PellePharm, Inc

STATISTICAL ANALYSIS PLAN

Protocol Number:	Pelle-926-201
Study Title:	Double-Blind, Randomized, Vehicle-Controlled Proof of Concept Clinical Trial of Patidegib Gel 2%, 4%, and Vehicle to Decrease the Number of Surgically Eligible Basal Cell Carcinomas in Gorlin Syndrome Patients
Development Phase of Study:	2A
Expected Sample Size:	18 subjects
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Prepared by:	PPD QST Consultations, Ltd.

APPROVAL

STUDY TITLE: Double-Blind, Randomized, Vehicle-Controlled Proof of Concept Clinical Trial of Patidegib Gel 2%, 4%, and Vehicle to Decrease the Number of Surgically Eligible Basal Cell Carcinomas in Gorlin Syndrome Patients.

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Approved by:

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PellePharm, Inc.

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

Change History:

Version	Date	Summary of Changes	Author
1	13Apr2017	Version 1	PPD
2	12May2017	Section 8.14.12: Add notes on combined/upper/lower analysis regions. Output updates: Table 14.2.2.1: Update to indicate combined. Table 14.2.2.2: Added. Table 14.2.7.1: Remove row 1 (not needed). Table 14.2.8.1: Remove 'n' rows (not needed due to LOCF). Tables 14.2.6.1 and 14.2.7.1: Update to use ANCOVA.	

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2. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

aBCCdex	Advanced Basal Cell Carcinoma Index
AE	Adverse event
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
BCC	Basal cell carcinoma
BCNS	Basal cell nevus syndrome
BUN	Blood urea nitrogen
DLQI	Dermatology Quality of Life Index
DSMB	Data Safety Monitoring Board
ET	Early Termination
GLI1	Glioma-associated oncogene homolog 1
HH	Hedgehog
ISGTA	Investigator Static Global Tumor Assessment
ITT	Intent-to-Treat
IUD	Intra Uterine Device
IWRS	Interactive web response system
LOCF	Last observation carried forward
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MedDRA	Medical dictionary for regulatory activities
mRNA	Messenger Ribonucleic Acid
N	Number of subjects
OMIM	Online Mendelian Inheritance in Man
RBC	Red blood cells
SAE	Serious adverse event
SD	Standard deviation
SEB	Surgically eligible basal cell carcinoma
SOP	Standard Operating Procedure
TEAE	Treatment-Emergent Adverse Event
UV	Ultraviolet
WBC	White blood cells
WHO	World Health Organization
WHO-DDE	World Health Organization Drug Dictionary

3. INTRODUCTION

Patients affected by the basal cell carcinoma syndrome (BCNS) (Gorlin syndrome, nevoid basal cell carcinoma syndrome; Online Mendelian Inheritance in Man [OMIM] #109400), a rare autosomal dominant inherited disorder, have a dramatically increased risk of developing basal cell carcinomas (BCCs) (developing hundreds to thousands of BCCs) as well as an increased risk of developing certain extra cutaneous tumors (e.g. medulloblastomas and rhabdomyosarcomas).

Inhibition of the hedgehog HH pathway with the oral HH inhibitor, vismodegib, has been shown to prevent BCC development and to shrink existing BCCs in BCNS patients as well as to control some advanced BCCs. In addition sonidegib another oral HH inhibitor has recently been approved for the treatment of locally advanced BCCs. However, oral HH inhibitors produce class-specific side effects such as hair loss, taste loss, weight loss, fatigue, and intense muscle cramps. The severity of the adverse events (AEs) associated with vismodegib is illustrated by the fact that 54% of BCNS patients in an oral vismodegib clinical trial discontinued treatment because of AEs, despite clear efficacy.

PellePharm hopes to decrease the number of facial surgically eligible basal cell carcinomas (SEBs) in BCNS patients by applying a topical HH inhibitor (patidegib) to produce good local effects without producing the side effects that occur with systemic administration of this class of drugs. PellePharm believes that there are two therapeutic effects that could decrease the patients' number of SEBs, namely (i) shrinking preexisting tumors and (ii) preventing the development of new tumors.

Patidegib is a semi-synthetic small molecule, and the topical drug product is manufactured with generally accepted, safe excipients. Oral patidegib has a good therapeutic effect on locally advanced and metastatic BCCs but produces the same types of adverse effects as do other systemic HH inhibitors. Topical patidegib has been shown to be stable in the developed gel formulation and deposits significant amounts of drug in the dermis after topical application to human cadaver skin in Franz chamber assays. Topical application of patidegib significantly reduces murine BCC tumor size in vivo and reduces glioma-associated oncogene homolog 1 (GLI1) biomarker expression in vitro in human BCC tumors.

The goal of the present trial is to evaluate topical patidegib's safety, tolerability, and effects on the size of preexisting SEBs and on the development of new SEBs. If the efficacy with topical patidegib can approach the level of efficacy of oral HH inhibitors seen in BCNS patients while avoiding their systemic side effects, it would represent a major advance for BCNS patients.

4. STUDY OBJECTIVES

4.1 Primary Objectives

The primary objectives of the study are to evaluate the following:

1. The clinical efficacy of patidegib as defined by the percent decrease in greatest diameter of Baseline treatment targeted Surgically Eligible basal cell carcinomas (SEBs) after 26 weeks of treatment. [SEBs are defined as clinically diagnosed BCCs 5 mm or greater in diameter on the face excluding the nose and periorbital skin, and 9 mm or greater at sites other than the face].
2. The molecular efficacy of treatment as defined by reduction in the hedgehog (HH) signaling pathway target gene GLI1 after treatment with patidegib gel 2% or 4% or vehicle applied twice daily for 6 weeks to treatment-targeted SEBs.
3. The safety and tolerability of treatment with patidegib gel 2% or 4% or vehicle applied twice daily for 26 weeks.

4.2 Secondary Objectives

The secondary objectives of the study are to evaluate the following:

1. The clinical efficacy of treatment as defined by percent decrease in greatest diameter of Baseline central facial SEBs (BCCs 3 mm or greater in diameter at Baseline located on the nose or periorbital area).
2. The frequency of new SEBs on the face (a new SEB is defined as a SEB first noted at a visit after Week 2 and that developed at a site where there was no visible BCC of any size at the Baseline or the Week 2 visit).
3. The proportion of non-central facial BCCs that at Baseline and/or Week 2 visit were less than 5 mm in greatest diameter but by the Week 6, 10, 14, 18, 22, or 26 visit have become greater than 5 mm in greatest diameter.
4. The proportion of Baseline treatment targeted SEBs that at the end of 26 weeks of treatment are no longer large enough to be classified as SEBs (i.e., that is the proportion of Baseline treatment targeted SEBs on the face that become less than 5 mm in greatest diameter and non-facial Baseline treatment targeted SEBs that become less than 9 mm in greatest diameter).

4.3 Exploratory Objective

To evaluate the utility of an investigator static global tumor assessment (ISGTA) in assessing the proportion of Baseline treatment targeted SEBs that are evaluated as being clear or almost clear.

5. INVESTIGATIONAL PLAN

5.1 Overall Study Design

This is a multicenter, double-blind, randomized, vehicle-controlled study to assess the efficacy and safety of patidegib gel, 2% and 4% in comparison with vehicle. To be eligible for the study, subjects must be at least 18 years of age and meet the diagnostic criteria for BCNS.

Approximately 18 subjects who meet the study entry criteria will be randomized in a 1:1:1 ratio to receive patidegib gel 2%, patidegib gel 4%, or vehicle gel. One or two tubes of the assigned study drug will be dispensed to the subject at the Baseline visit. The study drug will be applied topically to the entire face as well as to treatment-targeted SEBs at other anatomical sites twice daily for 26 weeks of treatment. Subjects will apply their twice daily treatments at home as explained by the study coordinator or designee at each study center. The subject will apply the initial application under the supervision of the study staff. If a subject has a treatment targeted SEB on an anatomical location that the subject cannot reach such as the back, a friend or family member may apply the treatment. In this case the friend or family member applying the gel cannot be a woman of childbearing potential, and the person should apply the gel using a latex or vinyl glove. As BCNS patients are routinely advised, all subjects will be instructed to avoid exposure to direct sunlight and to continue their use of sunscreens to minimize their exposure to ultraviolet (UV) radiation.

At each post-Baseline visit during the treatment period (Weeks 2, 6, 10, 14, 18, 22, and 26) the subjects will be asked to return their tubes of study drug which will be evaluated for drug usage compliance. It has been estimated that subjects will require 330 mg of gel to adequately cover their face and 20 mg of gel to adequately cover each non-facial SEBs. The Study Coordinator or designee at each study center will dispense new tube(s) of study drug to each subject at study center visits at Baseline through Week 22. The goal is that each subject will have an adequate supply of gel to last until the next clinic visit plus some extra in case of application errors and or delay in study visits. While individual usage rates of topical products have individual variability the use of dosing card should help limit the variation in dosing inherent with topical products. PellePharm estimates that subjects treating only the face, 1, 2, 3, 4, or 5 non-facial SEBs will consume 19.8 gm, 21 gm, 22.2 gm, 23.4 gm, 24.6 gm, and 25.8 gm of gel over the course of a 30 day month.

