16.1.9 Documentation of Statistical Methods

STATISTICAL ANALYSIS PLAN FOR STUDY ANB019-206

Trial Sponsor:	AnaptysBio, Inc.
Protocol Number:	ANB019-206
IND Number:	136145
EUDRACT Number:	2020-003476-41
Investigational Drug:	Anti-interleukin 36 receptor monoclonal antibody
Indication:	Ichthyosis
Drug Number:	ANB019 (Imsidolimab)
Dosage Form/Strength/Dose:	Solution for Injection/200 mg per Injection • Placebo Group: Placebo, administered as 2 mL x 2 SC injections on Day 1; 2 mL x 1 SC injection on Days 29, 57 and 85; 400-mg dose of imsidolimab, administered as 2 mL × 2 SC injections at 200 mg each on Day 113; 200-mg dose of imsidolimab, administered as 2 mL × 1 SC injection at 200 mg on Day 141, 169 and 197. • ANB019 Group: 400-mg dose, administered as 2 mL × 2 SC injections at 200 mg each on Day 1; 200-mg dose, administered as 2 mL × 1 SC injection at 200 mg on Day 29, 57, 85, 113, 141, 169 and 197.

Protocol Title: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ANB019 in the Treatment of Subjects with Ichthyosis

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SIGNATURES

Study Biostatistician: [redacted]

Everest Clinical Research, Inc.

[redacted] 12 Jan 2022 02:01:04 (-05:00)

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0cd33791-1e6c-4004-ab82-014a04636896

Signature **Date**

Peer Review Biostatistician: [redacted]

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d63bab85-895c-40aa-ac4a-72faf335fc86

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Approved by: [redacted]

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AnaptysBio, Inc.

[redacted] [redacted]
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[redacted] [redacted]
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Signature **Date**

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GLOSSARY OF ABBREVIATIONS

Abbreviation	Term
ADA	Anti-drug antibody
AE	Adverse event
ATC	Anatomical therapeutic chemical
BMI	Body mass index
BSA	Body surface area
CDLQI	Children's Dermatology Life Quality Index
CRF	Case report form
DLQI	Dermatology Life Quality Index
ECG	Electrocardiograms
eCRF	Electronic case report forms
eDiary	Electronic diary
EOS	End of Study
EudraCT	European Clinical Trials Database
Everest	Everest Clinical Research
FSH	Follicle-stimulating hormone
IASI	Ichthyosis Area Severity Index
IASI-E	Ichthyosis Area Severity Index (Erythema)
IASI-S	Ichthyosis Area Severity Index (Scaling)
IGA	Investigator global assessment
IgE	Immunoglobulin E
IL	Interleukin
IND	Investigational new drug
iQoL-32	Ichthyosis Quality of Life-32 Items
ITT	Intent-to-treat
MedDRA	Medical Dictionary for Regulatory Activities
NASA	Netherton Area and Severity Assessment
NRS	Numeric rating scale

GLOSSARY OF ABBREVIATIONS

OLE	Open-label extension
PGI-C	Patient Global Impression of Change
PGI-S	Patient Global Impression of Severity
PK	Pharmacokinetic
PT	Preferred Term
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SAS	Statistical analysis system
SC	Subcutaneous/subcutaneously
SD	Standard deviation
SoA	Schedule of Activities
SOC	System organ class
SOP	Standard operating procedure
TB	Tuberculosis
TEAE	Treatment-emergent adverse event
TEWL	Transepidermal water loss
WHO-DD	World Health Organization drug dictionary
WOCBP	Woman of childbearing potential

1. INTRODUCTION

This Statistical Analysis Plan (SAP) outlines the statistical methods for the display, summary and analysis of data collected within the scope of the latest version of the ANB019-206 Protocol (Version 1.0 dated October 30, 2020). As with any SAP, the proposed methods and approaches to the data analysis should be deemed as flexible. The analysis of the data should allow changes in the plan to the extent that deviations from the original plan would provide a more reliable and valid analysis of the data. As such, the statistical analysis to a certain degree is iterative since much of the planning is based on assumptions that require verification. The purpose of this plan is to provide general guidelines from which the analysis will proceed. Nevertheless, deviations from these guidelines must be substantiated by a sound statistical rationale.

The SAP should be read in conjunction with the study protocol and the Case Report Forms (CRFs). This version of the SAP has been developed using the final version of the protocol mentioned above and the final version of the annotated CRFs dated January 13, 2021.

This study is designed to evaluate the efficacy and safety of ANB019 in the treatment of subjects with ichthyosis. (See Protocol **Sections 2.1** to **2.3** for details). This study was terminated due to low subject enrollment, therefore no efficacy analyses will be conducted.

2. STUDY OBJECTIVES

2.1 Primary Objective

- To determine the effect of imsidolimab compared with placebo as measured by the Ichthyosis Area Severity Index (IASI) total score

2.2 Secondary Objectives

- To evaluate the effect of imsidolimab compared with placebo on ichthyosis signs and symptoms, and quality of life in subjects with ichthyosis
- To determine the safety of imsidolimab in the treatment of ichthyosis

2.3 Exploratory Objectives

- To further evaluate the effect of imsidolimab on ichthyosis signs and symptoms, and quality of life in subjects with ichthyosis
- To explore the effect of imsidolimab on cutaneous biomarkers
- To test for immunogenicity to imsidolimab
- To evaluate immunoglobulin E (IgE) levels in subjects with Netherton Syndrome
- To describe the pharmacokinetic (PK) profile of imsidolimab in subjects with ichthyosis

3. STUDY DESIGN

3.1 Study Design

This study is a Phase 2, multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of imsidolimab compared with placebo in adolescent and adult subjects with ichthyosis. This study will also characterize the PK profile of imsidolimab and explore the immune response to imsidolimab in subjects with ichthyosis. Approximately 24 male and female subjects, aged 12 to 75 years, with a clinically confirmed diagnosis of ichthyosis will be enrolled in this study. Subjects will have their ichthyosis subtype confirmed by genetic testing. In addition, the subjects will have the following characteristics at Day 1: (1) Ichthyosis Area Severity Index (IASI) total score of at least 18, (2) IASI-E (Erythema) score of at least 2 (moderate severity) in at least 1 body region and IASI-S (Scaling) score of at least 2 (moderate severity) in at least 1 body region, and (3) Body Surface Area (BSA) involved with ichthyosis of at least 50%.

The expected study duration per subject is approximately 44 weeks. The study will include a screening period of up to 30 days, followed by a 16-week placebo-controlled period, a 16-week open-label extension (OLE) period, and an 8-week safety follow-up period. During the placebo-controlled period, eligible subjects will be randomized (2:1) to receive either imsidolimab or placebo, subcutaneously (SC) administered on 4 occasions:

- 400-mg dose of imsidolimab or placebo on Day 1
- 200-mg dose of imsidolimab or placebo on Days 29, 57, and 85

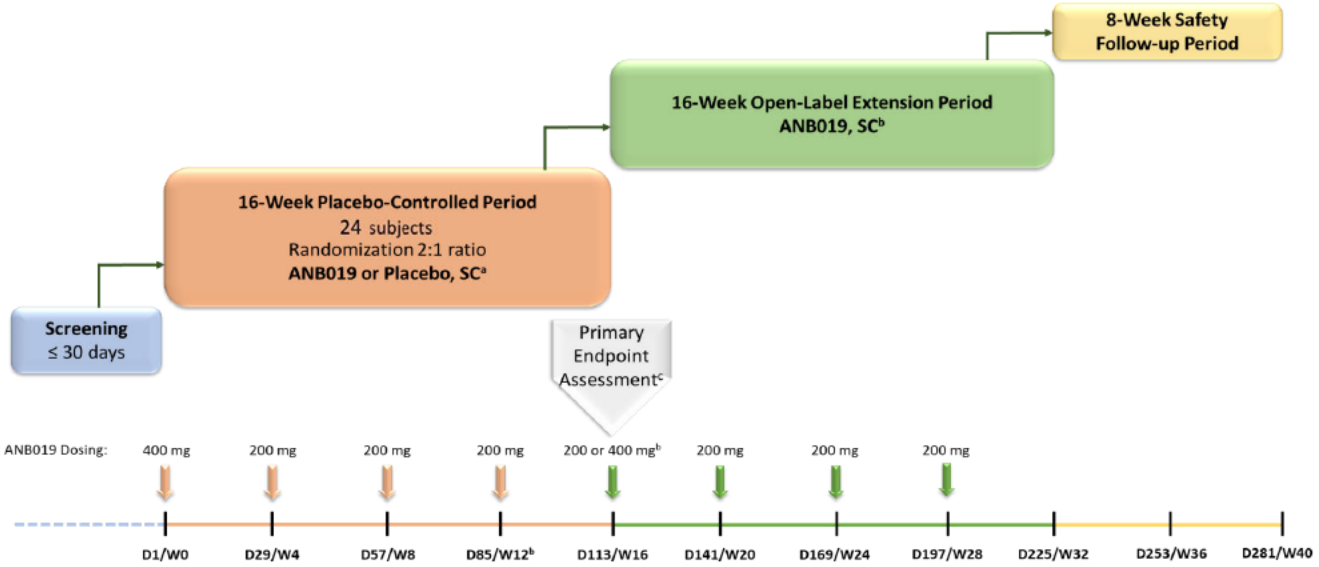
During the open-label extension period, all subjects were to receive imsidolimab, SC administered on 4 occasions:

- 400-mg dose of imsidolimab on Day 113 for subjects assigned to placebo during the placebo-controlled period
- 200-mg dose of imsidolimab on Day 113 for subjects assigned to imsidolimab during the placebo-controlled period
- 200-mg dose of imsidolimab on Days 141, 169, and 197 for all subjects

However, due to study termination, no subjects reached the open-label extension period.

The overall study design is summarized and illustrated in **Figure 1**.

Figure 1 Study Schema



Abbreviations: D, day; SC, subcutaneously; W, week

[a] During the placebo-controlled period, subjects will be randomized (2:1) to receive either ANB019 or placebo, SC administered on 4 occasions: 400-mg dose of ANB019 or placebo on Day 1; 200-mg dose of ANB019 or placebo on Days 29, 57, and 85

[b] During the open label extension, all subjects will receive ANB019, SC administered on 4 occasions Subjects assigned to ANB019 during the placebo-controlled period will continue to receive a 200-mg dose of ANB019 on Days 113, 141, 169, and 197 Subjects assigned to placebo during the placebo-controlled period will receive a 400-mg dose of ANB019 on Day 113, followed by a 200-mg dose of ANB019 on Days 141, 169, and 197

[c] All subjects will receive ANB019 during the open-label extension period starting on Day 113 (Week 16) visit until Day 197 (Week 28) visit The placebo-controlled period ends on Day 113 (Week 16) visit, before study treatment administration The open-label extension period starts when the study treatment is administered on Day 113 (Week 16) visit Pre-dose assessments performed on Day 113 (Week 16) will be used to evaluate the primary and secondary efficacy endpoints, as well as the safety, tolerability, and immune response of ANB019 compared with placebo

3.2 Randomization

On Day 1, after verification that all inclusion and no exclusion criteria have been met, the subjects will be randomized in a 2:1 ratio to receive imsidolimab or placebo. Randomization will be stratified based on erythema highest severity at baseline as evaluated by IASI-E [moderate (2) vs severe/very severe (3, 4)]. Subjects who receive the wrong treatment will be analyzed according to the treatment they were supposed to be randomized to in the efficacy analyses. In the safety analyses, subjects will be analyzed according to the treatment they actually received.

3.3 Interim Analysis

At least one interim analysis was planned but not conducted due to study termination.

Due to the termination of the study, the planned interim analysis will not be conducted.

3.4 Sample Size

The primary efficacy endpoint is the change from baseline in the IASI total score at Week 16. The null hypothesis (H_0) to be tested is that the mean change from baseline in IASI total score is the same for imsidolimab and placebo. Assuming a 0.5 correlation between IASI total scores at baseline and Week 16, a common standard deviation (SD) of 9, and an 11% dropout rate, an enrollment of 16 subjects (leaving 14 after dropout) in the imsidolimab treatment arm and 8 subjects (leaving 7 after dropout) will have at least 80% power to detect the overall treatment effect for a two sample t-test using a 2-sided significance level of α=0.05, where the difference in the mean change from baseline between the imsidolimab and placebo group is assumed to be 12.3 points. No adjustments to α are needed in this study for interim analysis or multiple comparisons.

