Official Title: An Open-Label, Phase 2, Safety, and Efficacy Study of Ruxolitinib Cream in Participants With Genital Vitiligo

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Statistical Analysis Plan

INCB 18424-219

An Open-Label, Phase 2, Safety, and Efficacy Study of Ruxolitinib Cream in Participants With Genital Vitiligo

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EU CT Number:	**2023-503737-22-00**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803** **United States**
Protocol Version:	**Protocol Amendment 1 dated 28 FEB 2023**
CRF Approval Date:	**10 OCT 2024**
SAP Version:	**Original**
SAP Author:	[redacted] [redacted] **Biostatistician, Biostatistics**
Date of Plan:	**06 NOV 2024**

This study is being conducted in compliance with Good Clinical Practice, including the archiving of essential documents.

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	adverse event
ASR	application site reaction
BID	twice daily
BMI	body mass index
BSA	body surface area
CI	confidence interval
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
eCRF	electronic case report form
FAS	full analysis set
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
[redacted]	[redacted]
[redacted]	[redacted]
PK	pharmacokinetic(s)
[redacted]	[redacted]
PT	preferred term
SAP	Statistical Analysis Plan
SOC	system organ class
T-BSA	total body surface area
TEAE	treatment-emergent adverse event
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
VASI	Vitiligo Area Scoring Index
[redacted]	[redacted]
[redacted]	[redacted]
WHO	World Health Organization

1. INTRODUCTION

This is an open-label study in which participants with nonsegmental vitiligo with genital involvement will apply ruxolitinib 1.5% cream BID to all depigmented areas (up to 10% BSA) for up to 48 weeks. Participants will continue to treat depigmented areas identified for treatment at baseline regardless of whether the area begins to improve or fully repigment. Following the last application of ruxolitinib 1.5% cream at Week 48, there will be a 30-day safety follow-up period.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the INCB 18424-219 Protocol. The scope of this plan will be executed by the Department of Biostatistics or designee, and the analyses of PK will be executed by the Department of Clinical Pharmacokinetics or designee.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 18424-219 Protocol Amendment 1 dated 28 FEB 2023 and CRF approved 10 OCT 2024. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol Amendments and CRF versions.

2.2. Study Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
To evaluate the efficacy of ruxolitinib cream in participants with genital vitiligo.	Genital VNS of "4 – A lot less noticeable" or "5 – No longer noticeable" at Week 48.
Secondary	
To evaluate the safety and tolerability of ruxolitinib cream.	AEs and changes in vital signs and laboratory data.
To further evaluate the efficacy of ruxolitinib cream.	• Genital-PhGVA of 0 or 1 at Week 48. • Change from baseline in affected BSA in the genital region at Weeks 24 and 48. • T-VASI50/75/90 at Weeks 24 and 48. • Genital VNS of "4 – A lot less noticeable" or "5 – No longer noticeable" at Week 24. • Each category of the color-matching question at Weeks 24 and 48.

Table 1: Objectives and Endpoints (Continued)

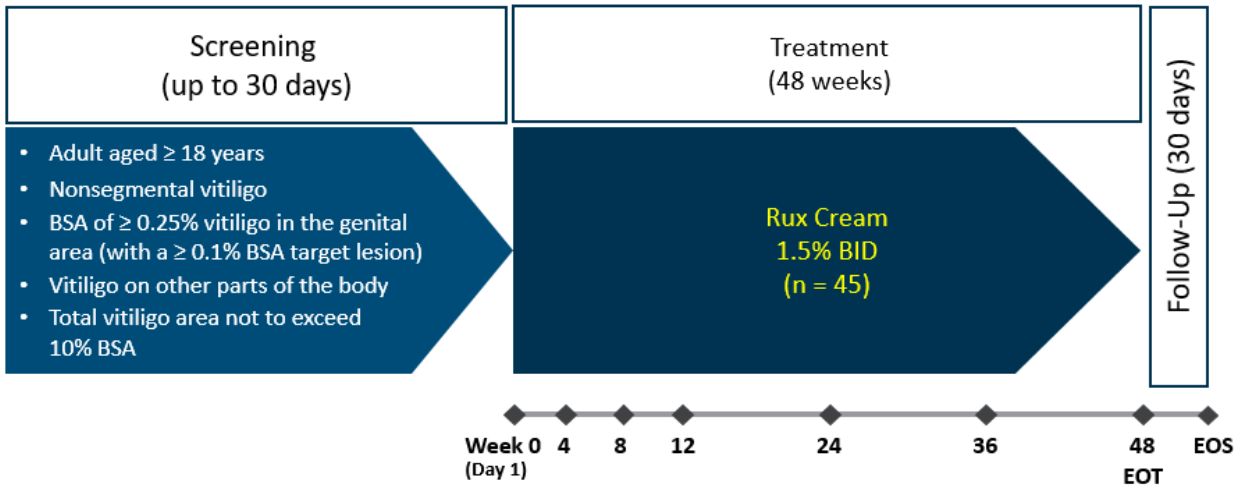
Objectives	Endpoints
Exploratory	
[redacted]	