5.2 Determination of Sample Size

Data from a trial of oral vismodegib (New England Journal of Medicine) given for 7 months resulted in a percent change in the sum of the greatest diameter of Baseline treatment targeted SEBs of 69.2 and 13.7 with a standard deviation of 17 and 23 for treated and control subjects, respectively. A sample size of 6 subjects enrolled in each treatment group with a minimum of 5 SEBs will have greater than 95 percent power to detect a statistically significant difference at an alpha of 0.05.

5.3 Treatments

5.3.1 Treatments Administered

The investigational center staff member will instruct the subject to apply the study drug to the affected treatment areas identified at the Baseline visit by the Investigator. The staff member will instruct the subject on the proper use of laminated dosing cards during the Baseline visit. In addition to the verbal instructions given during the visit, the subjects will be provided with written instructions.
Subjects will be instructed to apply a thin layer of study drug to the entire selected treatment area(s) as indicated on the body diagram twice daily up to the Week 26 visit.

5.3.2 Method of Subject Assignment to Treatment Groups

Approximately 18 adult subjects meeting study inclusion criteria (and not meeting any exclusion criteria) as defined in the protocol will be randomized in a 1:1:1 ratio into each study arm. The randomization assignment will be dynamically stratified by site and will follow the design as outlined in the study randomization plan. Study drug kits will be assigned sequentially within blocks by site with a total of approximately 6 subjects being enrolled at each investigational site.

5.3.3 Study Blinding and Maintenance of the Study Blind

During the conduct of the study all personnel will remain blinded to the true treatment assignment with the exception of the kit labeling and packaging group and the unblinded study team. The unblinded study team will be comprised of at least two individuals who will produce and validate the randomization list and have access to the treatment assignment during the study. Only individuals deemed as unblinded will have access to the treatment assignments during the study and all other study personnel will remain blinded. Once the clinical database is locked and the study unblinding process occurs the true randomization list will be released and applied to the data for summary and reporting purposes and the blind will have been broken.

Once all subjects complete 10 weeks of follow-up there will a Data Safety Monitoring Board (DSMB) meeting which will utilize data displays created using the true treatment assignment. These displays will be programmed and validated by blinded study personnel using a dummy treatment assignment file. After all data displays have completed development, the unblinded

study team will rerun the programs in a secure area not accessible by the blinded project team by replacing the dummy randomization list with the true randomization list and providing the data displays to the committee for review purposes.

6. CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

There are no changes in the conduct of the study or planned analyses.

7. EFFICACY AND SAFETY ENDPOINTS

7.1 Efficacy Endpoints

7.1.1 Primary Efficacy Endpoints

7.1.1.1 Percent Decrease in Tumor Size at Week 26

The percent decrease in tumor size is defined as the percent decrease in the sum of the greatest diameters of Baseline treatment targeted SEBs from Baseline to week 26 and is calculated as follows.

[Sum (Baseline) - sum (Week 26)] / [sum (Baseline)] x 100 = Percent Decrease in Tumor Size at Week 26

where sum = sum of the greatest diameters of Baseline treatment targeted SEBs

Note that if this calculation results in a positive number this indicates a percent decrease from Baseline.

7.1.1.2 Percent Decrease in GLI1 mRNA Levels at Week 6

A single baseline SEB designated as a treatment targeted tumor at Baseline will be biopsied at Baseline and following 6 weeks of treatment. This will be used to assess percent decrease in GLI1 mRNA levels as measured by the Hs-GLI1 H-Score as follows:

(Baseline – Week 6) / Baseline = Percent Decrease in GLI1mRNA

7.1.2 Secondary Efficacy Endpoints

7.1.2.1 Percent Decrease in Tumor Size at Weeks 6, 10, 14, 18 and 22

The percent decrease in tumor size at Weeks 6, 10, 14, 18 and 22 is calculated similarly to the primary endpoint.

[sum (Baseline) - sum (Week *x*)] / [sum (Baseline)] x 100 = Percent Decrease in Tumor Size at Week *x*

where *x* is 6, 10, 14, 18 or 22.

7.1.2.2 Percent Decrease in Central Facial SEBs at Weeks 6, 10, 14, 18, 22 and 26

The percent decrease at weeks 6, 10, 14, 18 and 22 in central facial SEBs, defined as those located on the nose or periorbital area (eyelids) which are 3mm or greater at Baseline, is calculated similarly to the primary endpoint using the sum of the greatest diameters of central facial SEBs as follows.

[sum (Baseline) - sum (Week *x*)] / [sum (Baseline)] x 100 = Percent Decrease in central facial SEBs at Week *x*

where *x* is 6, 10, 14, 18 or 22.

7.1.2.3 Count of New SEBs on Face

The investigators will identify any new SEBs on the face Week 6, 10, 14, 18, 22 and 26. New SEBs are defined as those located at a site where there was no visible BCC of any size at Baseline or the Week 2 visits. Any new SEBs per patient at each week will be counted.

7.1.2.4 Proportion of non-central facial BCCs Increasing to > 5mm

The proportion of non-central facial BCCs that at Baseline and/or Week 2 measure a greatest diameter of less than 5mm and increase to a diameter of greater than 5mm by Weeks 6, 10, 14, 18, 22 and 26 will be assessed.

At each of Weeks 6, 10, 14, 18, 22 and 26, the following will be calculated for each subject:

$$\frac{\#\ \text{non}-\text{central facial BCCs with greatest diameter}\ >\ 5\text{mm at Week}\ x}{\#\ \text{non}-\text{central facial BCCs with greatest diameter} \leq 5\text{mm at baseline}\ \frac{\text{and}}{\text{or}}\ \text{Week 2}}$$

7.1.2.5 Proportion of Treatment Targeted SEBs Decreasing to non SEBs at Week 26

The proportion of Baseline treatment targeted SEBs that at the end of 26 weeks of treatment are no longer large enough to be classified as SEBs (i.e., that is the proportion of Baseline treatment targeted SEBs on the face that become less than 5 mm in greatest diameter and non-facial Baseline treatment targeted SEBs that become less than 9 mm in greatest diameter) will be assessed.

At Week 26, the following will be calculated for each subject:

$$\frac{Number\ of\ baseline\ treatment\ targeted\ facial\ SEBs\ with\ greatest\ diameter < 5mm + baseline\ treatment\ targeted\ non-facial\ SEBs\ with\ greatest\ diameter < 9mm}{Number\ of\ baseline\ treatment\ targeted\ SEBs}$$

The proportion will also be evaluated for informational purposes only at Weeks 6, 10, 14, 18 and 22.

7.1.3 Exploratory Efficacy Endpoints

7.1.3.1 ISGTA Response at Weeks 6, 10, 14, 18, 22 and 26

The proportion of Baseline treatment targeted SEBs that are evaluated as being clear or almost clear at Week 6, 10, 14, 18, 22 and 26 based on the ISGTA.

At each of Weeks 6, 10, 14, 18, 22 and 26 the following will be calculated:

$$\frac{Number\ of\ baseline\ treatment\ targeted\ SEBs\ with\ ISGTA\ score\ of\ 0\ or\ 1\ at\ week\ x}{Number\ of\ baseline\ treatment\ targeted\ SEBs}$$

7.1.3.2 DLQI Total Score

The DLQI evaluates skin related quality of life and is evaluated at Baseline and Weeks 14 and 26. The DLQI questionnaire consists of 10 questions. The scores for all questions will be summed for a maximum total score of 30 (0 = best, 30 = worst).

If one question is left unanswered this is scored 0 and the scores are summed and expressed as usual out of a maximum of 30.

If two or more questions are left unanswered the questionnaire is not scored.

If question 7 is answered 'yes' this is scored 3. If question 7 is answered 'no' but then either 'a lot' or 'a little' is ticked this is then scored 2 or 1. If "Not relevant" is ticked, the score for Question 7 is 0. If it is answered 'no', but the second half is left incomplete, the score will remain 0.

The scoring of the response to each question is as follows[1]:

Response	Score
Very much	3
A lot	2
A little	1
Not at all	0
Not relevant	0
Question unanswered	0
Question 7: "prevented work	3

7.1.3.3 aBCCdex

The aBCCdex[2] has the following 5 scales, each transformed to have a range between 0 and 100: (1) Worry About Future Lesions; (2) Mental Health; (3) Social/Relationships; (4) Lesion Symptoms; and (5) Life Impact. If any scale has >50% of the responses missing, then the scale is missing. An item with multiple answers is considered missing.

Each scale is computed as follows:

1. Items are recoded as necessary.
2. Item scores are summed to obtain score (a).
3. Lowest possible score is calculated (b).
4. Highest possible score is calculated (c).
5. Range is calculated (d = (c-b)).

$$Scale = \frac{100 * \{a - b\}}{d}$$

Worry About Future Lesions scale

The Worry About Future Lesions scale is calculated using questions 3a, 3b, 3c, 3d, and 3e. No recoding or weighting is used.

Mental Health scale

The Mental Health scale has 2 parts.

Part 1 is calculated using questions 1d, 1e and 1f. These questions are recoded as follows: Did not have this symptom=1, 1 recoded to 2, 2 recoded to 3, 3 recoded to 4, 4 recoded to 5, 5 recoded to 6, 6 recoded to 7, 7 recoded to 8. Part 1 score is then calculated.