Historical data was used to support the power calculation. The common SD estimate of 9 in the sample size /power calculation was obtained from Paller, et al, 2017. The baseline IASI score of 30 was approximated from overall baseline IASI score from Paller, et al, 2017, which reported around 28 and was slightly modified due to varying estimate of ichthyosis subtypes. The between-group difference in reduction from baseline in IASI score at Week 16 was estimated as 12.3 points if the study could achieve 80% power using the common SD = 9 and two sample t-test with a 2-sided significance level of 0.05. Since placebo response is assumed to be an approximate 10% improvement from the baseline IASI score, given the estimated mean baseline IASI score of 30, this represents a 3-point reduction in the score for the placebo group. Thus, the assumption was made that the change from baseline would be -3 points for placebo, and the change from baseline in the imsidolimab group would be -15.3 points in order that the between-group difference of the change from baseline in IASI at Week 16 equals -12.3 points, which is calculated as -15.3 - (-3).

3.5 Study Procedures and Schedule of Activities

Study procedures and their timing are summarized in the Schedule of Activities (**Table 1**). Table 1 below has been modified according to the note to file of the protocol (dated 06-Nov-2020).

Table 1 Schedule of Activities

	Screening Period	Placebo-Controlled Period									Open-Label Extension Period					Follow-up Period	
Study visit Window (days)	Screening (-30 to -1)	D1 W0	D3	D8 W1 (±1)	D15 W2 (±2)	D29 W4 (±2)	D43 W6 (±4)	D57 W8 (±4)	D71 W10 (±4)	D85 W12 (±4)	D113 W16[a] (±4)	D141 W20 (±4)	D169 W24 (±4)	D197 W28 (±4)	D225 W32 (±4)	D253 W36 (±4)	D281 W40 (EOS/ET)[b] (±5)
Informed consent / assent (when applicable)[c]	X																
Demographics	X																
Inclusion and exclusion criteria	X	X															
Medical and surgical history	X	X															
Height and weight[d]	X	X									X				X		X
Pain and pruritus NRSs, DLQI, CDLQI, PGI-S, PGI-C[e]		X		X		X		X		X	X	X	X	X	X	X	X
iQoL-32[e]		X				X		X		X	X	X	X	X	X	X	X
BSA[e]	X	X		X		X		X		X	X	X	X	X	X	X	X
IGA[e]		X		X		X		X		X	X	X	X	X	X	X	X
IASI assessment[e]	X	X		X		X		X		X	X	X	X	X	X	X	X
NASA[e]		X		X		X		X		X	X	X	X	X	X	X	X
Complete physical examination[f]	X	X				X		X		X	X				X		X
12-Lead ECG[g]	X	X				X					X	X			X		X
Chest X-ray[h]	X																
Vital signs[i]	X	X		X		X		X		X	X	X	X	X	X	X	X
Hematology and biochemistry[j]	X	X		X		X		X		X	X	X	X	X	X	X	X
Urinalysis[j]	X	X				X		X		X	X	X		X	X		X
TB screening (QuantiFERON®-TB Gold test)[j]	X																
Viral serology[j]	X																
Serum pregnancy test (WOCBP only)[j]	X																X

	Screening Period	Placebo-Controlled Period									Open-Label Extension Period					Follow-up Period	
Study visit Window (days)	**Screening (-30 to -1)**	**D1 W0**	**D3**	**D8 W1 (±1)**	**D15 W2 (±2)**	**D29 W4 (±2)**	**D43 W6 (±4)**	**D57 W8 (±4)**	**D71 W10 (±4)**	**D85 W12 (±4)**	**D113 W16[a] (±4)**	**D141 W20 (±4)**	**D169 W24 (±4)**	**D197 W28 (±4)**	**D225 W32 (±4)**	**D253 W36 (±4)**	**D281 W40 (EOS/ET)[b] (±5)**
Urine pregnancy test (WOCBP only)[j]		X				X		X		X	X	X	X	X	X	X	
FSH[j]	X																
Blood samples for PK[k]		X[k]		X[l]		X		X		X[l]	X	X[l]	X[l]	X[l]	X	X[l]	X
Blood samples for ADA		X				X		X		X[l]	X	X[l]			X		X
Blood sample for IgE levels evaluation[m]		X									X				X		
TEWL		X				X		X		X	X						X
Tape strips collection[n]		X				X					X		X				
Skin biopsies (optional)[n]		X				X					X		X				
Randomization		X															
Photography[o]	X	X				X					X				X		X
Telephone contact[p]			X		X		X		X								
Study treatment administration[q]		X				X		X		X	X	X	X	X			
Subject diary distribution/collection /review[r]		X				X		X		X	X	X	X	X	X	X	X
AE/SAE review		X	Continuously														
Concomitant medication review		X	Continuously														

Abbreviations: ADA, anti-drug antibody; AE, adverse event; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; D, day; DLQI, Dermatology Life Quality Index; ECG, electrocardiogram; EOS, end of study; ET, early termination; FSH, follicle stimulating hormone; IASI, Ichthyosis Area and Severity Index; IGA, Investigator Global Assessment; IgE, immunoglobulin E; iQoL-32, Ichthyosis Quality of Life- 32 items; NASA, Netherton Area and Severity Assessment; NRS, Numeric Rating Scale; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity; PK, pharmacokinetics; SAE, serious adverse event; SC, subcutaneously; SoA, Schedule of Activities; TB, tuberculosis; TEWL, transepidermal water loss; W, week; WOCBP, woman of childbearing potential

[a] All subjects will receive ANB019 during the open-label extension period starting on Day 113 (Week 16) visit until Day 197 (Week 28) visit The placebo-controlled period ends on Day 113 (Week 16) visit, before study treatment administration The open-label extension period starts when the study treatment is administered on Day 113 (Week 16) visit

[b] The ET visit will include all procedures to be done at the ET/EOS visit (Day 281/Week 40 visit)

[c] Adolescent subjects who reach 18 years of age during the study must be reconsented as adults

[d] Height to be measured at screening only for subjects ≥ 18 years of age, and at screening, Day 113 (Week 16), and Day 281 (Week 40)/ET for subjects < 18 years of age

[e] Refer to Protocol **Section 8.1** for details and instructions regarding pain and pruritus NRSs (worst and average), iQoL-32 (subjects ≥ 15 years of age only), DLQI (subjects ≥ 16 years of age), CDLQI (subjects < 16 years of age), PGI-S, PGI-C, BSA, IGA, IASI, NASA, and TEWL PGI-C is not to be performed at Day 1

[f] Refer to Protocol **Section 8.2.4** for details regarding the complete physical examination

[g] Refer to Protocol **Section 8.2.6** for details and instructions regarding the ECG In addition to the time points specified in the SoA, ECGs may be performed at any time during the study if in the opinion of the Investigator it is clinically warranted

[h] Bidirectional posterior-anterior view and lateral view chest X-ray, or as indicated by local treatment guidelines or practice, will be performed at screening If a chest X-ray was performed within 6 months of screening and no clinically significant abnormality was observed, it can be skipped at screening

[i] Refer to Protocol **Section 8.2.5** for details and instructions regarding vital signs

[j] If a negative QuantiFERON®-TB test result was obtained within 6 months of screening, it can be skipped at screening The FSH testing is performed for women not of childbearing potential who are postmenopausal (at least 12 months of amenorrhea without an alternative medical cause) An adolescent patient who experiences menarche during the trial will be considered a WOCBP (refer to Appendix 1 for definition of WOCBP) and will be required to follow the contraceptive guidance in Appendix 1 and undergo scheduled pregnancy testing Additional pregnancy testing may be performed whenever a menstrual cycle is missed or when pregnancy is otherwise suspected Refer to Protocol **Appendix 10** for details and instructions regarding clinical laboratory parameters

[k] On Day 1, samples for PK will be collected at predose and 2 hours (± 10 min) post SC administration In addition, samples for PK will also be collected at the time points specified in Protocol **Table 4**

[l] On these days, blood for PK and ADA will only be collected from adult subjects (≥ 18 years) Adolescent subjects who reach 18 years of age during the study and are reconsented as adults will follow the adult schedule for PK and ADA assessments (refer also to Protocol **Table 4** and **Table 5**)

[m] For subjects with Netherton syndrome only

[n] All randomized subjects will be asked to participate in the skin biopsy test; however, the patient's participation is optional Subjects should provide their consent to participate in the skin biopsies Tape stripping will be performed for all randomized subjects as part of this study (not optional) Tape strips and punch biopsies will be collected from the same location (if applicable) on Day 1, 29, 113, and 169 (from lesional skin)

[o] At selected study centers only

[p] Subjects will be contacted by phone on Days 3, 15, 43, and 71, to assess for AEs and concomitant medications

[q] During the placebo-controlled period, subjects will receive either ANB019 or placebo SC administered as follows: a 400-mg dose of ANB019 or placebo on Day 1; a 200-mg dose of ANB019 or placebo on Days 29, 57, and 85 The placebo-controlled period ends on Day 113 (Week 16) visit, before study treatment administration All subjects will receive ANB019 on Day 113 (Week 16) visit Subjects assigned to ANB019 during the placebo-controlled period will continue to receive a 200-mg dose of ANB019 on Days 113, 141, 169, and 197 Subjects assigned to placebo during the placebo-controlled period will receive a 400-mg dose of ANB019 on Day 113, followed by a 200-mg dose of ANB019 on Days 141, 169, and 197

[r] Type/frequency of emollient application (if applicable) must be recorded by the patient in a diary throughout the study Bath/shower time and duration must be recorded by the patient in a diary throughout the study

[s] At screening, prior medications should be reviewed and documented Refer to Protocol **Section 6.5**

4. DATA AND ANALYTICAL QUALITY ASSURANCE

The overall quality assurance procedures for the study data, statistical programming and analyses are described in Everest's SOPs. Detailed data management procedures are documented in the Data Management Plan, Data Validation Check Specifications, and Data Review Plan. Detailed statistical and programming quality control and quality assurance procedures are documented in the Statistical Analysis and Programming Quality Control/Quality Assurance Plan.

The study endpoints and analytic approaches are both prospectively defined and documented in the protocol and in this SAP. The SAP will be finalized prior to the final database lock and data analysis. The Per Protocol Analysis will not be generated or used due to the study early termination. The list of protocol deviations may not be finalized prior to the final data base lock but will be prior to the final data analysis.

5. ANALYSIS SETS

5.1 Intent-to-Treat Analysis Set

The Intent-to-Treat (ITT) Analysis Set will include all randomized subjects. In this analysis set, treatment will be assigned based upon the treatment arm to which subjects were randomized regardless of which treatment they received. The ITT Analysis Set will be used for subject demographic summaries and efficacy listings.

5.2 Safety Analysis Set

The Safety Analysis Set will include all randomized subjects who receive at least 1 dose of imsidolimab or placebo. The Safety Analysis Set will be used for all safety analyses. Subjects will be analyzed as treated. If a subject receives both treatments during placebo-controlled period, they will be analyzed in the imsidolimab group. The Safety Analysis Set will be used for adverse event and laboratory summaries and safety listings.

5.3 Pharmacokinetic Analysis Set

The PK Analysis Set will not be derived because no PK samples will be analyzed.

6. SPECIFICATION OF ENDPOINTS AND VARIABLES

6.1 Demographic and Baseline Characteristics

6.1.1 Demography and Baseline Characteristics

Subject demographics will be summarized overall as well as by treatment arm in the baseline disease characteristics output. Demographics and baseline characteristics will be listed.

Demographic variables summarized will include the following:

- Age

- Age Group ([12, 18) years, [18, 65) years or [65,75] years)
- Age Group ([12, 16) years, >=16 years)
- Age Group ([12, 15) years, >=15 years)
- Sex
- Race
- Ethnicity (Hispanic or Non-Hispanic)
- Country
- Woman of childbearing potential (Yes or No)
- Weight (kg)
- Height (cm)
- Body mass index (BMI; kg/m^2)

6.1.2 Medical History

Medical history will be collected at the Screening visit and will be coded using the version of the Medical Dictionary for Regulatory Activities (MedDRA) specified in the approved Data Management Plan.