3. STUDY DESIGN

This is an open-label study in which participants with nonsegmental vitiligo with genital involvement will apply ruxolitinib 1.5% cream BID to all depigmented areas (up to 10% BSA) for up to 48 weeks. Participants will continue to treat depigmented areas identified for treatment at baseline regardless of whether the area begins to improve or fully repigment.

The study schema is shown below in Figure 1. All participants will have follow-up assessments 30 (+ 7) days after the last application of study drug.

Figure 1: Study Design Schema



3.1. Randomization

Not applicable.

3.2. Control of Type I Error

All statistical analyses for all endpoints are exploratory in nature. No alpha control will be implemented. Unless otherwise specified, all CIs provided will be at the 95% confidence level.

3.3. Sample Size Considerations

Due to the exploratory nature of the study, the sample size is not based on calculation of statistical power. The sample size is considered to be sufficient to obtain adequate efficacy, safety, tolerability, and PK data to achieve the objectives of the study.

Approximately 45 participants will apply ruxolitinib 1.5% cream BID for 48 weeks.

3.4. Schedule of Assessments

Refer to the Protocol Amendment 1 dated 28 FEB 2023 for a full description of all study procedures and assessment schedules for this study.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date of the first application of ruxolitinib 1.5% cream.

4.1.2. Study Day

If a visit/reporting date is on or after Day 1, then the study day at the visit/reporting date will be calculated as follows:

Day # = (visit/reporting date – Day 1 date + 1).

If the visit/reporting date is before Day 1, then the study day at the visit/reporting date will be calculated as follows:

Day # = (visit/reporting date – Day 1 date).

A study day of −1 indicates 1 day before Day 1.

4.1.3. Baseline Value

Baseline is the last nonmissing measurement obtained before (or on) the day of first application of ruxolitinib 1.5% cream.

4.1.4. Handling of Missing and Incomplete Data

In general, values for missing data will not be imputed unless methods for handling missing data are specified in this section or relevant sections. The original reported dates collected on the eCRF should be used in all relevant listings.

4.2. Variable Definitions

4.2.1. Body Mass Index

Body mass index will be calculated as follows:

BMI (kg/m^2) = [weight (kg)] / [height (m)]^2.

4.2.2. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first application of ruxolitinib 1.5% cream.

Concomitant medication is defined as any nonstudy medication that is started accordingly:

- Before the date of first application of ruxolitinib 1.5% cream and is ongoing throughout the study or ends on/after the date of first application of study treatment.
- On/after the date of first application of ruxolitinib 1.5% cream and is ongoing or ends during the course of study treatment.

A prior medication could also be classified as "both prior and concomitant medication," if the end date is on or after the first application of ruxolitinib 1.5% cream. In the listing, it will be indicated whether a medication is only prior, only concomitant, or both prior and concomitant.

For the purposes of analysis, all medications will be considered concomitant medications unless the medications can unequivocally be defined as not concomitant.

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9.1 or later) will be used for the generation of all tables and statistical analyses. Descriptive summaries for continuous variables will include but not be limited to the number of observations, mean, standard deviation, median, minimum, maximum, first quartile, third quartile, and 95% CI. Descriptive summaries for categorical variables will include the number and percentage of participants in each category.

5.2. Treatment Groups

This is an open-label study for up to 48-week treatment period where all participants will apply ruxolitinib 1.5% cream BID. Participants will be summarized overall by total only.

5.3. Analysis Populations

5.3.1. All-Screened Population

The all-screened population will include all participants who signed the informed consent form.

5.3.2. Full Analysis Set

The FAS will include all participants who applied ruxolitinib 1.5% cream at least once.