Part 2 is calculated using questions 21, 2b and 2c. No recoding of these items is necessary.

The Mental Health scale is the average of Part 1 and Part 2 i.e. (Part 1 score + Part 2 score) / 2.

Social / Relationships scale

Social / Relationships has 2 parts.

Part 1 is calculated using questions 5h and 5i. These questions are reverse recoded as follows: 1 = 7, 2 = 6, 3 = 5, 4 = 4, 5 = 3, 6 = 2, and 7 = 1.

Part 2 is calculated using Questions 4a, 4b and 4c. No recoding of these items is necessary.

The Social / Relationships scale is as follows: (0.4 * Part 1 score + 0.6 * Part 2 score).

Lesion Symptoms scale

The Lesions Symptoms scale is calculated using questions 1a, 1b and 1c. These questions are recoded as follows: Did not have this symptom=1, 1 recoded to 2, 2 recoded to 3, 3 recoded to 4, 4 recoded to 5, 5 recoded to 6, 6 recoded to 7, 7 recoded to 8.

Life Impact scale

The Life Impact scale is calculated using questions 5a, 5b, 5c, 5d, 5e, 5f and 5g. Questions 5b, 5c, 5d, 5e, 5f and 5g are reverse coded as follows: 1 = 7, 2 = 6, 3 = 5, 4 = 4, 5 = 3, 6 = 2, and 7 = 1.

7.2 Safety Endpoints

The following safety endpoints will be assessed:

- Dermal Safety and Tolerability including pain / burning, pruritus, erythema, edema, and scabbing/crusting at Baseline and Week 2, 6, 10, 14, 18, 22 and 26
- Systemic symptoms at Baseline and Weeks 2, 6, 10, 14, 18, 22 and 26
- Adverse Events
- Plasma concentration levels of patidegib (and other major metabolites) at Week 6, 14 and 26
- Clinical laboratory and vital sign assessments at Week 6 (labs only), 14 and 26

8. STATISTICAL METHODS AND ANALYSIS

8.1 General Methodology

All statistical processing will be performed using SAS® 9.3 or higher unless otherwise stated. All data will be summarized by treatment group and where appropriate by treatment group and visit. No formal interim analyses are planned, however a safety data review meeting will be held for a Data Safety Monitoring Board (DSMB) as outlined in the charter. Except where noted, all statistical tests will be two-sided and will be performed at the 0.05 level of significance.

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

Demographic data will be summarized by treatment group using descriptive statistics. Subjects' Baseline characteristics potentially related to efficacy analyses will be compared between treatment groups to evaluate Baseline balance between the treatment arms.

The number of subjects in each analysis set will be summarized. Reasons for study withdrawal during the blinded study will be summarized using frequencies and percentages by treatment group.

8.2 Handling of Dropouts or Missing Data

If a partial date is recorded for an adverse event start or end date, or a concomitant medication start or end date, the following procedure will be followed. Other missing safety data dates will not be imputed.

If a partial date is reported where the day is missing, then the day will be imputed as the first day of the month unless the month is the same month as the first dose then the day will be that of first dose with the month and year remaining the same. If a partial date is reported where the month is missing, then the month will be imputed to January unless the year is the same year as the first dose then the month will be that of first dose with the year remaining the same. If a partial date where both the day and month is missing, follow details as stated previously.

Missing data post-Baseline through Week 26 will be imputed using last observation carried forward (LOCF) for all efficacy endpoints except GLI1. Specifically for the primary endpoint of tumor size, if a single diameter is missing then that SEB's previous measurement will be carried forward. For GLI1, since only Baseline and Week 6 data is involved, no missing data will be imputed. No missing data will be imputed for missing safety data.

8.3 Interim Analyses and Data Monitoring

No interim analyses are planned.

Shortly after the last subject completes 10 weeks of treatment an independent Data Safety Management Board (DSMB) will evaluate all safety data as detailed in the DSMB charter.

8.4 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site with the intention of pooling the data for analysis. Every effort will be made to promote consistency in study execution at each investigational site. Due to the small number of sites and subjects formal testing for consistency across sites will not be performed.

8.5 Multiple Comparisons/Multiplicity

Since the study is a Phase 2, proof of concept study, no adjustments for multiplicity will be made.

8.6 Examination of Subgroups

Not applicable to this study.

8.7 Analysis Populations

Subjects who are randomized and dispensed study drug will be included in the intent-to-treat (ITT) population. All efficacy analyses will be performed using the ITT population.

All subjects who are randomized, receive at least 1 confirmed dose of study drug and have at least one post-Baseline safety assessment will be included in the safety population. Safety analyses will be performed using the safety population.

Listings will be presented for all available data.

8.8 Subject Disposition

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

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

8.9 Protocol Deviations

All protocol deviations will be reported to PellePharm and recorded throughout the study. A listing of protocol deviations by treatment by subject will be included in the final study report.

8.10 Demographic and Baseline Characteristics

All Baseline summaries will be done on the ITT population.

Sex, race, and ethnicity will be summarized by counts and percentages. Age, height (cm), and weight (kg) will be summarized with descriptive statistics.

Medical histories will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary and presented in a by-subject listing.

8.11 Prior and Concomitant Medications

Medications will be coded to preferred term and Anatomical Therapeutic Chemical (ATC) classification of ingredients using the World Health Organization (WHO) Drug Dictionary (WHO-DDE).

A by-subject listing of all prior and concomitant medications will be presented. Medications that start prior to first dose but continue after the first dose will be considered a concomitant medication. Medications that are unable to be classified as either prior or concomitant due to missing data will not be considered a concomitant medication.

8.12 Baseline assessments

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

The following Baseline assessments are to be performed within six weeks post Baseline and prior the first dose of study drug.

- DLQI (Dermatology Life Quality Index)
- aBCCdex
- Facial area dermal safety and tolerability
- BCC Assessments
    - Identification of treatment targeted BCCs (facial and nonfacial)
    - Identification of single SEB to be biopsied
    - ISGTA
    - Application site reactions
    - Measurement, body mapping, and imaging of BCCs
    - Determination of clinical tumor type
- Systemic symptoms
- Vital signs, Abbreviated Physical exam (including height)

8.13 Visit Windowing

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

Analysis Windows for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Window (Days)
Week 2	15	13 to 17
Week 6	43	40 to 46

Week 10	71	68 to 74
Week 14	99	96 to 102
Week 18	127	124 to 130
Week 22	155	152 to 158
Week 26	183	180 to 186

Data collected at early termination and unscheduled visits prior to study day 13 will not be analyzed, with the exception of those identified as Baseline values. Data collected at early termination and unscheduled visits after study day 186 will not be included in analyses.

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

Study Day Prior to Day 1 = Visit Date – Day 1 Date

Study Day On or After Day 1 = Visit Date – Day 1 Date + 1.

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

In the event of multiple values from unscheduled or early termination assessments within an analysis window, the value closest to the scheduled visit target study day will be used for analyses (assuming there were no results from the scheduled visit present). If two values tie as closest to the time point (for example, one value is before and the other value is after the time point), then the later value will be selected.

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

8.14 Analysis of Efficacy

8.14.1 Primary Efficacy Analysis

8.14.1.1 Percent Decrease in Tumor Size at Week 26

Percent Decrease in Tumor Size at Week 26 will be evaluated using an analysis of covariance (ANCOVA) model with factor of treatment group and sum of the greatest diameters of Baseline treatment targeted SEBs as covariate. LOCF will be used to impute missing data post Baseline. Pairwise comparisons between each active treatment and vehicle will be performed using contrasts within the ANCOVA model.

8.14.1.2 Percent Decrease in GLI1 mRNA Levels at Week 6

Percent decrease in GLI1 mRNA Levels at Week 6 will be evaluated using an ANCOVA model with treatment group as a factor and Baseline GLI1 mRNA Level as a covariate. No imputation will be used for missing data. Pairwise comparisons between each active treatment and vehicle will be performed using contrasts within the ANCOVA model.

H-scores will be available for all subjects for the 'combined' analysis region; this is the primary analysis. H-scores for upper and lower analysis regions will also be summarized for subjects with available data.

Results will also be summarized by visit.

8.14.2 Secondary Efficacy Analysis

8.14.2.1 Percent Decrease in Tumor Size at Weeks 6, 10, 14, 18 and 22

Percent decrease in tumor size at Weeks 6, 10, 14, 18 and 22 will be evaluated at each visit using ANCOVA with factor of treatment group and sum of the greatest diameters of Baseline treatment targeted SEBs as a covariate.

Percent decrease in tumor size will also be summarized by visit.

8.14.2.2 Percent Decrease in Central Facial SEBs at Weeks 6, 10, 14, 18, 22 and 26

Percent decrease in central facial SEBs at Weeks 6, 10, 14, 18, 22 and 26 will be evaluated at each visit using ANCOVA with factor of treatment group and sum of the greatest diameters of Baseline central facial SEBs as a covariate.

Percent decrease in central facial SEBs will also be summarized by visit.

8.14.2.3 Count of New SEBs on Face at Weeks 6, 10, 14, 18, 22 and 26

Frequency of new SEBs on the face will be evaluated with a Poisson regression at each visit with factors of treatment group and the Baseline number of surgically eligible tumors as a covariate. However, if there is insufficient data for this analysis, the data will simply be summarized.