6.1.3 Prior, Concomitant, and Rescue Medications/Treatments

All medications taken within 6 months prior to Day 1 and all concomitant therapy taken by the patient while on study will be recorded on the Concomitant Medications CRF page. Prior medication/treatment is any medication/treatment stopped prior to the first dose of study treatment.

Concomitant medication/treatment is any medication/treatment continued to be taken at the time of the first dose or started after the first dose of study treatment. Subjects must apply an emollient of their choice on their skin, including on lesions, throughout the study. The type and frequency of emollient application will be recorded via an electronic diary (eDiary) once per day.

Rescue medications taken by the subject to control intolerable symptoms of ichthyosis during the study will be recorded on the Rescue Medication CRF page.

Coding: Verbatim medication or treatment terms will be coded by Everest and will be assigned a preferred name and an Anatomical Therapeutic Chemical Class (ATC) term using the version of the World Health Organization drug dictionary (WHO-DD) specified in the approved Data Management Plan.

Multiple ATC assignments: If there are multiple ATC codes assigned to the same concomitant medication, the "primary" one based on a medical evaluation will be used.

Uncoded Medication: Before the database lock, uncoded medications/treatments may be assigned the string "UNCODED" as the ATC code, and the verbatim term will be used as the preferred name, so they can be included in the summary tables. In final datasets, all the names will be coded.

6.2 Efficacy

Due to study termination, not all efficacy endpoints will be derived, but all collected data will be presented in listings. The efficacy variables include: Ichthyosis Area Severity Index (IASI), Netherton Area and Severity Assessment (NASA), Investigator Global Assessment (IGA), pruritus Numeric Rating Scale (NRS), pain NRS, Body Surface Area (BSA), Dermatology Life Quality Index (DLQI), Children's

Dermatology Life Quality Index (CDLQI), Patient Global Impression of Severity (PGI-S), Patient Global Impression of Change (PGI-C), Ichthyosis Quality of Life-32 Items (iQoL-32), transepidermal water loss (TEWL), Investigator Global Assessment (IGA).

6.2.1 Ichthyosis Area Severity Index

The IASI will be assessed at the visits specified in the Schedule of Activities in **Section 3.5** The IASI quantifies the severity of a patient's ichthyosis based on the severity of erythema or scaling, and the percentage of BSA affected (Paller 2017, Malik 2019, Czarnowicki 2018). The IASI takes into account the degree of erythema and scaling (each scored separately with ranges from 0=none to 4=very severe) for each of four body regions (A1 = head and neck, A2 = upper limbs, A3 = trunk, and A4 = lower limbs), with adjustments for the percentage of BSA involved for each body region (B1 = percentage within head and neck, B2 = percentage within upper limbs, B3 = percentage within trunk, and B4 = percentage within lower limbs, each with values of 0 = 0%, 1 = 1-9%, 2 = 10-29%, 3 = 30-49%, 4 = 50-69%, 5 = 70-89%, and 6 = 90-100%) and for the proportion of the body region to the whole body (C1 = 0.1 for head and neck, C2 = 0.2 for upper limbs, C3 = 0.3 for trunk, and C4 = 0.4 for lower limbs). Three scores will be auto calculated in the electronic case report form (eCRF): IASI-E (Erythema) score (range from 0 to 24), IASI-S (Scaling) score (range from 0 to 24), and IASI total score (range from 0 to 48). The formulas for these scores are:

$$IASI\text{-}E = (A1_{erythemia})(B1)(C1) + (A2_{erythemia})(B2)(C2) + (A3_{erythemia})(B3)(C3) + (A4_{erythemia})(B4)(C4)$$

$$IASI\text{-}S = (A1_{scaling})(B1)(C1) + (A2_{scaling})(B2)(C2) + (A3_{scaling})(B3)(C3) + (A4_{scaling})(B4)(C4)$$

$$IASI\ total = ISAI\text{-}E + ISAI\text{-}S$$

6.2.2 Netherton Area and Severity Assessment

The Netherton Area and Severity Assessment (NASA) quantifies the severity of subjects' ichthyosis based on the severity of erythema, infiltration/papulation, lichenification, and scaling, and the percentage of BSA affected (Yan 2010). It will be assessed at the visits specified in the Schedule of Activities in **Section 3.5** for subjects with Netherton Syndrome.

Erythema (E), infiltration/papulation (I), lichenification (L), and scaling (S) will be scored separately for each of four body regions (head and neck, upper limbs, trunk, and lower limbs). Adjustments will be made for the area involved in each body region, represented by a 7-point numeric scale (0 = 0%, 1 = 1-9%, 2 = 10-29%, 3 = 30-49%, 4 = 50-69%, 5 = 70-89%, and 6 = 90-100%), and for the proportion of the body region to the whole body (0.1 for head and neck, 0.2 for upper limbs, 0.3 for trunk, and 0.4 for lower limbs). The average degree of severity of each body region will be scored separately (range from 0=none to 3=severe, half scores are allowed). Five scores will be auto calculated in the eCRF: $NASA_{Head/Neck}$, $NASA_{Upper\ limbs}$, $NASA_{Trunk,}$ $NASA_{Lower\ Limbs}$, and $NASA_{Total}$ (range from 0 to 72). The formulas for these scores are:

$$NASA_{Head/Neck} = \left(E_{Head/Neck} + I_{Head/Neck} + L_{Head/Neck} + S_{Head/Neck}\right) \times Area \times 0.1$$

$$NASA_{Upper\ limbs} = \left(E_{Upper\ limbs} + I_{Upper\ limbs} + L_{Upper\ limbs} + S_{Upper\ limbs}\right) \times Area \times 0.2$$

$$NASA_{Trunk} = (E_{Trunk} + I_{Trunk} + L_{Trunk} + S_{Trunk}) \times Area \times 0.3$$

$$NASA_{Lower\ limbs} = (E_{Lower\ limbs} + I_{Lower\ limbs} + L_{Lower\ limbs} + S_{Lower\ limbs}) \times Area \times 0.4$$

$$NASA_{Total} = \left(NASA_{Head/Neck} + NASA_{Upper\ limbs} + NASA_{Trunk} + NASA_{Lower\ limbs}\right)$$

6.2.3 Pruritus and Pain Numeric Rating Scale

The intensity of pruritus and pain will be assessed using worst numeric rating scale (NRS), respectively. The worst pruritis NRS will be assessed at the visits specified in the Schedule of Activities in **Section 3.5.** Subjects will be asked to assign a numerical score representing of the worst pruritus intensity over the last 24 hours on a scale of 0 (no symptoms) to 10 (worst imaginable symptoms). The intensity of average pruritus and pain over the last 7 days will also by assessed using the same numeric rating scale.

6.2.4 Body Surface Area

The overall BSA affected by ichthyosis will be evaluated (from 0% to 100%) at the visits specified in the Schedule of Activities in **Section 3.5.** The palmar surface of one hand (using the subject's hand and including the fingers) represents 1% of his or her total BSA (Thomas 2007).

6.2.5 Investigator Global Assessment

The IGA of ichthyosis severity will be assessed at the visits specified in the Schedule of Activities in **Section 3.5** The IGA will be used to evaluate the current state of ichthyosis on the entire body. It is a 5-point morphological assessment of overall ichthyosis severity: 0, clear; 1, almost clear; 2, mild; 3, moderate; 4, severe.

6.2.6 Dermatology Life Quality Index

The DLQI questionnaire is a simple 10-question validated questionnaire (Finlay 1994). These will be assessed at the visits specified in the Schedule of Activities in **Section 3.5**. The DLQI will be administered to subjects ≥ 16 years old.

6.2.7 Children's Dermatology Life Quality Index

The CDLQI questionnaires is a simple 10-question validated questionnaire (Lewis-Jones 1995). This will be assessed at the visits specified in the Schedule of Activities in **Section 3.5**. The CDLQI will be administered to subjects < 16 years old. Subjects will be administered the same questionnaire during the entire study based on their age at Day 1, so no subjects who begin the study with the CDLQI will switch to DLQI.

6.2.8 Patient Global Impression of Severity

PGI-S is a single-item question, which asks the patient to rate the current severity of the ichthyosis now ("Clear skin", "Mild", "Moderate", and "Severe"). This will be assessed at each visit as specified in the Schedule of Activities in **Section 3.5.**

6.2.9 Patient Global Impression of Change

PGI-C is a single item, self-administered questionnaire, which asks the patient to rate the change in their symptom severity ("Very much better" to "Very much worse"). The rating includes 7 scales, i.e., "Very much better", "Much better", "A little better", "No change", "A little worse", "Much worse", "Very much worse". This will be assessed at each visit as specified in the Schedule of Activities in **Section 3.5**.

6.2.10 Ichthyosis Quality of Life-32 Items

The iQoL-32 is a patient-reported questionnaire aimed measure how much ichthyosis has affected the patient's quality of life during the past 4 weeks. It will be assessed at the visits specified in the Schedule of Activities in **Section 3.5** Each item is scored from 0 to 4, and the total score is the sum of the individual items (range from 0 to 128). It will only be assessed for subjects >=15 years of age on Day 1 (it will not be administered to subjects who turn 15 after Day 1).

6.2.11 Transepidermal Water Loss

The TEWL evaluates the amount of water that passively evaporates through skin to the external environment to assess the clinical severity of ichthyosis and the associated effect on skin barrier function. It will be assessed at the visits specified in the Schedule of Activities in **Section 3.5**. At Day 1, the Investigator will select an anatomical region (as specified in the SRM) with representative ichthyosis lesions for each patient and perform 3 readings; the location will be recorded. TEWL readings will be taken in standard room ambient conditions (22°C to 25°C, 40% to 60% relative humidity).

6.3 Safety

Adverse events, serious adverse events (SAEs), AEs leading to discontinuation of study treatment, and AEs leading to withdrawal from study, as well as changes in vital signs, clinical laboratory parameters (hematology, biochemistry, and urinalysis), and 12-lead ECGs will be evaluated to meet the safety objectives of the study.

Adverse Events will be closely monitored on each patient throughout their participation in the study. Safety assessments for other safety variables will occur as detailed in the Schedule of Activities in **Section 3.5**.

6.3.1 Extent of Exposure to Study Medication and Compliance

The number of doses received by the patient for a study treatment will be calculated as the sum of the doses received in the placebo-controlled period and overall.

The number of days of exposure to a study treatment will be defined as (Date of last treatment – Date of first dose of treatment) + 1.

Total dose received will be the total amount (in mg) of study treatment taken during the entire treatment period (placebo-controlled + open label extension).

Dose intensity is for a specific period is defined as (total dose received during a period/total expected dose during the same period) x 100%.

During the placebo-controlled period, the expected number of doses for imsidolimab study treatment is:

- 400 mg for the first dose of study treatment.
- 200 mg for study drug administrations after the first dose of study treatment.

No subjects received study drug in the open label extension period, so the dose intensity will not be reported for this period.

6.3.2 Adverse Events

AEs experienced by the subjects will be collected throughout the entire study and will be coded using the version of the MedDRA specified in the approved Data Management Plan. Analysis of adverse events will be carried out on the Safety Analysis Set.

An adverse event is considered treatment-emergent if the date of onset is during or after first dose of study treatment, or if the AE present at baseline that worsens in either intensity or frequency after first dose of study treatment. An adverse event that begins on the same date as the first dose of study treatment is treatment-emergent if the AE begins on or after the time of first dose or if the time of AE onset is unknown.

The severity of AEs will be evaluated as “Mild”, “Moderate”, and “Severe” using the criteria specified in **Section 8.2.1.3.1** of the study protocol.

AEs will be classified as related, possibly related, unlikely to be related, or unrelated to study treatment using the criteria specified in **Section 8.2.1.3.2** of the study protocol.

Adverse events will be categorized as serious or non-serious using the definition specified in **Section 8.2.1.2** of the study protocol.

