Innovaderm Research

Statistical Analysis Plan

Study Title:	**A Randomized, Multicenter, Double-blind, Vehicle-controlled, Phase 2a Study to Assess the Safety, Pharmacokinetics, and Preliminary Efficacy of PP405 in Adults with Androgenetic Alopecia**
Protocol Number:	**PP405-2001**
Protocol Version and Date:	**Final Version 4.0, Amendment 3, dated 06-Dec-2024**
Product:	**PP405 Topical Gel, 0.05%**
Sponsor:	**Pelage Pharmaceuticals, Inc.** **907 Westwood Blvd, #384** **Los Angeles, California** **United States, 90024**
Version:	**Final, V1.0**
Date:	**05-Feb-2025**
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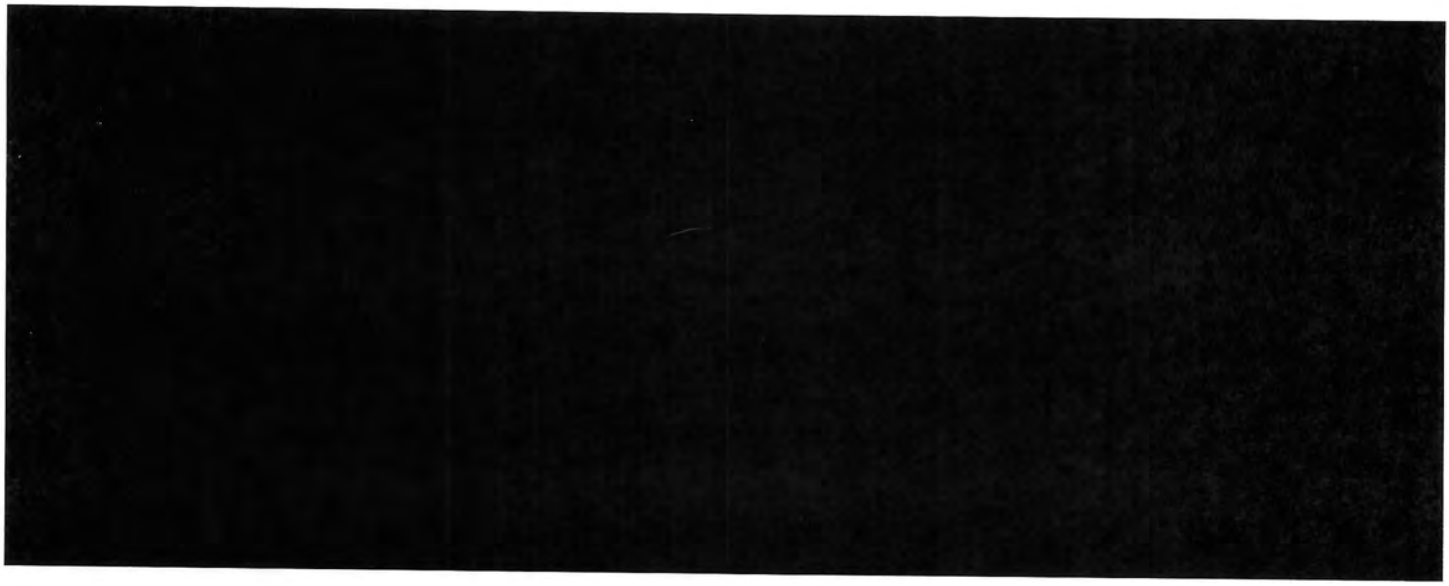
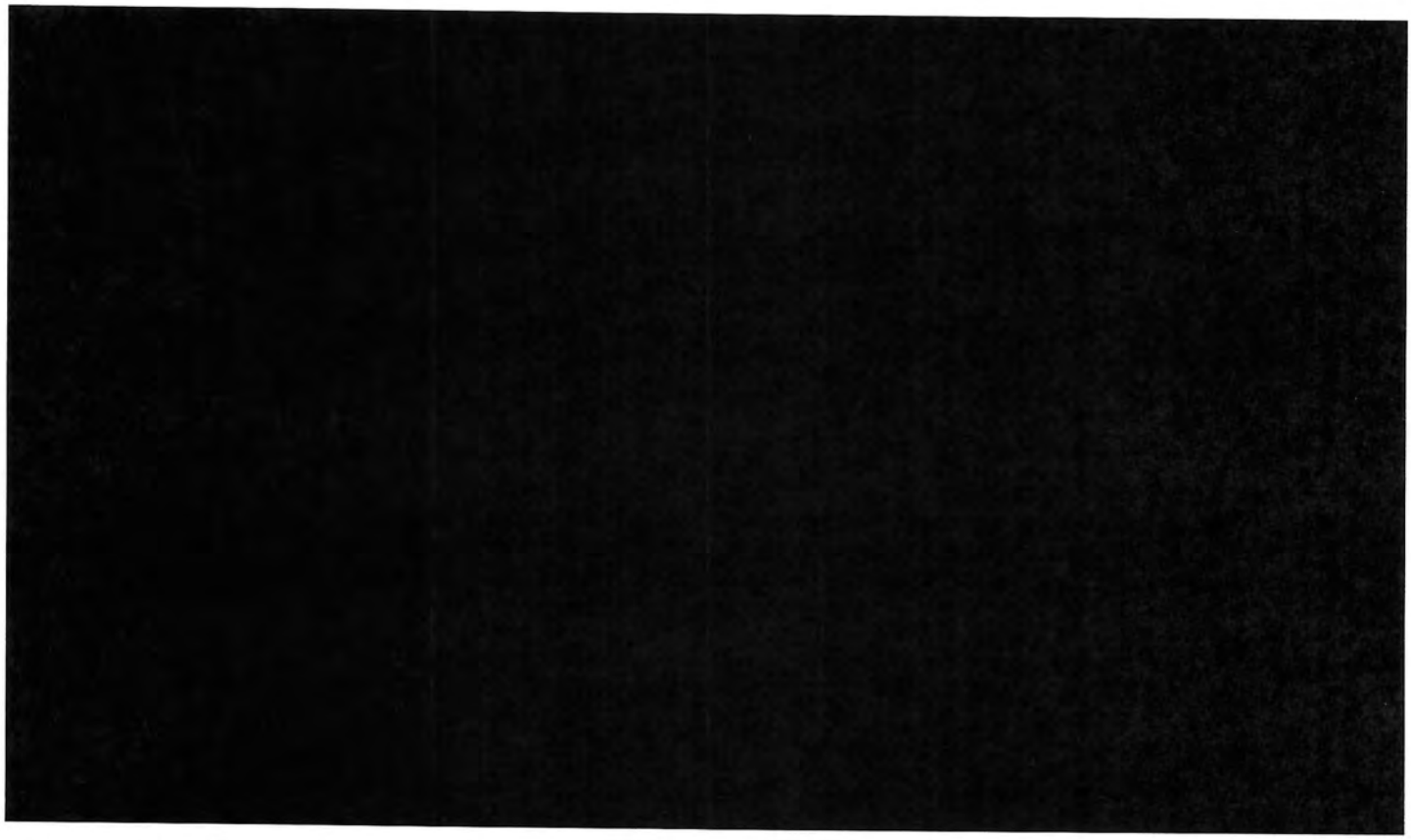
STATISTICAL ANALYSIS PLAN REVISION SUMMARY			
Version	**Version Date**	**Authors**	**Summary of Changes**
Final V1.0	05-Feb-2025	[redacted]	Initial version

SIGNATURE PAGE

AUTHOR





This statistical analysis plan will be reviewed and revised as needed. The most recent version will replace the previous version in place.

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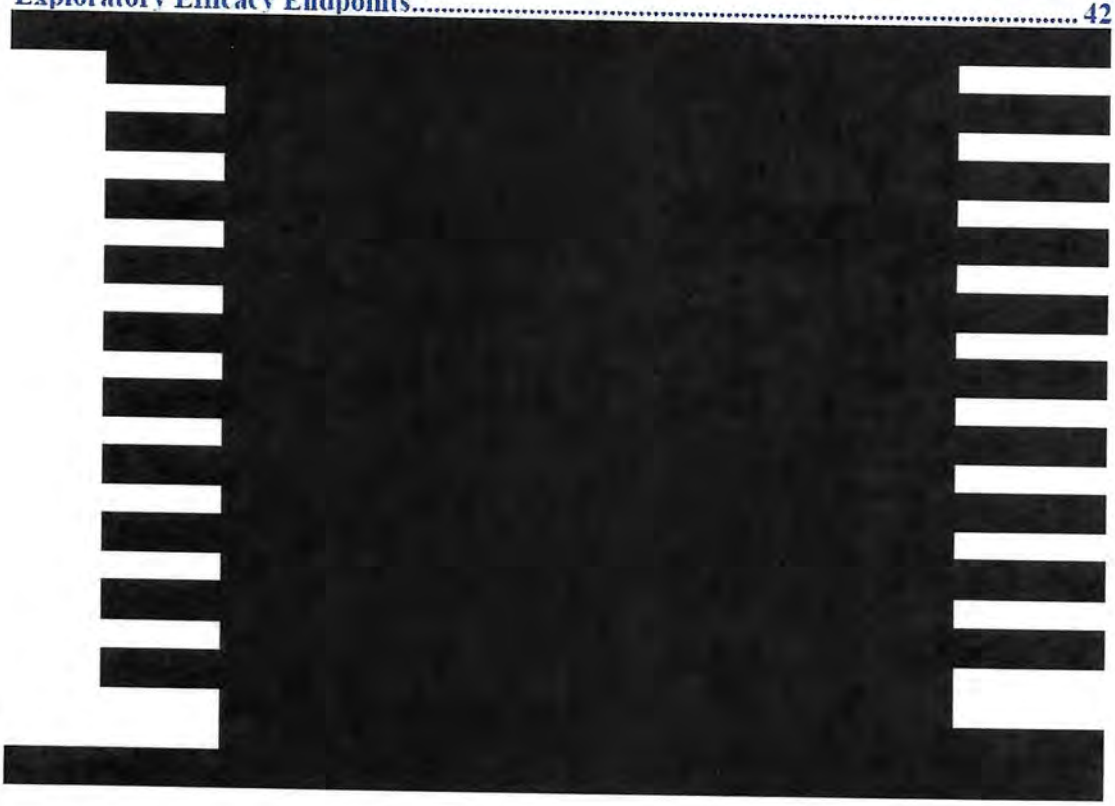
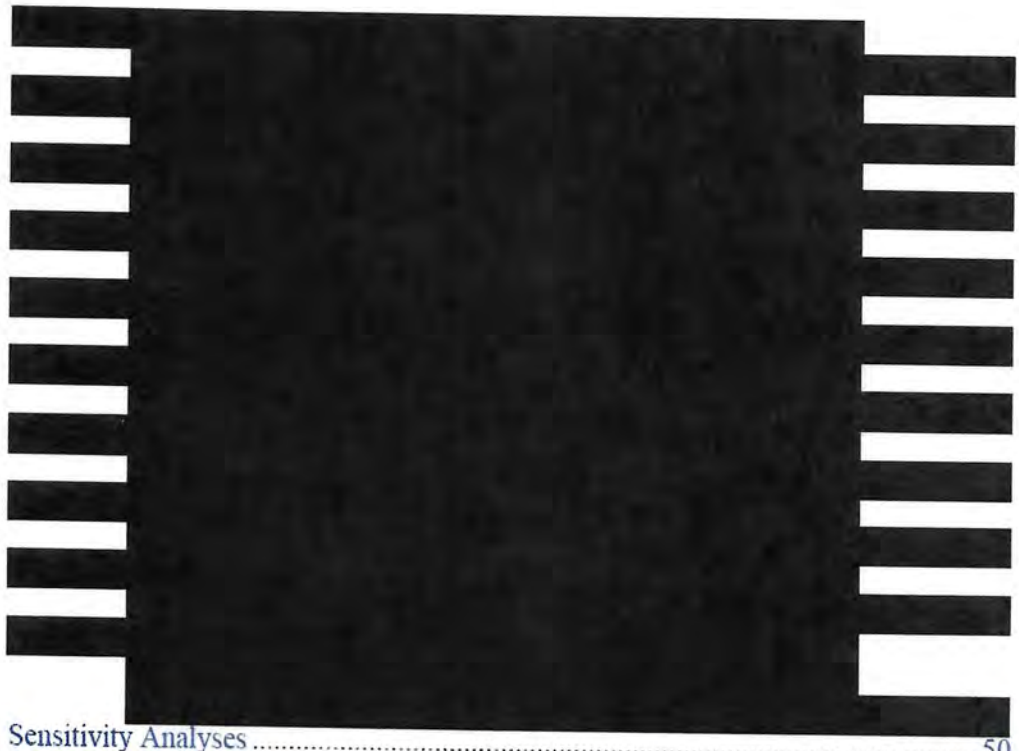




ABBREVIATIONS

AE	adverse event
ATC	anatomical therapeutic chemical
BLQ	below the limit of quantification
BMI	body mass index
CI	confidence interval
DBP	diastolic blood pressure
ECG	electrocardiogram
eCRF	electronic case report form
ET	early termination
IA	interim analysis
IWRS	interactive web response system
ITT	intent-to-treat
LLN	lower limit of normal
LLT	lowest level term
LSR	local skin reaction
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified intent-to-treat
msec	millisecond
n	number of subjects with non-missing data
OLE	open-label extension
PDMP	protocol deviation management plan
PP	per protocol
PK	pharmacokinetic
PRO	patient-reported outcome
PT	preferred term
QT	QT interval
QTcF	Fridericia's correction formula for QT interval
SAE	serious adverse event
SAP	statistical analysis plan
SAS	statistical analysis system®
SBP	systolic blood pressure
SD	standard deviation
SE	standard error
SOC	system organ class
[redacted]	[redacted]
TEAE	treatment-emergent adverse event
TLF	tables, listings, and figures
ULN	upper limit of normal
WHO-DD	World Health Organization Drug Dictionary
WOCBP	women of childbearing potential

1 INTRODUCTION

This statistical analysis plan (SAP) describes the planned analysis and reporting for the randomized portion of the Pelage Pharmaceuticals clinical protocol PP405-2001. The planned analysis and reporting for the open-label extension (OLE) period are described in a separate SAP. The analyses described in this SAP are based upon the protocol amendment 3, version 4.0, dated 06-Dec-2024.

This SAP has been developed and finalized prior to the first study database lock.

Pharmacodynamic analyses of the randomized portion of the study [redacted] are described in section 16 of this SAP. These analyses are under Pelage's responsibility and results will be included in a separate report. Of note, there are no shells associated to these analyses in the document describing the study's shells for tables, listings, and figures.

2 STUDY OBJECTIVES AND ENDPOINTS

2.1 Randomized portion of the study

The objectives and endpoints of the randomized portion of the study are presented below:

OBJECTIVES	ENDPOINTS
Primary	**Primary safety endpoints:**
To evaluate the safety and tolerability of PP405 in subjects with androgenetic alopecia	• Incidence and magnitude of treatment-emergent laboratory abnormalities, local skin reactions (LSR), adverse events (AE), treatment emergent adverse events (TEAE) and serious adverse events (SAE). • Change from baseline in vital signs. • Change from baseline in electrocardiogram (ECG).
Secondary	**Secondary efficacy endpoint:**
To assess the concentration of PP405 in plasma in subjects with androgenetic alopecia	• Plasma concentrations of PP405 on Days 1, 14, and 28.

OBJECTIVES	ENDPOINTS
Exploratory	**Exploratory efficacy endpoints:**
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]

These endpoints were defined after the finalization of the first protocol version and prior to the finalization of the SAP:

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]
[redacted]	[redacted]

2.2 OLE portion of the study

OBJECTIVES	ENDPOINTS
Primary	**Primary safety endpoints:**
To evaluate the safety and tolerability of 3 months of open-label treatment with daily PP405 in subjects with androgenetic alopecia	• Incidence and magnitude of treatment-emergent laboratory abnormalities, LSRs, AEs, TEAEs and SAEs. • Change from OLE baseline in vital signs. • Change from OLE baseline in ECGs.

OBJECTIVES	ENDPOINTS
Secondary	**Secondary efficacy endpoint:**
To assess the concentration of PP405 in plasma during 3 months of open-label treatment in subjects with androgenetic alopecia	• Plasma concentrations of PP405 on Days 1, 28 and 84.
Exploratory	**Exploratory efficacy endpoints:**
[redacted]	[redacted]

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

3 STUDY DESIGN

3.1 Overall Design

This is a multicenter, double-blind, vehicle-controlled study of the safety, tolerability, and preliminary efficacy of PP405 in subjects with androgenetic alopecia. Approximately 60 subjects will be randomized 2:1 to receive:

- PP405 Topical Gel, 0.05%, or
- PP 405 Vehicle Topical Gel (also referred as Vehicle)

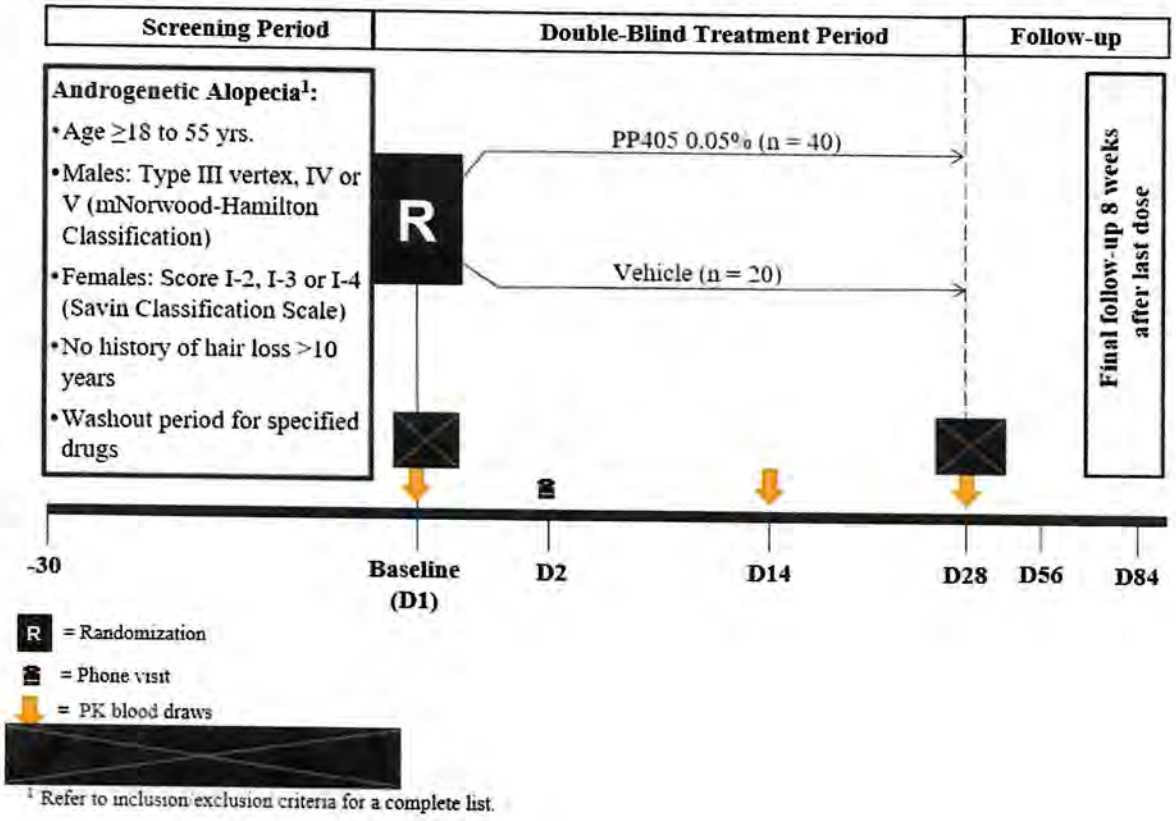
as once daily topical gels for 28 days. Subjects will have a final follow-up visit to evaluate the endpoints on Day 84. The study is composed of the randomized portion and an OLE period. Total duration of the randomized portion is up to approximately 114 days, including up to 30 days of screening, 28 days of treatment, and 56 days of post-treatment follow-up. Total duration of the OLE period is up to approximately 198 days, including up to 30 days of screening, 84 days of treatment, and 84 days of post-treatment follow-up.

Randomization will be stratified by sex at birth (male/female) and by the hair loss type based on the Norwood Hamilton Scale (men) (Type III vertex, Type IV, and Type V) or the Savin Scale (women) (I-2, I-3, and I-4). Enrollment of women will be capped at no more than 15 subjects (or 25% of the planned study population).

This study will be conducted at approximately 8 sites within the US. At selected study sites, [redacted] afety will be assessed through physical examination, vital signs, serum chemistry, hematology, urinalysis, 12-lead electrocardiogram, incidence and severity of local skin reactions, adverse events, treatment emergent adverse events, and serious adverse events before and after the treatment. [redacted] The Pharmacokinetic (PK) of PP405 will be evaluated in plasma. Assessment of these endpoints will occur at the timepoints specified in the Schedule of Assessments (refer to Table 1; randomized portion).

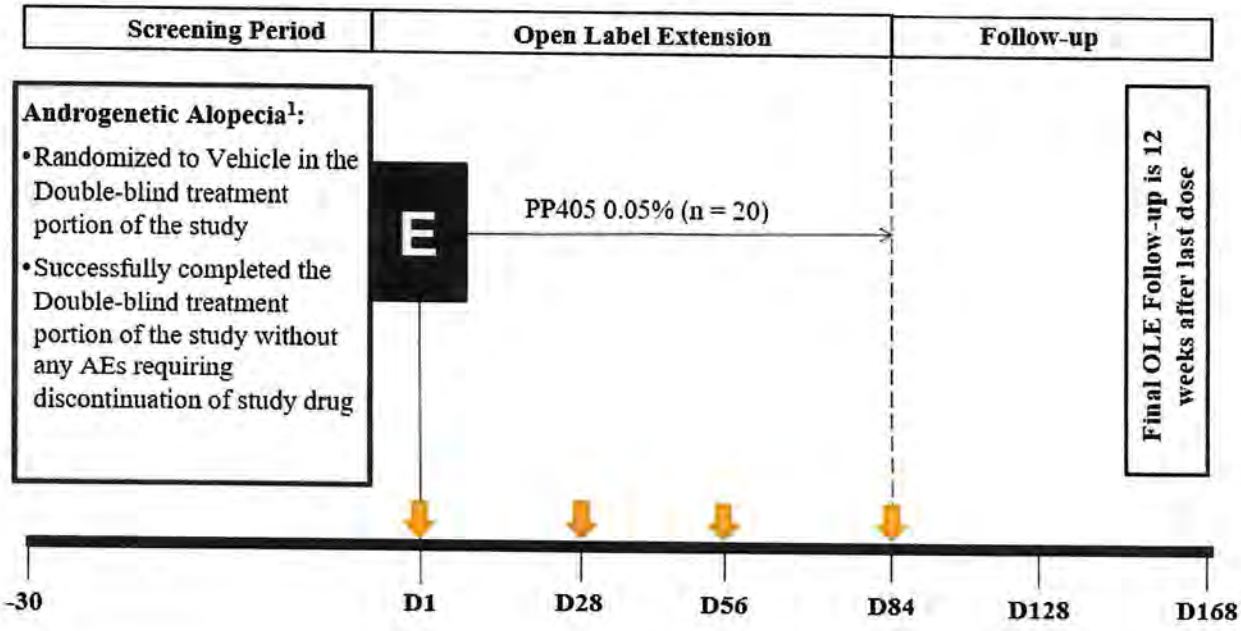
Subjects randomized to the vehicle arm in the randomized portion of this study who complete the treatment period, and the follow-up period may be eligible to participate in the OLE portion of the study. Subjects will be re-screened based on the OLE entry criteria and will then receive open-label treatment with once-daily PP405 topical gel for 12 weeks at the same dose (0.05%) administered in the randomized portion of the study. Subjects will be evaluated with a subset of the assessments used during the randomized portion, as shown in the Schedule of Assessments for the OLE portion (refer to Table 2).

The diagram below represents the study design for the randomized portion of the study.



[1] Refer to inclusion/exclusion criteria for a complete list.

The diagram below represents the study design for the OLE portion of the study.



E = Enroll

= PK blood draws

[1] Refer to inclusion/exclusion criteria for a complete list.

3.2 Schedule of Assessments

Table 1 provides a description of the procedures planned at each visit of the randomized portion of the study.