Descriptive statistics of new SEBs on the face will be summarized by visit.

8.14.2.4 Proportion of non-central facial BCCs Increasing to ≥ 5mm at Weeks 6, 10, 14, 18, 22 and 26

The proportion of non-central facial BCCs that at Baseline and/or Week 2 were < 5mm in greatest diameter increasing to equal to or greater than 5 mm will be evaluated at each visit using

ANCOVA with treatment group as a factor and number of eligible tumors at Baseline at each of Weeks 6 10, 14, 18, 22 and 26.

Results will also be summarized by visit.

8.14.2.5 Proportion of Treatment Targeted SEBs Decreasing to non SEBs at 26 Weeks

The proportion of Baseline treatment targeted SEBs that at Weeks 6, 10, 14, 18, 22 and 26 are no longer large enough to be classified as SEBs will be evaluated using ANCOVA with treatment group as a factor and number of eligible tumors at Baseline at each Week.

Results will also be summaried by visit.

8.14.3 Exploratory Efficacy Analysis

8.14.3.1 ISGTA Response at Weeks 6, 10, 14, 18, 22 and 26

The proportions of ISGTA responders (clear (0) or almost clear (1)) will be analyzed at each visit with a Cochran-Mantel-Haenszel test.

ISGTA scores will be summarized with descriptive statistics at Baseline and Weeks 6, 10, 14, 18, 22 and 26. Change from Baseline will also be summarized.

8.14.3.2 DLQI Score

DLQI scores will be summarized with descriptive statistics at Baseline and Weeks 14 and 26. Change from Baseline will also be summarized. ANCOVA will be conducted for the absolute change from Baseline with factor of treatment group and covariate of Baseline DLQI. P-values will be included for informational purposes only.

DLQI responses of “not relevant” will be excluded from the change from Baseline summaries.

8.14.3.3 aBCCdex

The aBCCdex scales will be summarized with descriptive statistics at Baseline and Weeks 14 and 26. Change from Baseline will also be summarized at Weeks 14 and 26. ANCOVA will be conducted at each visit for the absolute change from Baseline with factor of treatment group and covariate of Baseline aBCCdex. P-values will be included for informational purposes only.

8.15 Safety Analysis

8.15.1 Extent of Exposure and Compliance to Study Treatment

The extent of exposure to study drug in each treatment group will be summarized by days with applications, total number of applications, and number of missed applications. This data will also be provided in a listing.

8.15.2 Adverse Events

All AEs that occur during the study will be recorded and classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Treatment-emergent AEs (TEAEs) are defined as AEs with an onset on or after the date of the first study drug application. Adverse events noted prior to the first study drug administration that worsen after Baseline will also be reported as AEs and included in the summaries.

Treatment-emergent AEs will be summarized by treatment group, the number of subjects reporting a TEAE, SOC, preferred term, severity, relationship to study drug (causality), and seriousness. When summarizing AEs by severity and relationship, each subject will be counted once within a system organ class or a preferred term by using the event with the highest severity and greatest relationship within each classification.

If relationship to study drug is reported as unknown, possible, probable or definite, then this is defined as related. If relationship to study drug is reported as unlikely or not related, then this is defined as unrelated.

Serious AEs will be summarized by treatment group, severity and relationship to study drug.

Listings will be presented for all adverse events as well as for serious adverse events and adverse events leading to study drug withdrawal.

8.15.3 Dermal Safety and Tolerability

The frequency of dermal safety and tolerability assessments including pain/burning, pruritus, erythema, edema, and scabbing/crusting will be summarized by treatment group and visit. All dermal safety and tolerability results will be listed.

8.15.4 Systemic Symptoms

Systemic symptoms will be summarized by treatment group and visit. Additionally, results will be listed.

8.15.5 Physical Examination and Vital Signs

Vital signs will be summarized with descriptive statistics at Baseline and each applicable study visit. Changes from Baseline in vital signs will also be summarized.

Vital sign and physical exam measurements will be listed.

8.15.6 Laboratory Assessments

Changes from Baseline in safety laboratory values will be summarized with descriptive statistics for each treatment group at all applicable study visits.

Shift tables will be presented for changes in safety laboratory values to summarize laboratory test results collected at Baseline and Weeks 6, 14, and 26. Normal ranges established by the central laboratory will be used to determine the shifts. A listing of all out-of-range laboratory test results at any assessment time point will also be provided.

Determination of clinical significance for all out-of-range laboratory values will be made by each Investigator and included in the listing. In addition, a listing of all clinically significant laboratory test results will be provided.

9. REFERENCES

1. Cardiff University. Dermatology Life Quality Index. http://sites.cardiff.ac.uk/dermatology/quality-of-life/dermatology-quality-of-life-index-dlqi/dlqi-instructions-for-use-and-scoring/ Accessed 06Mar2017.

2. Mathias SD, Chren MM, Crosby RD, Colwell HH, Yim YM, Reyes C, Chen DM and Fosko SW (2015) *Reliability and validity of the Advanced Basal Cell Carcinoma Index (aBCCdex).* Br J Dermatology, Sep; 173(3): 713-9.

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Table 14.1.1: Summary of Subject Disposition
(All Subjects)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number of Subjects Randomized	xx	xx	xx
Number of Subjects Included in the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Completed Study			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation			
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Percentage based on number of subjects randomized.

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

Table 14.1.1.1: Summary of Subject Demographics and Baseline Characteristics
(Intent-to-Treat Population)
(Page 1 of 2)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.1.1.1: Summary of Subject Demographics and Baseline Characteristics
(Intent-to-Treat Population)
(Page 2 of 2)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Height (cm)			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xx	xxx.xx	xxx.xx
Min. to Max.	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x
Weight (kg)			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xx	xxx.xx	xxx.xx
Min. to Max.	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x

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

Table 14.2.1.1: Analysis of the Primary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Week 26
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Percent Decrease in Sum of Greatest Diameters of Treatment Targeted SEBs[a] at Week 26[b]			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
P-value[c]	x.xxx	x.xxx	

[a] Defined as clinically diagnosed basal cell carcinoma (BCC) 5 mm or greater in diameter on the face excluding the nose and periorbital skin, and 9 mm or greater at sites other than the face.
[b] Percent Decrease calculated as (Baseline – Week 26) / Baseline * 100.
[c] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.2.1: Analysis of the Primary Efficacy Endpoint: Percent Decrease in GLI1 mRNA Levels at Week 6
(Intent-to-Treat Population)

GLI1 mRNA H-Score (combined)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 6			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Percent Decrease from Baseline[a]			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
At least 40% decrease from baseline	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	

[a] Percent Decrease from Baseline calculated as (Baseline - Week 6) / Baseline * 100.
[b] P-value of pairwise comparison to vehicle gel using ANCOVA with a factor of treatment group and Baseline value as a covariate.
Note: Missing values are not imputed; all available data is summarized.

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

Table 14.2.2.2.: Summary of GLI1 mRNA Levels (Upper and Lower)
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
GLI1 mRNA H-Score (upper)			
Baseline			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 6			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
GLI1 mRNA H-Score (lower)			
Baseline			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Week 6			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x

Note: Missing values are not imputed; all available data is summarized.

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

Table 14.2.3.1: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Weeks 6, 10, 14, 18 and 22
(Intent-to-Treat Population)
(Page 1 of x)

Sum of the Greatest Diameter of Baseline Treatment Targeted SEBs[a] (mm)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Percent Decrease from Baseline[b]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[c]	x.xxx	x.xxx	

Continue for Weeks 10, 14, 18 and 22

Table 14.2.3.1: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Weeks 6, 10, 14, 18 and 22
(Intent-to-Treat Population)
(Page 1 of x)

Sum of the Greatest Diameter of Baseline Treatment Targeted SEBs[a] (mm)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			

[a] Defined as clinically diagnosed basal cell carcinoma (BCC) 5 mm or greater in diameter on the face excluding the nose and periorbital skin, and 9 mm or greater at sites other than the face.
[b] Percent decrease calculated as (Baseline - Follow-up) / Baseline * 100.
[c] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.4.1: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Central Facial Tumor Size by Visit
(Intent-to-Treat Population)

Sum of the Greatest Diameter of Central Facial Tumors[a] (mm)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 6			
n	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx
SD	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx
Min. to Max.	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
Percent Decrease from Baseline[b]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[c]	x.xxx	x.xxx	

Continue for Weeks 10, 14, 18, 22 and 26

[a] Defined as clinically diagnosed basal cell carcinoma (BCC) 3 mm or greater in diameter located on the nose or periorbital skin.
[b] Percent decrease calculated as (Baseline - follow-up) / Baseline * 100.
[c] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.5.1: Analysis of the Secondary Efficacy Endpoint: Frequency of New Facial SEBs by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number of New Facial SEBs[a] at Week 6			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	
Number of New Facial SEBs[a] at Week 10			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

[a] Defined as a SEB first noted on the face after Week 2 that developed at a site where there was no visible BCC of any size at Baseline or Week 2.
[b] P-value of pairwise comparison to vehicle gel using an Poisson regression with a factor of treatment group and using the Baseline number of surgically eligible tumors as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.5.1: Analysis of the Secondary Efficacy Endpoint: Frequency of New Facial SEBs by Visit
(Intent-to-Treat Population)
(Page 2 of 3)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number of New Facial SEBs[a] at Week 14			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	
Number of New Facial SEBs[a] at Week 18			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