Events with Partial Onset Dates

All treatment-emergent adverse events (TEAEs) will be included in the tabulations regardless of the completeness of the onset dates. Partial dates will be imputed in order to determine if an AE is treatment-emergent using the imputation rules in **Appendix 1**; however, imputed dates will not be provided in the data listings.

Uncoded Events: Before the database lock, uncoded events will be assigned the string “UNCODED” as the body system, and the verbatim term will be used as the preferred term, so they can be included in the summary tables. In the final dataset, all the adverse events will have been coded.

6.3.2.1 Deaths

All deaths which occur during the study will be listed.

6.3.3 Laboratory Data

Clinical laboratory tests that will be performed in this study are summarized in **Appendix 10** of the study protocol. Local laboratory samples will be collected in the eCRF when the central laboratory results are not available immediately, and the Investigator needs to take an immediate decision for any safety concerns. Local laboratory results will be used for the analysis in case of central laboratory results are missing. All lab data will be listed.

Conversion to the International System of Units

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All laboratory data will be stored in the database with the units in which they are originally reported. Laboratory data in summary tables and patient data listings will be presented in the International System of Units (SI units). Laboratory data not reported in SI units will be converted to SI units before further processing or data analysis.

Abnormal Values

Based upon laboratory normal ranges, laboratory test results will be categorized according to the normal range as low, normal, and high. Subjects with laboratory data outside the normal range will be listed with abnormal values flagged.

6.3.4 Vital Signs

Vital signs including body temperature (°C), pulse rate (bpm), systolic and diastolic blood pressure (mmHg), respiratory rate (breath/min), weight (kg), and height (cm) will be obtained in accordance with the Schedule of Activities in **Section 3.5**. All vital signs data will be listed.

6.3.5 Electrocardiogram (ECG)

ECG parameters including heart rate, as well as RR, PR, QRS, QT, and QTcF intervals will be collected according to the Schedule of Activities in **Section 3.5**.

The outcome of the overall evaluation is to be recorded as normal/abnormal in the eCRF, with any abnormalities being recorded as not clinically significant or clinically significant. All ECG data will be listed.

6.3.6 Other Safety Assessments

The following assessments will be performed, but will not be used to define additional safety parameters for the study: chest X-ray, physical examination, tuberculosis (TB) screening, pregnancy tests (serum or urine), viral serology, and follicle-stimulating hormone (FSH). Data from these assessments will be captured in the eCRF and will be listed.

6.4 Other Assessments

Due to study termination, other assessments planned in the protocol will not be assessed. This includes: PK, immunogenicity and immunoglobulin E levels.

7. STATISTICAL ANALYSIS

7.1 Subject Disposition

Disposition for all subjects will be tabulated and listed. The tabulation will include the number of subjects consented, screened, randomized and treated, randomized but not treated, the number of subjects completing the placebo-controlled period, the number of subjects completing the open-label extension period, the number of subjects who complete the study (including follow-up), the number of subjects who discontinued from study treatment, and the number of subjects who discontinue the study along with the reason for discontinuation.

Randomization stratification factors and treatment assignment will be listed together. If there are any subjects who took study treatment other than what was randomized during the study, both the treatment assigned at randomization and actual treatment(s) received during the double-blind treatment period will be listed. The duration of actual treatment will also be listed.

Randomized subjects who are declared as important protocol deviations will be listed.

7.2 Demographic and Baseline Characteristics

7.2.1 Demography and Physical Characteristics

Demographics variables which are listed in **Section 6.1** will be summarized overall and by treatment and all data will be provided in listings. Continuous baseline parameters will be summarized descriptively using number of subjects, mean, median, standard deviation, minimum, maximum, first quartile, and third quartile. For categorical baseline and demographic parameters, the number and frequencies and percentages of subjects will be provided along with descriptive statistics treating them as a continuous variable.

7.2.2 Medical History

Medical history will be listed for all subjects randomized.

7.2.3 Prior, Concomitant, and Rescue Medications/Treatments

Refer to **Appendix 1** **DATA HANDLING RULES** for definitions of prior and concomitant treatments. Prior, concomitant and rescue medications will be displayed in separate listings. eDiary data capturing emollient use and bath/shower time and duration will also be listed.

7.3 Efficacy Analyses

Due to study termination, no efficacy analysis will be performed. All efficacy data will be listed in data listings.

7.4 Safety Analyses

Safety analyses will be performed using the Safety Analysis Set. Safety parameters include AEs, exposure, clinical laboratory parameters (hematology, biochemistry, and urinalysis), vital signs, and ECGs. Listings of safety parameters will be presented.

7.4.1 Extent of Exposure to Study Medication and Compliance

Descriptive statistics (n, mean, standard deviation, median, minimum and maximum) will be presented for the number of doses received, the number of days of exposure to study treatment, total dose received, total dose expected, and dose intensity by treatment group and summarized for placebo-controlled period. In addition to summary statistics on the dose intensity as a continuous variable, this will also be categorized into bins: 0-20%, >20-40%, >40-60%, >60-80%, >80--100%, and >100%. Dose intensity and dosing information will be listed.

7.4.2 Adverse Events

Adverse events will be summarized by the number and percentage of subjects experiencing an event. Tables will show the overall incidence of AEs, and the incidence for each treatment group. All reported AEs will be listed, but only TEAEs will be summarized.

Adverse Events Counting Rules:

1. A subject with more than one different adverse event in a particular system organ class (SOC) will be counted only once in the total of subjects experiencing adverse events in that particular SOC.
2. A subject having experienced the same event (AE preferred term) more than once during the study will be counted only once in the number of subjects with that event for counts of subjects or incidence measures.
3. If an event changes in intensity or in seriousness during the study, it will be counted only once with the worst grade and seriousness respectively.
4. If the causal relationship to the study drug is assessed differently, it will be counted only once by considering the "Worst" documented degree of relationship.

A TEAE overview summary table will be provided with the incidences of subjects with at least one TEAE, at least one serious TEAE, at least one TEAE related to study treatment, at least one serious TEAE related to study treatment, at least one TEAE leading to treatment discontinuation, at least one serious TEAE leading to treatment discontinuation, at least one TEAE leading to withdrawal from study, at least one serious TEAE leading to withdrawal from study, at least one severe TEAE, at least one severe study treatment-related TEAE, and number of deaths.

Summary tabulation of all TEAEs will be prepared for all subjects, for each treatment, for each primary system organ class, and for each preferred term within a system organ class.

Supporting data listings will be provided with treatment group information, including:

- All adverse events (including any AEs reported in the study)
- Adverse events resulting in study treatment discontinuation
- Adverse events leading to study withdrawal

7.4.3 Laboratory Data

Shift tables (e.g., tables that show the number of subjects who are low, normal, or high at baseline versus each post-baseline scheduled assessment) will be produced for the Safety Analysis Sets.

All data will be displayed in patient data listings for Safety Analysis Sets.

7.4.4 Vital Signs

Vital sign measurements (pulse rate, systolic blood pressure, diastolic blood pressure, body temperature, respiratory rate, weight, and height) during the study will be displayed in a vital signs listing.

7.4.5 Electrocardiogram (ECG)

ECG data (Heart Rate, PR Interval, QRS Interval, QT Interval, and QTcF Interval) will be listed.

7.4.6 Other Safety Assessments

Chest X-ray, physical examination, TB test results, pregnancy test, viral serology, and FSH will be presented in listings for the Safety Analysis Set. Abnormal result of physical examination will be listed. No AEs of special interest will be defined.

8. CHANGES FROM METHODS PLANNED IN THE PROTOCOL

Due to termination of study, the analysis of efficacy and safety variables will be significantly reduced from the originally planned analyses in the study protocol.

9. STATISTICAL SOFTWARE

The statistical software to be used for generation of the tables, listings, and figures is statistical analysis system® (SAS) version 9.4 or higher.

10. REFERENCES

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2. Czarnowicki T, He H, Leonard A, et al. The major orphan forms of ichthyosis are characterized by systemic t-cell activation and Th-17/Tc-17/Th-22/Tc-22 polarization in blood. J Invest Dermatol. 2018 Oct;138(10):2157-2167.
3. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI): A simple practical measure for routine clinical use. Clin Exper Dermatol. 1994; 19:210-216.
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5. Malik K, He H, Huynh TN, et al. Ichthyosis molecular fingerprinting shows profound T(H)17 skewing and a unique barrier genomic signature. J Allergy Clin Immunol. 2019 Feb;143(2):604-618.
6. Paller A, Renert-Yuval Y, Suprun M, et al. An IL-17-dominant immune profile is shared across the major orphan forms of ichthyosis. J Allergy Clin Immunol. 2017 Jan;139(1):152-165.
7. Thomas CL, Finlay AY. The 'handprint' approximates to 1% of the total body surface area whereas the 'palm minus the fingers' does not. Br J Dermatol. 2007;157(5):1080-1081.
8. Yan AC, Honig PJ, Ming ME, et al. The safety and efficacy of pimecrolimus, 1%, cream for the treatment of Netherton Syndrome. Arch Dermatol. 2010; 146(1):57-62.

11. APPENDIX 1 DATA HANDLING RULES

The following table presents the algorithms to be used in SAS to calculate the derived variables, including rules for handling other missing data or partial dates, or irregular/unexpected data issues.

Category	Description	Data Handling Rules
1. Medical History	Medical History Beginning Date of Condition	• Missing day of begin date of condition will be imputed as the 1st of the month for the purpose of computing the onset day. • Missing month of begin date of condition will be imputed as June for the purpose of computing the onset day
	Medical History End Date of Condition	• Missing day of end date of condition will be imputed as the 30th of the month for the purpose of computing the onset day. • Missing month of end date of condition will be imputed as June for the purpose of computing the onset day
2. First and Last Treatment Dates	date/time of first and last dose of a study treatment	The date and time (24 hr. clock) of the first dose of study treatment will be taken from the Dosing eCRF. The date of the last dose of study treatment will be the last date of dosing from the Dosing eCRF for the treatment.
3. Last Visit Date	Date of Last Visit	Date of last visit according to the Visit eCRF.
4. Last Study Participation Date (SDTM variable, typically named RFPENDTC)	Last Study Participation Date (SDTM variable, RFPENDTC), where SDTM denotes Study Data Tabulation Model	Last study participation date is defined as last known date of contact which would be the later of the following dates: last visit date, date of the last dose, date of study completion or discontinuation, or death date.
5. Study Day Definitions	**Study Day** for assessment/event which occurs on or after the start of study treatment	Study Day = Date of assessment/event – date of the first dose of study treatment + 1.
	Study Day for assessments/events on days prior to the first dose of study treatment in the study	Study Day = date of assessment/event – first dose date of treatment in the study.
	Study Day of Randomization	Study Day of Randomization = date of randomization – date of the first dose of study treatment in the study + 1. Study Day is 1 if baseline day is on the day of randomization.
	First Dose Day	**First Dose Day** in the study is defined as the study day of the first dose of study treatment in the study (Study Day 1).

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Category	Description	Data Handling Rules
	Last Dose Day	**Last Dose Day** in the study is defined as the study day of the last dose of study treatment in the study (defined as the last date of dosing from the Dosing CRF pages).
	Last Study Day	**For subjects who did not receive study treatment in the study (e.g., Non-Randomized subjects)**, Last Study Day is defined as (the later of the last visit date and the date of study completion or discontinuation from the End of Study CRF) – Date of Screening Visit + 1. **For subjects who received study treatment in the study,** Last Study Day is defined as (the later of the last visit date and the date of study completion or discontinuation from the End of Study CRF) – first dose date in the study + 1.
	Days Since Last Dose for event (e.g., Death)	**Days Since Last Dose** is defined as date of event – date of last dose of study treatment.
6. Duration of event	The duration of any event	The duration of any event is defined as (stop date – start date + 1).
7. Prior and concomitant, medication / treatment	Prior and concomitant medication/treatment	**1.** Prior medication/treatment is any medication/treatment stopped prior to the first dose of study treatment (or the date of the randomization visit, Day 1, if the date of the start of study medication is missing). Medication/treatment continued into the treatment period will not be considered prior. **2.** A medication/treatment will be identified as a concomitant medication/treatment if any of the following are true: o The start date or the end date is on or after the date of the start of study treatment (or the date of randomization, Day 1, if missing). o The medication/treatment is checked as 'Ongoing', and the start date of the medication/treatment is prior to the first dose of study treatment (or the date of the randomization visit, Day 1, if the date of the start of study medication is missing). o The start date and the end date are both missing
8. Adverse event	Treatment-emergent adverse event	If the AE start date is partial/missing, then ● If AE start date is completely missing, then the AE is considered as treatment-emergent. ● If both AE start month and day are missing and AE start year is the same or after the first dose year, then the AE is considered as treatment-emergent. ● If AE start day is missing and AE start year and month are the same or after the first dose year and month, then the AE is considered as treatment-emergent.