Table 1: Schedule of Assessments of the randomized portion of the study

	Screening [a]	Double-blinded Treatment Period				Follow Up Period [a]	
Procedures	**-30 days**	**Day 1[a] (Baseline)**	**Day 2 [b] (Phone)**	**Day 14 [a]**	**Day 28 [a] (EOT/ET)**	**Day 56**	**Day 84 (EOS)**
Visit Window (days)			**+1**	**± 2**	**± 3**	**± 3**	**± 3**
Informed Consent	X						
Demographics	X						
Medical History	X	X					
Inclusion/Exclusion Criteria	X	X					
Height and Weight [c]	X	X		X	X	X	X
Vital Signs (Blood pressure [sitting], heart rate, respiration rate, and body temperature)	X	X		X	X	X	X
Physical Examination [d]	X	X		X	X	X	X
12-lead ECG	X	X			X		
Treatment Area Identification		X					
Modified Norwood Hamilton Scale or Savin Scale	X	X					
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							

Procedures	Screening [a]	Double-blinded Treatment Period				Follow Up Period [a]	
	-30 days	Day 1[a] (Baseline)	Day 2 [b] (Phone)	Day 14 [a]	Day 28 [a] (EOT/ET)	Day 56	Day 84 (EOS)
Visit Window (days)			+1	± 2	± 3	± 3	± 3
Randomization		X					
Local Skin Reactions [g]		X		X	X		
AE/TEAE/SAE collection [h]	X	X	X	X	X	X	X
Concomitant Medication	X	X	X	X	X	X	X
Serum Chemistry/Hematology/Urinalysis [i]	X	X		X	X		
COVID-19 Rapid Test	X	X					
Serum Pregnancy test for WOCBP	X						
Urine pregnancy test β hCG for WOCBP only [j]		X		X	X		X
Blood Sam le for PK [k]		X		X	X		
[redacted]							
Dispense Study Drug		X		X			
Confirm subject using approved Shampoo/Conditioner [m]	X	X	X	X	X	X	X
Study Drug accountability & Return [n]				X	X		
Dispense Dosing Diary		X					
Review Dosing Diary [o]			X	X	X		
Drug Application at the clinic [p]		X		X	X		

AE = adverse event; ClinRO = clinician-reported outcome; eCRF = electronic case report form; EDC = electronic data capture system; PK = pharmacokinetics; PRO = patient reported outcome; TEAE = treatment-emergent AE

[a] Subjects will be evaluated in the clinic. Investigators should make every effort to adhere to the schedule as outlined above. In the event a subject misses a clinic visit, the subject should be instructed to complete dosing at home and return to the clinic as soon as possible to complete all study assessments required for the missed clinic visit.

[b] During the Day 2 phone call visit, the site should confirm that the subject is able to properly apply study drug.

[c] Height is only required at screening. Weight should be collected at screening and all other clinic visits.

[d] At screening and Days 1 and 28, a complete physical examination is required. On Days 14, 56, and 84, a symptom-related brief physical examination will occur if the subject is experiencing symptoms or AEs. If a symptom-related brief physical exam is required, it should include a review of all body systems that relate to the symptoms and/or AE the subject is experiencing.

[e] At screening only Global photography is required, on Day 14 only macrophotography is required. At other visits both macro and global photography will be taken. In addition, male subjects who are being treated at both the vertex (crown) and frontal/temporal areas will have an option to complete the macrophotography at the frontal/temporal area as

[redacted]

[g] LSR assessment will be repeated pre and post application of study drug. See Section 10.10.5 of the Study Protocol for detailed instructions.

[h] SAEs will be collected at the time of informed consent and through the Day 84 follow-up visit. AEs and TEAEs will be collected from the first dose of study drug and through the Day 84 follow-up visit.

[i] If serum chemistry, hematology and urinalysis are completed ≤ 7 days prior to baseline, they will not need to be drawn on Day 1 and will be considered both screening and baseline labs. If serum chemistry, hematology, and urinalysis were completed > 7 days prior to baseline, then they will need to be drawn again on Day 1.

[j] A negative urine pregnancy test result must be obtained prior to application of the study drug. A positive urine pregnancy test at any time during the study requires immediate interruption of the study drug until a serum pregnancy test is performed and found to be negative. The subject must be discontinued from the study and followed if pregnancy is confirmed by a positive serum pregnancy test.

[k] Pk will be collected 2 hours (+/-10 minutes) post dose at each clinic visit.

[redacted]

[m] At each clinic visit, the investigator should confirm that the subject has not changed the shampoo/conditioner since the last visit. If the subject has changed their shampoo/conditioner, the new product should be added to the concomitant medication page in the eCRF.

[n] Subjects should be instructed to bring their study drug bottles with them for each clinic visit on Days 14 and 28. The investigator or designee will weigh the pump bottles prior to dispensing (after priming) on Days 1 and 14 (as applicable) and then after dosing on Days 14 and 28. The weight should be documented in the subject's drug accountability log. Refer to Section 7.7 of the Study Protocol for instructions for final disposition and return of used bottles. On Day 14 and extra bottle of study drug will be dispensed to male subjects who are dosing both the frontal/temporal and vertex (crown) areas.

[o] Site staff should review the dosing diary with the subject at each clinic visit. During the Day 2 phone call visit site staff should confirm that subjects are completing their diaries. See Section 7.8 of the study protocol for dosing diary instructions and compliance.

[p] See Appendix A of the Study Protocol for guidance on the proper way to apply study drug. Subjects will apply study drug once per day every day for 28 days. It is recommended that subjects apply study drug in the evening at least 2 hours prior to bedtime. On Day 1 the subject should apply study drug themselves in the clinic under the supervision of trained study staff to ensure a complete understanding of how to apply the study drug. On Days 14 and 28 subjects should be instructed to apply study drug in the clinic rather than their normal dosing time at home.

Table 2 provides a description of the procedures planned at each visit of the OLE portion of the study.

Table 2: Schedule of Assessments of the OLE portion of the study

	Screening [a]	Open-label Treatment Period				Follow-up Period [a]	
Procedures	**-30 days**	**Day 1 [a] (Baseline)**	**Day 28 [a]**	**Day 56 [a]**	**Day 84 [a] (EOT/ET)**	**Day 124**	**Day 168 (EOS)**
Visit Window (days)			**± 5**	**± 5**	**± 5**	**± 7**	**± 7**
Informed Consent	X						
Medical History	X	X					
Inclusion/Exclusion Criteria	X	X					
Weight	X	X	X	X	X	X	X
Vital Signs (Blood pressure [sitting], heart rate, respiration rate, and body temperature)	X	X	X	X	X	X	X
Physical Examination [b]	X	X	X	X	X	X	X
12-lead ECG	X	X			X		
Treatment Area Identification		X					
Modified Norwood Hamilton Scale or Savin Scale	X	X					
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
Local Skin Reactions [d]		X	X	X	X		
AE/TEAE/SAE collection [e]	X	X	X	X	X	X	X
Concomitant Medication	X	X	X	X	X	X	X
Serum Chemistry/Hematology/Urinalysis [f]	X	X	X	X	X		
COVID-19 Rapid Test	X	X					

Procedures	Screening [a]	Open-label Treatment Period				Follow-up Period [a]	
	-30 days	Day 1 [a] (Baseline)	Day 28 [a]	Day 56 [a]	Day 84 [a] (EOT/ET)	Day 124	Day 168 (EOS)
Visit Window (days)			± 5	± 5	± 5	± 7	± 7
Serum Pregnancy test for WOCBP	X						
Urine pregnancy test β hCG for WOCBP only [g]		X	X	X	X		X
Blood Sample for PK [h]		X	X	X	X		
Dispense Study Drug [i]		X	X	X			
Confirm subject using approved Shampoo/Conditioner [j]	X	X	X	X	X	X	X
Study Drug accountability & Return [k]			X	X	X		
Dispense Dosing Diary		X					
Review Dosing Diary [l]			X	X	X		
Drug Application at the clinic [m]		X	X	X	X		
Drug Application at the clinic [m]		X	X	X	X		

AE = adverse event; ClinRO = clinician-reported outcome; eCRF = electronic case report form; PK = pharmacokinetics; PRO = patient reported outcome; TEAE = treatment-emergent AE.

[a] Subjects will be evaluated and dosed in the clinic. Investigators should make every effort to adhere to the schedule as outlined above. In the event a subject misses a clinic visit, the subject should be instructed to complete dosing at home and return to the clinic as soon as possible to complete all study assessments required for the missed clinic visit.

[b] At screening and Days 1 and 84, a complete physical examination is required. On Days 28, 56, 84 and 124, and 168, a symptom-related brief physical examination will occur if the subject is experiencing symptoms or AEs. If a symptom-related brief physical exam is required, it should include a review of all body systems that relate to the symptoms and/or AE the subject is experiencing.

[redacted]

[d] LSR assessment will be repeated pre and post application of study drug. See Section 10.10.5 of the Study Protocol for detailed instructions.

[e] SAEs will be collected at the time of informed consent for the OLE and through the Day 168 follow-up visit. AEs and TEAEs will be collected from the first dose of OLE study drug and through the Day 168 follow-up visit.

[f] If serum chemistry, hematology and urinalysis are completed ≤ 7 days prior to baseline, they will not need to be drawn on Day 1 and will be considered both screening and baseline labs. If serum chemistry, hematology, and urinalysis were completed > 7 days prior to baseline, then they will need to be drawn again on Day 1.

[g] A negative urine pregnancy test result must be obtained prior to application of the study drug. A positive urine pregnancy test at any time during the study requires immediate interruption of the study drug until a serum pregnancy test is performed and found to be negative. The subject must be discontinued from the study and followed if pregnancy is confirmed by a positive serum pregnancy test.

[h] PK will be collected 2 hours (+/-10 minutes) post dose on Days 1, 28 and 56. For the Day 84 visit samples will be collected at 1, 2, and 4 hours post dose (+/-10 minutes).

[i] At every visit, 2 bottles will be dispensed for those subjects treating 1 area and 3 bottles for those treating 2 areas.

[j] At each clinic visit the investigator should confirm that the subject has not changed the shampoo/conditioner since the last visit. If the subject has changed their shampoo/conditioner, the new product should be added to the concomitant medication page in the eCRF.

[k] Subjects should be instructed to bring their study drug bottles with them for each clinic visit on Days 28, 56, and 84. The investigator or designee will weigh the pump bottles prior to dispensing (after priming) on Days 1, 28, and 56 and then again after dosing. On Days 28 and 56 subjects should return the used study drug and new bottles should be dispensed. Subjects will be dosed in the clinic with the new bottles on Days 28 and 56. On Day 84 subjects will receive a final dose in the clinic and final weight of the bottle should be documented after dosing. The weight should be documented in the subject's drug accountability log. Refer to Section 8.7 of the Study Protocol or instructions for final disposition and return of used bottles.

[l] Site staff should review the dosing diary with the subject at each clinic visit and confirm completeness. See Section 8.8 of the Study Protocol for dosing diary instructions and compliance.

[m] See Appendix A of the Study Protocol for guidance on the proper way to apply study drug. Subjects will apply study drug once per day every day for 84 days. It is recommended that subjects apply study drug in the evening at least 2 hours prior to bedtime. On Day 1 the subject should apply study drug themselves in the clinic under the supervision of trained study staff to ensure a complete understanding of how to apply the study drug. On Days 28, 56, and 84 subjects should be instructed to apply study drug in the clinic rather than their normal dosing time at home.

3.3 Treatment Groups, Randomization, Replacement, Blinding, and Unblinding Procedures

Randomization and Treatment Groups

Approximately 60 subjects will be randomized 2:1 to receive:

- PP405 Topical Gel, 0.05%, or
- PP405 Vehicle Topical Gel (also referred as Vehicle)

as once daily topical gels for 28 days, during the randomized portion of the study. Randomization will be stratified by sex at birth (male/female) and by hair loss type based on the Norwood Hamilton Scale (men; Type III vertex, Type IV, and Type V) or the Savin Scale (women; I-2, I-3, and I-4). No more than 15 women (or 25% of the planned study population) will be randomized to the trial.

During the OLE portion of the study, the subjects who received vehicle initially during the randomized portion of the study and who consent to participate and are eligible to participate, will enter the OLE to receive active treatment.

Subject Replacement

Subject enrollment will continue until approximately 60 subjects have been randomized. Subjects who are randomized and do not complete the study will not be replaced.

Blinding and Unblinding Procedures

In this blinded study, the designated group and treatment assigned to each subject will not be revealed to the investigator, the subject, or the Sponsor or designee, until the decision is made to unblind the study. Data from individual subjects may be unblinded if deemed medically necessary by the investigator or as required by local regulation in the case of an unexpected SAE. The IWRS will be used to perform emergency unblinding by authorized individuals.

The master randomization schedule will be maintained within the IWRS system and will be kept secured until the study blind is broken at the end of the study. The Sponsor or designee will specify the names of the individuals who will be unblinded prior to the database lock within the study Unblinding Plan. Refer to the study Unblinding Plan for more details. Further guidance and information on randomization via IWRS can be obtained in a separate manual.

During the study, the blind is to be broken only when the safety of a subject is at risk and the treatment plan is dependent on the study drug received. If the unblinding occurs without the knowledge of the Sponsor and/or designee, the investigator must notify the Sponsor and/or designee as soon as possible and no later than the next business morning. All circumstances surrounding a premature unblinding must be clearly documented in the source records. The subject for whom the blind has been broken will be discontinued from the study and the investigator should make every effort to complete all procedures for the ET visit.

The sponsor or designee will not release the randomization schedule to any party except upon formal written request by the Sponsor. The request must be approved by the appropriate Sponsor personnel. Details of any disclosure of the randomization schedule will be recorded in the site's study files and the Trial Master File (TMF). A copy will also be sent to the Sponsor and/or designee. The blinding of the study will be broken after the database has been locked. Refer to the study Unblinding Plan for more details.

3.4 Changes from Planned Analyses Described in the Protocol

Changes to the analyses planned in the protocol are listed in Table 3.

Table 3: Summary of Changes from Planned Analyses Described in the Protocol

Description of the change	Rationale for change
PK analysis (refer to section 13.2.2 of the study protocol) • PK analysis will be performed based on the PK analysis population and not based on the intent-to-treat analysis population.	The PK population is already defined in the study protocol and the PK analysis should be performed based on the PK analysis population which considers use of study drug and available plasma concentrations.
[redacted]	[redacted]

Description of the change	Rationale for change
[redacted]	

4 PLANNED ANALYSES

4.1 Data Monitoring Committee

Not applicable.

4.2 Interim Analyses

Not applicable.

4.3 Final Analysis

Final analysis will be performed after signature of this SAP, clinical trial data are entered into the database, any discrepancies in the data are resolved, database is locked, and study is unblinded.

5 ANALYSIS POPULATIONS

The list of subjects included or excluded from each analysis population will be reviewed, finalized, and approved in a blinded fashion by the Sponsor prior to the database lock for the final analysis.

5.1 All Screened Subjects Analysis Population

The 'all screened subjects' analysis population will include all subjects who signed an informed consent.

This analysis population will be used to summarize disposition data.

5.2 Intent-to-Treat Analysis Population

The Intent-to-Treat (ITT) analysis population will include all randomized subjects.

5.3 Modified Intent-to-Treat Analysis Population

The modified Intent-to-Treat (mITT) analysis population will include all randomized subjects who receive any amount of study drug and have at least 1 assessment at baseline and post-baseline [redacted] Pharmacodynamics' endpoint will not be considered to define the mITT population.

Subjects will be analyzed according to their randomized treatment group and randomized stratum. [redacted]

5.4 Per-Protocol Analysis Population

The per-protocol (PP) analysis population will include all randomized subjects who do not have any major protocol deviations (refer to Section 8.2).

All subjects will be analyzed according to the actual treatment they received and actual stratum. [redacted]

5.5 Safety Analysis Population

The safety analysis population will include all randomized subjects who receive any amount of study drug.

All subjects will be analyzed according to the actual treatment they received. This analysis population will be used to summarize demographic and other baseline characteristics, surgical and medical history, disease history, prior and concomitant medications, exposure to and compliance with study drug, and all safety data.

5.6 Pharmacokinetic Analysis Population

The Pharmacokinetic (PK) analysis population will include all randomized subjects who receive at least one dose of PP405 0.05% and have at least one post-baseline plasma concentration available.

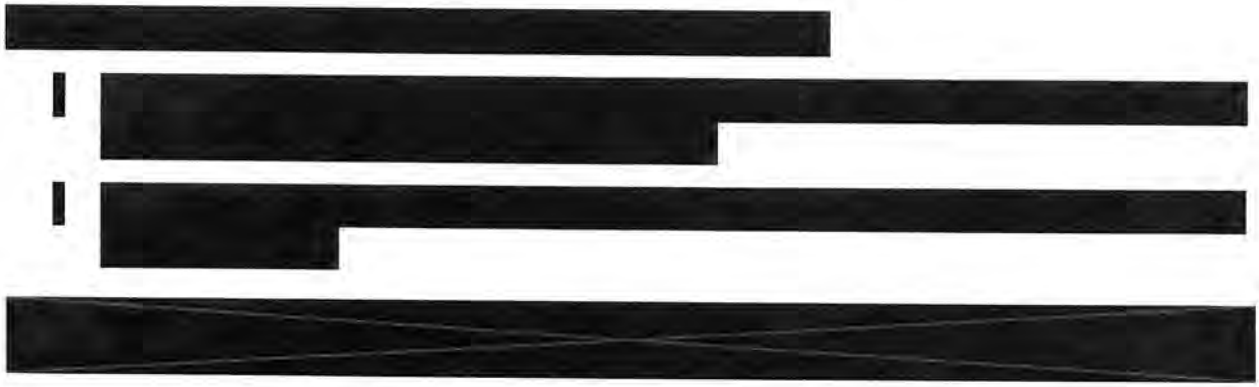
All subjects will be analyzed according to the actual treatment they received. This analysis population will be used to summarize PP405 plasma concentrations.

6 GENERAL CONSIDERATIONS

Table, listing, and figure (TLFs) Shells will be provided in a separate document. Refer to Appendix 1 for a general description of TLF format and layout.

6.1 Baseline

Unless otherwise specified, baseline is defined as the last non-missing assessment performed prior to the first application of study drug (including unscheduled assessments). If the last non-missing assessment is performed on the same date as the first application of study drug and time is not available, then the assessment will be considered as baseline, except for adverse events (AEs) and medications starting on the date as the first application of study drug which will be considered post-baseline.



6.2 Change and Percent Change from Baseline

Change from baseline at post-baseline visit X will be calculated as:

Assessment value at post-baseline visit X – Baseline value

Percent change from baseline at visit X will be calculated as:

[(Assessment value at post-baseline visit X – Baseline value) / Baseline value] * 100

Should the baseline value be 0 (zero), percent change from baseline will be set to missing.

6.3 Study Day

Study Day will be calculated from the first application of study drug as follows and will be used to show the start/end day of assessments or events:

(Date of assessment/event – Date of first application of study drug) if the date of assessment/event is before the date of the first application of study drug.

or

(Date of assessment/event – Date of first application of study drug) + 1 if the date of assessment/event is on or after the date of the first dose/application of study drug.

When the assessment/event date is partially or completely missing, the Study Day will be considered as missing.

6.4 Windowing Conventions

For by-visit summary and analysis (when applicable), visits will be summarized and analyzed as scheduled (refer to Table 1). Retest, unscheduled, and early termination (ET) visits will only be considered if a scheduled measurement is not available and a retest, unscheduled, and/or ET measurement falls within the protocol-adjusted analysis visit window for that scheduled measurement, as described in Table 4 to Table 10.

For summary and analysis (when applicable) not presented by visit (e.g., worst post-baseline value), all data (scheduled, retest, unscheduled, and ET) will be considered.

All data collected during scheduled, retest, unscheduled, and ET visits will be listed.

Table 4: Protocol-Adjusted Analysis Visit Windows for Vital Signs, Weight, [redacted]

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 14	14	Post baseline	21
Day 28	28	22	42
Day 56	56	43	70
Day 84	84	71	n/a

Table 5: Protocol-Adjusted Analysis Visit Windows [redacted]

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 28	28	Post baseline	42
Day 56	56	43	70
Day 84	84	71	n/a

Table 6: Protocol-Adjusted Analysis Visit Windows [redacted]

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 28	28	Post baseline	42
Day 56	56	43	n/a

Table 7: Protocol-Adjusted Analysis Visit Windows [redacted]

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 28	28	Post baseline	56
Day 84	84	57	n/a

Table 8: Protocol-Adjusted Analysis Visit Windows [redacted]

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 84	84	77	n/a

Table 9: Protocol-Adjusted Analysis Visit Windows for 12-lead ECG

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 28	28	21	n/a

Table 10: Protocol-Adjusted Analysis Visit Windows for Chemistry, Hematology, Urinalysis, and Local Skin Reactions

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
Day 14	14	Post baseline	21
Day 28	28	22	n/a

If more than one assessment falls within the same protocol-adjusted analysis visit windows and a scheduled measurement is not available, the measurement collected closest to the scheduled visit target study day will be used for the by-visit summary. If two measurements or more are equidistant from a scheduled visit target study day, the measurement collected after the scheduled visit target study day will be used.

6.5 Software Version

All analyses will be performed using SAS® software Version 9.4 or higher.

7 STATISTICAL CONSIDERATIONS

7.1 Sample Size Determination

The sample size has been based on clinical considerations only. The planned sample size of 60 male and female subjects is considered sufficient to meet all the objectives. [redacted] With a 20% dropout rate, the sample size of 15 male subjects in the vehicle group and 30 male subjects in PP405 group will be enrolled.

Up to 15 female subjects will be included to evaluate gender effect. So, a total of 60 male and female subjects will be randomized 2:1 to receive PP405 0.05% or vehicle stratified by sex at birth (75% male and 25% female) and hair loss type based on the Norwood Hamilton Scale (male) or the Savin Scale (female).

7.2 Multicenter Studies

This study will be conducted by multiple investigators at approximately 8 sites within the United States. Data from all sites will be pooled together in the summaries and analyses.

7.3 Handling of Dropouts or Missing data

Unless otherwise specified in the sections below, no missing data will be imputed.

7.3.1 Efficacy Data

[redacted]

7.3.2 Safety Data

Partially or completely missing medication and AE start and stop dates will be imputed as described in Appendix 2 and will only be used for the classification of each medication as prior or concomitant (refer to Section 11) and each AE as prior or treatment-emergent (refer to Section 14.1). That is, imputed dates will not be used to compute duration and will not be presented in subject data listings.

7.4 Descriptive Statistics

Continuous endpoints will be summarized using descriptive statistics i.e., number of subjects with non-missing data (n), mean, standard deviation (SD), median, minimum, and maximum.

Categorical endpoints will be summarized using frequencies and percentages.

7.5 Adjustment for Covariates and/or Fixed Effect

The following covariate and fixed effects will be included [redacted]

- Baseline value [redacted]

- Hair loss-type (Norwood Hamilton Scale)
- Treatment group
- Visit as the time factor, when applicable
- Interaction term for treatment-by-visit, when applicable

Sex at birth and hair-loss type (Savin scale) are not included as fixed effects [redacted]

[redacted]

7.6 Coverage of Confidence Intervals and Statistical Tests

Confidence intervals (CIs) will be two-sided with 95% coverage.

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

7.7 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons/multiplicity will be made for this study.

7.8 Examination of Subgroups

Subgroups analyses will be performed for the exploratory efficacy endpoints for the following subgroups:

- Baseline clinical onset of AGA (≤5 years, >5 years)
- Age category (≥18 and <30 years, ≥30 and <40 years, ≥40 and <50 years, ≥50 years)
- Hair loss type (Norwood Hamilton Scale for men: Type III vertex, Type IV, and Type V or Savin Scale for women: I-2, I-3, and I-4)
- Life stress category (≥1 and ≤3, 4 and 5), based on the first question of the Life Stress questionnaire

8 STUDY SUBJECTS

8.1 Disposition of Subjects

All subjects who provide informed consent will be accounted for in this study. The number of subjects screened and rescreened will be presented. The number and percentage of subjects with screen failure will be presented for all screened subjects, except for those who were rescreened and did not fail the second screening. Reason for screen failure will be summarized similarly but for subjects with screen failure.

The number of subjects randomized will be presented overall and by treatment group. Number and percentage of subjects included in each analysis population, who completed or discontinued early from study drug, and who completed or discontinued early from study will be presented overall and by treatment group for all randomized subjects (ITT analysis population). Reason for discontinuation from study drug and reason for discontinuation from study will be presented similarly but for subjects who discontinued early from study drug and who discontinued early from study, respectively.