The FAS will be used for the summary of demographics, baseline characteristics, participant disposition, and analyses of all efficacy and safety data.

[redacted]

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

6.1. General Considerations

For all continuous variables, the actual value and change and/or percentage from baseline (if available) will be analyzed. For continuous measurements, summary statistics will include sample size, mean, median, standard deviation, standard error of the mean, minimum, and maximum. For categorical measurements, summary statistics will include sample size, frequency, and percentages. All by-visit analyses will include the follow-up period if the data are available.

6.2. Demographics, Baseline Characteristics, and Disease History

6.2.1. Demographics and Baseline Characteristics

The following demographics will be summarized for the FAS Population: age, age group (18 to < 65 and ≥ 65 and older), sex, race, ethnicity, geographic region, weight, height, BMI.

6.2.2. Baseline Disease Characteristics and Disease History

The following baseline disease characteristics will be summarized for the FAS Population and will include but not limited to the following:

- Time since initial diagnosis of vitiligo
- Vitiligo diagnosed in childhood (no/yes [age]: 0-5 years, 6-11 years, 12-17 years)
- Disease status (stable/progressive)
- Skin type (Fitzpatrick scale Type I/II/III/IV/V/VI)
- Other autoimmune disorders
- History of acne (no/yes)
- Currently have acne on the face (no/yes)
- Itching associated with the vitiligo lesions (no/yes)
- Time since initial diagnosis of vitiligo in genital area
- Baseline Genital-VASI
- Baseline T-VASI
- Baseline Genital-BSA involvement (% of the total body)
- Baseline T-BSA involvement (% of the total body)

6.2.3. Prior Therapies for Vitiligo

Prior nondrug therapies (referred simply as "prior therapies" elsewhere) for vitiligo will be separately summarized for the FAS population.

6.2.4. Medical History

For participants in the FAS, medical history will be summarized. This summary will include the number and percentage of participants with medical history for each body SOC/PT as documented in the eCRF.

6.3. Disposition of Participants

The number and percentage of participants who were enrolled, who were treated, who completed study treatment, who discontinued study treatment with a primary reason for discontinuation, who completed the study, and who withdrew from the study with a primary reason for withdrawal will be summarized for the FAS. The number of participants enrolled by country and/or site will also be provided.

6.4. Protocol Deviations

Protocol deviations recorded on the eCRF will be summarized and listed by category (important and nonimportant).

6.5. Exposure

For participants in the FAS population, exposure will be summarized descriptively for duration of treatment, average daily dose, and total dose. The average daily dose is defined as total dose divided by time from first to last dose.

6.6. Study Cream Application Compliance

For the participants in the FAS population, overall compliance (%) for the application of ruxolitinib 1.5% cream during the treatment period will be calculated for all participants as follows:

Study cream application compliance (%) = 100 × [total number of actual applications / total number of prescribed applications].

where

Total number of prescribed applications = number of planned applications – number of interrupted applications.

In this study, any gaps in patient-reported application data should be regarded as compliance.

6.7. Prior and Concomitant Medications

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary. The number and percentage of participants in the FAS Population for each prior and concomitant medication will be summarized by WHO drug class and WHO drug preferred term. Prior and concomitant medications, prior medications for treating vitiligo, and prior medications other than those for treating vitiligo, will also be summarized for the FAS Population.

7. EFFICACY

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

7.1. Efficacy Hypotheses

Not applicable.

7.2. Efficacy Measures

7.2.1. Body Surface Area

The BSA depigmented by vitiligo will be estimated at each visit. Body surface area assessments will be performed using the palmar method and should be estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (ie, the palm plus 5 digits) should be considered as 1% BSA, and the approximate size of the participant's thumb should be considered as 0.1% BSA.

In addition to the total BSA, the BSA depigmented by vitiligo will be assessed for the genital areas.

Total-BSA considers the depigmented areas for each of the following body regions: head/neck (including face and scalp), upper extremities (including axillae), hands, trunk (including genitalia), lower extremities (including buttocks), and feet.

Genital-BSA accounts for the depigmented areas of the labia majora, labia minora, and perineum in females and the penis, scrotum, and perineum in males.