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Category	Description	Data Handling Rules
		Missing/incomplete (partial) AE start and end dates will not be imputed for data listings.
	Missing relationship to study drug	For TEAE summary by relationship, a TEAE with a missing relationship to study drug will be considered as related.
9. Vital Signs	Multiple assessments for the same visit	If there are multiple vital sign values for the same parameter at a given visit, the last value will be chosen for analysis.

12. APPENDIX 2 MOCKUP TABLES, LISTINGS, AND GRAPHS (TLGS)

Mockup tables, listings, and graphs are presented in a separate document.

SPECIFICATION OF END-OF-TEXT STANDARD OUTPUT TABLES, LISTINGS, AND FIGURES (TFLs)

Protocol Title: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ANB019 in the Treatment of Subjects with Ichthyosis

ANB019-206

Study Phase:	II
Product Name:	Anti-interleukin 36 receptor monoclonal antibody
IND Number	136145
Indication:	Ichthyosis
Sponsor:	AnaptysBio, Inc.
Author	[redacted]
Date of Issue	12-Jan-2022
Version	Version 1.0

Signed Agreement on Table, Listing, and Figure Specifications

SIGN-OFF SIGNATURES

Author: [redacted]
Everest Clinical Research, Inc.

[redacted] [redacted]
12 Jan 2022 02:01:49 (-05 00)
REASON: I approve this document.
0cd33791-1e6c-4004-ab82-014a04636896

Signature | Date

Peer Reviewer: [redacted]
Everest Clinical Research, Inc.

[redacted] [redacted]
12 Jan 2022 14:35:26 (-05 00)
REASON: I approve this document.
d63bab85-895c-40aa-ac4a-72faf335fc86

Signature | Date

Approved by: [redacted]
Everest Clinical Research, Inc.

[redacted] [redacted]
12 Jan 2022 09:29:44 (-05:00)
REASON: I approve this document.
effda0b6-2b58-43c6-bf93-c4f487523739

Signature | Date

Approved by: [redacted]
AnaptysBio, Inc.

[redacted] [redacted]
12 Jan 2022 12:46:43 (-05 00)
REASON: I approve this document.
0be82a8c-7f33-4b1f-95d0-4a561b278c5d

Signature | Date

DocUUID 5f304d69-fa51-4f4c-b33f-c61c50388239

Approved by: [redacted]

AnaptysBio, Inc.

[redacted] 12 Jan 2022 02:14:03 (-05:00)

REASON: I approve this document.

0f2ecb62-dc73-49d7-8d6e-163a75def8ef

Signature Date

Approved by: [redacted]

AnaptysBio, Inc.

[redacted] 12 Jan 2022 10:55 57 (-05 00)

REASON: I approve this document.

7749d470-9305-47e0-9605-51d032b2185b

Signature Date

General Instructions for End-of-Text TFLs

Following are the specifications for end of text standard tables, listings, and figures (TFLs).

Header

The following header should appear at the very top of each page of a table, a listing, or a figure (TFL):

```
AnaptysBio, Inc.                                                    Imsidolimab
Protocol: ANB019-206                                                Page n of N
```

Footer

The following footer should appear at the bottom of each page of a TFL generated in SAS:

Report generated by program:/sasdir/PGNAME.sas Version YYYY-mm-dd hh:mm

where: PGNAME = SAS program name. Version will be replaced by “Draft” or “Final”.

Title

At least three (3) lines should be reserved for the whole title. The first line is for the TFL number (i.e , title index #); the second line is for the actual title (title); and the third line is reserved for the analysis population descriptor (population). All titles should be centered, as shown in the following example:

```
                                Table 3.1
                            Demographics
                        Safety Analysis Set
```

Footnotes

- In general, a footnote serves as a brief explanation/clarification/definition/concept of a flag symbol or a character, an abbreviation, a terminology, etc., that appears in or related directly to the displayed content of a TFL. Detailed/technical elaboration of, for example, a mathematical/statistical formula, a statistical term/test, or an algorithm for deriving a parameter value, should be addressed in the text of the statistical analysis plan (SAP).
- All footnotes should follow immediately after a horizontal solid line. There should be one and only one space between the last footnote and the footer.
- Each line of a complete footnote should end with a period. When a footnote needs more than 1 line, one (1) period is needed.
- If a footnote is very long – i.e. is longer than the length (per page) of the main body of a table or listing, then the footnote will be shown only on the final page of the table or listing.

Page Layout

- All output should be in landscape orientation. A margin of 1.5, 1, 1, and 1 inch should be on the top, right, left, and bottom, respectively.
- All efforts should be made to present all Treatment groups in one page.
- When 3 or more Treatment groups are designed for a study and if it is not possible to fit all of them in one page, the 4th and 5th treatment groups should be displayed on the 2nd page, etc. The Study Biostatistician will pre-determine the order for the display of the treatment groups.

Page Format

- There should be a solid line at the top of the tables and listings just below the title.

- There should be a solid line just below the column headings that runs completely across the width of the tables and listings.
- There should be a solid line at the bottom of the tables and listings just above the footnote(s) on every page.

Font

- The default font to be used in the actual study tables/listings should be Courier New 8 point which is approximately equivalent to the acceptable font size of Times New Roman 9-10 in accordance with the FDA's guidance on Electronic Common Technical Document Specification.
- The use of Courier New 7 point is optional for some tables/listings and will be determined at the study level by the Study Biostatistician and Study Programmer. However, it is recommended that this option be used primarily for data listings.

Descriptive Statistics

By default, descriptive statistics in this template covers: n, Mean, Median, Standard Deviation (SD), Minimum (Min), and Maximum (Max). Unless otherwise specified in the actual table shells, the mean, standard deviation, standard error of the mean, and median should be displayed to one more decimal place than the original data. The standard error of the mean will be displayed with at least 2 significant digits for efficacy tables.

Rounding for Percentage

Unless specified in the actual table shells for a study, all percentages will be rounded to 1 decimal place in all TFLs. If the percentage is less than 0.1 but greater than 0 then print "<0.1". If the percentage is greater than 99.9 but less than 100 then print ">99.9".

Unless specified in the actual table shells for a study, p-values will be presented with 4 decimal places. If the p-value is less than 0.0001 then print "<0.0001".

Alignment of Decimals

- It is recommended that all the decimal places be aligned in summary tables, as shown in the following example:

	Decimal Align
n	xxx
Mean	xx.xx
SD	xx.xx
Median	xx.xx
Min, Max	xx.x, xx.x

The example above is intended only to show how decimal places will be aligned. It is not intended to show how many decimal places will be given for various fields for various tables. It is also not intended to show which fields will be displayed on which lines.

- When numbers with decimal points are included in brackets (e.g., percentages), have the brackets aligned to the right and then padded to allow for all possible percentages and then the left brackets will also be aligned. For example:

Brackets Align	
(99.9)	(xx.x)
(9.9)	(x.x)

- It is recommended that all column entries in a summary tables and listings are aligned to the center.

- Columns for text fields are all left justified. Columns with whole numbers are all right justified.
- For graphs, the lines are distinguishable and that the symbols for each line are appropriate. Legend is consistent across output for Treatment names and abbreviations.

Use of N Versus n

- N = total number of subjects in the defined analysis set.
- n = total number of subjects in the specific category.
- If N is specified in the column heading then any reference to the number of subjects in the body should be small n, as shown in the following example:

Demographic Parameter	Treatment Group A (N=xxx)	Treatment Group B (N=xxx)	Total (N=xxx)
Age (years)			
n	xxx	xxx	xxx
Mean	xx x	xx x	xx.x
SD	x xx	x xx	x.xx
Median	xx x	xx x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

The example above is intended only to illustrate the use of N and n. It is not intended to show other aspects of table structure.

A Note for Subject Data Listings

- Observed Dates/AE Severity/Relationship to investigational product are used in subject data listings.

TABLE OF CONTENTS FOR END-OF-TEXT TFLs

SHELLS FOR END-OF-TEXT TFLS

14.1 Subject Disposition, Demographic, Baseline, and Other Summary Tables

Table 14.1.1
Summary of Subject Disposition
All Subjects Screened

	Imsidolimab	Placebo	All Subjects
Screened, n			xx
Randomized, n	xx	xx	xx
Not Treated, n (%) [a]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treated, n (%) [a]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed placebo-controlled period, n (%)[b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed open-label extension period, n (%) [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed the Study including follow-up, n (%)[b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from Study Treatment, n (%) [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
	xx (xx.x)	xx (xx.x)	xx (xx.x)
Early Discontinuation from Study, n (%)[b]			
Reasons for Discontinuation			
Any significant AE, laboratory abnormality, or other medical condition or situation occurs, such that continued participation in the study would not be in the best interest of the subject, in the opinion of the Investigator, n (%) [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression which requires discontinuation of the study treatment, n (%) [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal of consent, n (%) [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrew consent due to possible/perceived lack of efficacy by subject, n (%) [c]			
Withdrew consent due to AEs experienced, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative reasons/Other, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Termination of the subject participation by the Investigator or Sponsor, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Use of any prohibited medication or treatment that in the opinion of the Investigator necessitates the subject being withdrawn, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Significant deviation/lack of compliance with protocol, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other, n (%)[c]	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] The denominator for the percentages uses the number of subjects who were randomized.
[b] The denominator for the percentages uses the number of subjects who were randomized and treated.
[c] The denominator for the percentages uses the number of subjects who discontinued early from study.

Source: Listing x.x.

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Notes to Programmer: Patients who completed placebo-controlled period is defined as patients who have completed predose safety/efficacy assessment at Week 16
Patients who discontinued from study treatment includes 1) those who early discontinued from study, and 2) those who did not receive all doses through Week 28

Table 14.1.2
Summary of Demographics
ITT Analysis Set

Parameter	Imsidolimab (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
Age at Baseline (Years) [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
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Age Group at Baseline, n (%)			
[12, 18) years	xx (xx.x)	xx (xx.x)	xx (xx.x)
[18, 65) years	xx (xx.x)	xx (xx.x)	xx (xx.x)
[65, 75] years	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	x (xx.x)	x (xx.x)	x (xx.x)
[12, 16) years	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 16 years	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	x (xx.x)	x (xx.x)	x (xx.x)
[12, 15) years	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 15 years	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	x (xx.x)	x (xx.x)	x (xx.x)
Sex, n (%)			
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	x (xx.x)	x (xx.x)	x (xx.x)
Race, n (%) [a]			
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Parameter	Imsidolimab (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
Ethnicity, n (%)			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not-Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	x (xx.x)	x (xx.x)	x (xx.x)
Country, n (%)			
Canada	xx (xx.x)	xx (xx.x)	xx (xx.x)
Poland	xx (xx.x)	xx (xx.x)	xx (xx.x)
United States	xx (xx.x)	xx (xx.x)	xx (xx.x)
Woman of Childbearing Potential, n (%)			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	x (xx.x)	x (xx.x)	x (xx.x)
Weight (kg)			
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
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Height (cm)			
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
Q1, Q3	xxx.x, xxx.x	xxx.x, xxx.x	xxx.x, xxx.x
Min, Max	xxx.x, xxx.x	xxx.x, xxx.x	xxx.x, xxx.x
BMI (kg/m^2) [b]			
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
Q1, Q3	xxx.x, xxx.x	xxx.x, xxx.x	xxx.x, xxx.x
Min, Max	xxx.x, xxx.x	xxx.x, xxx.x	xxx.x, xxx.x

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Parameter	Imsidolimab (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

N = Total number of subjects in the defined analysis set; n = Total number of subjects in the specific category.
[a] Subjects were allowed to select more than one race. Percentages can therefore add up to more than 100% in each treatment group.
[b] BMI = Weight(kg) / [Height(m)^2].