The number of days in the study will be calculated as follows and summarized overall and by treatment group:

(Date of completion/discontinuation – Date of randomization) +1

A listing of the subject's disposition will be provided. Information on first screening for subjects who were rescreened, including the rescreened subject identifier, will be presented under the first screening subject identifier. A listing of the subject's randomization information and a listing of subjects included/excluded from each of the analysis populations, with reason for exclusion, will also be provided.

8.2 Protocol Deviations

A blinded data review will be conducted before the database lock and study unblinding by the Medical Monitor and Sponsor to classify each protocol deviation as important or non-important (refer to Protocol Deviation Management Plan [PDMP]).

During this blinded data review, important protocol deviations will be further classified as major or minor by the Medical Monitor and Sponsor, where a major protocol deviation is defined as an important protocol deviation potentially having an impact on efficacy data. Major protocol deviations include, but are not limited to:

- Violation of key inclusion/exclusion criteria
- Being discontinued from the treatment because of non-compliance with study drug based on the investigator's and/or medical monitor's judgement (e.g., end of treatment eCRF)
- Having received a clinically meaningful amount of prohibited medications

With the following exception, classification of each protocol deviation as important or non-important and of each important protocol deviation as major or minor will be finalized and approved by Sponsor before the database lock and study unblinding. The exception is that after the database lock and study unblinding, randomized subjects who received a mixed of more than one treatment group will also be considered as having an important major protocol deviation.

The number of events and the number and percentage of subjects with at least one important protocol deviation will be summarized by deviation category and sub-category overall and by treatment group based on the safety analysis population. Site-level protocol deviations will be reported once for each subject randomized at that site.

Major protocol deviations will be summarized similarly.

A listing of all protocol deviations will be provided, and important and major deviations will be flagged.

9 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographics will be summarized overall and by treatment group using descriptive statistics based on the safety analysis population. Other baseline characteristics will also be summarized overall and by treatment group using descriptive statistics based on the safety analysis population. The list of demographics to be summarized includes:

- Age (years) as collected on electronic Case Report Form (eCRF)
- Sex at birth (Female, Male)
- Gender identity (Man, Woman, Nonbinary, Other)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
- Race (American Indian or Alaska native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White)

The list of baseline characteristics to be summarized includes:

- Baseline height (cm)
- Baseline weight (kg)
- Baseline body mass index (BMI; kg/m^2), derived as the baseline weight (kg) divided by the square of the baseline height (m^2) i.e., baseline height (m) x baseline height (m)
- Baseline hair loss type
    - Modified Norwood Hamilton Scale (male)
    - Savin Scale (female)
- Baseline treatment area identification (Vertex [Crown], Superior [Frontal-Temporal], Superior [Midline Parting])
- Baseline scores of Life Stress questionnaire
- Baseline status of "Subject using approved Shampoo/Conditioner" (Yes, No)

- Baseline clinical onset of AGA (i.e. time since start of AGA, months)

Subjects who reported more than one race will be counted once under each reported race.

Time since start of AGA (months) will be calculated as follows:

> Time since start of AGA (months) = (Date of first dose administration – start date of AGA)/ 30.4375.

Completely or partially missing dates for the start date of AGA will be imputed as follows:

- Completely missing: leave missing.
- Missing day and month: impute to January 1st.
- Missing day: impute to the 1st of the month.

If the start date of AGA is completely missing, then the time since start of AGA will be missing.

A listing of all demographics and other baseline characteristics will be provided.

A listing of contraceptive methods will also be provided.

10 SURGICAL AND MEDICAL HISTORY

Surgical and medical history will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA), version 27.0 or higher.

Incidence of surgical and medical history including AGA disease history will be summarized by system organ class (SOC) and preferred term (PT) overall and by treatment group based on the safety analysis population. Subjects who experienced the same surgical and medical history multiple times within the same SOC will be counted only once for the corresponding SOC. Similarly, subjects who experienced the same surgical and medical history multiple times within the same PT will be counted only once for the corresponding PT. Surgical and medical history will be sorted alphabetically by SOC and within each SOC, PTs will be presented by decreasing order of overall frequency.

A listing of all surgical and medical history will be provided, followed by a separate listing for Androgenetic Alopecia disease history at screening and a separate listing of AGA non-drug therapies and procedures, based on the safety analysis population.

11 PRIOR AND CONCOMITANT MEDICATIONS

Medications will be coded according to the World Health Organization Drug Dictionary (WHO-DD), B3 March 2024 or higher.

Prior medications, including prior AGA medications, are defined as any medication started and discontinued prior to the first application of study drug. Concomitant medications are defined as any medication taken on or after the first application of study drug, including those that started prior to the date of the first application of study drug and continued past that date. See Appendix 2 for handling of partially or completely missing medication start and stop dates.

Incidence of prior medications will be summarized by anatomical therapeutic chemical (ATC) class level 3 and preferred drug name overall and by treatment group based on the safety analysis population. Subjects with multiple medications within the same ATC class level 3 will be counted only once for that ATC class level 3. Similarly, subjects with multiple medications within the same preferred drug name will be counted only once for that preferred drug name. Prior medications will be sorted alphabetically by ATC class level 3 and within each ATC class level 3, the preferred drug name will be presented by decreasing order of overall frequency. Incidence of prior AGA medications will also be summarized similarly.

Concomitant medications will be summarized similarly.

A listing of all medications (prior and concomitant) will be provided. A listing of all prior AGA medications will also be provided.

Information on whether subjects are using an approved shampoo/conditioner or not will also be listed.

12 EXPOSURE TO AND COMPLIANCE WITH STUDY DRUG

Duration of exposure to study drug, in days, is defined as follows:

(Date of last application of study drug – Date of first application of study drug) + 1

The cumulative dose (g) per subject will be calculated by subtracting the total weight of bottles (g) returned after application of the product from the total weight of bottles (g) dispensed. Data for the bottles that are dispensed but not returned will be considered as missing and the concerned bottles will be excluded from this calculation.

Mean daily exposure (g/day) will be calculated by dividing the cumulative dose (g) by duration of exposure (days).

Compliance with study drug (%) will be calculated as follows:

$$\frac{\textbf{Cumulative dose per subject (grams)}}{\textbf{Duration of exposure (days) x Expected dose per day (grams)}} \textbf{ x 100}$$

where the number of expected doses per day is equal to 1g (equivalent to 1mL) for subjects treating one area and equal to 2g (equivalent to 2mL) for subjects treating both the vertex and the superior area.

Compliance with study drug (%) will also be categorized as follows:

- <80%
- ≥80% and ≤100%
- >100%

Duration of exposure to study drug (days), cumulative dose (g), mean daily exposure (g/day), and compliance with study drug (%) will be summarized using descriptive statistics by treatment group based on the safety analysis population. Number and percentage of subjects in each category of compliance with study drug (%) will also be presented by treatment group based on the safety analysis population.

Study drug accountability, exposure, and compliance will be listed.

13 EFFICACY ANALYSES

Unless otherwise specified, all efficacy endpoints will be summarized by sex at birth, treatment group and visit, when applicable, [redacted] (refer to Section 5.3).

All efficacy data will be [redacted]

13.1 Primary Efficacy Endpoints

The primary objective of the study is to evaluate the safety and tolerability of PP405 in subjects with androgenetic alopecia. There are no primary efficacy endpoints in this study.

13.2 Secondary Efficacy Endpoints

The secondary objective of the study is to assess the concentration of PP405 in plasma in subjects with androgenetic alopecia. This will be covered in the PK analysis section. Refer to Section 15 for more details. There are no other secondary efficacy endpoints in this study.

13.3 Exploratory Efficacy Endpoints

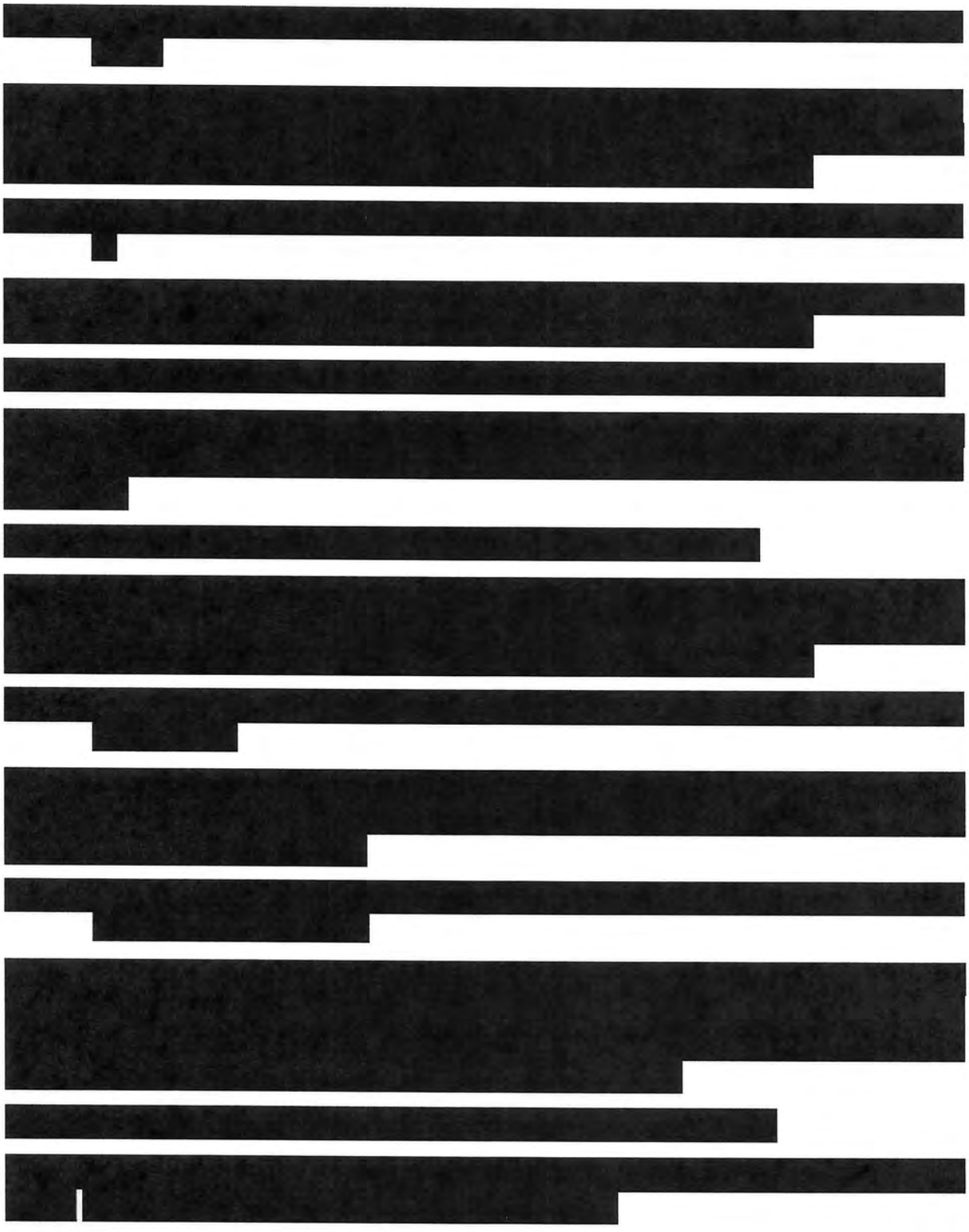
13.3.1 Definition of Exploratory Efficacy Endpoints

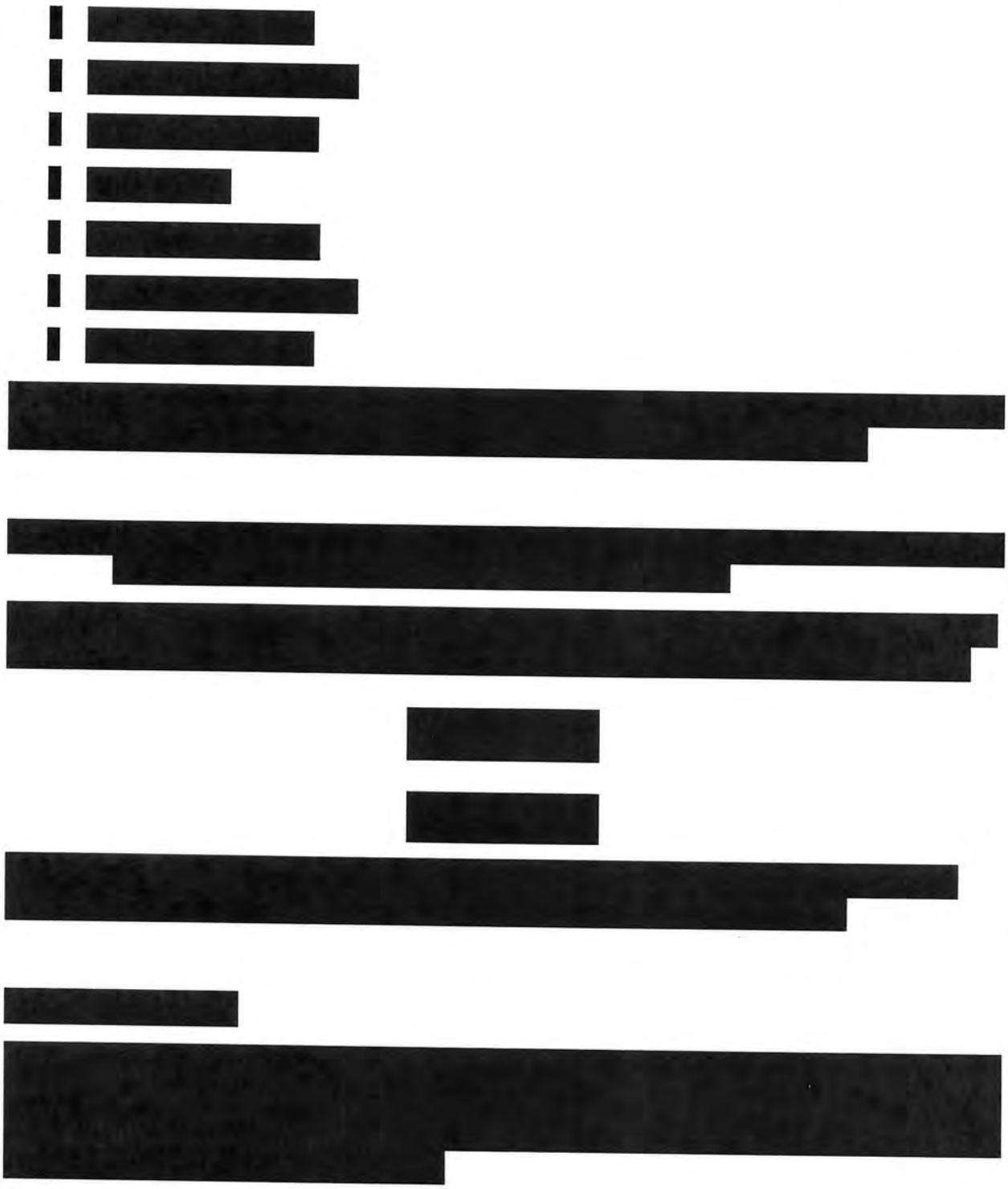
Endpoints defined in Sections 13.3.1.1 to 13.3.1.8 are based on parameters that will be [redacted]

Global Photograph:

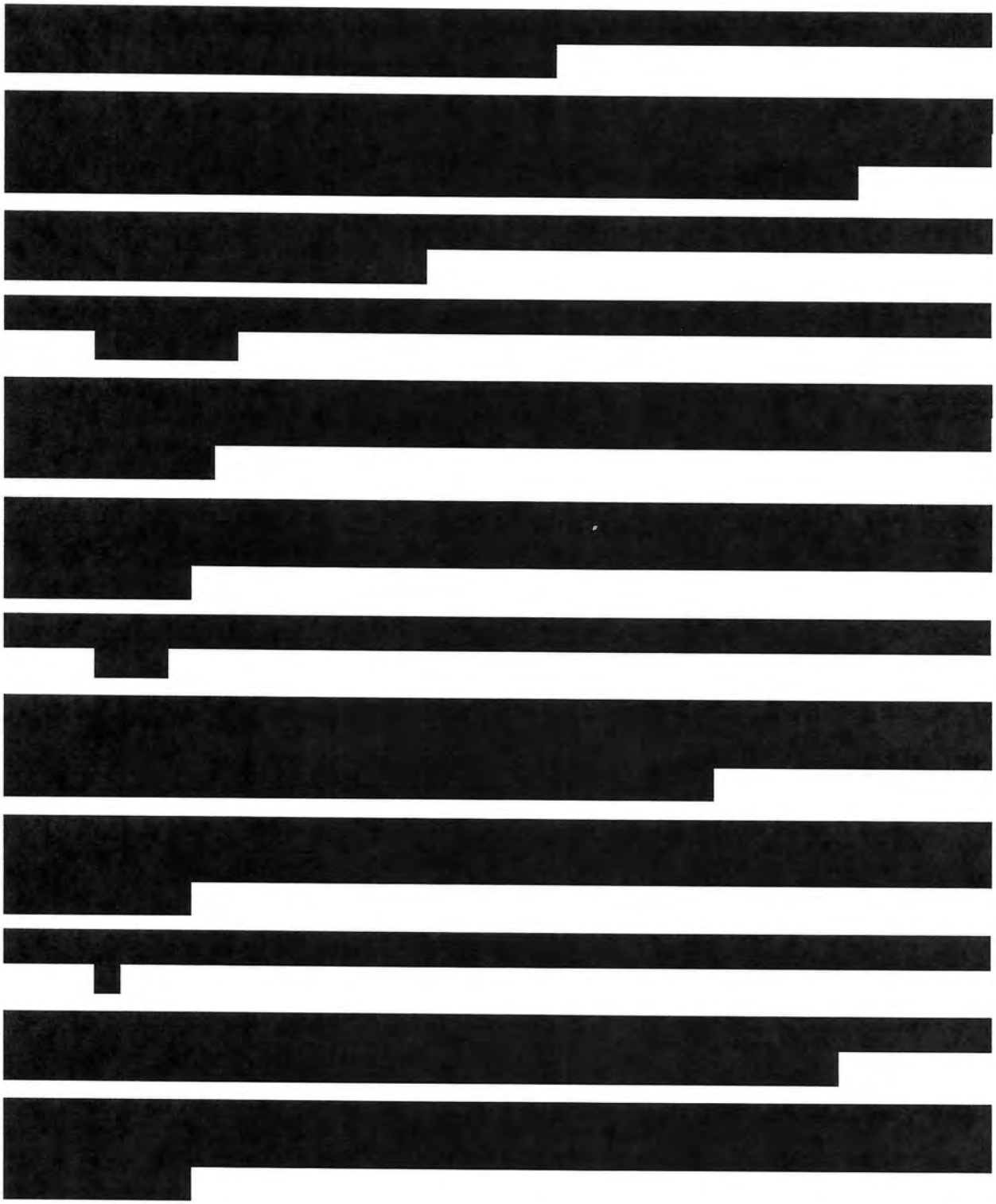
The global images are to be captured as outlined in Section 3.2. During the screening visit global images are to be captured and approved prior to Baseline and target area selection. For male subjects the global images will consist of the vertex (crown) and superior images, and for female subjects only the superior image. Refer to the user manual supplied by the vendor for further details.

[redacted]





[redacted]



[redacted]

[redacted]

[redacted]

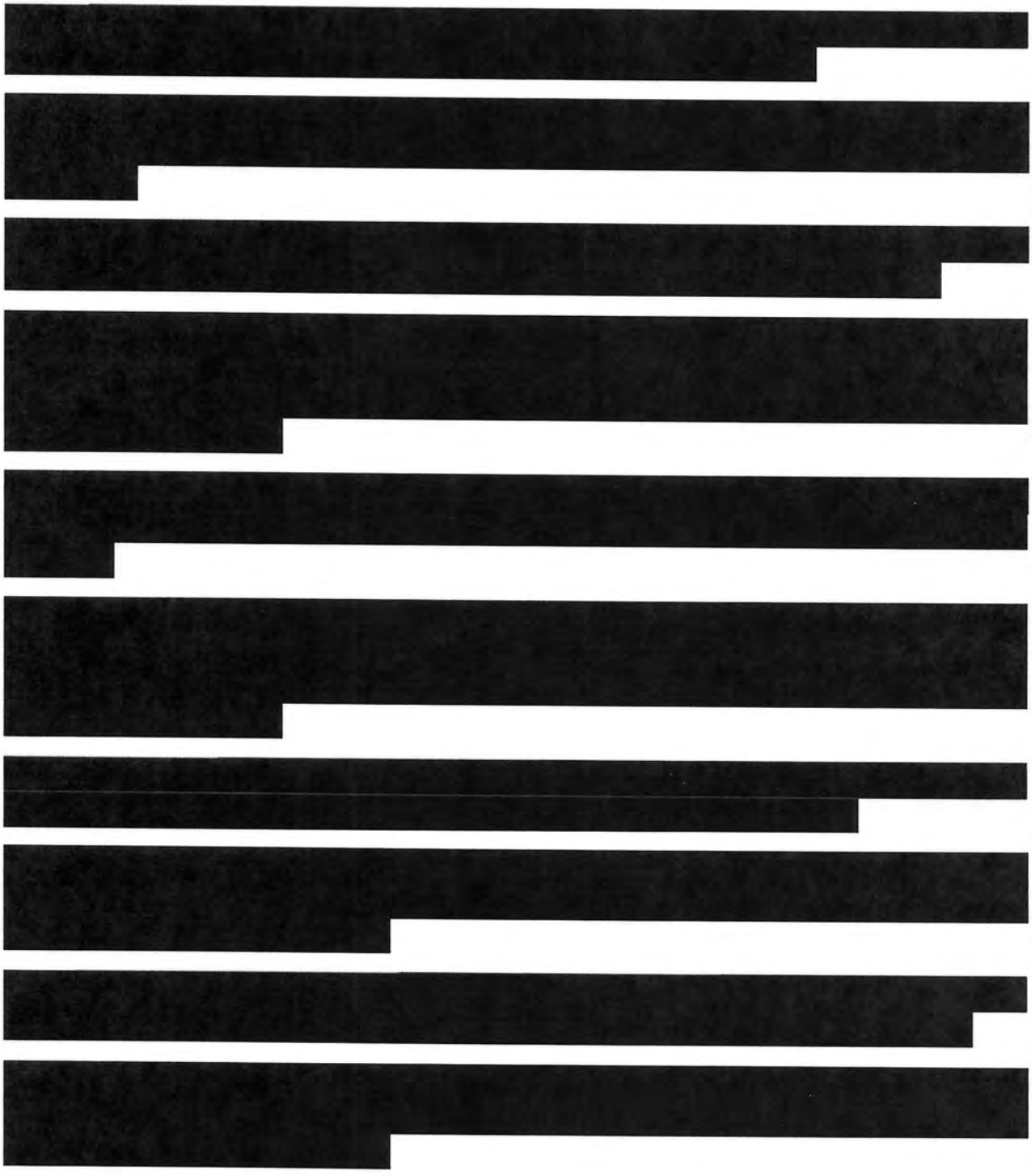
13.3.3 Sensitivity Analyses

No sensitivity analyses for exploratory efficacy endpoints are planned in the study.