[a] Defined as a SEB first noted on the face after Week 2 that developed at a site where there was no visible BCC of any size at Baseline or Week 2.
[b] P-value of pairwise comparison to vehicle gel using a Poisson regression with a factor of treatment group and using the Baseline number of surgically eligible tumors as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.5.1: Analysis of the Secondary Efficacy Endpoint: Frequency of New Facial SEBs by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number of New Facial SEBs[a] at Week 22			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	
Number of New Facial SEBs[a] at Week 26			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

[a] Defined as a SEB first noted on the face after Week 2 that developed at a site where there was no visible BCC of any size at Baseline or Week 2.
[b] P-value of pairwise comparison to vehicle gel using a Poisson regression with a factor of treatment group and using the Baseline number of surgically eligible tumors as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.6.1: Analysis of the Secondary Efficacy Endpoint: Non-Central Facial BCCs Becoming ≥ 5 mm in Greatest Diameter by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number of subjects with non-central facial BCCs < 5 mm at Baseline	xx	xx	xx
Week 6			
Greater than or equal to 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Less than 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 10			
Greater than or equal to 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Less than 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 14			
Greater than or equal to 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Less than 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	

[a] P-value of pairwise comparison to vehicle gel using an ANCOVA model with treatment group as a baseline factor and number of eligible tumors at Baseline as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.6.1: Analysis of the Secondary Efficacy Endpoint: Non-Central Facial BCCs Becoming Greater than 5 mm in Diameter by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
Greater than or equal to 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Less than 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 22			
Greater than or equal to 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Less than 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 26			
Greater than or equal to 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Less than 5 mm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	

[a] P-value of pairwise comparison to vehicle gel using an ANCOVA model with treatment group as a baseline factor and number of eligible tumors at Baseline as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.7.1: Analysis of the Secondary Efficacy Endpoint: Baseline Treatment Targeted SEBs No Longer Classified as SEBs by Visit
(Intent-to-Treat Population)
(Page 1 of 2)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 6			
No longer classified as SEBs[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Still classified as SEBs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	
Week 10			
No longer classified as SEBs[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Still classified as SEBs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	
Week 14			
No longer classified as SEBs[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Still classified as SEBs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	

[a] Defined as Baseline treatment targeted SEBs on the face that have become less than 5 mm in greatest diameter and non-facial Baseline treatment targeted SEBs that have become less than 9 mm in greatest diameter.

[b] P-value of pairwise comparison to vehicle gel using an ANCOVA model with treatment group as a baseline factor and number of eligible tumors at Baseline as a covariate.

Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.7.1: Analysis of the Secondary Efficacy Endpoint: Baseline Treatment Targeted SEBs No Longer Classified as SEBs by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
No longer classified as SEBs[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Still classified as SEBs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	
Week 22			
No longer classified as SEBs[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Still classified as SEBs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	
Week 26			
No longer classified as SEBs[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Still classified as SEBs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[b]	x.xxx	x.xxx	

[a] Defined as Baseline treatment targeted SEBs on the face that have become less than 5 mm in greatest diameter and non-facial Baseline treatment targeted SEBs that have become less than 9 mm in greatest diameter.

[b] P-value of pairwise comparison to vehicle gel using an ANCOVA model with treatment group as a baseline factor and number of eligible tumors at Baseline as a covariate.

Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.8.1: Analysis of the Exploratory Efficacy Endpoint: Proportion with ISGTA Response Clear or Almost Clear by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 6			
Clear or Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minimal Residual Tumor or Clearly Visible Tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 10			
Clear or Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minimal Residual Tumor or Clearly Visible Tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 14			
Clear or Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minimal Residual Tumor or Clearly Visible Tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	

[a] P-value of pairwise comparison to vehicle gel using a Cochran-Mantel-Haenszel test.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.8.1: Analysis of the Exploratory Efficacy Endpoint: Proportion with ISGTA Response Clear or Almost Clear by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
Clear or Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minimal Residual Tumor or Clearly Visible Tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 22			
Clear or Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minimal Residual Tumor or Clearly Visible Tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	
Week 26			
Clear or Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minimal Residual Tumor or Clearly Visible Tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value[a]	x.xxx	x.xxx	

[a] P-value of pairwise comparison to vehicle gel using a Cochran-Mantel-Haenszel test.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.9.1: Analysis of the Exploratory Efficacy Endpoint: DLQI by Visit
(Intent-to-Treat Population)
(Page 1 of 2)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 14			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

[a] Change from Baseline calculated as Baseline - follow-up.
[b] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.9.1: Analysis of the Exploratory Efficacy Endpoint: DLQI by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 26			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

[a] Change from Baseline calculated as Baseline - follow-up.
[b] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.10.1: Analysis of the Exploratory Efficacy Endpoint: aBCCdex by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Worry About Future Lesions			
Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Week 14			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

[a] Change from Baseline calculated as Baseline - follow-up.
[b] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.2.10.1: Analysis of the Exploratory Efficacy Endpoint: aBCCdex by Visit
(Intent-to-Treat Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Worry About Future Lesions			
Week 26			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
P-value[b]	x.xxx	x.xxx	

Continue table for Mental Health, Social/Relationships, Lesion Symptoms and Life Impact scales.

[a] Change from Baseline calculated as Baseline - follow-up.
[b] P-value of pairwise comparison to vehicle gel using ANCOVA with treatment group as a factor and Baseline value as a covariate.
Note: Missing values imputed using Last Observation Carried Forward.

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

Table 14.3.1.1: Summary of Extent of Exposure
(Safety Population)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number of days of exposure			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Total number of applications			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Total number of missed applications	x.xxx	x.xxx	
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

Note: The total number of applications was calculated from the first date of treatment and the last date of treatment minus the missed applications.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 1 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Pain/Burning	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 2 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Pain/Burning (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 10						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 18						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 3 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Pain/Burning (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 22						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 4 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Pruritus	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 5 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Pruritus (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 10						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 18						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 6 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Pruritus (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 22						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 7 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Erythema	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 8 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Erythema (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 10						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 18						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 9 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Erythema (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 22						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 10 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Edema	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 11 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Edema (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 10						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 18						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 12 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Edema (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 22						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 13 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Scabbing/Crusting	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 14 of 15)

	On or Around a Tumor			Non Tumor Facial Skin		
Scabbing/Crusting (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 10						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 18						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 15 of 15)

Scabbing/Crusting (continued)	On or Around a Tumor			Non Tumor Facial Skin		
	Patidegib Gel 2% (N=xx)	Patidegib Gel 2% (N=xx)	Vehicle Gel (N=xx)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 22						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26						
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Local skin reactions are reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 1 of 18)

Fatigue	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 2 of 18)

Fatigue (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 3 of 18)

Loss or Change in Taste	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 4 of 18)

Loss or Change in Taste (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.5.2: Summary of Systemic Symptoms
(Safety Population)
(Page 5 of 18)

Nausea	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 6 of 18)

Nausea (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 7 of 18)

Vomiting	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 8 of 18)

Vomiting (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 9 of 18)

Diarrhea	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 10 of 18)

Diarrhea (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 11 of 18)

Muscle Spasms or Cramps	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 12 of 18)

Muscle Spasms or Cramps (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 13 of 18)

Changes of Quality or Quantity of Hair in Treated Areas	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 14 of 18)

Changes of Quality or Quantity of Hair in Treated Areas (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 15 of 18)

Change in Frequency of Shaving	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 16 of 18)

Change in Frequency of Shaving (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 17 of 18)

Other Systemic Sign or Symptom	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 10			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 18 of 18)

Other Systemic Sign or Symptom (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 22			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Table 14.3.1.3.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 1 of 2)

	Patidegib Gel 2% (n=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number (%) of Subjects Reporting At Least One Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects Reporting At Least One Adverse Event Leading to Study Drug Withdrawal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity			
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongest Relationship to Study Medication			
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable or Definite. Any unknown relationship is defined as Related. A subject is counted once according to maximum severity and relationship.

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

Table 14.3.1.3.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 2 of 2)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Maximum Severity within Relationship to Study Medication			
Not Related			
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related			
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable or Definite. Any unknown relationship is defined as Related. A subject is counted once according to maximum severity and relationship.

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

Table 14.3.1.3.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class Preferred Term	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse events are those with an onset after use of study medication.

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

Table 14.3.1.3.3: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
System Organ Class	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse events are those with an onset after use of study medication.

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

Table 14.3.1.3.4: Summary of Treatment-Emergent Adverse Events by Relationship
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
System Organ Class	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable, or Definite.

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

Table 14.3.1.4.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 1 of 2)

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects Reporting At Least One Serious Adverse Event Leading to Study Drug Withdrawal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity			
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongest Relationship to Study Medication			
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable, or Definite. A subject is counted once acccording to maximum severity and relationship.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

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

	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Maximum Severity within Relationship to Study Medication			
Not Related			
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related			
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable or Definite. Any unknown relationship is defined as Related. A subject is counted once acccording to maximum severity and relationship.

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

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

System Organ Class Preferred Term	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

Note: Treatment-emergent adverse events are those with an onset after use of study medication.