Source: Listing x.x.

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Notes to Programmer: Please do not display 'Missing' category with 0 counts across all columns

14.3 Safety Data Summary Tables

Extent of Exposure to Study Medication and Compliance

Table 14.3.1
Study Treatment Exposure and Compliance
Safety Analysis Set

	Imsidolimab (N=xx)	Placebo (N=xx)
Number of Doses Received		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Duration of Exposure to Study Treatment (days) [a]		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Total Dose Received (mg)		
n	xx	
Mean	xx.x	
SD	xx.xx	
Median	xx.x	
Min, Max	xx, xx	
Total Dose Expected (mg) [b]		
n	xx	
Mean	xx.x	
SD	xx.xx	
Median	xx.x	
Min, Max	xx, xx	
Dose Intensity (%) [c]		
n	xx	
Mean	xx.x	
SD	xx.xx	
Median	xx.x	
Min, Max	xx, xx	

0 – < 20%, n (%)	xx (xx.x)
20 – < 40%, n (%)	xx (xx.x)
40 – < 60%, n (%)	xx (xx.x)
60 – < 80%, n (%)	xx (xx.x)
80 – 100%, n (%)	xx (xx.x)
>100%, n (%)	xx (xx.x)
Missing	x (xx.x)

N = Total number of subjects in the defined analysis set; n = Total number of subjects in the specific category.
[a] Exposure (days) = (Date of last treatment – Date of first dose of treatment) + 1.
[b] The expected number of doses for the first dose of study treatment was 400 mg; the expected number of doses for study drug administrations after the first dose of study treatment was 200 mg.
[c] Dose intensity is defined as (Total dose received/total expected dose) x 100%.

Source: Listing x.x.

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Adverse Events

Table 14.3.2.1.1
Overall Summary of Treatment-Emergent Adverse Events
Safety Analysis Set

	Imsidolimab (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
	n (%) [Events]	n (%) [Events]	n (%) [Events]
Subjects with at least one TEAE [a]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Subjects with at least one TEAE related to study treatment [b]	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xx.x]
Subjects with at least one serious TEAE	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Subjects with at least one serious TEAE related to study treatment [b]	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Subjects with at least one TEAE			
Leading to early treatment discontinuation	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Leading to withdrawal from study	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Leading to death	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Subjects with at least one serious TEAE			
Leading to early treatment discontinuation	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Leading to withdrawal from study	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Leading to death	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]

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Subjects with at least one severe TEAE	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Subjects with at least one severe study treatment-related TEAE [b]	xx (xx.x) [xxx]	xx (xx.x) [xxx]	xx (xx.x) [xxx]
Deaths	xx (xx.x)	xx (xx.x)	xx (xx.x)

N = Total number of subjects in the defined analysis set; n = Total number of subjects in the specific category.
[a] TEAE = Treatment-Emergent Adverse Event. An adverse event is considered treatment-emergent if the date of onset is during or after first dose of study treatment, or if the AE present at baseline that worsens in either intensity or frequency after first dose of study treatment.
[b] Related = Possibly related, related, or missing.

Source: Listing x.x.

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Table 14.3.2.2.1
Summary of Subjects with Treatment-Emergent Adverse Events by Primary System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Imsidolimab (N=xx) n (%) [Events]	Placebo (N=xx) n (%) [Events]	All Subjects (N=xx) n (%) [Events]
At Least One TEAE [a]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
System Organ Class 1	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Preferred Term 1	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Preferred Term 2	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
System Organ Class 2	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Preferred Term 1	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Preferred Term 2	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Etc.…			

N = Total number of subjects in the defined analysis set; n = Total number of subjects in the specific category.
MedDRA Version xx.x was used to code adverse events.
[a] TEAE = Treatment-Emergent Adverse Event. An adverse event is considered treatment-emergent if the date of onset is during or after first dose of study treatment, or if the AE present at baseline that worsens in either intensity or frequency after first dose of study treatment. AEs started on or after dosing on the Week 16 visit will not be considered as TEAEs in placebo-controlled period.

Source: Listing x.x.

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmers:
Sort System Organ Class and Preferred Term by descending frequency of subjects, then by number of events for All Subjects column, and then in alphabetical order

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Table 14.3.3.1
Shift Table for Laboratory Hematology Data
Safety Analysis Set

Parameter 1 (unit)

		Imsidolimab (N=xx) Baseline				Placebo (N=xx) Baseline				All Subjects (N = xx) Baseline			
		Low	Normal	High	Missing	Low	Normal	High	Missing	Low	Normal	High	Missing
Visit	Normal Range	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Week 1	Low	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Normal	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	High	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Missing	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Week 4	Low	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Normal	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	High	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Missing	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

<Repeat for Week 8, 12, 16, 20, 24, 28, 32, 36, and 40>

N = Total number of subjects in the defined analysis set; n = Total number of subjects in the specific category.
By study design, patients might receive different study treatments during placebo-controlled period and extension period. The first study treatment in extension period is scheduled at Week 16.
Low and High are defined as out of normal lower range and upper range respectively.
Source: Listing x.x.

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Notes to Programmer: Repeat for all remaining post-baseline scheduled visits up to Week 40 Repeat for each laboratory test required within Hematology at the beginning of each page

Table 14.3.3.2
Shift Table for Laboratory Biochemistry Data
Safety Analysis Set

Notes to Programmer: *Repeat format of Table 14 5 3 4 for biochemistry*

Table 14.3.3.3
Shift Table for Urinalysis Data
Safety Analysis Set

Notes to Programmer: *Repeat format of Table 14 5 3 4 for urinalysis*

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16. Subject Data Listings

Listing 16.1.1
Subject Disposition
All Subjects Screened

Subject ID	Age(yrs)/ Sex/Race	Erythema Severity	Treatment Assigned	Date of Informed Consent/ Date of Screening	Randomized? (Study Day) [a]	Date of Study Completion/ Discontinuation (Study Day) [b]	Study Completion Status Discontinuation Reason	ITT/Safety Analysis Set
xxxxxx	xx/M/x	xxxxxx		YYYY-MM-DD	Yes (xx)	YYYY-MM-DD (xx)	Completed	Yes/Yes
xxxxxx	xx/F/x	xxxxxxx		YYYY-MM-DD	Yes (xx)	YYYY-MM-DD (xx)	Early Terminated Lost to Follow-up	Xxx/xxx
xxxxxx	xx/M/x	xxxxxxxx		YYYY-MM-DD	Yes (xx)	YYYY-MM-DD (xx)	Early Terminated Withdrawal of Consent	Xxx/xxx
xxxxxx	xx/M/x	xxxxxxx		YYYY-MM-DD	No(NA)	YYYY-MM-DD (xx)	Screen Failure Inclusion/Exclusion Criteria	No/No

NA = Not applicable.
Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day of randomization = date of randomization - first dose of study treatment + 1.
[b] For subjects not randomized, Study Day is the last visit date - date of Screening Visit + 1; For treated subjects, Study Day is date of study completion or discontinuation on the 'End of Study' CRF - date of first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.1.2
Treatment Assignment and Duration of Treatment
ITT Analysis Set

Subject ID	Age(yrs)/ Sex/ Race	Randomization Date	Erythema Severity	Randomized Treatment	Actual Treatment	Start Treatment Day and time (24 hr clock)	End Treatment Day and time (24 hr clock)
xxxxxx	xx/M/x	YYYY-MM-DD	Moderate	xxxxxxxxxx	xxxxxxxxxx	YYYY-MM-DD hh:mm	YYYY-MM-DD hh:mm
xxxxxx	xx/F/x	YYYY-MM-DD	Moderate	xxxxxxxxxx	xxxxxxxxxx	YYYY-MM-DD hh:mm	YYYY-MM-DD hh:mm
xxxxxx	xx/M/x	YYYY-MM-DD	Severe	xxxxxxxxxx	xxxxxxxxxx	YYYY-MM-DD hh:mm	YYYY-MM-DD hh:mm

Age is the age at the time of Informed Consent.
Sex: F=Female, M=Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.1.3
Protocol Deviations
ITT Analysis Set

Subject ID	Treatment Group	Erythema Severity	Date of Deviation Occurred	Deviation Category	Protocol Deviation Specifications
xxxxxx	Imsidolimab	xxxxxxxx	YYYY-MM-DD	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
xxxxxx	Placebo	xxxxxxxxxx	YYYY-MM-DD	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxx		YYYY-MM-DD	xxxxxx	xxxxxxxxxxxxxxxxxxxxx

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Listing 16.2.1
Demographics

ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Ethnicity	Country	Childbearing Potential?	Height (cm)	Weight (kg)	BMI (kg/m^2)
xxxxxx	Imsidolimab	xx/F/x	xxxxxxxx	xxxxxxx	xxxxx	No	xxx	xxx.x	xx.xx

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
BMI = Body Mass Index = Height(kg)/Weight(m)^2.
Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.2.2
Baseline Disease Characteristics
ITT Analysis Set

Subject ID	Treatment Group	BSA affected (%)	Ichthyosis Subtype	IASI					DLQI/ CDLQI	Pruritus NRS Worst/ Average	Pain NRS Worst/ Average	iQoL-32	TEWL	PGI-S
				Erythema	Scaling	Total	NASA	IGA						
xxxxxx	Imsidolimab	xx.x	xxxxxxxxx	xx	xx	xxx	xx	xx	-/xx	x/x	x/x	x	x	x

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
NASA = Netherton Area and Severity Assessment; IGA = Investigator global assessment; DLQI = Dermatology Life Quality Index; CDLQI = Children's Dermatology Life Quality Index; TEWL = Transepidermal water loss.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Listing 16.2.3
Medical History
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	System Organ Class	Diagnosis/ (Preferred Term)	Start Date (Start Day) [a]	Still Present?	End Date (End Day) [b]
xxxxxx	Imsidolimab	xx/M/x	xxxxxxxxxxx	xxxxxxxx	xxxxx/(xxxx)	YYYY-MM-DD (-xxx)	No	YYYY-MM-DD (-xxx)
				xxxxxx	xxxxx/(xxxx)	YYYY-MM-DD (-xxx)	No	YYYY-MM-DD (-xxx)
xxxxxx	Placebo	xx/F/x	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxx	xxxxx/(xxxx)	YYYY-MM-DD (-xxx)	No	YYYY-MM-DD (-xxx)
				xxxxxxxxxx	xxxxx/(xxxx)	YYYY-MM-DD (-xxx)	Yes	

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] Start Day = Start date of condition – date of the first dose of study treatment. Missing day is imputed as 1st of the month. Missing month is imputed as June.
[b] End Day = End date of condition – date of the first dose of study treatment. Missing day is imputed as 30th of the month. Missing month is imputed as June.
MedDRA version xx.x.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID and Start Day If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.2.4 1
Prior Medications
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/Sex/Race	Erythema Severity	Medication Verbatim Term (Preferred Name)	Dose/ Unit/ Route/ Frequency	Indication	Start Date (Start Day) [a]	End Date (End Day) [a]	Continuing	Duration (Days) [b]
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxxx	xxxxxxxxxxx (xxxxxx)	90/ MCG/ IH/ PRN	COPD	YYYY-MM-DD (-xx)	YYYY-MM-DD (-xx)	No	xxx
xxxxx	Placebo	xx/F/x	xxxxxxxxxxxx	xxxxxxxxxxx (xxxxxx)	90/ MCG/ IH/ PRN	COPD Exacerbation	YYYY-MM-DD (-xx)	YYYY-MM-DD (-xx)	No	xxx

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
Prior medication is any medication stopped prior to the first dose of study treatment.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.
[b] Number of days on rescue medication = End date of rescue medication – start date of rescue medication + 1.
WHO Drug Version xxxxx.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Preferred Name, and Start Date of medication If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.2.4 2
Concomitant Medications
Safety Analysis Set

Notes to Programmer: Follow same format as listing 14 2 4 1 Sort by Subject ID, Preferred Name, and Start Date of medication
If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".
In footnote, remove definition for prior medication, and add below:
Concomitant medication is any medication continued to be taken at the time of the first dose or started after the first dose of study treatment Also, add "Pxx = Days after last dose " At the then of footnote [a]