[redacted]

13.4 Other Efficacy Endpoints

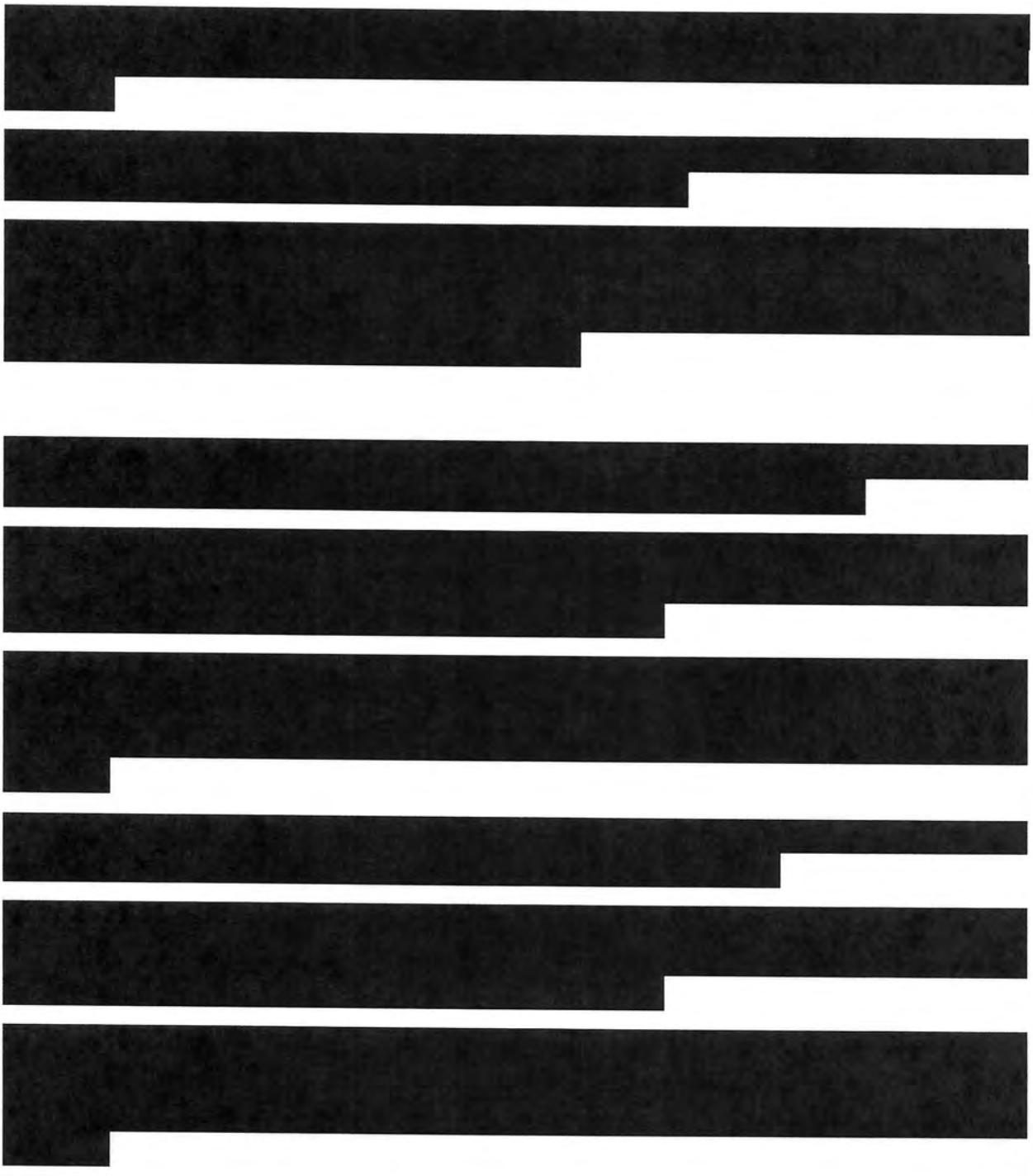
[redacted]



13.4.2 Main Analysis

[redacted]

[redacted]



13.4.3 Sensitivity Analyses

[redacted]

13.4.4 Supportive Analyses

[redacted]

14 SAFETY ANALYSES

All safety endpoints will be summarized by treatment group and visit, when applicable, based the safety analysis population.

14.1 Adverse Events

AEs will be coded according to the MedDRA, version 27.0 or higher.

According to the study protocol, an AE is considered to be treatment emergent (TEAE) if:

- It is not present when the active phase of the study begins and is not a chronic condition that is part of the subject's medical history; or,
- It is present at the start of the active phase of the study or as part of the subject's medical history, but the severity or frequency increases during the active phase.

The active phase of the study begins at the time of the first dose of the study drug and ends at the Day 84 Follow-up visit. The TEAE variable collected in EDC will only be presented in the listings. Refer to Section 10.10.6 of the Study Protocol for further details.

For statistical analyses purposes, TEAEs are defined as any AEs with onset date on or after the date of the first dose of study drug. See Appendix 2 for handling of partially or completely missing AE start and stop dates. In the case where it is not possible to define an AE as treatment emergent or not, the AE will be classified as treatment emergent.

An overall summary table for AEs will be provided. The number of events and the number and percentage of subjects who experienced at least one AE, TEAE, TEAE by greatest reported relationship to study drug, TEAE by worst reported severity, local skin reaction TEAE, TEAE with an outcome of death, serious TEAE, non-serious TEAE, TEAE leading to discontinuation from study drug, TEAE leading to discontinuation from study, and TEAE leading to interruption of study drug will be presented.

Incidence of TEAEs will be summarized by SOC and PT. Subjects experiencing multiple TEAEs within a SOC will be counted only once for that SOC. Similarly, subjects experiencing multiple TEAEs within a PT will be counted only once for that PT. TEAEs will be presented by SOC sorted by decreasing order of total frequency, and within each SOC, PTs will also be presented by decreasing order of total frequency.

Incidence of TEAEs will be further broken down by greatest reported relationship with study drug, where a treatment-related TEAE is defined as any TEAE that is assessed by the investigator as definitely, or possibly related to study drug while not treatment-related TEAE is defined as any TEAE that is assessed as not related to study drug. Subjects experiencing multiple TEAEs within the same SOC/PT but in different categories of relationship to study drug will be reported only

once under the greatest reported relationship to study drug. A TEAE with an unknown relationship will be considered as treatment-related.

Incidence of TEAEs will also be further broken down by worst reported severity. Subjects experiencing multiple TEAEs within the same SOC/PT but in different categories of severity will be reported only once under the worst severity. A TEAE with an unknown severity will be considered as severe.

Incidence of serious TEAEs, non-serious TEAEs, local skin reaction TEAE, TEAEs leading to discontinuation from study drug, and TEAEs leading to discontinuation from study will be summarized separately by SOC and PT. Subjects experiencing multiple TEAEs within a SOC will be counted only once for that SOC. Similarly, subjects experiencing multiple TEAEs within a PT will be counted only once for that PT. TEAEs will be presented by SOC sorted by decreasing order of total frequency, and within each SOC, PTs will be presented by decreasing order of total frequency.

Listings of all AEs with an outcome death, all serious AEs, all local skin reaction TEAE, all TEAEs leading to discontinuation from study drug, all TEAEs leading to discontinuation from study, and all TEAEs leading to interruption of study drug will be provided. A listing of all AEs will also be provided where local skin reaction TEAEs will be flagged.

14.2 Clinical Laboratory

Laboratory data will be presented in SI units.

Observed values and changes from baseline in chemistry, hematology, and quantitative urinalysis tests will be summarized using descriptive statistics. Frequencies and percentages will be presented for each category of qualitative urinalysis tests.

Shift tables from baseline to each post-baseline visit describing shifts to abnormality based on the central laboratory reference ranges (low, normal, high) will be provided. Only subjects with a baseline result and a result at the specified post-baseline visit will be considered.

Separate listings of data for chemistry, hematology, and urinalysis will be provided for each test where a subject had at least one abnormal result i.e., below the lower limit of normal (LLN) or above the ULN.

In addition, separate listings of all data for pregnancy, COVID-19 rapid test, chemistry, hematology, and urinalysis tests will be provided.

14.3 Vital Signs

Vital signs data will be presented in SI units.

Observed values and changes from baseline in vital signs (systolic blood pressure [SBP], diastolic blood pressure [DBP], pulse rate, respiratory rate, body temperature, and weight) will be summarized using descriptive statistics.

A listing of all vital sign assessments will be provided.

14.4 Electrocardiogram

Observed values and changes from baseline in ECG tests/intervals (heart rate, RR interval, PR interval, QRS interval, QT interval, and QTcF interval) will be summarized using descriptive statistics at each visit.

ECG measurements meeting the pre-defined markedly abnormal criteria specified in ICH E14 will be identified i.e.,

- QTcF interval (msec) observed values:
    - > 450 with no pre-existing condition (i.e., baseline value ≤ 450)
    - > 480 with no pre-existing condition (i.e., baseline value ≤ 450)
    - > 500 with no pre-existing condition (i.e., baseline value ≤ 450)
- QTcF interval (msec) increases from baseline:
    - > 30
    - > 60

For each of these markedly abnormal criteria, the number and percentage of subjects with at least one measurement meeting a criterion after baseline will be provided.

For central ECG overall interpretation, shift tables from baseline to each post-baseline visit describing shifts to abnormality will be provided. Only subjects with a baseline result and a result at the specified visit will be considered.

A listing of all ECG tests, intervals, and overall interpretation will be provided. Markedly abnormal measurements will be flagged.

14.5 Physical Examination

Information for all physical examinations will be included in the source documents. Any significant change will be reported as an AE in the source document and eCRF.

14.6 Local Skin Reactions

A static assessment of local skin reactions (LSRs) will be conducted in all subjects. LSRs include burning/stinging, pruritus, edema, erythema, dryness, and scaling. Each LSR will be scored as 0 (None), 1 (Mild), 2 (Moderate) or 3 (Severe).

Burning/stinging and pruritus will be assessed by the subject and edema/swelling, erythema, dryness, and scaling will be assessed by the investigator/designee. Refer to Section 10.10.5 of the study protocol for further details.

On Day 1, Day 14, and Day 28 visit, LSRs will be collected prior to study drug application and approximately 15 to 45 minutes following application of study drug. LSRs that occur or worsen following study drug application will be recorded as AEs.

Each LSR will be summarized by number and percentage of participants for each evaluator separately (investigator/subject), by treatment group, scheduled visit, and time point (pre-/post-dose), as applicable.

All local skin reactions data will be listed.

15 PHARMACOKINETIC ANALYSIS

PK tables and listings will be presented using the PK analysis population. PK data will be presented by visit, in summaries.

15.1 General considerations

For descriptive statistics, plasma concentrations that are below the limit of quantification (BLQ) will be treated as zero.

15.2 Plasma concentrations

PK samples are collected from each subject, 2 hours (+/-10 minutes) post dose on Days 1, 14, and 28. PK collections that have an actual sampling time that deviates from the predefined collection time windows will be flagged in the data listings and will be included in the calculation of

concentration summary statistics. The number of minutes in deviation will also be presented in data listings.

The number of minutes in deviation will be calculated as follows:

(Actual Sampling Time – Predefined Collection Time).

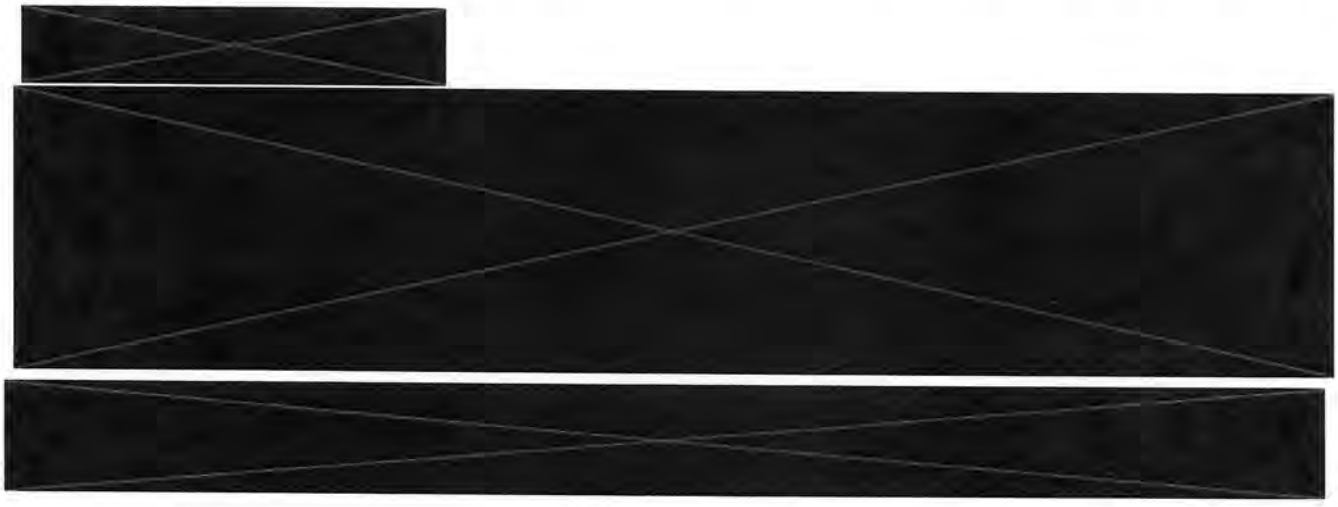
Individual plasma concentrations will be presented in data listings and summarized separately using descriptive statistics (number of observations, arithmetic mean, standard deviation, coefficient of variation [CV], geometric mean, geometric CV, median, minimum, and maximum) by visit.

16 PHARMACODYNAMIC ANALYSIS

Individual exploratory pharmacodynamic endpoints will be presented by treatment group and visit in a separate report.

16.1 General considerations

Summary statistics such as mean, median, and standard deviation (SD) will be provided by treatment group.



APPENDICES

APPENDIX 1

Output Conventions

TLF will be generated using SAS® and will be displayed on letter size paper with landscape orientation, 1 inch margin, and 9 pt Courier New font.

The header section will comprise the sponsor's name, protocol number, delivery description, data cut-off date or date of database lock, as applicable, and page number (Page X of Y).

TLF title section will include TLF number, TLF title, and analysis population.

The footer section will include the source listing(s) (if applicable), list of abbreviations, TLF footnotes, name of the SAS program name, and date and time of the execution of the program.

For categorical summary tables, percentages will be reported to one decimal place. Percentages between 0 and 0.1 (both exclusive) will be displayed as "<0.1" and percentages between 99.9 and 100.0 (both exclusive) will be displayed as ">99.9". Percentages will be based on total number of subjects in the analysis population within each treatment grou [redacted] nd based on number of subjects in the analysis population with available data within each treatment group for any other type of data.

For descriptive statistics, for all endpoint [redacted] efined in the next paragraph, the minimum and maximum values will keep the same number of decimal places as the original value; the mean and median will be displayed with one additional decimal place than the original value; and the SD, standard error (SE), and CI will be displayed with two additional decimal places than the original value. If derived endpoints are to be summarized, the number of decimals of the derived values is to be chosen on a case-by-case basis, but the rule above applies.

[redacted]

P-values between 0.001 and 0.999, both inclusive, will be reported to 3 decimal places, p-values less than 0.001 will be reported as "<0.001", and p-values greater than 0.999 will be reported as ">0.999".

Listings will be ordered by treatment group, subject number, endpoint/test, date of assessment/ collection/measurement, and time of assessment/collection/measurement, if applicable. Imputed dates and imputed missing data will not be presented in the listings. For visit names, nominal visit names will be presented followed by the analysis visit name when both are different (e.g., 'Unscheduled/Week X', etc.) Otherwise, only the nominal visit names will be presented.

Dates & Times Format

Date and time (if available) will be presented in the format yyyy-mm-dd/hh:mm.

Presentation of Treatment Groups

When applicable, treatment groups will be represented as follows:

Treatment Group Full Name	Treatment Group Short Name for TLFs
PP405 Topical Gel, 0.05%	PP405 0.05%
PP405 Vehicle Topical Gel	PP405 Vehicle

APPENDIX 2

Algorithm for Imputation of Start/Stop Date of Adverse Events and Prior/Concomitant Medications

Event Start Date Imputation

- Imputation of event end date should be done before imputation of event start date.
- *Completely missing*: Impute to the first study treatment date.
- *Missing day and month*: Impute to January 1st, unless year is the same as year of first study treatment dose then impute to the first study treatment date.
- *Missing day*: Impute to the 1st of the month, unless month and year are the same as month and year of first study treatment dose then impute to the first study treatment date.
- If imputed event start date is after event end date (imputed or not), set the event start date to the imputed event end date.

Event Stop Date Imputation

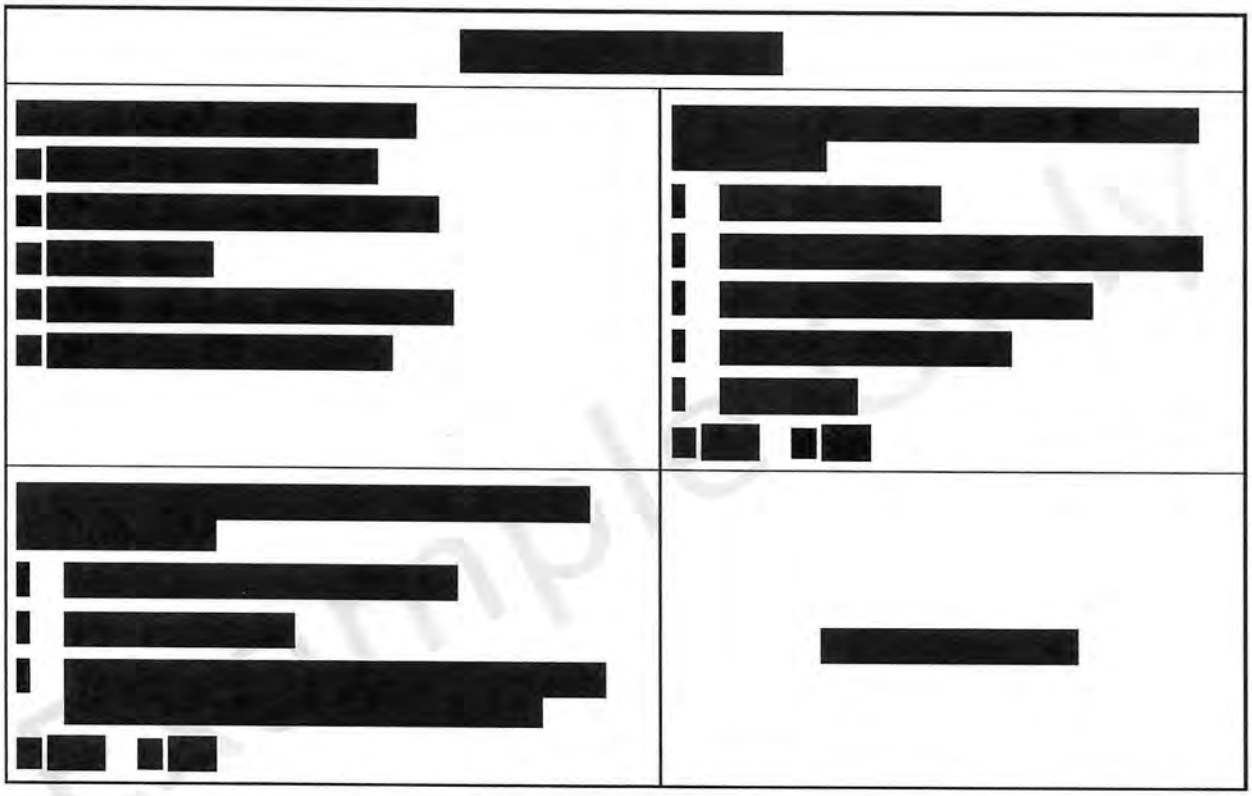
- *Completely missing (and not flagged as "ongoing")*: Impute to the last contact date.
- *Missing day and month*: Impute to December 31st, unless year is the same as last contact date then impute to the last contact date.
- *Missing day*: Impute to the last day of the month, unless year and month are the same as year and month of last contact date then impute to the last contact date.

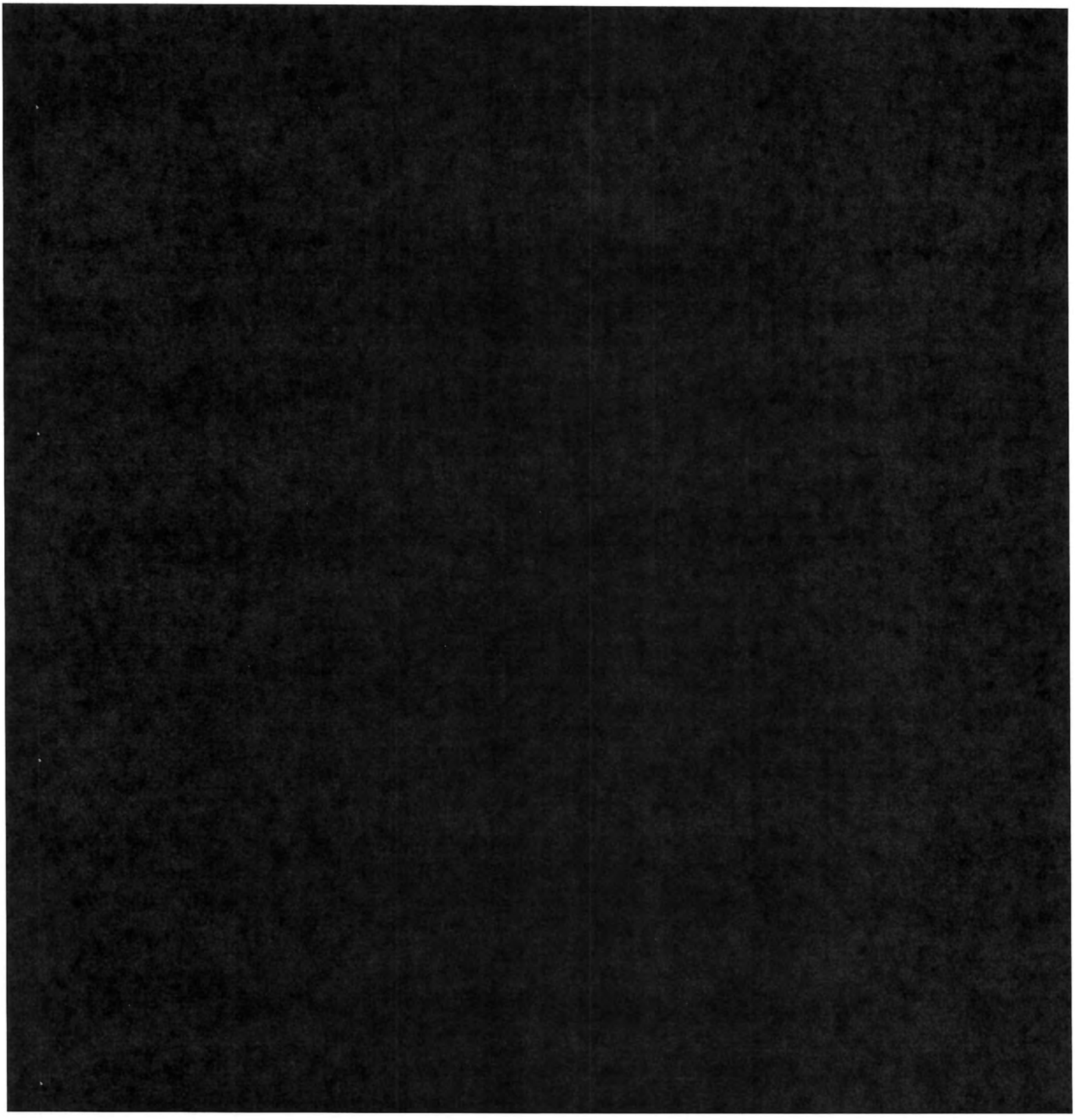
APPENDIX 3

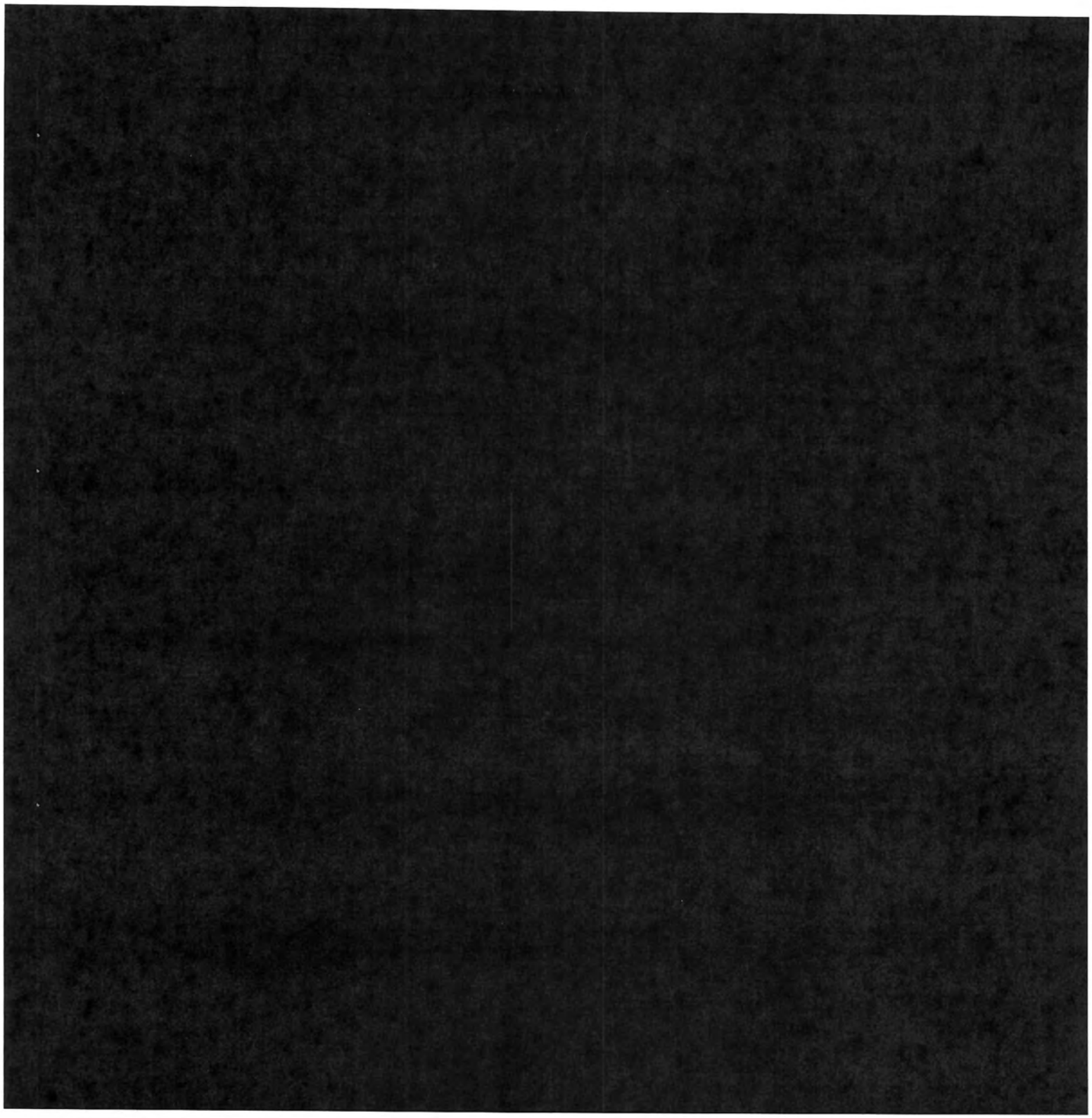
[redacted]