7.2.2. Vitiligo Area Scoring Index

Areas affected by depigmentation due to vitiligo will be assessed using the VASI (Hamzavi et al 2004). It is based on a composite estimate of the overall area of vitiligo patches at baseline and the degree of macular repigmentation within these patches over time. The %BSA (hand unit) vitiligo involvement is estimated by the investigator using the palmar method. The hand unit is based on participant's hand size. The investigator will use their hand to mimic the participant's hand size to evaluate %BSA vitiligo involvement. The degree of depigmentation for each vitiligo involvement site is determined and estimated to the nearest of the following percentages: 0%, 10%, 25%, 50%, 75%, 90%, or 100%. At 100% depigmentation, no pigment is present; at 90%, specks of pigment are present; at 75%, the depigmented area exceeds the pigmented area; at 50%, the depigmented and pigmented area are equal; at 25%, the pigmented area exceeds the depigmented area; and at 10%, only specks of depigmentation are present. Data will be collected so that VASI scores can be calculated for each of the 6 body regions noted for the total BSA as well as for the genitals.

The body is divided into the following 6 separate and mutually exclusive sites: 1) head/neck (including face and scalp), 2) upper extremities (including axillae), 3) hands, 4) trunk (including genitalia), 5) lower extremities (including buttocks), and 6) feet.

Genital-VASI is measured by percentage of vitiligo involvement (%BSA) and the degree of depigmentation in the genital areas. The Genital-VASI is then derived by multiplying the values

assessed for the vitiligo involvement by the percentage of affected skin for each site on the genitals, summing the values of all sites together.

[redacted]

7.2.3. Target Lesion

Participants must have at least 1 genital target lesion that is ≥ 0.1% BSA that has a pigmented hair within it at screening and baseline. The longest diameter will be measured in millimeters as well as the measurement perpendicular to the longest diameter. This lesion will be assessed and measured at each subsequent visit. Additionally, photography will be employed to track the response of the lesion to topical drug. A note should be made, and baseline photographs can be marked with the location of the target lesion.

[redacted]

7.2.6.1. Itch Numerical Rating Scale

The Itch NRS is a participant-reported measure of itch intensity assessed using an 11-point scale (0 = No itch to 10 = Worst imaginable itch). Participants will be asked to record their highest (worst) level of itch during the past week.

7.2.6.2. Vitiligo Noticeability Scale

The VNS is a patient-reported measure of vitiligo treatment success that has a 5-point scale (Batchelor et al 2016). The baseline genital photograph will be shown to the participants for reference, and a mirror will be provided for the participants to assess the vitiligo on their genital area. The participant will be asked to respond to the following query:

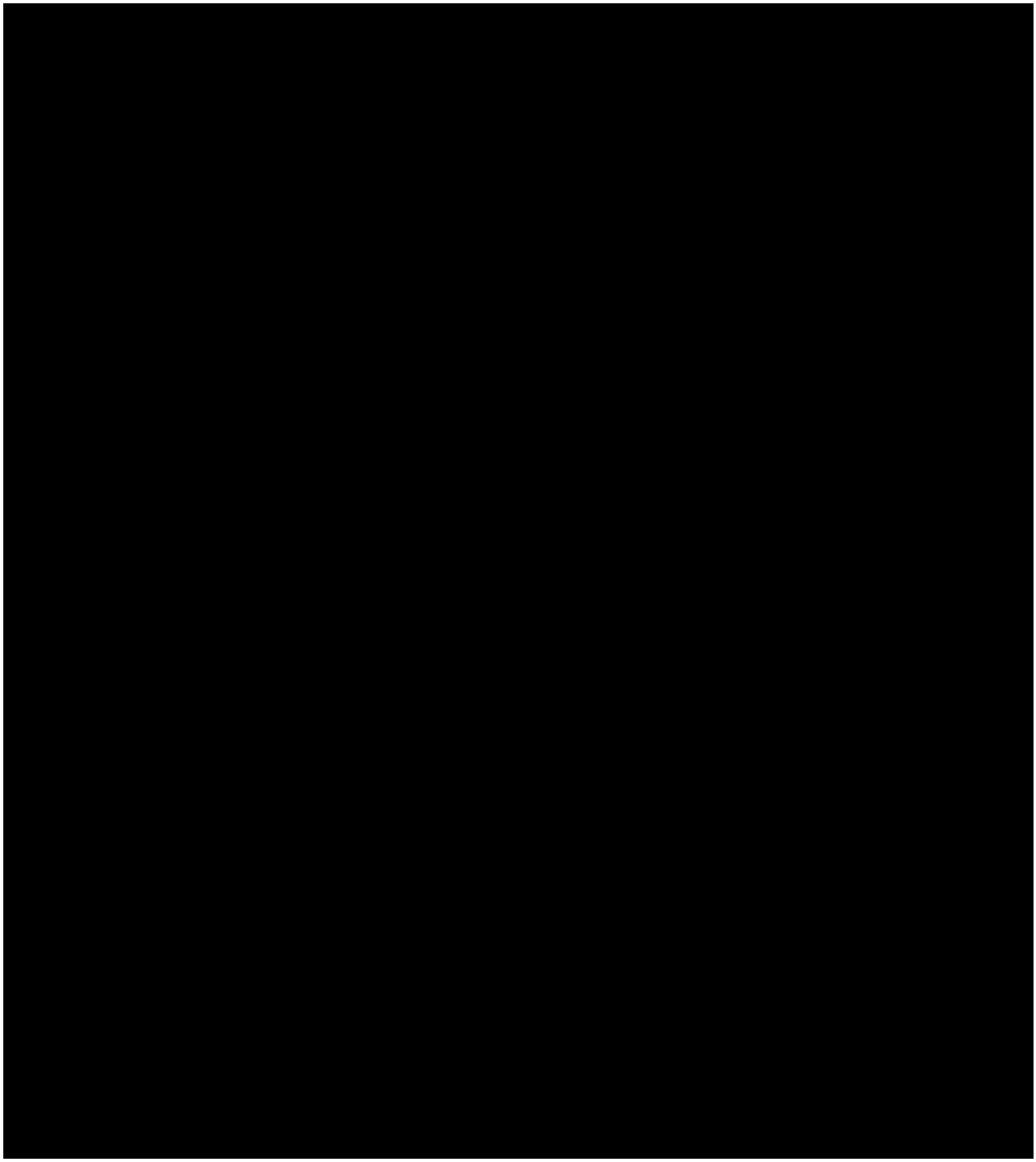
> Compared with before treatment, how noticeable is the vitiligo now? Responses: (1) More noticeable, (2) As noticeable, (3) Slightly less noticeable, (4) A lot less noticeable, and (5) No longer noticeable.

A VNS score of 4 or 5 can be interpreted as treatment success.

7.2.6.3. Color-Matching Question

Participants will be provided a mirror and will be shown their baseline genital photograph for reference. Each participant will be asked to respond to the following query:

> At this point of your treatment, how well does your skin color match between your genital treated vitiligo skin and genital normal skin? Responses: (1) Excellent, (2) Very good, (3) Good, (4) Poor, and (5) Very poor.



[redacted]

7.3. Efficacy Analysis

7.3.1. Primary Efficacy Analysis

The primary endpoint is a genital VNS of "4 – A lot less noticeable" or "5 – No longer noticeable" at Week 48. The proportion of participants achieving the primary endpoint will be analyzed using summary statistics, which will include sample size, frequency, percentages, and standard error of percentage, and the 95% CI at each visit.

7.3.2. Secondary and Exploratory Efficacy Analysis

7.3.2.1. Continuous Efficacy Endpoints

By-visit summary statistics for the following continuous measurements, including actual measurement, change from baseline, and percentage change from baseline, will be presented:

[redacted]

Among these, the actual measurement, change from baseline, and percentage change from baseline of Genital-BSA will also be summarized by sex. Summary statistics, including sample size, mean, median, standard deviation, minimum, maximum, first quartile, third quartile, and 95% CI, will be presented by visit.

7.3.2.2. Categorical Efficacy Endpoints

For the following categorical parameters, summary statistics will include sample size, frequency, percentages and standard error of percentage, and the 95% CI at each visit.

[redacted]

[redacted]

9. SAFETY AND TOLERABILITY

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

9.1. General Considerations

The analyses in this section will be provided for the FAS.

Summary tables may be replaced with listings when appropriate. For instance, an AE frequency table may be replaced with a listing if it only contains a few unique PTs reported on relatively few participants.

9.2. Adverse Events

9.2.1. Adverse Event Definitions

A TEAE is any AE either reported for the first time or worsening of a pre-existing event after first application of study drug and within 30 days of the last application of study drug. Analysis of AEs (as discussed below) will be limited to TEAEs, but data listings will include all AEs regardless of their timing in relation to study drug application.