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

Table 14.3.1.4.3: Summary of Treatment-Emergent Serious Adverse Events by Relationship
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
System Organ Class	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect number of subjects reporting one or more adverse events that map to the MedDRA dictionary (Version xx). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the strongest reported relationship. Not Related includes Not Related and Unlikely. Related includes Possible, Probable, or Definite.

Note: Treatment-emergent adverse events are those with an onset after use of study medication.

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

Table 14.3.2.1: Summary of Patidegib Plasma Concentrations
(Safety Population)
(Page 1 of 2)

Patidegib Plasma Concentration (units)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)
Screening		
n	xx	xx
Mean	xxx.x	xxx.x
SD	xxx.xx	xxx.xx
Median	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx
Week 6		
n	xx	xx
Mean	xxx.x	xxx.x
SD	xxx.xx	xxx.xx
Median	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx
Week 14		
n	xx	xx
Mean	xxx.x	xxx.x
SD	xxx.xx	xxx.xx
Median	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx
Week 26		
n	xx	xx
Mean	xxx.x	xxx.x
SD	xxx.xx	xxx.xx
Median	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx

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

Table 14.3.3.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page xx of yy)

Test name (units)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 6			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page xx of yy)

Test name (units) (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 14			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 26			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.2: Summary of Hematology Laboratory Results
(Safety Population)
(Page xx of yy)

Test name (units)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 6			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.2: Summary of Hematology Laboratory Results
(Safety Population)
(Page xx of yy)

Test name (units) (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 14			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 26			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.3: Summary of Quantitative Urinalysis Laboratory Results
(Safety Population)
(Page xx of yy)

Test name (units)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 6			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.3: Summary of Quantitative Urinalysis Laboratory Results
(Safety Population)
(Page xx of yy)

Test name (units) (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 14			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 26			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline[a]			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.4: Summary of Categorical Urinalysis Laboratory Results
(Safety Population)
(Page xx of yy)

Test name	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline[a]			
n	xx	xx	xx
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6			
n	xx	xx	xx
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 14			
n	xx	xx	xx
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 26			
n	xx	xx	xx
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Result	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

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

Table 14.3.3.5: Summary of Chemistry Laboratory Results – Shift Table
(Safety Population)

Test name (units)

	Patidegib Gel 2% (N=xx)			Patidegib Gel 4% (N=xx)			Vehicle Gel (N=xx)		
	Week 6			Week 6			Week 6		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 14			Week 14			Week 14		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 26			Week 26			Week 26		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
Baseline is the last non-missing assessment prior to the first dose of study drug.
No imputation of missing values.

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

Table 14.3.3.6: Summary of Hematology Laboratory Results – Shift Table
(Safety Population)
(Page 1 of x)

Test name (units)

	Patidegib Gel 2% (N=xx)			Patidegib Gel 4% (N=xx)			Vehicle Gel (N=xx)		
	Week 6			Week 6			Week 6		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 14			Week 14			Week 14		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 26			Week 26			Week 26		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
Baseline is the last non-missing assessment prior to the first dose of study drug.
No imputation of missing values.

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

Table 14.3.3.7: Summary of Quantitative Urinalysis Laboratory Results – Shift Table
(Safety Population)

Test name (units)

	Patidegib Gel 2% (N=xx)			Patidegib Gel 4% (N=xx)			Vehicle Gel (N=xx)		
	Week 6			Week 6			Week 6		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 14			Week 14			Week 14		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 26			Week 26			Week 26		
Baseline	BNL	WNL	ANL	BNL	WNL	ANL	BNL	WNL	ANL
BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
Baseline is the last non-missing assessment prior to the first dose of study drug.
No imputation of missing values.

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

Table 14.3.4.1: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

Systolic Blood Pressure (mmHg)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 2			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

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

Table 14.3.4.1: Summary of Vital Signs
(Safety Population)
(Page 2 of xx)

Systolic Blood Pressure (mmHg) (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 10			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 14			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

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

Table 14.3.4.1: Summary of Vital Signs
(Safety Population)
(Page 3 of xx)

Systolic Blood Pressure (mmHg) (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 18			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Week 22			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

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

Table 14.3.4.1: Summary of Vital Signs
(Safety Population)
(Page 4 of x)

Systolic Blood Pressure (mmHg) (continued)	Patidegib Gel 2% (N=xx)	Patidegib Gel 4% (N=xx)	Vehicle Gel (N=xx)
Week 26			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Change from Baseline			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx

Continue for all vital signs.

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

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Listing 16.1.7: Randomization Scheme
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Subject	Age/Sex	Eval	Randomization Date	Assigned Arm
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx

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

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

Subject	Age/Sex	Eval	Date of First Application of Study Drug	Date of Last Application of Study Drug	Date of Study Completion/ Discontinuation (Day)[1]	Did Subject Complete the Study	Primary Reason for Study Discontinuation
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Note to Programmer: The 'If Adverse Event, Protocol Violation, or Other, Please Specify' free text box should all be concatenated with Primary Reason for Study Discontinuation

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

Subject	Age/Sex	Eval	Date of First Application of Study Drug	Date of Last Application of Study Drug	Date of Study Completion/ Discontinuation (Day)[1]	Did Subject Complete the Study	Primary Reason for Study Discontinuation
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

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

Note to Programmer: The 'If Adverse Event, Protocol Violation, or Other, Please Specify' free text box should all be concatenated with Primary Reason for Study Discontinuation

Listing 16.2.2: Inclusion/Exclusion Criteria Violations
(Page xx of yy)

Subject	Age/Sex	Eval	Criteria Failed	Description
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx

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

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

Subject	Age/Sex	Population	Included	Reason(s) Excluded
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	

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

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

Subject	Eval	Date of Birth	A: Age S: Sex	R: Race E: Ethnicity	Informed Consent Date
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx

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

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

MedDRA System Organ Class	MedDRA Preferred Term	Medical History Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 19.0).

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

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

Listing 16.2.4.2.2: Medical History
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Medical History Verbatim Term	B: Body System P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Start Date E: End Date O: Ongoing
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	B: xxxxxxxxxx P: xxxx xxx xxxxx S: xxxx xxx xxxxx	S: xxxxxxx E: xxxxxxx O: xxxxxxx
			xxxxxxxxx	B: xxxxxxxxx P: xxxxxxxxx S: xxxxxxxxxx xxx	S: xxxxxxx E: xxxxxxx O:
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	B: xxxxxxxxxx P: xxxx xxx xxxxx S: xxxx xxx xxxxx	S: xxxxxxx E: xxxxxxx O: xxxxxxx
			xxxxxxxxx	B: xxxxxxxxx P: xxxxxxxxx S: xxxxxxxxxx xxx	S: xxxxxxx E: xxxxxxx O: xxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 19.0).

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

Listing sorted by Subject Number, Verbatim Term, Start Date, and End Date.

Listing 16.2.4.3: Abbreviated Physical Examination
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Was Physical Examination Performed?
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx

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

Listing 16.2.4.4: Concurrent Illnesses
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Examination	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxx	xx
					xxxx xx xxxxxx xx xxxxx	xx
					xxxxxx	xx
					xxxxxxxx	xxx
					xxxxxxxx	xx
					xxxxxx xxxxxx xx xxxxxx	xx
					xxxxxxx xx xxxxxxx xx xxxxxxx xx xxxx xx xxxxxxx xxxxx	xxx
					xxxxxx xx xxxxxxxxx xx xxxxxxx	xxx
					xxxxx xxxxxxx xxxx xx xxxxxxx	xx
			xxxx x	xxxxxxxxxx	xxxxxxx	xx
					xxxx xx xxxxxx xx xxxxx	xx
					xxxxxx	xx
					xxxxxxxx	xxx
					xxxxxxxx	xx
					xxxxxx xxxxxx xx xxxxxx	xx
					xxxxxxx xx xxxxxxx xx xxxxxxx xx xxxx xx xxxxxxx xxxxx	xxx
					xxxxxx xx xxxxxxxxx xx xxxxxxx	xxx
					xxxxx xxxxxxx xxxx xx xxxxxxx	xx
			xxxx x	xxxxxxxxxx	xxxxxxx	xx
					xxxx xx xxxxxx xx xxxxx	xx
					xxxxxx	xx
					xxxxxxxx	xxx
					xxxxxxxx	xx
					xxxxxx xxxxxx xx xxxxxx	xx
					xxxxxxx xx xxxxxxx xx xxxxxxx xx xxxx xx xxxxxxx xxxxx	xxx
					xxxxxx xx xxxxxxxxx xx xxxxxxx	xxx
					xxxxx xxxxxxx xxxx xx xxxxxxx	xx

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

Listing 16.2.4.4.1: Unique Medication Names Coded to WHO-DD ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Standardized Medication Name	Medication Name	I: Indication R: Route
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx

Note: Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version March 1, 2016).