APPENDIX 4

[redacted]







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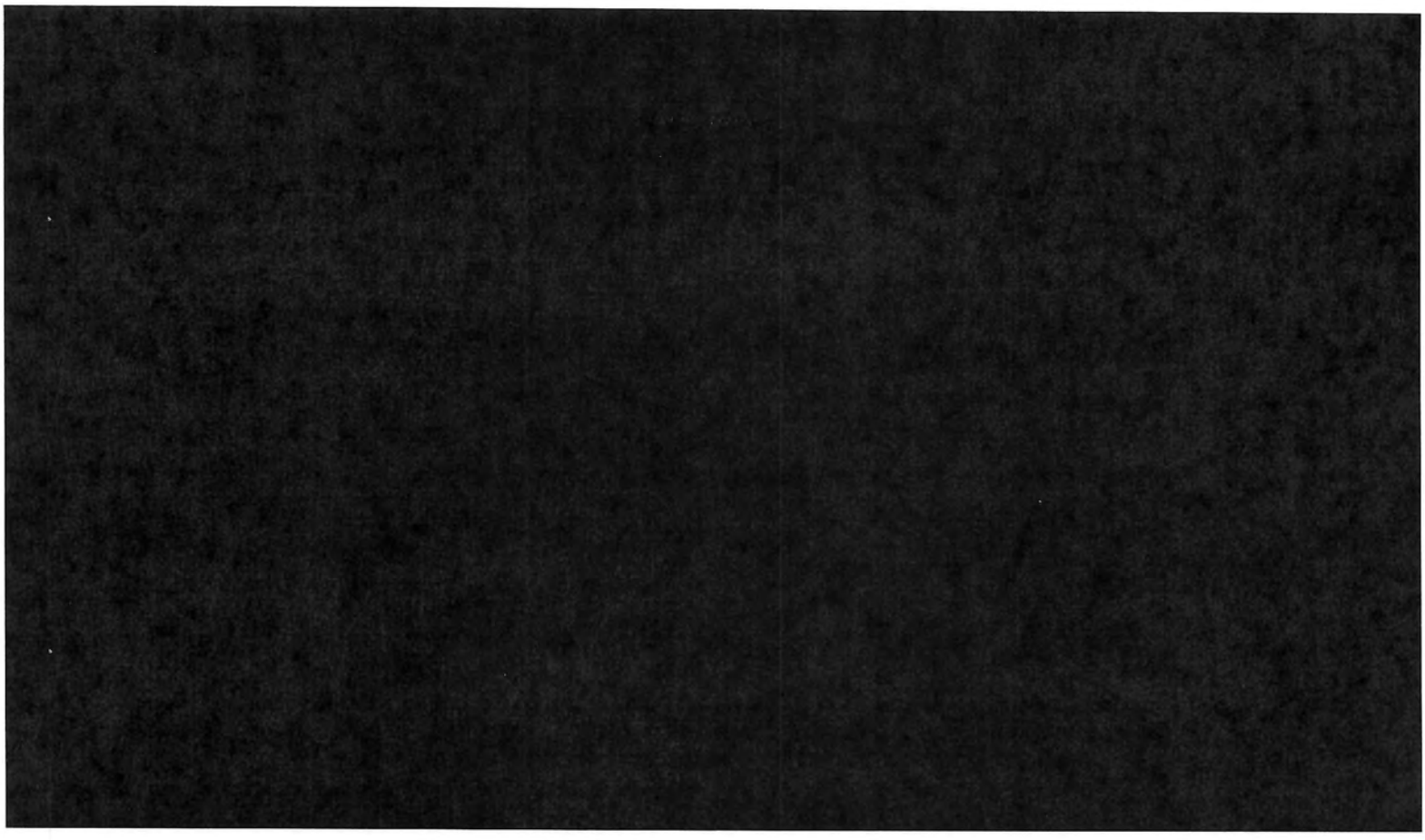

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Statistical Analysis Plan - Open-label Extension

Study Title:	**A Randomized, Multicenter, Double-blind, Vehicle-controlled, Phase 2a Study to Assess the Safety, Pharmacokinetics, and Preliminary Efficacy of PP405 in Adults with Androgenetic Alopecia**
Protocol Number:	**PP405-2001**
Protocol Version and Date:	**Final Version 4.0, Amendment 3, dated 06-Dec-2024**
Product:	**PP405 Topical Gel, 0.05%**
Sponsor:	**Pelage Pharmaceuticals, Inc.** **907 Westwood Blvd, #384** **Los Angeles, California** **United States, 90024**
Version:	**Final, V1.0**
Date:	**05-Feb-2025**
Prepared by:	**Innovaderm Research Inc.** **3530 Saint-Laurent boulevard, Suite 300** **Montreal, Quebec, H2X 2V1** **Canada**

STATISTICAL ANALYSIS PLAN [OLE] REVISION SUMMARY			
Version	**Version Date**	**Authors**	**Summary of Changes**
Final V1.0	05-Feb-2025	[redacted]	Initial version

SIGNATURE PAGE

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Name	Title	Signature	Date (DD-MMM-YYYY)
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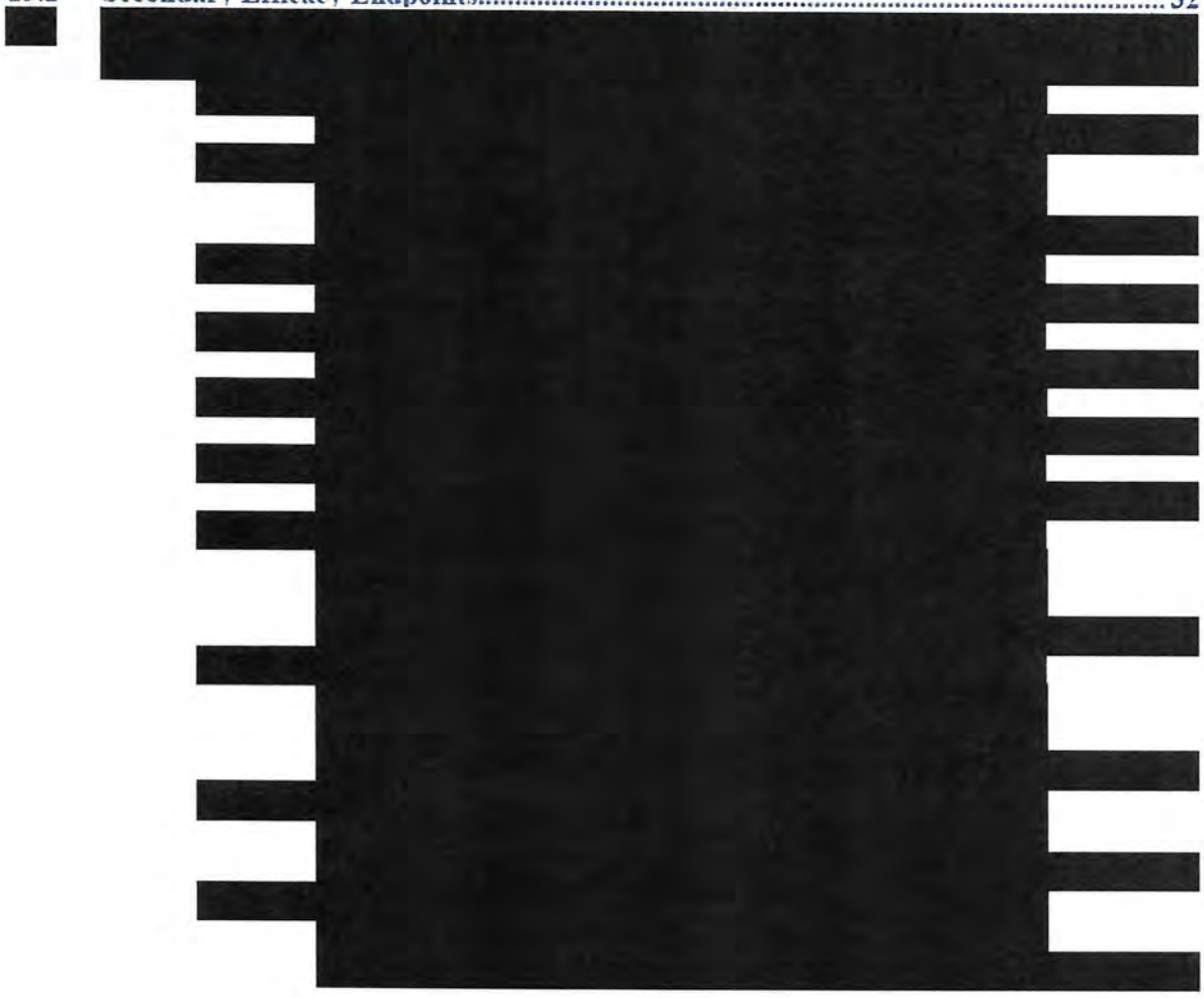
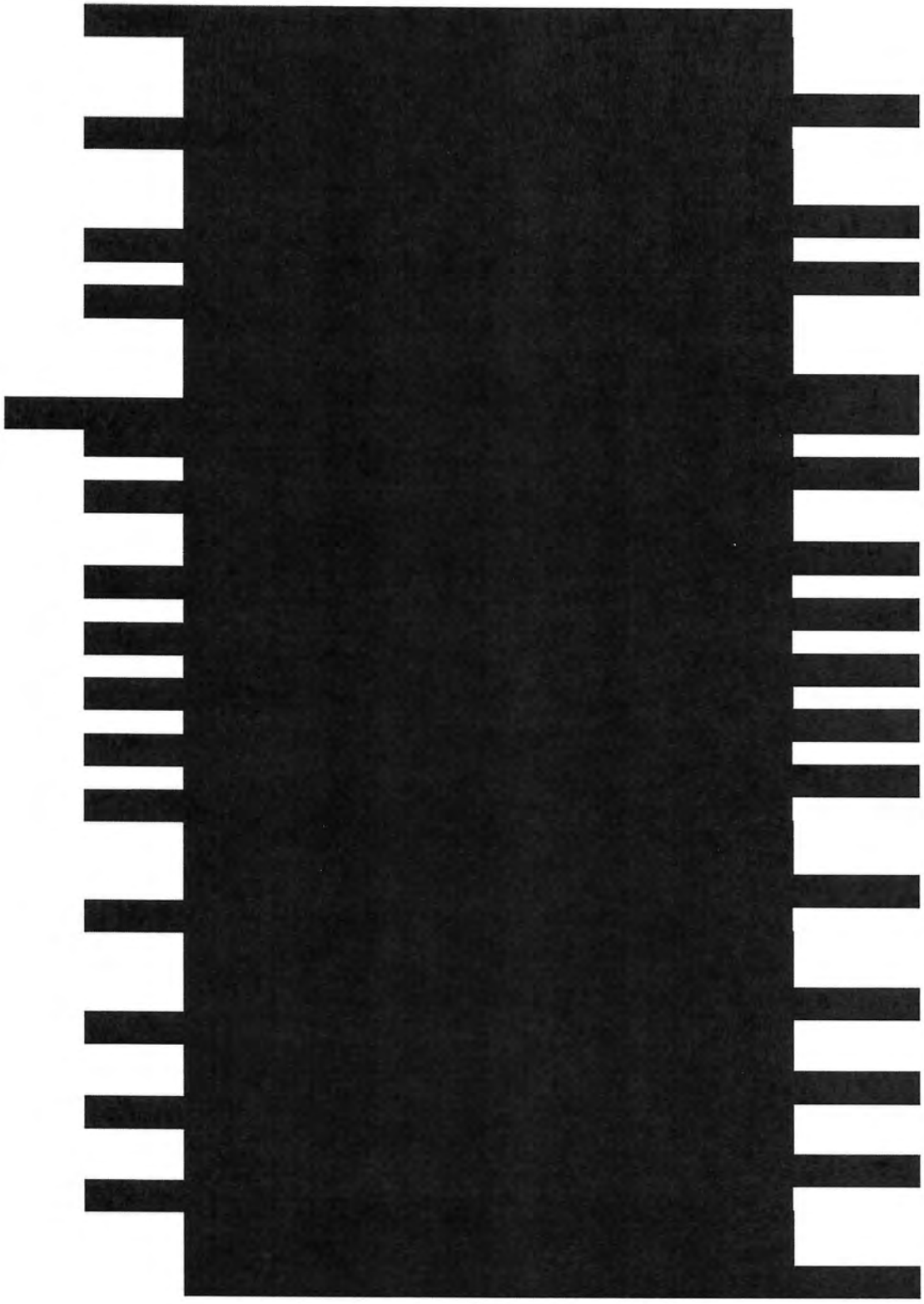
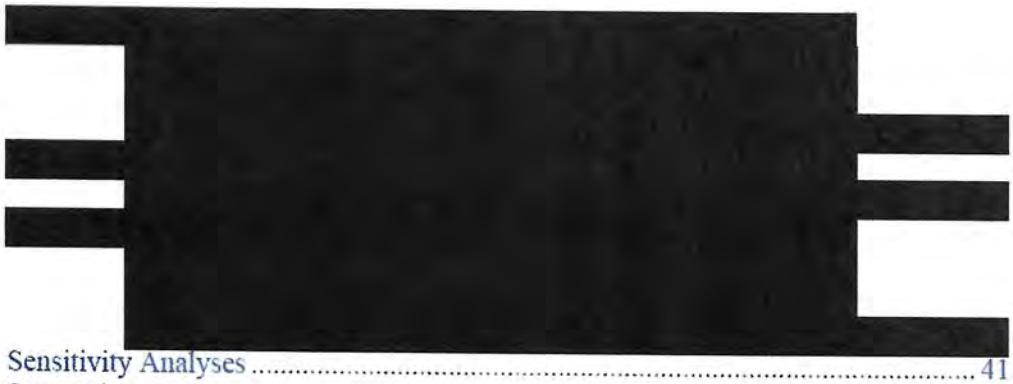
[redacted]	Biostatistician, Consultant Pelage Pharmaceuticals, Inc.

This statistical analysis plan (SAP) is for the open-label extension (OLE) portion of the PP405-2001 study and will be reviewed and revised as needed. If applicable, the most recent version of the SAP (OLE) will replace a previous version in place for the SAP (OLE).

TABLE OF CONTENT







ABBREVIATIONS

AE	adverse event
ATC	anatomical therapeutic chemical
BLQ	below the limit of quantification
BMI	body mass index
DBP	diastolic blood pressure
ECG	electrocardiogram
eCRF	electronic case report form
ET	early termination
IA	interim analysis
IWRS	interactive web response system
ITT	intent-to-treat
LLN	lower limit of normal
LLT	lowest level term
LSR	local skin reaction
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified intent-to-treat
msec	millisecond
n	number of subjects with non-missing data
OLE	open-label extension
PDMP	protocol deviation management plan
PP	per protocol
PK	pharmacokinetic
PRO	patient-reported outcome
PT	preferred term
QT	QT interval
QTcF	Fridericia's correction formula for QT interval
SAE	serious adverse event
SAP	statistical analysis plan
SAS	statistical analysis system®
SBP	systolic blood pressure
SD	standard deviation
SE	standard error
SOC	s stem or an class
[redacted]	arge area a r ar ness
TAHW	target area hair width
TEAE	treatment-emergent adverse event
TLF	tables, listings, and figures
ULN	upper limit of normal
WHO-DD	World Health Organization Drug Dictionary
WOCBP	women of childbearing potential

1 INTRODUCTION

This statistical analysis plan (SAP) describes the planned analysis and reporting of the open-label extension (OLE) portion for Pelage Pharmaceuticals clinical protocol PP405-2001. The planned analysis and reporting for the randomized portion (double-blinded portion) of the study are described in a separate SAP. The analyses described in this SAP are based upon the protocol amendment 3, version 4.0, dated 06-Dec-2024.

This SAP has been developed and finalized prior to the first database lock of the study.

2 STUDY OBJECTIVES AND ENDPOINTS (OPEN-LABEL EXTENSION)

OBJECTIVES	ENDPOINTS
Primary (OLE)	**Primary safety endpoints:**
To evaluate the safety and tolerability of 3 months of open-label treatment with daily PP405 in subjects with androgenetic alopecia	• Incidence and magnitude of treatment-emergent laboratory abnormalities, local skin reactions (LSR), adverse events (AE), treatment emergent adverse events (TEAE) and serious adverse events (SAE). • Change from OLE baseline in vital signs. • Change from OLE baseline in electrocardiogram (ECG).
Secondary (OLE)	**Secondary efficacy endpoint:**
To assess the concentration of PP405 in plasma during 3 months of open-label treatment in subjects with androgenetic alopecia	• Plasma concentrations of PP405 on Days 1, 28, 56, and 84.
[redacted]	[redacted]
[redacted]	[redacted]

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

OBJECTIVES	ENDPOINTS
[redacted]	
[redacted]	[redacted]

These endpoints were not defined in the protocol:

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]
[redacted]	[redacted]

OBJECTIVES	ENDPOINTS
[redacted]	[redacted]

3 STUDY DESIGN

3.1 Overall Design

This is a multicenter, double-blind, vehicle-controlled study of the safety, tolerability, and preliminary efficacy of PP405 in subjects with androgenetic alopecia. Approximately 60 subjects will be randomized 2:1 to receive:

- PP405 Topical Gel, 0.05%, or
- PP 405 Vehicle Topical Gel (also referred as Vehicle)

as once daily topical gels for 28 days. Subjects will have a final follow-up visit to evaluate the endpoints on Day 84. The study is composed of the randomized portion and an OLE period. Total duration of the randomized portion is up to approximately 114 days, including up to 30 days of screening, 28 days of treatment, and 56 days of post-treatment follow-up. Total duration of the OLE period is up to approximately 198 days, including up to 30 days of screening, 84 days of treatment, and 84 days of post-treatment follow-up.

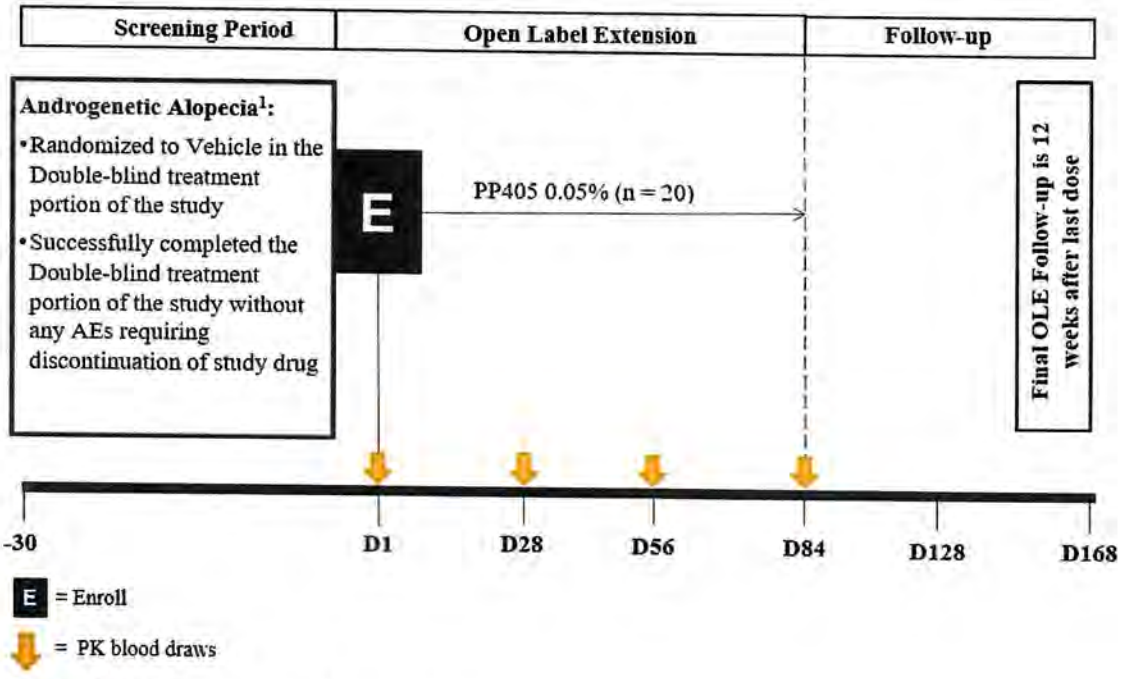
Randomization will be stratified by sex at birth (male/female) and by the hair loss type based on the Norwood Hamilton Scale (men) (Type III vertex, Type IV, and Type V) or the Savin Scale (women) (I-2, I-3, and I-4). Enrollment of women will be capped at no more than 15 subjects (or 25% of the planned study population).

This study will be conducted at approximately 8 sites within the US. [redacted]. Safety will be assessed through physical examination, vital signs, serum chemistry, hematology, urinalysis, 12-lead electrocardiogram, incidence and severity of local skin reactions, adverse events, treatment emergent adverse events, and serious adverse events before and after the treatment. [redacted]

[redacted] The Pharmacokinetic (PK) of PP405 will be evaluated in plasma.

Subjects randomized to the vehicle arm in the randomized portion of this study who complete the treatment period, and the follow-up period may be eligible to participate in the OLE portion of the study. Subjects will be re-screened based on the OLE entry criteria and will then receive open-label treatment with once-daily PP405 topical gel for 12 weeks at the same dose (0.5%) administered in the randomized portion of the study. Subjects will be evaluated with a subset of the assessments used during the randomized portion, as shown in the Schedule of Assessments for the OLE portion (refer to Table 1).

The diagram below represents the study design for the OLE portion of the study.



[1] Refer to inclusion/exclusion criteria for a complete list.

3.2 Schedule of Assessments

Table 1 provides a description of the procedures planned at each visit for the OLE portion.