Listing 16.2.4 3
Emollient Use, Bath and Shower (eDiary)
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Collection Date (Day)	eDiary Entered	Bath/ Shower Time	Duration (min)	Additive Used	Emollient Type	Emollient Frequency
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxxx	YYYY-MM-DD (-xx)	Yes	Hh:ss	xx	xxxxxxxxxx xxx	xxxxxxxx	xxxxxxx
xxxxx	Placebo	xx/F/x	xxxxxxxxxx xxx	YYYY-MM-DD (-xx)	Yes	Hh:ss	xx		xxxxxxxx	xxxxxxxx

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Note: Placeholder, mock shell to be added when data becomes available

Listing 16.2.5
Rescue Medications
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/Sex/Race	Erythema Severity	Medication Verbatim Term (Preferred Name)	Dose/ Unit/ Route/ Frequency	Indication	Start Date (Start Day) [a]	End Date (End Day) [a]	Continuing	Duration (Days) [b]
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxxxx	xxxxxxxxxxx (xxxxxx)	90/ MCG/ IH/ PRN	COPD	YYYY-MM-DD (-xx)	YYYY-MM-DD (Pxx)	No	xxx
xxxxx	Placebo	xx/F/x	xxxxxxxxxxx	xxxxxxxxxxx (xxxxxx)	90/ MCG/ IH/ PRN	COPD Exacerbation	YYYY-MM-DD (-xx)	YYYY-MM-DD (-xx)	No	xxx

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
Rescue medication is defined as a treatment, other than emollient, taken to control intolerable symptoms of ichthyosis.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1. Pxx = Days after last dose.
[b] Number of days on rescue medication = End date of rescue medication – start date of rescue medication + 1.
MedDRA version xx.x.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Preferred Name, and Start Date of medication If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.1 1
Ichthyosis Area Severity Index (IASI) - Erythema
ITT Analysis Set

											Erythema		
Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	IASI-E	Body Region	Total Extent of Body Region	Intensity	Percentage of Involvement (%)	Body Region Total
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxx	Screening	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx
								Upper Limbs	0.2	xx	xx	xx
								Trunk	0.3	xx	xx	xx
								Lower Limbs	0.4	xx	xx	xx
				Week 0	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx
								Upper Limbs	0.2	xx	xx	xx
								Trunk	0.3	xx	xx	xx
								Lower Limbs	0.4	xx	xx	xx
				Week x	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx
								…				

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.3.1 2
Ichthyosis Area Severity Index (IASI) - Scaling
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	IASI-S	Body Region	Scaling			
									Total Extent of Body Region	Intensity	Percentage of Involvement (%)	Body Region Total
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxx	Screening	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx
								Upper Limbs	0.2	xx	xx	xx
								Trunk	0.3	xx	xx	xx
								Lower Limbs	0.4	xx	xx	xx
				Week 0	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx
								Upper Limbs	0.2	xx	xx	xx
								Trunk	0.3	xx	xx	xx
								Lower Limbs	0.4	xx	xx	xx
				Week x	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx
								…				

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.3.1 3
Ichthyosis Area Severity Index (IASI) - Overall
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Visit	IASI-S	IASI-E	IASI	Not done, Reason
xxxxx	Imsidolimab	xx/M/x	xxxxxxxx	Screening	xx	xx	xx	
				Week 0*	xx	xx	Xx	
				Week x	xx	xx	xx	
				…				

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
*Baseline visit is marked with *. Baseline is defined as the last available measurement taken prior to the first dose of study treatment.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.2 1
Netheron Area and Severity Assessment (NASA) – Body Regions
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs) /Sex/ Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	NASA	Body Region	Total Extent of Body Region	Subscores[b] E	I	L	S
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxx	Week 0	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx	
								Upper Limbs	0.2	xx	xx	xx	
								Trunk	0.3	xx	xx	xx	
								Lower Limbs	0.4	xx	xx	xx	
				Week x	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx	
								Upper Limbs	0.2	xx	xx	xx	
								Trunk	0.3	xx	xx	xx	
								Lower Limbs	0.4	xx	xx	xx	
				Week x	YYYY-MM-DD (-xx)	hh:mm	xx	Head and Neck	0.1	xx	xx	xx	
								…					

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1. Pxx = Days after last dose.
[b] E = Erythema; I = Infiltration/papulation; L = Lichenification; S = Scaling. Scores: 0=None, 1=Mild, 2=Moderate, 3=Severe.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.3.2 2
Netheron Area and Severity Assessment (NASA) - Overall
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Visit	NASA	Not done, Reason
xxxxx						
	Imsidolimab	xx/M/x	xxxxxxxx	Week 0*	Xx	
				Week x	xx	
				…		
				…		

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
*Baseline visit is marked with *. Baseline is defined as the last available measurement taken prior to the first dose of study treatment.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1. Pxx = Days after last dose.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.3
Investigator Global Assessment (IGA)
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	IGA, Erythema	IGA, Scaling	IGA	Not Done, Reason
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxx	Week 0*	YYYY-MM-DD (-xx)	hh:mm	xx	xx	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	xx	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	xx	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	xx	xx	
				Week x						COVID-19

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.
IGA scores: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe.
*Baseline visit is marked with *. Baseline is defined as the last available measurement taken prior to the first dose of study treatment.
** Change from baseline values that are less than -2 are marked with **.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.4
Pruritus Numeric Rating Scale (NRS)
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	Worst Pruritis NRS	Average Pruritus NRS	Not Done, Reason
xxxxx	Imsidolimab	xx/M/x	xxxxxxx	Week 0*	YYYY-MM-DD (-xx)	hh:mm	xx	xx	
				Week 1	YYYY-MM-DD (xx)	hh:mm	xx xx	xx xx	
				Week 4					COVID-19

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.
*Baseline visit is marked with *. Baseline is defined as the last available measurement taken prior to the first dose of study treatment.
Pruritis NRS is a Likert scale ranging from 0 = No itch to 10 = worst imaginable itch.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.3.5
Pain Numeric Rating Scale (NRS)
ITT Analysis Set

Notes to Programmer: Follow the layout of listing 16 3 4 replace 'Pruritus' with 'Pain' Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx". Replace last footer with "Pain NRS is a Likert rating scale ranging from 0 = No pain to 10 = Worst imaginable pain."

Listing 16.3.6
Body Surface Area (BSA)
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/Sex/Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	BSA affected (%)	Not Done, Reason
xxxxx	Imsidolimab	xx/M/x	xxxxxxxx	Week 0*	YYYY-MM-DD (-xx)	hh:mm	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	
				Week x				COVID-19

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1. Pxx = Days after last dose.
*Baseline visit is marked with *. Baseline is defined as the last available measurement taken prior to the first dose of study treatment.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.7
Dermatology Life Quality Index (DLQI) for Subjects 16 Years or Older at Baseline
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/Race	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	Question	Answer	Not Done, Reason
xxxxx	Imsidolimab	xx/M/x	Week 0	YYYY-MM-DD (-xx)	hh:mm	Over the last week, how itchy, sore, painful or stinging has your skin been?	Very Much	
						Over the last week, how embarrassed or self-conscious have you been because of your skin?	Very Much	
						…	…	
			Week x					COVID-19
			Week X	YYYY-MM-DD (-xx)	hh:mm	Over the last week, how itchy, sore, painful or stinging has your skin been?	Very Much	
						…	…	

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
DLQI is collected for patients >=16 years of age at baseline.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment, question sequence as in CRF If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.3.8
Children's Dermatology Life Quality Index (CDLQI) for Subjects Less than 16 Years at Baseline
ITT Analysis Set

Notes to Programmer: Follow the layout of listing 16 3 7 Sort by Subject ID, Date of Assessment, and Time of Assessment, question sequence as in CRF If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx". Footnote as:
Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
CDLQI is collected for patients <16 years of age at baseline.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.

DocUUID 5f304d69-fa51-4f4c-b33f-c61c50388239

Listing 16.3.9
Patient-Global Impression of Severity (PGI-S)
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/Sex/Race	Erythema Severity	Visit	Date of Assessment (Study Day) [a]	Time of Assessment	PGI-S	Not Done, Reason
xxxxx	Imsidolimab	xx/M/x	xxxxxxxxxx	Week 0	YYYY-MM-DD (-xx)	hh:mm	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	
				Week x	YYYY-MM-DD (xx)	hh:mm	xx	
				Week x				COVID-19

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1. Pxx = Days after last dose.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.3.10
Patient Global Impression of Change (PGI-C)
ITT Analysis Set

Notes to Programmer: Follow the layout of listing 16 3 9 Replace 'PGI-S' with 'PGI-C' Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.11
Ichthyosis Quality of Life-32 Items (iQOL-32) for Subjects 15 Years or Older at Baseline
ITT Analysis Set

Notes to Programmer: Follow the layout of listing 16 3 7 Sort by Subject ID, Date of Assessment, and Time of Assessment, question sequence as in CRF If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.3.12
Transepidermal Water Loss (TEWL)
ITT Analysis Set

Subject ID	Treatment Group	Age(yrs)/Sex/Race	Visit	Date of Collection (Study Day) [a]	Time of Collection	Mean TEWL ($g/m^2/hr$)	Body Area	TEWL Rate ($g/m^2/hr$)
xxxxx	Imsidolimab	xx/M/x	Week 0	YYYY-MM-DD	hh:mm	Xx	Chest	xx
							Back	Xx
							Other: xxx	Xx
			Week x	YYYY-MM-DD	hh:mm	xx	Chest	xx
							…	

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B = Black or African American, W = White, NHPI = Native Hawaiian or other Pacific Islander, AIAN = American Indian or Alaska Native, A = Asian, O = Other, M = Multi-Race.
[a] A negative number for study day denotes the number of days prior to the start of study treatment. Otherwise, study day is date of interest - date of the first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report Generated by Program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Date of Assessment, and Time of Assessment If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.4.1
Study Drug Administration
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Visit	Date of Drug Administration (YYYY-MM-DD)	Study Day [a]	Single/Double Administration	Vial ID	Dose(mg)	Anatomical Site of Administration	Post Administration Observations	Not Done, Reason
xxxxxx	Imsidolimab	xx/x/x	Xxxxx	YYYY-MM-DD	xx	Double	XXXXXXX	200	xxxxxxxxxx	xxxxxxxxxx	
				YYYY-MM-DD	xx	Double	XXXXXXX	200	xxxxxxxxxx	xxxxxxxxxx	
			Xxxxx	YYYY-MM-DD	xx	Single	XXXXXXX	200	xxxxxxxxxx	xxxxxxxxxx	
			Xxxxx	YYYY-MM-DD	xx	Single	XXXXXXX	200	xxxxxxxxxx	xxxxxxxxxx	
			……								
xxxxxx	Placebo	xx/x/x	xxxxx	YYYY-MM-DD	xx	xxx	XXXXXXX	200			
			xxxxx								COVID-19

……

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of drug administration – date of the first dose of study treatment + 1.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Actual Treatment, Visit, and Vial ID If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.4.2
Study Drug Compliance
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Number of Doses Received	Date of First Treatment (YYYY-MM-DD)	Date of Last Treatment (YYYY-MM-DD)	Duration of Exposure to Study Treatment[a]	Total Dose Received(mg)	Total Dose Expected(mg)	Dose Intensity(%)[b]
xxxxxx	Imsidolimab	xx/x/x	xxxxxxxxxxx	xx	YYYY-MM-DD	YYYY-MM-DD	xx	xx	xx	xx
xxxxxx	Placebo	xx/x/x	xxxxxxx	xx	YYYY-MM-DD	YYYY-MM-DD	xx	xx	xx	xx
xxxxxx	xxxxxx	xx/x/x	xxxxxxxx	xx	YYYY-MM-DD	YYYY-MM-DD	xx	xx	xx	xx
xxxxxx	xxxxxx	xx/x/x	xxxxxxxxx	xx	YYYY-MM-DD	YYYY-MM-DD	xx	xx	xx	xx