Adverse events will be tabulated by MedDRA PT and SOC. Severity of AEs will be graded using the NCI CTCAE v5. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

The subset of AEs considered by the investigator to be related to study drug will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AE to study drug, the AE will be considered to be treatment-related. The incidence of AEs and treatment-related AEs will be tabulated. In addition, serious AEs will also be tabulated.

Any missing onset date, causality, or severity must be queried for resolution. Unresolved missing causality and severity will be handled according to the following rules:

- An unresolved missing causality will be considered treatment-related.
- An unresolved missing severity will be identified as an unknown severity.

For purposes of analysis, all AEs will be considered TEAEs unless the AE can unequivocally be defined as not treatment-emergent.

9.2.2. Adverse Event Summaries

An overall summary of AEs will include the following:

- Number (%) of participants reporting any TEAEs
- Number (%) of participants reporting any serious TEAEs
- Number (%) of participants reporting any Grade 3 or higher TEAEs
- Number (%) of participants reporting any treatment-related TEAEs
- Number (%) of participants who temporarily interrupted study drug because of TEAEs
- Number (%) of participants who permanently discontinued study drug because of TEAEs
- Number (%) of participants who had any fatal TEAEs
- Number (%) of participants who had any ASRs

The following summaries will be produced by MedDRA term (if 5 or fewer participants appear in a table, a listing may be appropriate):

- Summary of TEAEs by MedDRA SOC, PT, and maximum severity
- Summary of TEAEs by MedDRA SOC and PT
- Summary of TEAEs by MedDRA PT in decreasing order of frequency
- Summary of Grade 3 or higher AEs by MedDRA SOC and PT
- Summary of Grade 3 or higher AEs by MedDRA PT in decreasing order of frequency
- Summary of serious TEAEs by MedDRA SOC and PT
- Summary of serious TEAEs by MedDRA PT in decreasing order of frequency
- Summary of ASRs by MedDRA SOC and PT
- Summary of ASRs by MedDRA PT in decreasing order of frequency
- Summary of treatment-related TEAEs by MedDRA SOC and PT
- Summary of treatment-related TEAEs by MedDRA PT in decreasing order of frequency
- Summary of Grade 3 or higher treatment-related TEAEs by MedDRA SOC and PT
- Summary of treatment-related serious TEAEs by MedDRA SOC and PT
- Summary of TEAEs with a fatal outcome by MedDRA SOC and PT
- Summary of TEAEs leading to dose interruption of study drug by MedDRA SOC and PT
- Summary of TEAEs leading to discontinuation of study drug by MedDRA SOC and PT

9.3. Clinical Laboratory Tests

9.3.1. Laboratory Value Definitions

Laboratory values and change from baseline values will be summarized descriptively by visit. The baseline value will be determined using the nonmissing values collected before the first dose using the priority defined in Table 4. The last record before administration in the highest priority will be considered the baseline record. For baseline laboratory candidates with the same date and time in the same priority category, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

Table 4: Identification of Baseline Record

Priority	Laboratory Visit	Central or Local Laboratory
1	Scheduled	Central
2	Scheduled	Local
3	Unscheduled	Central
4	Unscheduled	Local

9.3.2. Laboratory Value Summaries

Actual values and changes from baseline in clinical laboratory test results will be summarized using descriptive statistics. Laboratory test values outside the normal range will be assessed for severity based on the normal ranges for the clinical reference laboratory. The incidence of abnormal laboratory values will be tabulated.

Laboratory data will be classified into Grades 1 through 5 using CTCAE v5. The following summaries will be produced for the laboratory data:

- Number and percentage of participants with worst postbaseline CTCAE grade (regardless of baseline value).

  Note: Each participant will be counted only for their worst grade observed postbaseline.

- Shift tables from baseline to the worst postbaseline value using CTCAE grade.

9.4. Vital Signs

Values at each scheduled visit, change, and percentage change from baseline for vital signs, including systolic blood pressure, diastolic blood pressure, pulse, temperature, and respiratory rate will be summarized descriptively.