Table 1: Schedule of Assessments – Open-label Extension

Procedures	Screening [a]	Open-label Treatment Period				Follow-up Period [a]	
	-30 days	Day 1 [a] (Baseline)	Day 28 [a]	Day 56 [a]	Day 84 [a] (EOT/ET)	Day 124	Day 168 (EOS)
Visit Window (days)			± 5	± 5	± 5	± 7	± 7
Informed Consent	X						
Medical History	X	X					
Inclusion/Exclusion Criteria	X	X					
Weight	X	X	X	X	X	X	X
Vital Signs (Blood pressure [sitting], heart rate, respiration rate, and body temperature)	X	X	X	X	X	X	X
Physical Examination [b]	X	X	X	X	X	X	X
12-lead ECG	X	X			X		
Treatment Area Identification		X					
Modified Norwood Hamilton Scale or Savin Scale	X	X					
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
Local Skin Reactions [d]		X	X	X	X		
AE/TEAE/SAE collection [e]	X	X	X	X	X	X	X
Concomitant Medication	X	X	X	X	X	X	X
Serum Chemistry/Hematology/Urinalysis [f]	X	X	X	X	X		

Procedures	Screening [a]	Open-label Treatment Period				Follow-up Period [a]	
	-30 days	Day 1 [a] (Baseline)	Day 28 [a]	Day 56 [a]	Day 84 [a] (EOT/ET)	Day 124	Day 168 (EOS)
Visit Window (days)			± 5	± 5	± 5	± 7	± 7
COVID-19 Rapid Test	X	X					
Serum Pregnancy test for WOCBP	X						
Urine pregnancy test β hCG for WOCBP only [g]		X	X	X	X		X
Blood Sample for PK [h]		X	X	X	X		
Dispense Study Drug [i]		X	X	X			
Confirm subject using approved Shampoo/Conditioner [j]	X	X	X	X	X	X	X
Study Drug accountability & Return [k]			X	X	X		
Dispense Dosing Diary		X					
Review Dosing Diary [l]			X	X	X		
Drug Application at the clinic [m]		X	X	X	X		

AE = adverse event; ClinRO = clinician-reported outcome; eCRF = electronic case report form; PK = pharmacokinetics; PRO = patient reported outcome; TEAE = treatment-emergent AE.

[a] Subjects will be evaluated and dosed in the clinic. Investigators should make every effort to adhere to the schedule as outlined above. In the event a subject misses a clinic visit, the subject should be instructed to complete dosing at home and return to the clinic as soon as possible to complete all study assessments required for the missed clinic visit.

[b] At screening and Days 1 and 84, a complete physical examination is required. On Days 28, 56, 84 and 124, and 168, a symptom-related brief physical examination will occur if the subject is experiencing symptoms or AEs. If a symptom-related brief physical exam is required, it should include a review of all body systems that relate to the symptoms and/or AE the subject is experiencing.

[redacted]

[d] LSR assessment will be repeated pre and post application of study drug. See Section 10.10.5 of the study protocol for detailed instructions.

[e] SAEs will be collected at the time of informed consent for the OLE and through the Day 168 follow-up visit. AEs and TEAEs will be collected from the first dose of OLE study drug and through the Day 168 follow-up visit.

[f] If serum chemistry, hematology and urinalysis are completed ≤ 7 days prior to baseline, they will not need to be drawn on Day 1 and will be considered both screening and baseline labs. If serum chemistry, hematology, and urinalysis were completed > 7 days prior to baseline, then they will need to be drawn again on Day 1.

[g] A negative urine pregnancy test result must be obtained prior to application of the study drug. A positive urine pregnancy test at any time during the study requires immediate interruption of the study drug until a serum pregnancy test is performed and found to be negative. The subject must be discontinued from the study and followed if pregnancy is confirmed by a positive serum pregnancy test.

[h] PK will be collected 2 hours (+/-10 minutes) post dose on Days 1, 28 and 56. For the Day 84 visit samples will be collected at 1, 2, and 4 hours post dose (+/-10 minutes).

[i] At every visit, 2 bottles will be dispensed for those subjects treating 1 area and 3 bottles for those treating 2 areas.

[j] At each clinic visit the investigator should confirm that the subject has not changed the shampoo/conditioner since the last visit. If the subject has changed their shampoo/conditioner, the new product should be added to the concomitant medication page in the eCRF.

[k] Subjects should be instructed to bring their study drug bottles with them for each clinic visit on Days 28, 56, and 84. The investigator or designee will weigh the pump bottles prior to dispensing (after priming) on Days 1, 28, and 56 and then again after dosing. On Days 28 and 56 subjects should return the used study drug and new bottles should be dispensed. Subjects will be dosed in the clinic with the new bottles on Days 28 and 56. On Day 84 subjects will receive a final dose in the clinic and final weight of the bottle should be documented after dosing. The weight should be documented in the subject's drug accountability log. Refer to Section 8.7 of the study protocol for instructions for final disposition and return of used bottles.

[l] Site staff should review the dosing diary with the subject at each clinic visit and confirm completeness. See Section 8.8 of the study protocol for dosing diary instructions and compliance.

[m] See Appendix A of the study protocol for guidance on the proper way to apply study drug. Subjects will apply study drug once per day every day for 84 days. It is recommended that subjects apply study drug in the evening at least 2 hours prior to bedtime. On Day 1 the subject should apply study drug themselves in the clinic under the supervision of trained study staff to ensure a complete understanding of how to apply the study drug. On Days 28, 56, and 84 subjects should be instructed to apply study drug in the clinic rather than their normal dosing time at home.

3.3 Treatment Groups, Replacement, Blinding, and Unblinding Procedures

Treatment Group

No randomization will occur during the OLE portion of the study. Subjects randomized to the vehicle arm in the randomized portion of this study who complete the treatment period and the follow-up period may be eligible to participate in the OLE portion of the study. Subjects will be re-screened based on the OLE entry criteria and will then receive:

- PP405 Topical Gel, 0.05%

as once daily for 84 days (12 weeks). Enrollment to the OLE and study drug dispensation will be managed as per the IWRS manual.

Subject Replacement

Subjects who do not complete the OLE portion will not be replaced.

Blinding and Unblinding Procedures

After database lock of the randomized portion of the study, all subjects who were on vehicle and are eligible to participate in the OLE will receive active study medication without blinding.

3.4 Changes from Planned Analyses Described in the Protocol

Changes to the analyses planned in the protocol are listed in Table 2.

Table 2: Summary of Changes from Planned Analyses Described in the Protocol

Description of the change	Rationale for change
Secondary efficacy endpoint – OLE (refer to section 5.2 of the study protocol) • This endpoint "Plasma concentrations of PP405 on Days 1, 28 and 84" is renamed to add Day 56 since plasma concentrations are assessed at this day and of interest.	Plasma concentrations is assessed at Day 56 and of interest.
Analysis Sets (refer to section 13.1 of the study protocol) • An OLE modified intent-to-treat analysis population will be defined in this SAP [redacted]	The main reason for this change is to be consistent with the randomized portion of the study and so that when comparing [redacted] during the OLE portion vs the randomized portion, all subjects will have received at least one dose of study treatment.

4 PLANNED ANALYSES

4.1 Data Monitoring Committee

Not applicable.

4.2 Interim Analyses

Not applicable.

4.3 Final Analysis

The final analysis will be performed after signature of this SAP (OLE), clinical trial data of the OLE portion are entered into the database, any discrepancies in the data are resolved, and database is locked.

5 ANALYSIS POPULATIONS

The list of subjects included or excluded from each OLE analysis set will be reviewed and finalized prior to the database lock for the final analysis.

5.1 All OLE Screened Subjects Analysis Population

The 'All OLE screened subjects' analysis set will include all subjects who signed the informed consent to participate in the OLE portion of the study.

This analysis set will be used to summarize disposition data.

5.2 OLE Intent-to-Treat Analysis Population

The OLE Intent-to-Treat (OLE ITT) analysis population will include all enrolled subjects in the OLE portion of the study. This analysis set will be used to summarize disposition data.

5.3 OLE Modified Intent-to-Treat Analysis Population

The OLE modified Intent-to-Treat (OLE mITT) analysis population will include all enrolled subjects in the OLE portion who receive at least one dose of study drug during the OLE portion and have at least 1 assessment at OLE baseline and post-OLE baseline [redacted]

5.4 OLE Safety Analysis Population

The OLE safety analysis population will include all enrolled subjects in the OLE portion of the study who receive any amount of study drug during the OLE portion. This analysis population will be used to summarize demographic and other baseline characteristics, surgical and medical history, disease history, prior and concomitant medications, exposure to and compliance with study drug, and all safety data.

5.5 OLE Pharmacokinetic Analysis Population

The OLE Pharmacokinetic (OLE PK) analysis population will include all enrolled subjects in the OLE portion of the study who receive at least one dose of PP405 0.05% during the OLE portion and have at least one post-OLE baseline plasma concentration available.

This analysis population will be used to summarize PP405 plasma concentrations.

6 GENERAL CONSIDERATIONS

Table, listing, and figure (TLFs) Shells will be provided in a separate document. Refer to Appendix 1 for a general description of TLF format and layout.

6.1 OLE Baseline

Unless otherwise specified, OLE baseline is defined as the last non-missing assessment performed after the completion of the follow-up period of the randomized portion of the study and prior to the first application of study drug (including unscheduled assessments) in the OLE portion. If the last non-missing assessment is performed on the same date as the first application of study drug during the OLE and time is not available, then the assessment will be considered as OLE baseline, except for adverse events (AEs) and medications starting on the date as the first application of study drug during OLE which will be considered post-OLE baseline.

6.2 Change and Percent Change from OLE Baseline

Change from OLE baseline at post-OLE baseline visit X will be calculated as:

Assessment value at post-OLE baseline visit X – OLE Baseline value

Percent change from OLE baseline at visit X will be calculated as:

[(Assessment value at post-OLE baseline visit X – OLE Baseline value) / OLE Baseline value] * 100

Should the OLE baseline value be 0 (zero), percent change from OLE baseline will be set to missing.

6.3 Study Day

Study Day will be calculated from the first application of study drug during the OLE portion as follows and will be used to show the start/end day of assessments or events:

(Date of assessment/event – Date of first application of study drug during OLE) if the date of assessment/event is before the date of the first application of study drug during OLE.

or

(Date of assessment/event – Date of first application of study drug during OLE) + 1 if the date of assessment/event is on or after the date of the first dose/application of study drug during OLE.

When the assessment/event date is partially or completely missing, the Study Day will be considered as missing.

6.4 Windowing Conventions

For by-visit summary and analysis (when applicable), visits will be summarized and analyzed as scheduled (refer to Table 1). Retest, unscheduled, and early termination (ET) visits will only be considered if a scheduled measurement is not available and a retest, unscheduled, and/or ET measurement falls within the protocol-adjusted analysis visit window for that scheduled measurement, as described in Table 3 to Table 7.

For summary and analysis (when applicable) not presented by visit (e.g., worst post-baseline value), all data (scheduled, retest, unscheduled, and ET) will be considered.

All data collected during scheduled, retest, unscheduled, and ET visits will be listed.

Table 3: Protocol-Adjusted Analysis Visit Windows for Vital Signs, Weight, Photographic Assessments with Canfield (Macrophotography and Global)

Analysis Visit OLE	Target Study Day	Lower Limit	Upper Limit
OLE Day 28	28	Post OLE baseline	42
OLE Day 56	56	43	70
OLE Day 84	84	71	104
OLE Day 124	124	105	146
OLE Day 168	168	147	n/a

[redacted]

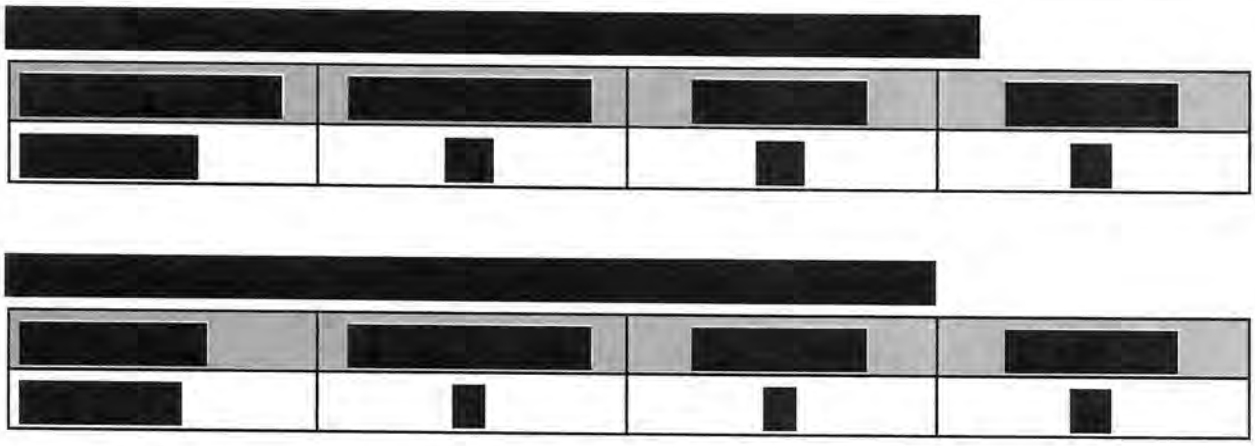


Table 7: Protocol-Adjusted Analysis Visit Windows for Chemistry, Hematology, Urinalysis, and Local Skin Reactions

Analysis Visit	Target Study Day	Lower Limit	Upper Limit
OLE Day 28	28	Post OLE baseline	42
OLE Day 56	56	43	70
OLE Day 84	84	71	n/a

If more than one assessment falls within the same protocol-adjusted analysis visit windows and a scheduled measurement is not available, the measurement collected closest to the scheduled visit target study day will be used for the by-visit summary. If two measurements or more are equidistant from a scheduled visit target study day, the measurement collected after the scheduled visit target study day will be used.

6.5 Software Version

All analyses will be performed using SAS® software Version 9.4 or higher.

7 STATISTICAL CONSIDERATIONS

7.1 Sample Size Determination

Enrollment into the OLE of at least 16 of the subjects who were randomized to the vehicle arm in the randomized portion of this study (who completed the Day 28 treatment period and the follow-up period) will provide

[redacted]

7.2 Multicenter Studies

This study will be conducted by multiple investigators at approximately 8 sites within the United States. Data from all sites will be pooled together in the summaries and analyses.

7.3 Handling of Dropouts or Missing data

Unless otherwise specified in the sections below, no missing data will be imputed.

7.3.1 Efficacy Data

For the main analysis and supportive analysis of [redacted] endpoints that are continuous in nature (refer to Section 13.3), missing post-baseline data will not be imputed before being analyzed.

7.3.2 Safety Data

Partially or completely missing medication and AE start and stop dates will be imputed as described in Appendix 2 and will only be used for the classification of each medication as prior or concomitant (refer to Section 11) and each AE as prior or treatment-emergent (refer to Section 14.1). That is, imputed dates will not be used to compute duration and will not be presented in subject data listings.

7.4 Descriptive Statistics

Continuous endpoints will be summarized using descriptive statistics i.e., number of subjects with non-missing data (n), mean, standard deviation (SD), median, minimum, and maximum.

Categorical endpoints will be summarized using frequencies and percentages.

7.5 Adjustment for Covariates and/or Fixed Effect

The following covariate and fixed effects will be included in the main analysis of [redacted] endpoints:

- Baseline value [redacted]
- Treatment group

[redacted]

Sex at birth and hair-loss type (Norwood Hamilton Scale for men; Savin Scale for women) are not included as fixed effects since the main analysis [redacted] is performed based on male subjects only and due to the number of subjects included in the OLE portion of the study.

7.6 Coverage of Confidence Intervals and Statistical Tests

Unless otherwise specified, all statistical tests will be two-sided and will be performed with a significant level of 0.05. Only nominal p-values will be presented.

7.7 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons/multiplicity will be made for this study.

7.8 Examination of Subgroups

No subgroups analyses will be performed.

8 STUDY SUBJECTS

8.1 Disposition of Subjects

All subjects who provide informed consent for the OLE portion of the study will be accounted for. The number of subjects screened for OLE and rescreened will be presented. The number and percentage of subjects with OLE screen failure will be presented for all screened subjects, except for those who were rescreened and did not fail the second screening. Reason for screen failure will be summarized similarly but for subjects with screen failure.

Number and percentage of subjects included in each OLE analysis population, who completed or discontinued early from study drug, and who completed or discontinued early from the OLE portion of the study will be presented for all enrolled subjects in OLE (OLE ITT analysis population). Reason for discontinuation from study drug and reason for discontinuation from study will be presented similarly but for subjects who discontinued early from study drug and who discontinued early from study, respectively.

The number of days in the OLE portion of the study will be calculated as follows and summarized overall:

> (Date of completion/discontinuation of OLE portion – Date of enrollment in OLE portion) +1

A listing of the subject's disposition will be provided. A listing of subjects included/excluded from each of the OLE analysis populations, with reason for exclusion, will also be provided.

8.2 Protocol Deviations

A data review will be conducted before the database lock by the Medical Monitor and Sponsor to classify each protocol deviation as important or non-important (refer to Protocol Deviation Management Plan [PDMP]).

During this data review, important protocol deviations will be further classified as major or minor by the Medical Monitor and Sponsor, where a major protocol deviation is defined as an important protocol deviation potentially having an [redacted] Major protocol deviations include, but are not limited to:

- Violation of key inclusion/exclusion criteria
- Having a compliance with study drug < 80% or > 120%
- Having received a clinically meaningful amount of prohibited medications

Classification of each protocol deviation as important or non-important and of each important protocol deviation as major or minor will be finalized and approved by Sponsor before the database lock of the OLE portion.

The number of events and the number and percentage of subjects with at least one important protocol deviation will be summarized by deviation category and sub-category overall based on the OLE safety analysis population. Site-level protocol deviations will be reported once for each subject enrolled in the OLE portion at that site.

Major protocol deviations will be summarized similarly.

A listing of all protocol deviations will be provided, and important and major deviations will be flagged.

9 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

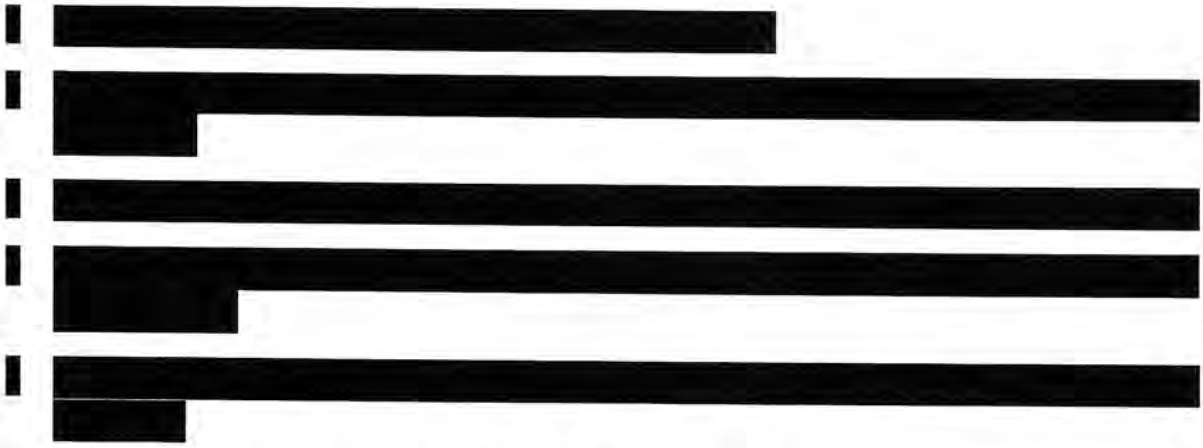
Demographics will be summarized overall using descriptive statistics based on the OLE safety analysis population. Other baseline characteristics will also be summarized overall using descriptive statistics based on the OLE safety analysis population. The list of demographics to be summarized includes:

- Age (years) as collected on electronic Case Report Form (eCRF)
- Sex at birth (Female, Male)
- Gender identity (Man, Woman, Nonbinary, Other)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
- Race (American Indian or Alaska native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White)

The list of OLE baseline characteristics to be summarized includes:

- DB Baseline height (cm)
- OLE Baseline weight (kg)
- OLE Baseline body mass index (BMI; kg/m^2), derived as the OLE baseline weight (kg) divided by the square of the baseline height (m^2) i.e., baseline height (m) x baseline height (m)
- OLE Baseline hair loss type
    - Modified Norwood Hamilton Scale (male)
    - Savin Scale (female)
- OLE Baseline treatment area identification (Vertex [Crown], Superior [Frontal-Temporal], Superior [Midline Parting])
- [redacted]
- OLE Baseline status of "Subject using approved Shampoo/Conditioner" (Yes, No)

[redacted]



- DB Baseline clinical onset of AGA (i.e. time since start of AGA, months)

Subjects who reported more than one race will be counted once under each reported race.

Time since start of AGA (months) will be calculated as follows:

> Time since start of AGA (months) = (Date of first dose administration during the randomized portion – start date of AGA)/ 30.4375.

Completely or partially missing dates for the start date of AGA will be imputed as follows:

- Completely missing: leave missing.
- Missing day and month: impute to January 1st.
- Missing day: impute to the 1st of the month.

If the start date of AGA is completely missing, then the time since start of AGA will be missing.

A listing of all demographics and other baseline characteristics will be provided.

A listing of contraceptive methods will also be provided.

10 SURGICAL AND MEDICAL HISTORY

Surgical and medical history captured during the OLE Screening will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA), version 27.0 or higher.

Incidence of surgical and medical history captured after the subject has completed the randomized portion of the study through Day 1 of the OLE portion will be summarized by system organ class

(SOC) and preferred term (PT) overall based on the OLE safety analysis population. Subjects who experienced the same surgical and medical history multiple times within the same SOC will be counted only once for the corresponding SOC. Similarly, subjects who experienced the same surgical and medical history multiple times within the same PT will be counted only once for the corresponding PT. Surgical and medical history will be sorted alphabetically by SOC and within each SOC, PTs will be presented by decreasing order of overall frequency.

A listing of all surgical and medical history captured after the subject has completed the randomized portion of the study through Day 1 of the OLE portion will be provided, followed by a separate listing of AGA non-drug therapies and procedures captured during the OLE screening, based on the safety analysis population.

11 PRIOR AND CONCOMITANT MEDICATIONS

Medications will be coded according to the World Health Organization Drug Dictionary (WHO-DD), B3 March 2024 or higher.

Prior medications are defined as any medication started from completion of the follow-up period of the randomization portion of the study and discontinued prior to the first application of study drug during the OLE portion. Concomitant medications are defined as any medication taken on or after the first application of study drug during the OLE potion, including those that started prior to the date of the first application of study drug during the OLE portion and continued past that date. See Appendix 2 for handling of partially or completely missing medication start and stop dates.

Incidence of prior medications will be summarized by anatomical therapeutic chemical (ATC) class level 3 and preferred drug name overall based on the OLE safety analysis set. Subjects with multiple medications within the same ATC class level 3 will be counted only once for that ATC class level 3. Similarly, subjects with multiple medications within the same preferred drug name will be counted only once for that preferred drug name. Prior medications will be sorted alphabetically by ATC class level 3 and within each ATC class level 3, the preferred drug name will be presented by decreasing order of overall frequency. Incidence of prior AGA medications will also be summarized similarly.

Concomitant medications will be summarized similarly.

A listing of all medications (prior and concomitant) will be provided.

Information on whether subjects are using an approved shampoo/conditioner or not will also be listed.

12 EXPOSURE TO AND COMPLIANCE WITH STUDY DRUG

Duration of exposure to study drug during the OLE portion of the study, in days, is defined as follows:

> (Date of last application of study drug during OLE – Date of first application of study drug during OLE) + 1

The cumulative dose (g) per subject will be calculated by subtracting the total weight of bottles (g) returned after application of the product from the total weight of bottles (g) dispensed. Data for the bottles that are dispensed but not returned will be considered as missing and the concerned bottles will be excluded from this calculation.

Mean daily exposure (g/day) will be calculated by dividing the cumulative dose (g) by duration of exposure (days).

Compliance with study drug (%) will be calculated as follows:

$$\frac{\textbf{Cumulative dose per subject (grams)}}{\textbf{Duration of exposure (days) x Expected dose per day (grams)}} \textbf{ x 100}$$

where the number of expected doses per day is equal to 1g (equivalent to 1mL) for subjects treating one area and equal to 2g (equivalent to 2mL) for subjects treating both the vertex and the superior area.

Compliance with study drug (%) will also be categorized as follows:

- <80%
- ≥80% and ≤100%
- >100%

Duration of exposure to study drug (days), cumulative dose (g), mean daily exposure (g/day), and compliance with study drug (%) will be summarized using descriptive statistics based on the OLE safety analysis population. Number and percentage of subjects in each category of compliance with study drug (%) will also be presented based on the OLE safety analysis population.

Study drug accountability, exposure, and compliance will be listed.

13 EFFICACY ANALYSES

Unless otherwise specified, all efficacy endpoints will be summarized by sex at birth and visit, when applicable, based on the OLE mITT analysis population (refer to Section 5.3).

All efficacy data will be listed based on the OLE mITT analysis population.