……

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Number of days of exposure to study treatment = Date of last treatment – date of the first dose of study treatment + 1.
[b] Dose intensity = (Total dose received/total dose expected) x 100%.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.5.1
Adverse Events
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Start Date (Study Day)[a]	End Date (Study Day)[a]	System Organ Class/ Preferred Term/ Reported Term [b]	Treatment-Emergent?/ Serious?	Severity/ Relationship	Action Taken	Outcome
xxxxxx	Imsidolimab	xx/x/x	xxxxxxxx	YYYY-MM-DD (xx)	YYYY-MM-DD (xx)	Xxxxxxxxxx/ Xxxxxxxxx/ Xxxxxxxxxx	Yes/ No	Moderate/ Possibly	xx	xxxxxx
				YYYY-MM-DD (xx)	-(-)	Xxxxxxxxxx/ Xxxxxxxxx/ Xxxxxxxxxx	Yes/ No	Moderate/ Possibly	xx	xxxxxx
xxxxxx	Placebo	xx/x/x	xxxxxxx	YYYY-MM-DD (xx)	YYYY-MM-DD (xx)	Xxxxxxxxxx/ Xxxxxxxxx/ Xxxxxxxxxx	Yes/ Yes	Xxxxxxx/ Xxxxxxx	xx	xxxxxxx
xxxxxx	Placebo	xx/x/x	xxxxxxxx	YYYY-MM-DD (xx)	YYYY-MM (-)	Xxxxxxxxxx/ Xxxxxxxxx/ Xxxxxxxxxx	No/ No	Xxxxxxxx/ Xxxxxxxx	Other:xxxxxxxx	xxxxxx

……

Age is the age at the time of Informed Consent.
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Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of event – date of the first dose of study treatment, if event occurred prior to the first dose of study treatment.
Study Day = Date of event – date of the first dose of study treatment + 1, if event occurred on or after the first dose of study treatment.
[b] MedDRA version xxxx.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Actual Treatment, AE start date, system organ class, preferred term If Other Action Taken is selected in the CRF, please specify it in the 'Action Taken with Study Treatment' column. *If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g ,* "O: xxxxxx", "M: xxxxxx".

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Listing 16.5.2
Adverse Events Leading to Study Treatment Discontinuation
Safety Analysis Set

Notes to Programmer: Follow the layout of Listing 14 5 1, include AEs leading to study treatment discontinuation

Listing 16.5.3
Adverse Events Leading to Study Withdrawal
Safety Analysis Set

Notes to Programmer: Follow the layout of Listing 14 5 1, include AEs leading to study treatment discontinuation

Listing 16.6.1
Laboratory Test Results – Hematology
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Visit	Collection Date and Time (Study Day)[a]	Overall Evaluation [b]	Parameter (Unit)	Result Value	Reference Range	Outside Normal Range [c]	Lab Type	Not Done, Reason
xxxxxx	Imsidolimab	xx/x/x	xxxxxxx	Xxxxxxx	YYYY-MM-DD hh:mm (xx)	Normal	Xxxxx (xxx)	xx.x	Xx.x – xx.x	RH	Central	
				Xxxxxxx	YYYY-MM-DD hh:mm (xx)	Normal	Xxxxx (xxx)	xx.x	Xx.x – xx.x	RL	Local	
				Xxxxxxx	YYYY-MM-DD hh:mm (xx)	Normal	Xxxxx (xxx)	xx.x	Xx.x – xx.x	CH	Central	
xxxxxx	Placebo	xx/x/x	xxxxxxx	Xxxxxxx	YYYY-MM-DD hh:mm (xx) YYYY-MM-DD hh:mm (xx)	Abnormal - CS	Xxxxx (xxx)	xx.x	Xx.x – xx.x		Central	
				Xxxxxxx	YYYY-MM-DD hh:mm (xx)	Abnormal - NCS	Xxxxx (xxx)	xx.x	Xx.x – xx.x		Local	
				xxxxxx								COVID-19

……

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of assessment – date of the first dose of study treatment, if assessment occurred prior to the first dose of study treatment. Study Day = Date of assessment – date of the first dose of study treatment + 1, if assessment occurred on or after the first dose of study treatment.
[b] CS = Clinically significant; NCS = Not clinically significant.
[c] RH=Reference High, RL=Reference Low, NH=Notable High, NL=Notable Low, CH=Critical High, CL=Critical Low, BL=Blinded.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer:
1 Sort by Subject ID, visit, collection date, lab parameter Please include hematology parameters as outlined in protocol appendix 7
2 Overall evaluation can be retrieved from question in CRF: what were the results of the lab test collected?
3 If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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Listing 16.6.2
Laboratory Test Results – Biochemistry
Safety Analysis Set

```
Notes to Programmer:
1  Follow the format of Listing 16 8 1
2  Sort by Subject ID, visit, collection date, lab parameter  Please include biochemistry parameters as outlined in protocol
appendix 7
3  Overall evaluation can be retrieved from question in CRF: what were the results of the lab test collected?
4  If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O:
xxxxxx", "M: xxxxxx".
```

Listing 16.6.3
Laboratory Test Results – Urinalysis
Safety Analysis Set

```
Notes to Programmer:
1  Follow the format of Listing 16 8 1
2  Sort by Subject ID, visit, collection date, lab parameter  Please include urinalysis parameters as outlined in protocol
appendix 7
3  Overall evaluation can be retrieved from question in CRF: what were the results of the lab test collected?
4  If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O:
xxxxxx", "M: xxxxxx".
```

DocUUID 5f304d69-fa51-4f4c-b33f-c61c50388239

Listing 16.6.4
Laboratory Test Results – Pregnancy Test
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Visit	Type of Test	Collection Date (Study Day)[a]	Collection Time	Result	Not Done, Reason
xxxxxx	Imsidolimab	xx/x/x	Xxxxxxx	Xxxxxxxxxx	Serum	YYYY-MM-DD(xx)	hh:mm	Negative	
				Xxxxxxxxx	Urine	YYYY-MM-DD(xx)	hh:mm	Negative	
				Xxxxxxxxx	Urine	YYYY-MM-DD(xx)	hh:mm	Negative	
				……					
xxxxxx	Placebo	xx/x/x	xxxxxxxx	Xxxxxxxxx	Serum	YYYY-MM-DD(xx)	hh:mm	Negative	
				xxxxxxx					COVID-19
……									

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of assessment – date of the first dose of study treatment, if assessment occurred prior to the first dose of study treatment. Study Day = Date of assessment – date of the first dose of study treatment + 1, if assessment occurred on or after the first dose of study treatment.

Source: xxxxxxx.sas7bdat
Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Actual Treatment, visit, collection date If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.6.5
Laboratory Test Results - Other
Safety Analysis Set

Notes to Programmer:
1 Follow the format of Listing 16 6 1
2 Sort by Subject ID, visit, collection date, lab parameter Please include Viral serology, TB, and FSH parameters
3 Overall evaluation can be retrieved from question in CRF: what were the results of the lab test collected? Populate only when applicable
4 If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.7.1
Vital Signs
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Visit	Collection Date (Study Day)[b]	Collection Time	Overall Evaluation [a]	Parameter (Unit)	Result Value	Not Done, Reason
xxxxxx	Imsidolimab	xx/x/x	xxxxxxx	Xxxxxxx	YYYY-MM-DD (xx)	hh:mm	Normal	Xxxxx (xxx)	xx.x	
								Xxxxx (xxx)	xx.x	
								Xxxxx (xxx)	xx.x	
xxxxxx	Placebo	xx/x/x	xxxxxx	Xxxxxxx	YYYY-MM-DD (xx)	hh:mm	Abnormal - CS	Xxxxx (xxx)	xx.x	
				Xxxxxxx						COVID-19

…

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] CS = Clinically significant; NCS = Not clinically significant.
[b] Study Day = Date of assessment – date of the first dose of study treatment, if assessment occurred prior to the first dose of study treatment. Study Day = Date of assessment – date of the first dose of study treatment + 1, if assessment occurred on or after the first dose of study treatment.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer:
1 Sort by Subject ID, visit, collection date, collection time, VS parameter Please include pulse rate, systolic blood pressure, diastolic blood pressure, body temperature, respiratory rate, weight, height and BMI
2 Overall evaluation can be retrieved from question in CRF: what were the results of the vital signs? Populate only when applicable
3 If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.7.2
Electrocardiogram Results
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Visit	Collection Date and Time (Study Day)[a]	Overall Evaluation [b]	Heart Rate (unit)	PR Interval (unit)	RR Interval (unit)	QRS Interval (unit)	QT Interval	QTcF Interval (unit)	Not Done, Reason
xxxxxx	Imsidolimab	xx/M/x	Xxxxxx	YYYY-MM-DD hh:mm (xx)	Normal	xx	xx	xx	xx	xx	xx	
			Xxxxxx	YYYY-MM-DD hh:mm (xx)	Normal	xx	xx	xx	xx	xx	xx	
			Xxxxxx	YYYY-MM-DD hh:mm (xx)	Normal	xx	xx	xx	xx	xx	xx	
xxxxxx	Placebo	xx/F/x	Xxxxxx	YYYY-MM-DD hh:mm (xx)	Abnormal - CS	xx	xx	xx	xx	xx	xx	
			xxxxxx									COVID-19

……

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Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of assessment – date of the first dose of study treatment, if assessment occurred prior to the first dose of study treatment. Study Day = Date of assessment – date of the first dose of study treatment + 1, if assessment occurred on or after the first dose of study treatment.
[b] CS = Clinically significant; NCS = Not clinically significant.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer:
1 Sort by Subject ID, visit, collection date
2 Overall evaluation can be retrieved from question in CRF: what were the results of the 12 Lead ECG?
3 If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.7.3
Abnormal Physical Examination Results
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Visit	Date of Assessment (YYYY-MM-DD)	Study Day[a]	Result of Physical Exam [b]	Not Done, Reason
xxxxxx	Imsidolimab	xx/x/x	xxxxxxxx	Xxxxxxxxx	YYYY-MM-DD	xx	Abnormal - NCS	
					YYYY-MM-DD	xx	Abnormal - CS	
xxxxxx	xxxxxx	xx/x/x	xxxxxxxxxx	xxxxxxxxxx xxxxxx	YYYY-MM-DD	xx	Abnormal - NCS	
				…				COVID-19

……

Age is the age at the time of Informed Consent.
Sex: F = Female, M = Male.
Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of assessment – date of the first dose of study treatment, if assessment occurred prior to the first dose of study treatment. Study Day = Date of assessment – date of the first dose of study treatment + 1, if assessment occurred on or after the first dose of study treatment.
[b] CS = Clinically significant; NCS = Not clinically significant.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID, Visit, date of assessment Only include abnormal results If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

Listing 16.7.4
Chest X-Ray
Safety Analysis Set

Subject ID	Treatment Group	Age(yrs)/ Sex/ Race	Erythema Severity	Timepoint of Assessment	Date of Assessment (YYYY-MM-DD)	Study Day [a]	Result of Chest X-ray [b]	Not Done, Reason
xxxxxx	Imsidolimab	xx/x/x	xxxxxxxxxx	Screening	YYYY-MM-DD	xx	Normal	
xxxxxx	xxxxxx	xx/x/x	xxxxxxxxxx	Screening	YYYY-MM-DD	xx	Normal	
xxxxxx	xxxxxx	xx/x/x	xxxxxxxxxxx	In the past 6 months	YYYY-MM-DD	xx	Normal	
xxxxxx	xxxxxx	xx/x/x	xxxxxxxxxx	Not Done				COVID-19

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Race: B=Black or African American, W=White, NHPI=Native Hawaiian or other Pacific Islander, AIAN=American Indian or Alaska Native, A=Asian, O=Other, M=Multi-Race.
[a] Study Day = Date of assessment – date of the first dose of study treatment, if assessment occurred prior to the first dose of study treatment. Study Day = Date of assessment – date of the first dose of study treatment + 1, if assessment occurred on or after the first dose of study treatment.
[b] CS = Clinically significant; NCS = Not clinically significant.

Source: xxxxxxx.sas7bdat

Report generated by program: <study>/<analysis>/statout/xxx.sas Version YYYY-MM-DD hh:mm

Notes to Programmer: Sort by Subject ID If Race is Other ("O") or Multi-Race ("M"), concatenate the specified race after 'O' or 'M' within parenthesis, e g , "O: xxxxxx", "M: xxxxxx".

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