Normal ranges for vital sign values are defined in Table 5. For participants exhibiting vital sign abnormalities, the abnormal values will be listed along with their assigned treatment group. Alert vital signs are defined as an absolute value outside the defined normal range and percentage change greater than 25%. Note that the definition of alert vital signs does not apply for body temperature and. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 5: Normal Ranges for Vital Sign Values

Parameter	High Threshold	Low Threshold
Systolic blood pressure	≤ 155 mmHg	≥ 85 mmHg
Diastolic blood pressure	≤ 100 mmHg	≥ 40 mmHg
Pulse	≤ 100 bpm	≥ 45 bpm
Temperature	≤ 38°C	≥ 35.5°C
Respiratory rate	≤ 20 breaths/min	≥ 8 breaths/min

10. INTERIM ANALYSES

No formal interim analysis is planned in this study.

11. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 6.

Table 6: Statistical Analysis Plan Versions

SAP Version	Date
Original	06 NOV 2024

11.1. Changes to Protocol-Defined Analyses

All endpoints in Section 2.2 have been rephrased from the Protocol in a more concise and direct manner. The rephrasing is a change in presentation only and does not alter the interpretation or intended analyses of these endpoints from the Protocol.

No analysis related to Facial-BSA and Facial-VASI will be performed since this a study of genital vitiligo.

After review, it is determined that PROMIS Sexual Functional Screeners shall be summarized by responses in each category instead of changes from baseline values as specified in the Protocol.

11.2. Changes to the Statistical Analysis Plan

Not applicable.

12. REFERENCES

Batchelor JM, Tan W, Tour S, Yong A, Montgomery AA, Thomas KS. Validation of the Vitiligo Noticeability Scale: a patient-reported outcome measure of vitiligo treatment success. Br J Dermatol 2016;174:386-394.

Ezzedine K, Ahmed M, Tovar-Garza A. Cross-cultural validation of a short-form of the Vitiligo Impact Patient scale (VIPs). J Am Acad Dermatol 2019;81:1107-1114.

Hamzavi I, Jain H, McLean D, Shapiro J, Zeng H, Lui H. Parametric modeling of narrowband UV-B phototherapy for vitiligo using a novel quantitative tool: the Vitiligo Area Scoring Index. Arch Dermatol 2004;140:677-683.

Salzes C, Abadie S, Seneschal J. The Vitiligo Impact Patient scale (VIPs): development and validation of a vitiligo burden assessment tool. J Invest Dermatol 2016;136:52-58.

Weinfurt KP, Lin L, Bruner DW. Development and initial validation of the PROMIS(®) Sexual Function and Satisfaction Measures Version 2.0. J Sex Med 2015;12:1961-1974.

APPENDIX A. PLANNED TABLES AND LISTINGS

This appendix provides a list of the planned tables and listings for the Clinical Study Report. Shells are provided in a separate document for tables that are not in the Standard Safety Tables v1.6.

The list of tables and listings are to be used as guidelines. Modifications of the lists that do not otherwise affect the nature of the analysis will not warrant an amendment to the SAP.

Tables

Table No.	Title	Population	Standard
Baseline and Demographic Characteristics			
1.1.1	Analysis Populations	All	X
1.1.2	Summary of Participant Disposition	FAS	X
1.1.3	Summary of Number of Participants Enrolled by Country and Site	FAS	X
1.1.4	Summary of Protocol Deviations	FAS	X
1.2	Summary of Demographics and Baseline Characteristics	FAS	X
1.3	Summary of Baseline Disease Characteristics	FAS	X
1.4.1	Summary of Prior Medications for Vitiligo	FAS	X
1.4.2	Summary of Prior Therapies for Vitiligo	FAS	X
1.4.3	Summary of Prior Medications	FAS	X
1.4.4	Summary of Concomitant Medications	FAS	X
1.5	Summary of General Medical History	FAS	X
Efficacy			
Genital VNS			
2.1.1	Summary and Analysis of Participants Achieving Genital VNS Scores of 4 or 5 During the Treatment Period	FAS	
2.1.2	Summary and Analysis of Participants by Sex Achieving Genital VNS Scores of 4 or 5 During the Treatment Period	FAS	
2.1.3	Summary of Participants in Each Category of Genital VNS Scores During the Treatment Period	FAS	
[redacted]			
2.2.1	[redacted]	FAS	
2.2.2		FAS	
2.3.1		FAS	
2.3.2		FAS	
Genital-BSA/T-BSA			
2.4.1	Summary and Analysis of Genital-BSA During the Treatment Period	FAS	
2.4.2	Summary and Analysis of Genital-BSA by Sex During the Treatment Period	FAS	
2.5.1	Summary and Analysis of T-BSA During the Treatment Period	FAS	