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

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

Listing 16.2.4.4.2: Prior and Concomitant Medications
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	M: Medication Name P: Standardized Medication Name A: ATC Level 2 Term I: Indication T: Taken for Adverse Event	F: Date of First Application S: Medication Start Date (Day)[1] E: Medication End Date (Day)[1] O: Ongoing	D: Dose U: Unit F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxx xxxxxxxx T: xxxxxxxx	F: xxxxxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx O: xxxxxxx	D: xx U: xx F: xxxx R:xxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxx xxxxxxxx I: xxxxxxxx T: xxx	S: xxxxxxxxxx E: xxxxxxxxxx O: xxxxxxx	U: xx F: xxxx R:xxxx

[1] Day is calculated as date – Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date – Date of first dose + 1 for dates on or after Baseline.

Note: Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version March 1, 2016).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, Medication Name, Indication, and Route.

Listing 16.2.4.4.3: Prior and Concomitant Therapies and Procedures
Treatment Arm
(Page xx of yy)

Subject	Age/Sex Eval	M: Procedure/Therapy Name I: Indication F: Date of First Application	S: Procedure Start Date (Day)[1] E: Procedure End Date (Day)[1] O: Ongoing	T: BCC Treatment Y/N B: BCC Category I: BCC ID
xxxxxx	xxxx xx	M: xxxxxxxxxxxxx I: xxxxxx xxxxxxx F: xxxxxxxxxx	S: xxxxxxxxxx E: xxxxxxxxxx xxxx O: xxxxxxxxxx xxxx	T: xxx B: xxxxxxxxxxxxx xxxxxxx xxxxx I: xxx

[1] Day is calculated as date – Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date – Date of first dose + 1 for dates on or after Baseline.
Note: Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version March 1, 2016).

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

Listing sorted by Subject Number, Start Date, End Date, Procedure/Therapy Name, Indication, and Route.

Listing 16.2.4.5: Cleansers, Sunscreens and Moisturizers
Treatment Arm
(Page xx of yy)

Subject	Age/Sex Eval	P: Product Name T: Product Type F: Date of First Application	S: Procedure Start Date (Day)[1] E: Procedure End Date (Day)[1] O: Ongoing	F: Frequency
xxxxxx	xxxx xx	P: xxxxxxxxxxxxx T: xxxxxx xxxxxxx F: xxxxxxxxxx	S: xxxxxxxxxx E: xxxxxxxxxx xxxx O: xxxxxxxxxx xxxx	F: xxx

[1] Day is calculated as date – Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date – Date of first dose + 1 for dates on or after Baseline.
Note: Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version March 1, 2016).

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

Listing sorted by Subject Number, Start Date, End Date, Product Name, Type.

Listing 16.2.5.1: Drug Exposure Information
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	F: Date of First Application L: Date of Last Application	F: Number of Doses on Date of First Applicaton L: Number of Doses on Date of Last Application	D: Date of Missed Application(s) N: Number of Missed Application(s) R: Reason for Missed Application(s)
S: xxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: xxxxxxx	D: xxxxxxxxxx N: xxxxxxx R: x xxxxxxxx xxxx x xxxxxx xxx xxx xxxxxxxxxxx xx xxxx xxxxxxxx xx xxxxxxxxxxx xxx xxx xxxxx xx
			D: xxxxxxxxxx N: x R: xxxx xxxxxxx
S: xxxxxx A: xxxx E: xxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: x	
S: xxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: x	
S: xxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: xxxxxxx	D: xxxxxxxxxx N: x R: xxxxxxx xxxxxx
S: xxxxxx A: xxxx E: xxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: x	

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

Listing Format May Be Altered on Confirmation of Dosing Data Capture.

Listing 16.2.5: Study Medication Accountability Log
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date Dispensed	Kit Number	Tube Number	Date Returned	Action
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxx	xxx		Tube Not Returned
			xxxxxxxxxx	xxx	xxx	xxxxxxxxxx	
			xxxxxxxxxx	xxx	xxx	xxxxxxxxxx	
			xxxxxxxxxx	xxx	xxx	xxxxxxxxxx	
			xxxxxxxxxx	xxx	xxx	xxxxxxxxxx	
				xxx	xxx		Tube Not Dispensed
			xxxxxxxxxx	xxx	xxx	xxxxxxxxxx	
			xxxxxxxxxx	xxx	xxx	xxxxxxxxxx	

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

Listing 16.2.6.1.1: Assessment of Treatment Targeted Basal Cell Carcinomas
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date	I: BCC ID L: Body Location C: Centrality P: Photographed	D: Diameter (mm) C: Classification P: Punch Biopsy B: Biopsied	Investigator Static Global Tumor Assessment	Test	Result
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxxxxxx	I: xxxxxxxx L: x xxxxxxxxx xxxxx C: xxxxxxxxxxx P: xx	D: xxxxx C: xxxxxxxxx xx xxxxxxxxxx P: xxx B: xx	xxxxxxx xxxxxxxx xxxxx	PAIN/BURNING PRURITUS ERYTHEMA EDEMA SCABBING/CRUSTING	xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx
		I: xxxxxxxx L: x xxxxxxxxx xxxxx C: xxxxxxxxxxx P: xxx	D: xxxxx C: xxxxxxxxx xx xxxxxxxxxx P: xxx B: xx	xxxxxxx xxxxxxxx xxxxx	PAIN/BURNING PRURITUS ERYTHEMA EDEMA SCABBING/CRUSTING	xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx
		I: xxxxxxxx L: x xxxxxxxxx xxxxx C: xxxxxxxxxxx P: xxx	D: xxxxx C: xxxxxxxxx xx xxxxxxxxxx P: xxx B: xx	xxxxxxx xxxxxxxx xxxxx	PAIN/BURNING PRURITUS ERYTHEMA EDEMA SCABBING/CRUSTING	xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx

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

Listing 16.2.6.1.2: Assessment of Non-Treatment Targeted Basal Cell Carcinomas
Treatment Arm
(Page xx of yy)

		I: BCC ID	D: Diameter (mm)
S: Subject	V: Visit	L: Body Location	C: Classification
A: Age/Sex	D: Date	C: Centrality	
E: Eval		P: Photographed	
S: xxxxxx	V: xxxxxxxx	I: xxxxxxxx	D: xxxxx
A: xxxx	D: xxxxxxxx	L: x xxxxxxxxx xxxxx	C: xxxxxxxxx xx
E: xxxxxxxx		C: xxxxxxxxxxx	xxxxxxxxxx
		P: xx	
		I: xxxxxxxx	D: xxxxx
		L: x xxxxxxxxx xxxxx	C: xxxxxxxxx xx
		C: xxxxxxxxxxx	xxxxxxxxxx
		P: xxx	

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

Listing 16.2.6.2: GLI1 mRNA Levels
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date	Tumor ID Region	T: Total # Cells A: Avg Dots/Cell QC: QC Pass/Fail	C0: % cells in Bin 0 C1: % cells in Bin 1 C2: % cells in Bin 2	C3: % cells in Bin 3 C4: % cells in Bin 4	H:Hs-GLI1 H-Score P:Percent Change from baseline
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxxxxxx	xx xxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: --
		xx xxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx
		xx xxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx
	V: xxxxxxxx D: xxxxxxxx	xx xxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxxxxxx	xx xxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx
	V: xxxxxxxx D: xxxxxxxx	xx xxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx

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

Listing sorted by Subject Number, Visit, Date, Category.

Listing 16.2.6.3: Assessment of New SEBs
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date	A: Assessed for new facial tumors?	N: Number of new facial tumors	S: Number of new facial tumors considered to be SEBs
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxxxxxx	A: xxx	N: xx	S: xx

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

Listing 16.2.6.4: aBCCdex
Treatment Arm
(Page xx of yy)

S: Subject
A: Age/Sex
E: Eval

Visit	Visit Date	aBCCdex Question / Scale	Result
xxxxxxxx	xxxxxxxxxx	x xxxxxx xxx xxxx xxxxx xxx xxx xxxxxxxxxx xxxxxxxx xxxx xxxxxxxxxx	xxx xxx xxxx xxxx xxxxxxx
		xxxxxx xxx xxxx xxxxx xxx xxx xxxxxxxxxxx xxxxxx xx xxxxxxxxx xxxxx xxxxxxxxxx	x
		xxxxxx xxx xxxx xxxxx xxxx xxxx xxxxxxxxxx xxxxxxxxx xx xxxxxx xxxx xxxxxxx xxx xxxxxxxxxx	x
		xxxxxx xxx xxxx xxxxxx xxx xxx xxxxxxxxxx xx xxxxxxx xxxxxx	x
		xx xxxxxx xxx xxxx xxxxx xxx xxxx xxxxxxxxxxx xx xxxxxxx xxxxxx xx xxxxx xx xxx xx xxx xxxxxxxxxx	xxx xxx xxxx xxxx xxxxxxx
		xx xxxxxx xx xxxx xxxxx xxx xxx xxxxxxxxxxx xx xxxxxxxxx xxxxxxxxx	x
		xx xxxxxxx xxx xxxx xxxxx xxxxxxxx xx xxxxx xxxxxxxxxx xxx xxxx xx xxx xxxxx xxxxx xxx xxxx xx xxxxxxxx	x
		xx xxxxxxxx xxx xxxx xxxxx xxxxxxxx xx xxxx xxxxxxxxx xxx xxxx xx xxx xxxxx xxxxx xxxx xxxx xx xxxxxx	x
		xx xxxxxxxx xxx xxxx xxxxx xxxxxxxx xx xxxx xxxxxxxxxx xxx xxxx xx xxx xxxxx xxxxx xxxx xxxx xx xxxx	x
		xx xx xxx xxxx xxxxx xx x xxxxxx xx xxxx xxxxxxxx xxx xx xxxxxx xxx xxxxxxx xxxx xxx xxxxx xx xxxx xxxx xxxx xxxxxx xxxx xxxxxxxx	x

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

Note to Programmer: List each question in order including question number, and then name and list the 5 scales results.