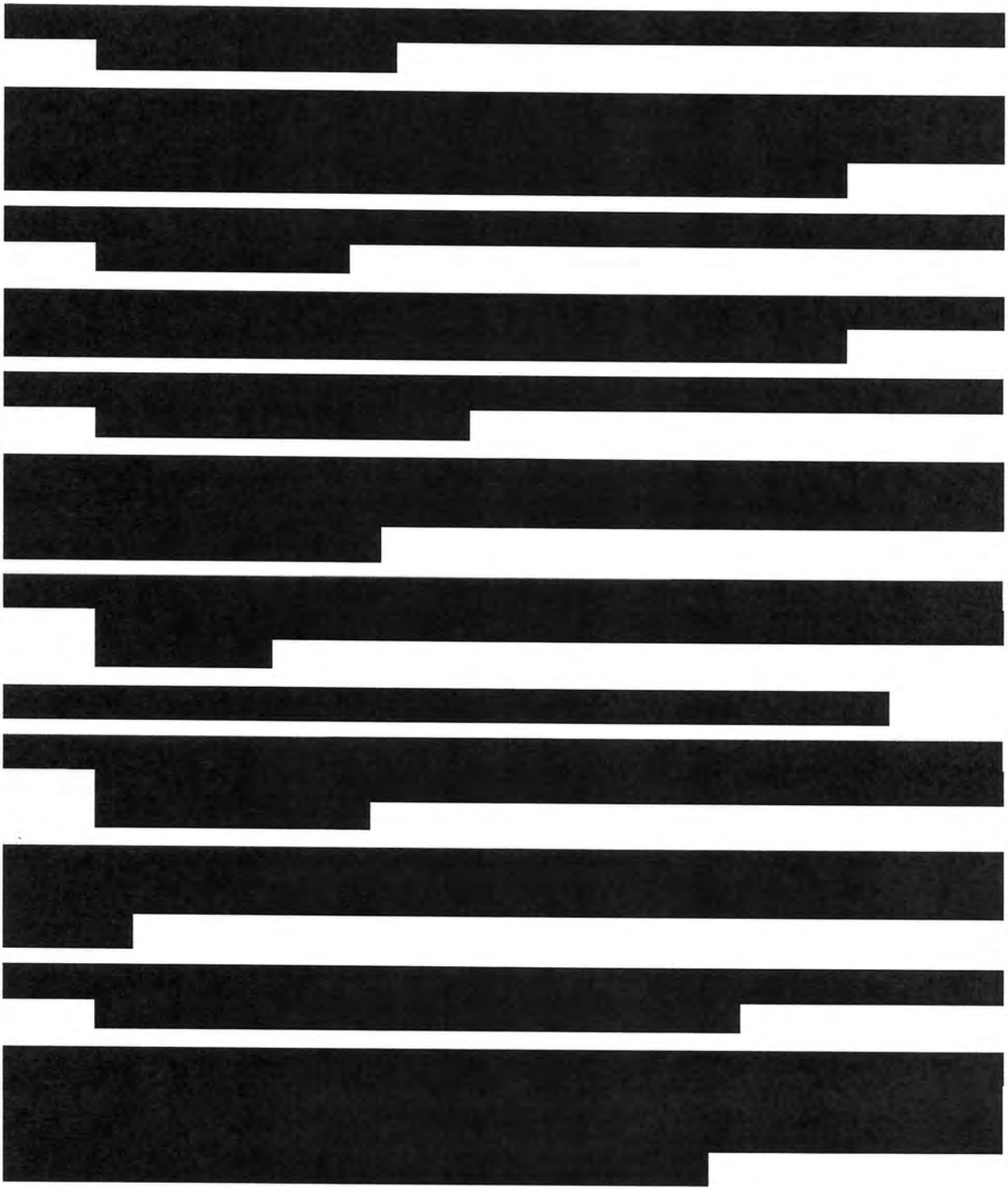
13.1 Primary Efficacy Endpoints

The primary objective of the OLE portion of the study is to evaluate the safety and tolerability of 3 months of open-label treatment with daily PP405 in subjects with androgenetic alopecia. There are no primary efficacy endpoints in this study.

13.2 Secondary Efficacy Endpoints

The secondary objective of the OLE portion of the study is to assess the concentration of PP405 in plasma during 3 months of open-label treatment in subjects with androgenetic alopecia. This will be covered in the PK analysis section. Refer to Section 15 for more details. There are no other secondary efficacy endpoints in this study.

[redacted]



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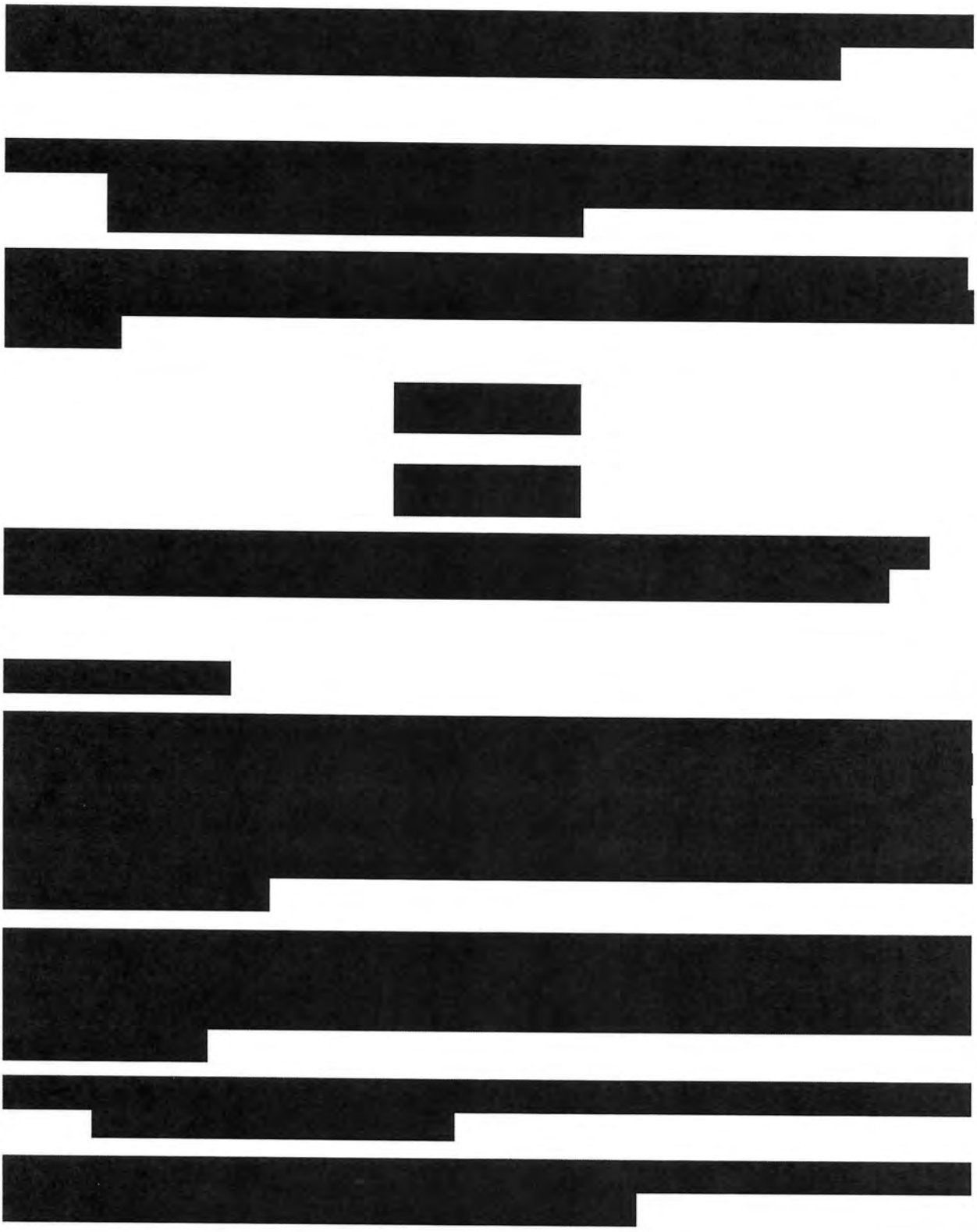
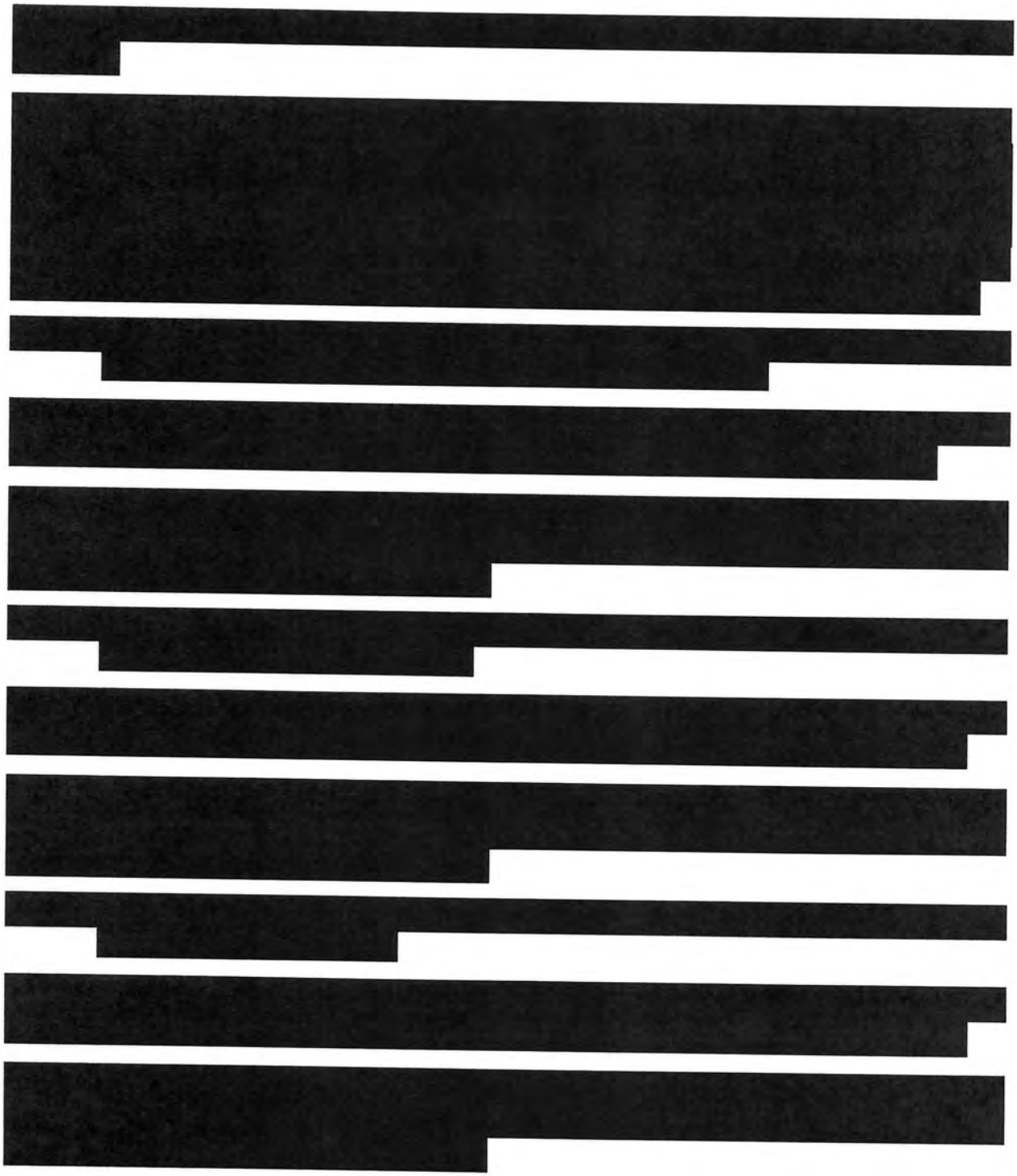
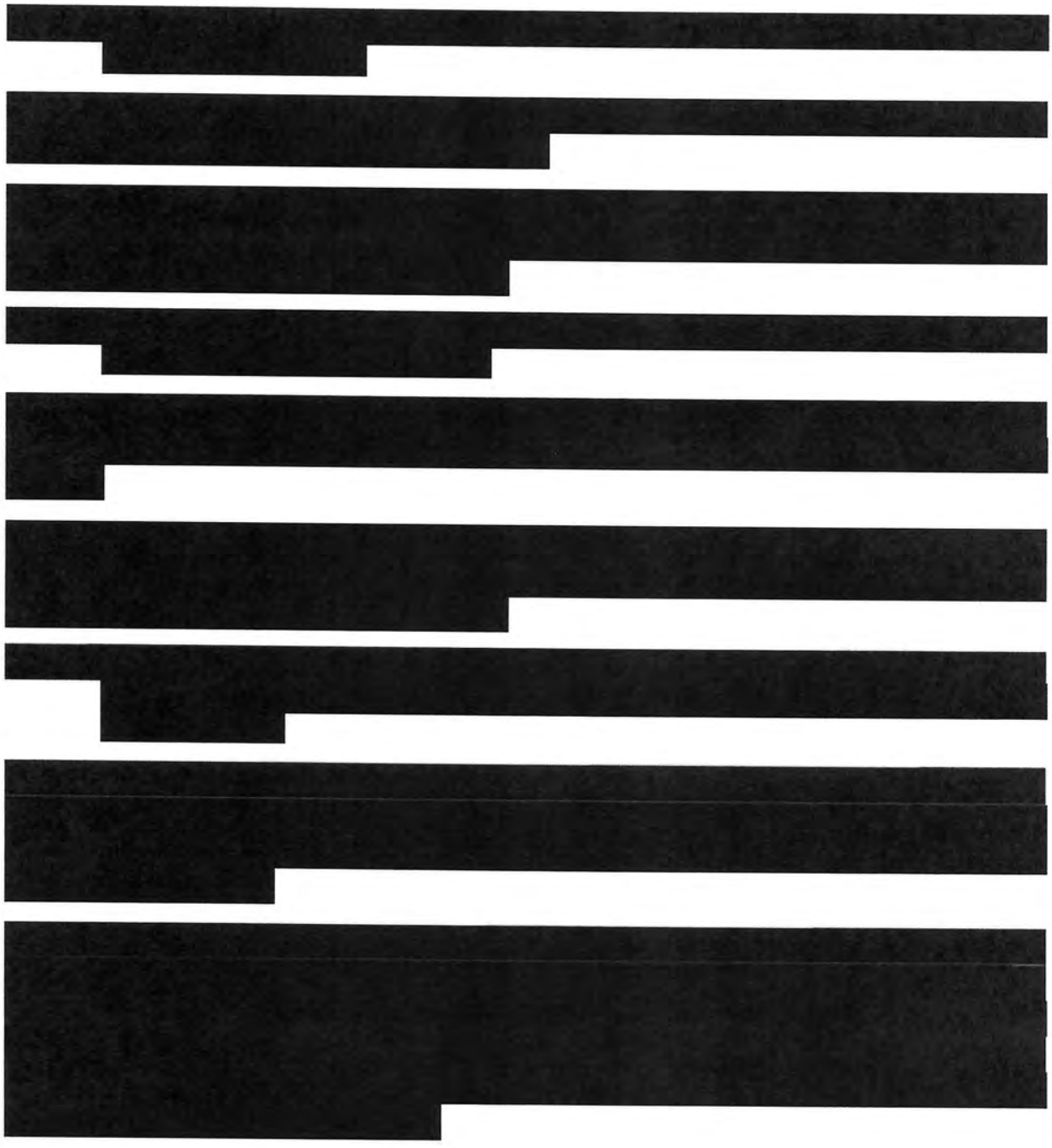
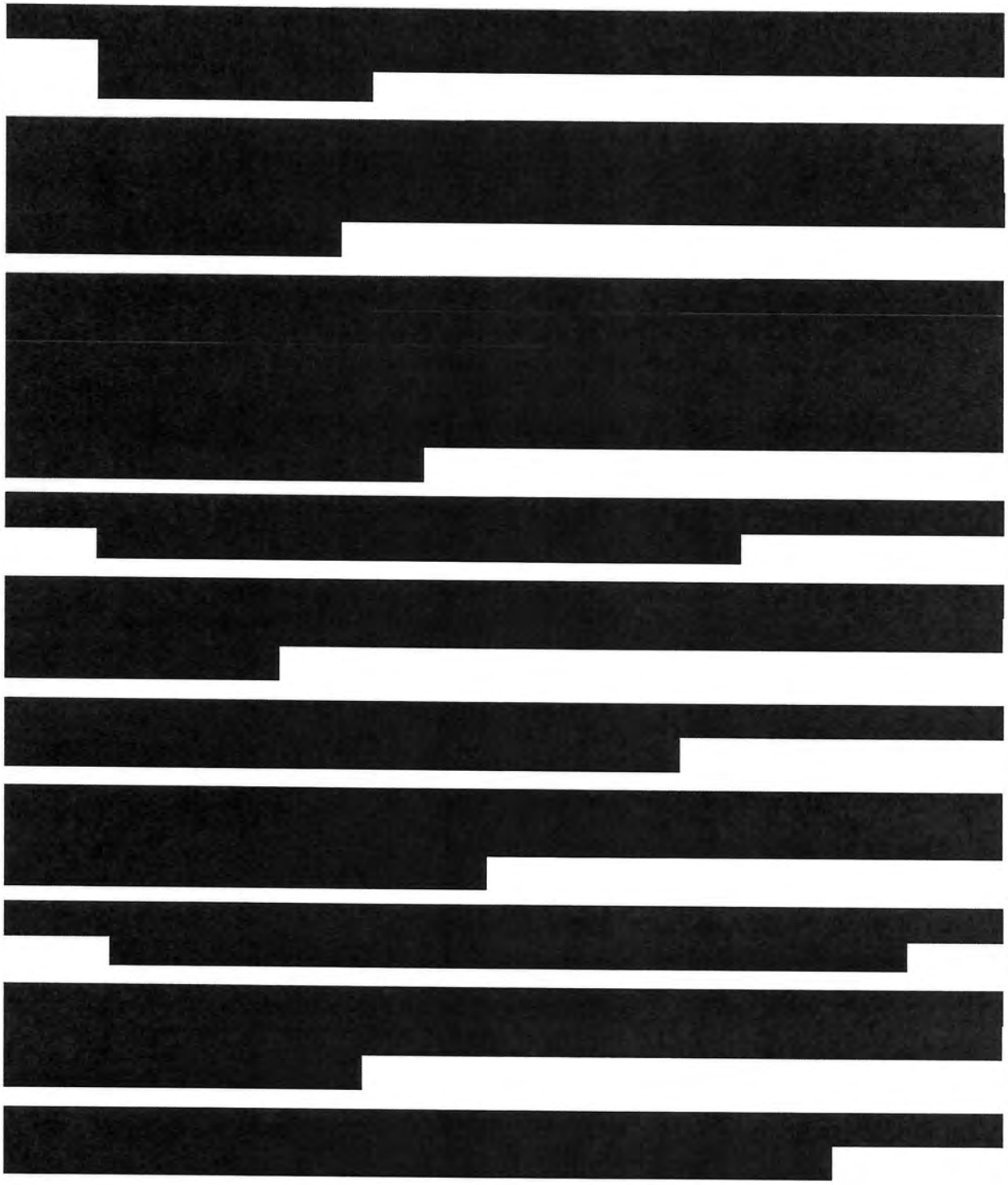








[redacted]

[redacted]

13.3.3 Sensitivity Analyses

No sensitivity analyses for exploratory efficacy endpoints are planned in the study.

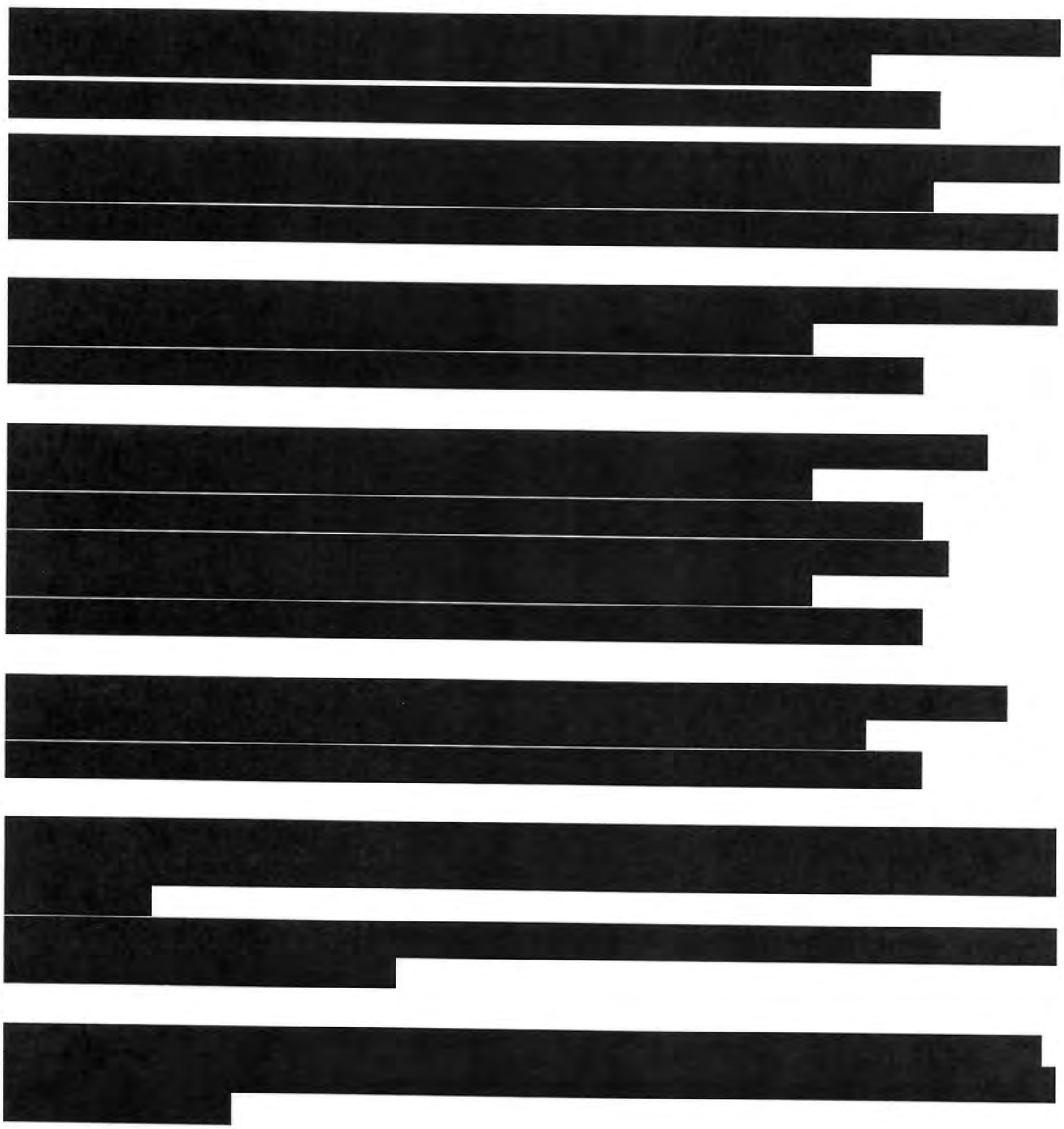
13.3.4 Supportive Analyses

No supportive analyses for exploratory efficacy endpoints are planned in the study.

13.4 Other Efficacy Endpoints

These endpoints were defined when writing the SAP.

13.4.1 Definition of Other Efficacy Endpoints



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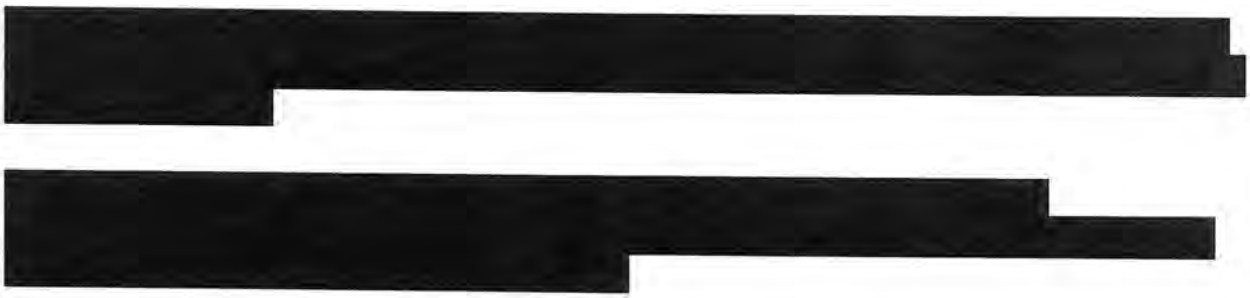


13.4.3 Sensitivity Analyses

No sensitivity analyses will be performed for other efficacy endpoints.