Table No.	Title	Population	Standard
Genital-VASI/[redacted]			
2.6	Summary and Analysis of Genital-VASI During the Treatment Period	FAS	
2.7.1	[redacted]	FAS	
2.7.2		FAS	
2.7.3		FAS	
2.7.4		FAS	
Color-Matching Questions			
2.8	Summary and Analysis of Participants in Each Category for the Color-Matching Question During the Treatment Period	FAS	
[redacted]			
2.9.1	[redacted]	FAS	
2.9.2		FAS	
[redacted]			
2.10.1	[redacted]	FAS	
2.10.2		FAS	
Itch NRS			
2.11	Summary and Analysis of Itch NRS During the Treatment Period	FAS	
[redacted]			
2.12	[redacted]	FAS	
[redacted]			
2.13.1	[redacted]	FAS	
2.13.2		FAS	
Target Lesion			
2.14	Summary and Analysis of Size of Target Lesion in the Genital Region During the Treatment Period	FAS	
Safety			
Exposure and Compliance			
3.1.1	Summary of Exposure During Treatment Period	FAS	X
3.1.2	Summary of Study Drug Compliance During Treatment Period	FAS	X
Adverse Events			
3.2.1	Overall Summary of Treatment-Emergent Adverse Events	FAS	X
3.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	FAS	X
3.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X

Table No.	Title	Population	Standard
3.2.5.	Summary of Application Site Reactions by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.6	Summary of Application Site Reactions by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.7	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.8	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.9	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.10	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.11	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.12	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.13	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.14	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.15	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.16	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.17	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	FAS	X
Laboratory Values and Vital Signs			
3.3.1	Summary of Laboratory Values - Hematology	FAS	X
3.3.2	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Abnormal Value	FAS	X
3.3.3	Summary of Laboratory Values - Chemistry	FAS	X
3.3.4	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Abnormal Value	FAS	X
3.4.1	Summary of Systolic Blood Pressure	FAS	X
3.4.2	Summary of Diastolic Blood Pressure	FAS	X
3.4.3	Summary of Pulse	FAS	X
3.4.4	Summary of Respiration Rate	FAS	X
3.4.5	Summary of Body Temperature	FAS	X

Listings

Listing No.	Title
Demographic and Baseline Characteristics	
2.1.1	Participant Enrollment and Disposition Status
2.1.2	Participant Inclusion and Exclusion Criteria Violations
2.2.1	Protocol Deviations and Violations
2.3	Analysis Populations

Listing No.	Title
2.4.1	Demographic Characteristics
2.4.2	Baseline Disease Characteristics
2.4.3	Medical History
2.4.4	Prior and Concomitant Medications
2.4.5	Prior Medications for Vitiligo
2.4.6	Prior Therapies for Vitiligo
2.5	Study Drug Exposure and Compliance
Efficacy	
2.6.1	Genital VNS Score
2.6.2	[redacted]
2.6.3	[redacted]
2.6.4	Genital-BSA
2.6.5	T-BSA
2.6.6	Genital-VASI Score
2.6.7	[redacted]
2.6.8	Color-Matching Questions
2.6.9	[redacted]
2.6.10	[redacted]
2.6.11	Itch NRS Score
2.6.12	[redacted]
2.6.13	[redacted]
2.6.14	Size of Target Lesion in the Genital Region
Adverse Events	
2.7.1	Adverse Events
2.7.2	Serious Adverse Events
2.7.3	Grade 3 or Higher Adverse Events
2.7.4	Adverse Events with a Fatal Outcome
2.7.5	Treatment-Related Adverse Events
2.7.6	Adverse Events Leading to Interruption of Study Drug
2.7.7	Adverse Events Leading to Study Drug Discontinuation
2.7.8	Application Site Reactions
2.7.9	Adverse Events of Interest
Laboratory Data and Vital Signs	
2.8.1.1	Clinical Laboratory Values - Hematology
2.8.1.2	Clinical Laboratory Values - Chemistry
2.8.1.3	Abnormal Clinical Laboratory Values - Hematology
2.8.1.4	Abnormal Clinical Laboratory Values - Chemistry
2.8.2.1	Vital Signs
2.8.2.2	Abnormal Vital Sign Values
2.8.2.3	Alert Vital Sign Values