Day) of Sample[1]	Category	Parameter (Unit)	Reference Range	Results	Abnormality	CFBL
XX-XXX	Visit 1/Day 1	DDMMMYYYY (XX)	Biochemistry	XXXX	XXXX,XXXX	XX.XX	High	--
			Hematology	XXXX	XXXX,XXXX	XX.XX	High	--
			Urinalysis	XXXX	XXXX,XXXX	XX.XX		XXX.X
	Visit 3/Week 4	DDMMMYYYY (XX)		XXXX	XXXX,XXXX	XX.XX	Low	XXX.X
	Visit 4/Week 8	DDMMMYYYY (XX)		XXXX	XXXX,XXXX	XX.XX		XXX.X

CFBL = Change from Baseline
[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.8.4: Vital Signs
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	SBP (mmHg)		DBP (mmHg)		Pulse Rate (bpm)	
			Observed	CFBL	Observed	CFBL	Observed	CFBL
XX-XXX	Screening	DDMMYYYY (XX)	XX.X	--	XX.X	--	XX.X	--
	Visit 1/Day 1	DDMMYYYY (XX)	XX.X	--	XX.X	--	XX.X	--
	Visit 2/Week 2	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Visit 3/Week 4	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Visit 4/Week 6	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Visit 5/Week 8	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

Note: SBP=Systolic blood pressure; DBP=Diastolic blood pressure; CFBL= change from baseline
[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.8.5: Physical Examination
Randomized Subjects with Abnormal Results
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	Findings
XX-XXX	Screening	DDMMMYYYY (XX)	Abnormal Not Clinically Significant
XX-XXX	XXXX	DDMMMYYYY (XX)	Abnormal Clinically Significant

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.8.6: 12-Lead ECG Results
All Randomized Subjects
[MC2-01 Cream][Active Comparator]

Subject Number	Visit	Visit Date (Day) [1]	ECG Test (Units)	Result
XX-XXX	Visit 1/Day 1	DDMMMYYYY (XX)	Interpretation	Abnormal Not Clinically Significant
		DDMMMYYYY (XX)	ECG Finding 1	XXXXX
		DDMMMYYYY (XX)	ECG Finding 2	XXXX
			Summary (Mean) Heart Rate (beats/min)	
			Summary (Mean) RR Duration (msec)	
			Etc.	
	Visit 3/Week 4	DDMMMYYYY (XX)	XXXXX	XXXXX
	Visit 5/Week 8	DDMMMYYYY (XX)	XXXXX	XXXXX

[1] Study day is calculated relative to date of first application of study drug (Day 1).

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

Data Listing 16.2.9: General Comments
[MC2-01 Cream][Active Comparator]

Subject Number	Comment Reference	Comment
XX-XXX	Visit 3/Week 4	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XX-XXX	Visit 5/Week 8	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

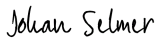
Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Certificate Of Completion

Envelope Id: C72CEACD45E649FEBAEF9862708CB5E6
Status: Completed
Subject: Please DocuSign: MC2-01-C3 SAP 21sep2018 Amendment 1_clean.pdf
Source Envelope:
Document Pages: 84
Signatures: 2
Envelope Originator:
Certificate Pages: 5
Initials: 0
jin Wei
AutoNav: Enabled
1700 Perimeter Park Drive
EnvelopeId Stamping: Disabled
Morrisville, NC 27560
Time Zone: (UTC-05:00) Eastern Time (US & Canada)
Jin.Wei2@novellaclinical.com
IP Address: 192.69.83.249

Record Tracking

Status: Original
9/21/2018 11:36:32 AM
Holder: jin Wei
Jin.Wei2@novellaclinical.com
Location: DocuSign

Signer Events	Signature	Timestamp
Carol Udell Carol.Udell@novellaclinical.com Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: CE741CD0-FE97-41EC-A29C-B39E84B183BB Using IP Address: 192.69.82.248 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 9/21/2018 11:40:43 AM Viewed: 9/21/2018 12:13:46 PM Signed: 9/21/2018 12:15:46 PM
Electronic Record and Signature Disclosure: Accepted: 6/29/2017 9:05:59 AM ID: 23a67abb-661c-48d7-a3b0-5cd8fbe94ff5		
Johan Selmer jse@mc2therapeutics.com Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 0CB84AC3-A754-477D-9A78-70027DF16AE6 Using IP Address: 77.72.48.114 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): Jeg godkender dette dokument	Sent: 9/21/2018 11:40:43 AM Viewed: 9/21/2018 11:42:51 AM Signed: 9/21/2018 11:43:37 AM
Electronic Record and Signature Disclosure: Accepted: 5/16/2018 6:58:25 AM ID: 7622460b-6a54-44da-884b-23e798fe761d		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp
Birgitte Vestbjerg bve@mc2therapeutics.com Security Level: Email, Account Authentication (Required) **Electronic Record and Signature Disclosure:** Accepted: 8/21/2017 9:01:36 AM ID: 2f1c7a3f-d74e-4f4c-b2f9-9471674f2918	COPIED	Sent: 9/21/2018 11:40:44 AM

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	9/21/2018 11:40:44 AM
Certified Delivered	Security Checked	9/21/2018 12:13:47 PM
Signing Complete	Security Checked	9/21/2018 12:15:46 PM
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Payment Events	Status	Timestamps

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Email:	Access to a valid email account
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