13.4.4 Supportive Analyses

No supportive analyses will be performed for other efficacy endpoints.

14 SAFETY ANALYSES

All safety endpoints will be summarized by visit, when applicable, based the OLE safety analysis set.

14.1 Adverse Events

AEs during the OLE portion of the study will be coded according to the MedDRA, version 27.0 or higher.

According to the study protocol, an AE is considered to be treatment emergent (TEAE) if:

- It is not present when the active phase of the study begins and is not a chronic condition that is part of the subject's medical history; or,
- It is present at the start of the active phase of the study or as part of the subject's medical history, but the severity or frequency increases during the active phase.

For the OLE portion of the study, the active phase of the study begins at the time of first dose of study drug during the OLE and ends at the Day 168 Follow-up visit. The TEAE variable collected in EDC will only be presented in the listings. Refer to Section 10.10.6 of the Study Protocol for further details.

For statistical analyses purposes, TEAEs are defined as any AEs with onset date on or after the date of the first dose of study drug during OLE portion. See Appendix 2 for handling of partially or completely missing AE start and stop dates. In the case where it is not possible to define an AE as treatment emergent or not, the AE will be classified as treatment emergent.

An overall summary table for AEs will be provided. The number of events and the number and percentage of subjects who experienced at least one AE, TEAE, TEAE by greatest reported relationship to study drug, TEAE by worst reported severity, local skin reaction TEAE, TEAE with an outcome of death, serious TEAE, non-serious TEAE, TEAE leading to discontinuation from study drug, TEAE leading to discontinuation from study, and TEAE leading to interruption of study drug will be presented.

Incidence of TEAEs will be summarized by SOC and PT. Subjects experiencing multiple TEAEs within a SOC will be counted only once for that SOC. Similarly, subjects experiencing multiple TEAEs within a PT will be counted only once for that PT. TEAEs will be presented by SOC sorted by decreasing order of total frequency, and within each SOC, PTs will also be presented by decreasing order of total frequency.

Incidence of TEAEs will be further broken down by greatest reported relationship with study drug, where a treatment-related TEAE is defined as any TEAE that is assessed by the investigator as definitely, or possibly related to study drug while not treatment-related TEAE is defined as any TEAE that is assessed as not related to study drug. Subjects experiencing multiple TEAEs within the same SOC/PT but in different categories of relationship to study drug will be reported only once under the greatest reported relationship to study drug. A TEAE with an unknown relationship will be considered as treatment-related.

Incidence of TEAEs will also be further broken down by worst reported severity. Subjects experiencing multiple TEAEs within the same SOC/PT but in different categories of severity will be reported only once under the worst severity. A TEAE with an unknown severity will be considered as severe.

Incidence of serious TEAEs, non-serious TEAEs, local skin reaction TEAE, TEAEs leading to discontinuation from study drug, and TEAEs leading to discontinuation from study will be summarized separately by SOC and PT. Subjects experiencing multiple TEAEs within a SOC will be counted only once for that SOC. Similarly, subjects experiencing multiple TEAEs within a PT will be counted only once for that PT. TEAEs will be presented by SOC sorted by decreasing order of total frequency, and within each SOC, PTs will be presented by decreasing order of total frequency.

Listings of all AEs with an outcome of death, all serious AEs, all local skin reaction TEAE, all TEAEs leading to discontinuation from study drug, all TEAEs leading to discontinuation from study, and all TEAEs leading to interruption of study drug will be provided. A listing of all AEs will also be provided where local skin reaction TEAEs will be flagged.

14.2 Clinical Laboratory

Laboratory data will be presented in SI units.

Observed values and changes from OLE baseline in chemistry, hematology, and quantitative urinalysis tests will be summarized using descriptive statistics. Frequencies and percentages will be presented for each category of qualitative urinalysis tests.

Shift tables from baseline to each post-OLE baseline visit describing shifts to abnormality based on the central laboratory reference ranges (low, normal, high) will be provided. Only subjects with an OLE baseline result and a result at the specified post-OLE baseline visit will be considered.

Separate listings of data for chemistry, hematology, and urinalysis will be provided for each test where a subject had at least one abnormal result i.e., below the lower limit of normal (LLN) or above the ULN.

In addition, separate listings of all data for pregnancy, COVID-19 rapid test, chemistry, hematology, and urinalysis tests will be provided.

14.3 Vital Signs

Vital signs data will be presented in SI units.

Observed values and changes from OLE baseline in vital signs (systolic blood pressure [SBP], diastolic blood pressure [DBP], pulse rate, respiratory rate, body temperature, and weight) will be summarized using descriptive statistics.

A listing of all vital sign assessments will be provided.

14.4 Electrocardiogram

Observed values and changes from OLE baseline in ECG tests/intervals (heart rate, RR interval, PR interval, QRS interval, QT interval, and QTcF interval) will be summarized using descriptive statistics at each visit.

ECG measurements meeting the pre-defined markedly abnormal criteria specified in ICH E14 will be identified i.e.,

- QTcF interval (msec) observed values:
    - o > 450 with no pre-existing condition (i.e., OLE baseline value ≤ 450)
    - o > 480 with no pre-existing condition (i.e., OLE baseline value ≤ 450)
    - o > 500 with no pre-existing condition (i.e., OLE baseline value ≤ 450)
- QTcF interval (msec) increases from OLE baseline:
    - o > 30
    - o > 60

For each of these markedly abnormal criteria, the number and percentage of subjects with at least one measurement meeting a criterion after baseline will be provided.

For central ECG overall interpretation, shift tables from OLE baseline to each post-OLE baseline visit describing shifts to abnormality will be provided. Only subjects with an OLE baseline result and a result at the specified post-OLE baseline visit will be considered.

A listing of all ECG tests, intervals, and overall interpretation will be provided. Markedly abnormal measurements will be flagged.

14.5 Physical Examination

Information for all physical examinations will be included in the source documents. Any significant change will be reported as an AE in the source document and eCRF.

14.6 Local Skin Reactions

A static assessment of local skin reactions (LSRs) will be conducted in all subjects. LSRs include burning/stinging, pruritus, edema, erythema, dryness, and scaling. Each LSR will be scored as 0 (None), 1 (Mild), 2 (Moderate) or 3 (Severe).

Burning/stinging and pruritus will be assessed by the subject and edema/swelling, erythema, dryness, and scaling will be assessed by the investigator/designee. Refer to Section 10.10.5 of the study protocol for further details.

On Day 1, Day 28, Day 56, and Day 84 visits, LSRs will be collected prior to study drug application and approximately 15 to 45 minutes following application of study drug. LSRs that occur or worsen following study drug application will be recorded as AEs.

Each LSR will be summarized by number and percentage of participants for each evaluator separately (investigator/subject), by treatment group, scheduled visit, and time point (pre-/post-dose), as applicable.

All local skin reactions data will be listed.

15 PHARMACOKINETIC ANALYSIS

PK tables and listings will be presented using the OLE PK analysis population. PK data will be presented by visit, in summaries.

15.1 General considerations

For descriptive statistics, plasma concentrations that are below the limit of quantification (BLQ) will be treated as zero.

15.2 Plasma concentrations

PK samples are collected from each subject, 2 hours (+/-10 minutes) post dose on OLE Days 1, 28, and 54. For OLE Day 84, samples will be collected at 1, 2, and 4 hours (+/-10 minutes) post dose. PK collections that have an actual sampling time that deviates from the predefined collection time windows will be flagged in the data listings and will be included in the calculation of concentration summary statistics. The number of minutes in deviation will also be presented in data listings.

The number of minutes in deviation will be calculated as follows:

(Actual Sampling Time – Predefined Collection Time).

Individual plasma concentrations will be presented in data listings and summarized separately using descriptive statistics (number of observations, arithmetic mean, standard deviation, coefficient of variation [CV], geometric mean, geometric CV, median, minimum, and maximum) by visit.

APPENDICES

APPENDIX 1

Output Conventions

TLF will be generated using SAS® and will be displayed on letter size paper with landscape orientation, 1 inch margin, and 9 pt Courier New font.

The header section will comprise the sponsor's name, protocol number, delivery description, data cut-off date or date of database lock, as applicable, and page number (Page X of Y).

TLF title section will include TLF number, TLF title, and analysis set.

The footer section will include the source listing(s) (if applicable), list of abbreviations, TLF footnotes, name of the SAS program name, and date and time of the execution of the program.

For categorical summary tables, percentages will be reported to one decimal place. Percentages between 0 and 0.1 (both exclusive) will be displayed as "<0.1" and percentages between 99.9 and 100.0 (both exclusive) will be displayed as ">99.9". Percentages will be based on total number of subjects in the analysis set within each treatment group [redacted] ased on number of subjects in the analysis set with available data within each treatment group for any other type of data.

For descriptive statistics, for all endpoints [redacted] efined in the next paragraph, the minimum and maximum values will keep the same number of decimal places as the original value; the mean and median will be displayed with one additional decimal place than the original value; and the SD, standard error (SE), and CI will be displayed with two additional decimal places than the original value. If derived endpoints are to be summarized, the number of decimals of the derived values is to be chosen on a case-by-case basis, but the rule above applies.

[redacted]

P-values between 0.001 and 0.999, both inclusive, will be reported to 3 decimal places, p-values less than 0.001 will be reported as "<0.001", and p-values greater than 0.999 will be reported as ">0.999".

Listings will be ordered by treatment group, subject number, endpoint/test, date of assessment/ collection/measurement, and time of assessment/collection/measurement, if applicable. Imputed dates and imputed missing data will not be presented in the listings. For visit names, nominal visit names will be presented followed by the analysis visit name when both are different (e.g., 'Unscheduled/Week X', etc.) Otherwise, only the nominal visit names will be presented.

Dates & Times Format

Date and time (if available) will be presented in the format yyyy-mm-dd/hh:mm.

Presentation of Treatment Groups

When applicable, treatment groups will be represented as follows:

Treatment Group Full Name	Treatment Group Short Name for TLFs
PP405 Topical Gel, 0.05%	PP405 0.05%
PP405 Vehicle Topical Gel	PP405 Vehicle

APPENDIX 2

Algorithm for Imputation of Start/Stop Date of Adverse Events and Prior/Concomitant Medications

Event Start Date Imputation

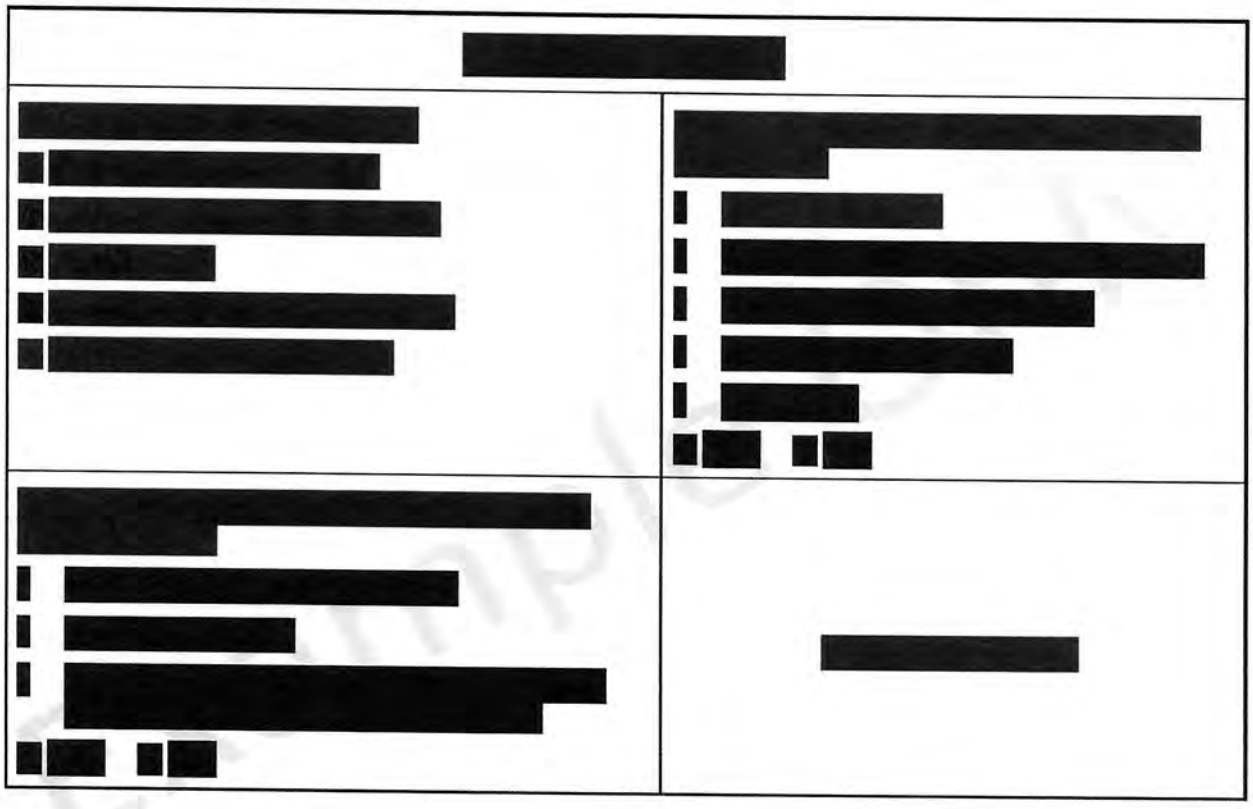
- Imputation of event end date should be done before imputation of event start date.
- *Completely missing*: Impute to the first study treatment date.
- *Missing day and month*: Impute to January 1st, unless year is the same as year of first study treatment dose then impute to the first study treatment date.
- *Missing day*: Impute to the 1st of the month, unless month and year are the same as month and year of first study treatment dose then impute to the first study treatment date.
- If imputed event start date is after event end date (imputed or not), set the event start date to the imputed event end date.

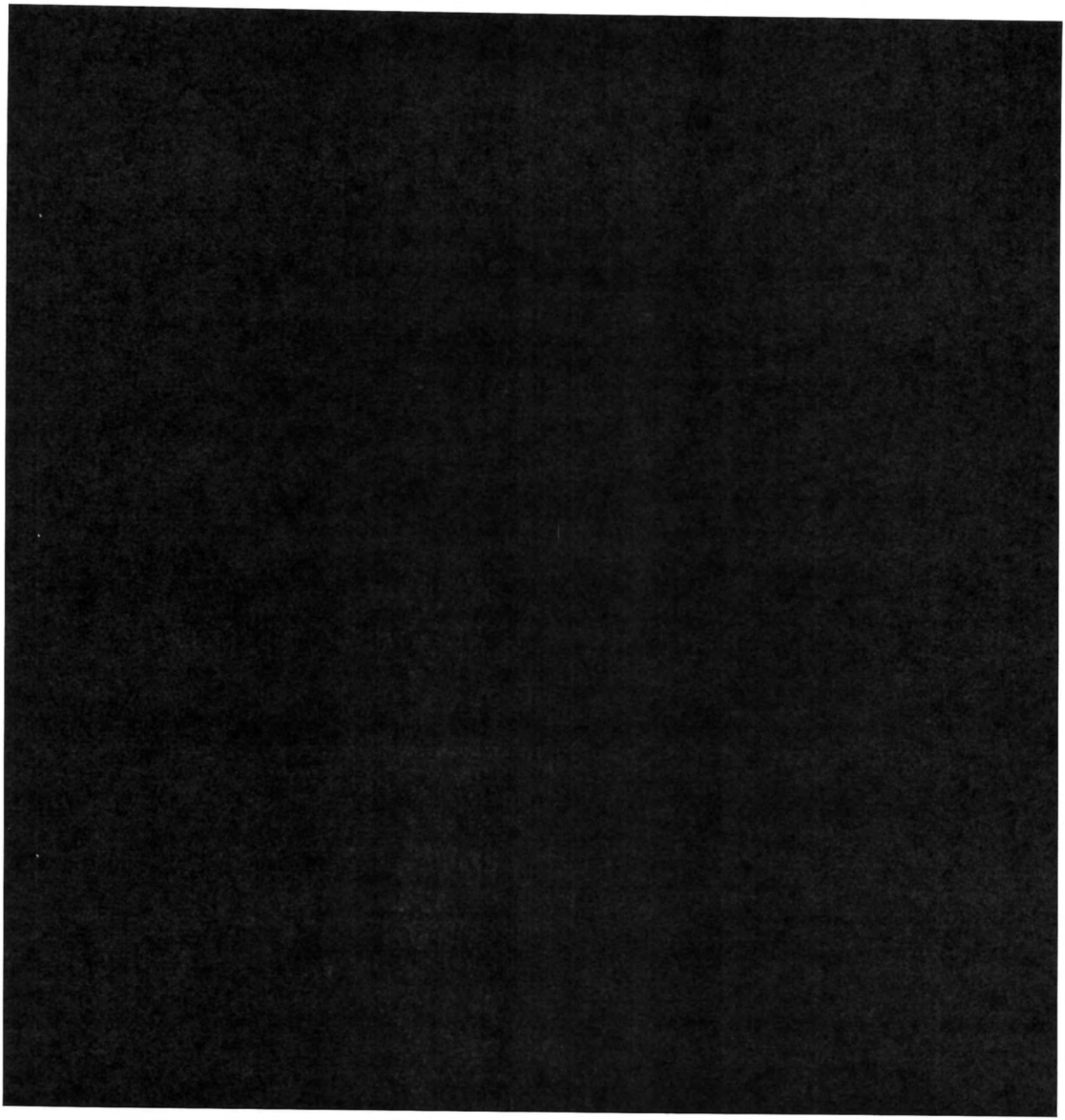
Event Stop Date Imputation

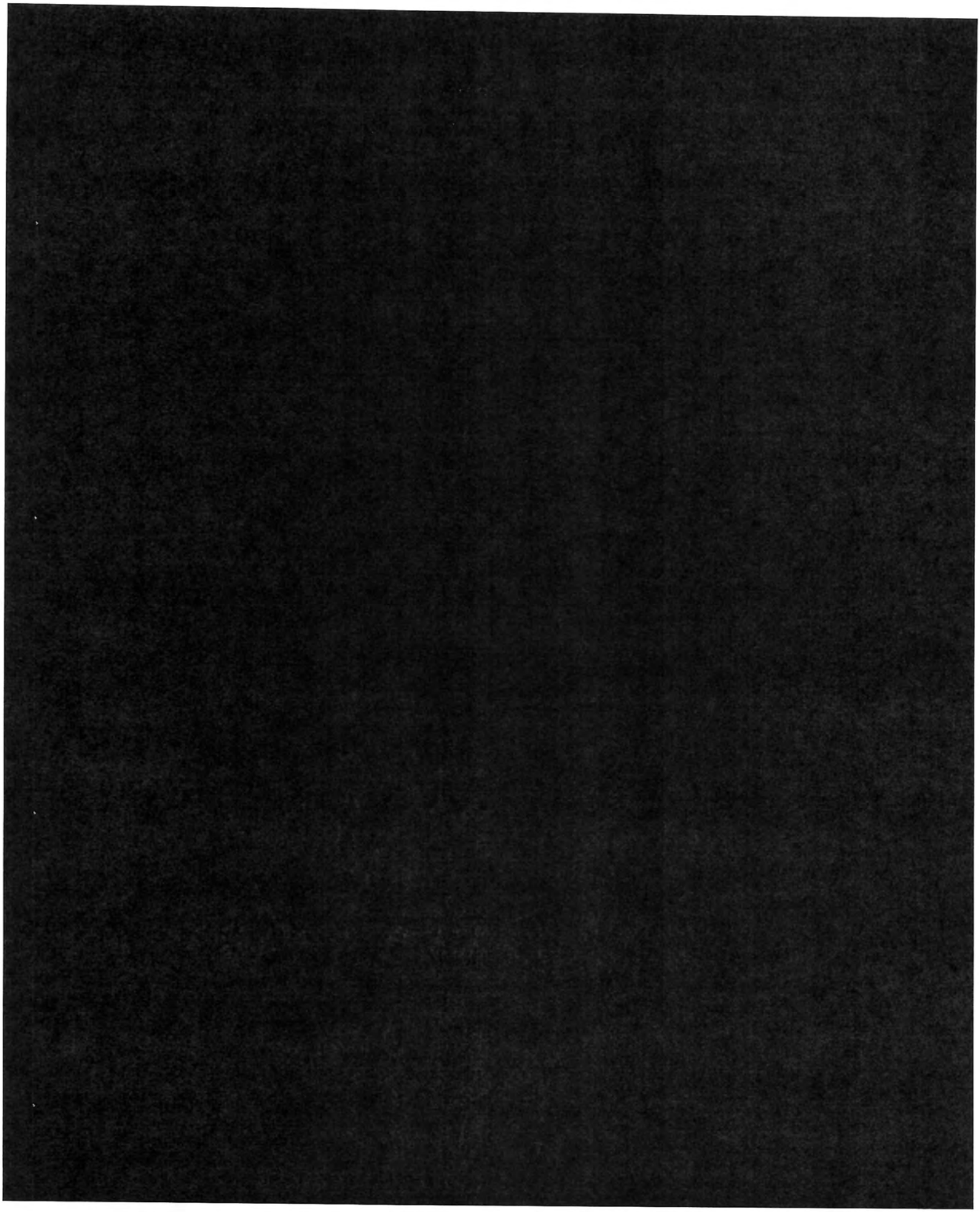
- *Completely missing (and not flagged as "ongoing")*: Impute to the last contact date.
- *Missing day and month*: Impute to December 31st, unless year is the same as last contact date then impute to the last contact date.
- *Missing day*: Impute to the last day of the month, unless year and month are the same as year and month of last contact date then impute to the last contact date.

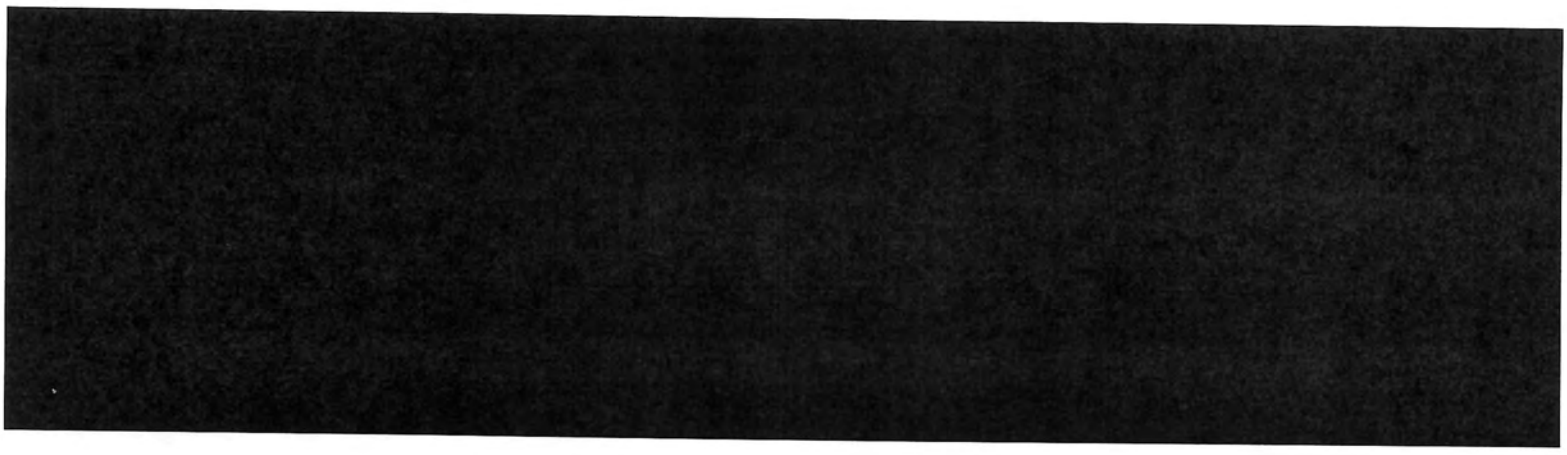
[redacted]

[redacted]









[redacted]

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

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Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

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Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

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To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at [redacted] and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

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