Listing 16.2.6.5: Dermatology Life Quality Index
Treatment Arm
(Page xx of yy)

S: Subject
A: Age/Sex
E; Eval

Visit	Date	Dermatology Life Quality Index Question / Score	Result
xxxxxxxx	xxxxxxxxxx	xx xxxx xxx xxxx xxxxx xxx xxxxxx xxxxx xxxxxxx xx xxxxxxxx xxx xxxx xxxx xxxx	xxx xxxxxxxx
		xx xxxx xxx xxxx xxxxx xxx xxxxxxxxxxx xx xxxx xxxxxxxxx xxxx xxx xxxx xxxxxxxx xx xxxx xxxxx	xxxx xxxx
		xx xxxx xxx xxxx xxxxx xxx xxxx xxx xxxx xxxx xxxxxxxxxx xxxx xxx xxxxx xx xxxxxxx xxxxx xxxx xxxx xx xxxxxxx	xxx xx xxx
		xx xxxx xxx xxxx xxxxx xxx xxxx xxx xxxx xxxx xxxxxxxxxx xxx xxxxxxx xxx xxxxx	x xxx
		xx xxxx xxx xxxx xxxxxx xxx xxxx xxx xxxx xxxx xxxxxxxx xxx xxxxxx xx xxxxxxx xxxxxxxxxx	xxx xxxx
		xx xxxx xxx xxxx xxxxx xxx xxxx xxx xxxx xxxx xxxx xx xxxxxxxxx xxx xx xx xxx xxx xxxxxx	xxx xxxxxxxx
		xx xxxx xxx xxxx xxxxx xxx xxxx xxxx xxxxxxxxx xxx xxxx xxxx xx xxxxxxxx	x xxxxxx
		xx xxxx xxx xxxx xxxxx xxx xxxx xxx xxxx xxxx xxxxxxx xxxxxxxxx xxxx xxxx xxxxxxx xx xxx xx xxxx xxxxxx xxxxxxx xx xxxxxxxxxx	xxxx xxxx
		xx xxxx xxx xxxx xxxxxx xxx xxxx xxx xxxx xxxx xxxxxx xxx xxxxxx xxxxxxxxxxxxx	x xxx
		xxx xxxx xxx xxxx xxxxx xxx xxxx xx x xxxxxxx xxx xxx xxxxxxxxx xxx xxxx xxxx xxxxx xxx xxxxxxx xx xxxxxxx xxxx xxxx xxxxxx xx xx xxxxxx xx xxxxx	xxx xx xxx
xxxx x	xxxxxxxxxx	xx xxxx xxx xxxx xxxxx xxx xxxxxx xxxxxx xxxxxxx xx xxxxxxxx xxx xxxx xxxx xxxxx	x xxx
		xx xxxx xxx xxxx xxxxxx xxx xxxxxxxxxxx xx xxxx xxxxxxxx xxxx xxx xxxx xxxxxxx xx xxxx xxxxx	xxx xxxxxxxx

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

Programming Note: Include question number with text and then list score.

Listing 16.2.7.1.1: Systemic Symptoms
Treatment Arm
(Page 1 of xx)

Subject	Age/Sex	Eval	Visit	Visit Date	Systemic Symptom	Result
xxxxx	xx/X	ITT/S	Baseline	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx
					Changes of Quality or Quantity of Hair in Treated Areas	Xxx
					Change in Frequency of Shaving	Xxx
					Other	Xxx
			Week 2	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx
					Changes of Quality or Quantity of Hair in Treated Areas	Xxx
					Change in Frequency of Shaving	Xxx
					Other	Xxx
			Week 6	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx
					Changes of Quality or Quantity of Hair in Treated Areas	Xxx
					Change in Frequency of Shaving	Xxx
					Other	Xxx
			Week 10	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx

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

Listing 16.2.7.1.2: Facial Area Dermal Safety and Tolerability
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Visit Date	Site	Test	Result
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xx xx xxxxxx x xxxxx	PAIN/BURNING	xxxxxxxx
					xxxx	PRURITUS	xxxxxxxx
					xxx xxxxx xxxxxx xxxx	ERYTHEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	EDEMA	xxxxxxxx
					xxxx	SCABBING/CRUSTING	xxxxxxxx
					xxxx	PAIN/BURNING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PRURITUS	xxxxxxxx
					xx xx xxxxxx x xxxxx	ERYTHEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	EDEMA	xxxxxxxx
					xxx xxxxx xxxxxx xxxx	SCABBING/CRUSTING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PAIN/BURNING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PRURITUS	xxxxxxxx
					xx xx xxxxxx x xxxxx	ERYTHEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	EDEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	SCABBING/CRUSTING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PAIN/BURNING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PRURITUS	xxxxxxxx
					xx xx xxxxxx x xxxxx	ERYTHEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	EDEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	SCABBING/CRUSTING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PAIN/BURNING	xxxxxxxx
					xx xx xxxxxx x xxxxx	PRURITUS	xxxxxxxx
					xx xx xxxxxx x xxxxx	ERYTHEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	EDEMA	xxxxxxxx
					xx xx xxxxxx x xxxxx	SCABBING/CRUSTING	xxxxxxxx

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

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

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxxxx xxxxx	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxxx
	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxxx
	xxxxxxxxxx	xxxxx xxxxx xxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA dictionary (Version 19.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.7.2.2: Adverse Events
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	C: System Organ Class P: Preferred Term V: Verbatim T: In Treatment Area	F: Date of First Application S: Start Date (Day) E: End Date (Day)1	S: Severity R: Relationship to Study Drug E: Serious O: Outcome	A: Action Taken O: Other Action
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxx O: xxxxxxxxxxxx
			S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xxx O: xxxxxxxxx	A: xxxxxxxxxxxx O: xxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxx O: xxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version xx.x).
[1] Day is calculated as date - Date of first dosefor dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, and Adverse Event.
Note Action Taken will consist of a concatenation of Action Taken Regarding Study Drug, Action Taken Regarding Hospitalization, Action Taken Concomitant Medication, Action Taken Procedure/Therapy, Action Taken Other, and Specify

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

Subject	Age/Sex	Eval	C: System Organ Class P: Preferred Term V: Verbatim T: In Treatment Area	F: Date of First Application S: Start Date (Day) E: End Date (Day)1	S: Severity R: Relationship to Study Drug E: Serious O: Outcome	A: Action Taken O: Other Action
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxx O: xxxxxxxxxxxx
			S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xxx O: xxxxxxxxx	A: xxxxxxxxxxxx O: xxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxx O: xxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version xx.x).
[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)
Listing sorted by Subject Number, Start Date, End Date, and Adverse Event.
Note Action Taken will consist of a concatenation of Action Taken Regarding Study Drug, Action Taken Regarding Hospitalization, Action Taken Concomitant Medication, Action Taken Procedure/Therapy, Action Taken Other, and Specify

Listing 16.2.7.2.4: Subjects Who Prematurely Discontinued Study and/or Discontinued Study Drug Due to Adverse Events
Treatment Arm
(Page xx of yy)

	Discontinuation		Adverse Events	
S: Subject A: Age/Sex E: Eval	F: Date of First Application L: Date of Last Application	D: Date (Day)[1] R: Primary Reason	A: Verbatim S: Severity R: Relationship to Study Drug	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxxxxxxxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxxxxxxx L: xxxxxxxxxxxxxxx	D: xxxxxxxxxxxxxxx R: xxxxxxxxxxxxxxx	A: xxxxxxxxxxxxxxx S: xxxxxxxxxx R: xxxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx
S: xxxxxxxxxxxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxxxxxxx L: xxxxxxxxxxxxxxx	D: xxxxxxxxxxxxxxx R: xxxxxxxxxxxxxxx	A: xxxxxxxxxxxxxxx S: xxxxxxxxxx R: xxxxxxxxxx	S: xxxxxxxxxxxxxxx E: xxxxxxxxxxxxxxx

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

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

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

Listing 16.2.8.1: Serum Pregnancy Test
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Was the Specimen Collected	Results
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xx	
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx

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

Listing 16.2.8.2.1: Chemistry Laboratory Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx

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

Listing filtered on LBCAT = 'Biochemistry' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.2.2: Hematology Laboratory Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx

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

Listing filtered on LBCAT='Haematology' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.2.3: Urinalysis Laboratory Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx
	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx

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

Listing filtered on LBCAT='Urinalysis' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.3.1: Abnormal Chemistry Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx
	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx

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

Listing filtered on LBCAT='Haematology' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.3.2: Abnormal Hematology Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxxx	xxx	xxxxxx				xx

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

Listing filtered on LBCAT='Haematology' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.3.3: Abnormal Urinalysis Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx
	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx

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

Listing filtered on LBCAT=Urinalysis and sorted by Subject Number, Test, Visit Date.

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

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

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

Listing sorted by Subject Number, Visit, Date, Vital Sign.