PPD

Polichem

Protocol No.: PM1541

A Multicenter, Randomized, Double-blind, Parallel-Group, Controlled Study, to Assess The Efficacy and Safety of P-3074 Cutaneous Spray Solution, In The Treatment of Male Pattern Baldness

PPD

STATISTICAL ANALYSIS PLAN

Version: Final 1.0
Date of Issue: 22-January-2018

Author: PPD

PPD

Polichem S.A
Via Senago 42 D
Lugano-Pazzallo CH-6912
Switzerland

APPROVALS

The undersigned agree that all required reviews of this document are complete, and approve this Statistical Analysis Plan as final. Programming of the tables, figures and listings based upon the specifications within this document can proceed.

Covance Approval:

PPD

Signature

PPD

Date

PPD / Principal Statistician

Printed Name/Title

Polichem Approval:

PPD

Signature

PPD

Date

PPD

Printed Name/Title

PPD

Signature

PPD

Date

PPD

Printed Name/Title

REVIEWERS

The following reviews of the SAP were conducted:

Name and Title	Role	Version Last Reviewed	Company/ Organization
PPD	Peer Review Statistician	Internal draft 1.0	PPD
PPD	Lead Programmer	Internal draft 1.0	PPD
PPD	Medical Writer	Internal draft 1.0	PPD
PPD	Project Physician	Internal draft 1.0	PPD
PPD	Project Manager	Internal draft 1.0	PPD
PPD	Project Manager	External draft 0.1	Polichem
PPD	Lead Statistician	External draft 0.1	Polichem
PPD	Lead Statistician	External Final 1.0 working	Almirall
PPD	Lead Statistician	External Final 0.1 Dated on 06-Dec-2017	Polichem

VERSION HISTORY

Version Number	Version Date	Summary and rational of change(s)
External Final 1.0 - working	30-Jun-2017	Final working version before signed off
External Final 1.0	5-Dec-2017	Final version to sign off
External Final 1.0	22-Jan-2018	1. CCI summary by number of recommended sprays 2. Include Skin irritation incidence rate Final version to sign off

<Only final versions of the SAP need to be recorded here.>

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GLOSSARY OF ABBREVIATIONS

Abbreviation	Term
AE	Adverse event
ALT	Alanine aminotransferase
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
BCA	Best Case Analysis
BLQL	Below the Lower Quantification Limit
CI	Confidence Interval
CCI	[redacted]
eCRF	Electronic Case report form
IMP	Investigational Medicinal Product
ITT	Intention-to-treat
LOCF	Last observation carried forward
MedDRA	Medical Dictionary for Regulatory Activities
MHGQ	Male Hair Growth Questionnaire
NC	Not Calculated
O.D.	Once Daily
PD	Pharmacodynamics
PK	Pharmacokinetics
PT	Preferred Term
PPP	Per Protocol Population
PTAE	Pre-Treatment Adverse Event
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SI units	International System of units
SOC	System Organ Class
TAHC	Target Area Hair Count
TEAE	Treatment-Emergent Adverse Event
TESAE	Treatment-Emergent Serious Adverse Event
WCA	Worst Case Analysis

1 SOURCE DOCUMENTS

The Statistical Analysis Plan (SAP) was written based on the following documentation:

Document	Date	Version
Protocol Amendment	8-Mar-2017	Final Version 4.0
<e>CRF	21-Sep-2017	Version 4.0

2 PROTOCOL DETAILS

2.1 Study Objectives

The primary objective of this pivotal Phase III study is to determine whether 24 weeks of a daily treatment with P-3074, increases hair count in men with male pattern baldness compared to the vehicle.

2.2 Study Endpoints

2.2.1 Primary Endpoint

- Hair growth assessed by Target Area Hair Count (TAHC) in the vertex at 24 weeks.

2.2.2 Secondary Endpoints

- Hair growth assessed by TAHC in the vertex at 12 Weeks;
- Target Area Hair Width (TAHW) in the vertex at Weeks 12 and 24;
- Patient assessment in Male Hair Growth Questionnaire (MHGQ) Score at Weeks 12 and 24;
- Investigator Assessment of Improvement from Baseline to Week 12 and from Baseline to Week 24, assessed for vertex;
- Blind Assessor Assessment of Improvement from Baseline to Week 12 and from Baseline to Week 24, assessed for vertex;
- Assessment of sexual function at every visit (Sexual Function Index, IIEF-2);
- Assessment of adverse events (AEs) throughout the study;
- Assessment of the local tolerability by means of severity scores for skin irritation;

For the purpose of assessment of changes in hair growth by investigators and blind assessor, screening visits (where global photos are taken) will act as Baseline.

2.2.3 Exploratory Endpoints

- CCI [redacted]

2.3 Overall Study Design

This is a Phase III, multicenter, randomized, double-blind, double-dummy, parallel-group study. The aim is to evaluate the efficacy and safety of P-3074 cutaneous topical solution versus an active comparator of

oral Finasteride in the treatment of the male pattern baldness across three treatment arms, in the ratio of 2:2:1 (A:B:C).

Group A: P-3074 o.d. + placebo of oral Finasteride 1 mg o.d.
Or
Group B: P-3074 Vehicle + placebo of oral Finasteride 1 mg o.d.
Or
Group C: Finasteride 1 mg o.d. + P-3074 Vehicle

The study consists of a screening visit (Visit 1), a randomization visit (Visit 2), a treatment phase of 24 weeks (assessed at 4 or 12 week intervals) and a 1-month follow up.

2.4 Sample Size and Power

Group sample sizes of 144 patients randomized to P-3074 and 144 patients randomized to placebo achieve 99% power to detect superiority using a one-sided, two-sample t-test with a significance level (alpha) of the test equal to 0.025. The margin of superiority, i.e. the distance above the reference (placebo) mean that is required to be considered superior, is set to a 41 hair count while the true difference between P-3074 and placebo is assumed to be an 82 hair count and is estimated assuming a mean change from baseline to 6 months in hair count equal to -14 and +68 in placebo and P-3074 respectively. The data are drawn from populations with standard deviations (SD) of 88 in P-3074 and 75 in placebo.
Approximately 72 patients will be randomized to the active comparator arm (oral Finasteride 1 mg). Group sample sizes of 144 patients randomized to P-3074 and 72 patients randomized to oral Finasteride achieve a power close to one to reject the null hypothesis of equal serum CCI inhibition assuming a mean serum CCI inhibition equal to 45.6 and 26.2 in oral Finasteride and P-3074 respectively, with a SD for both groups of 19.0(2) and with a significance level (alpha) of 0.050 using a two-sided two-sample equal-variance t-test.
Assuming an attrition rate equal to 20%, the total number of patients should be no less than 450 patients randomized to P-3074, placebo and oral Finasteride in a 2:2:1 allocation ratio. All computations were performed using PASS 13 Software.

3 EFFICACY AND SAFETY VARIABLES

3.1 Primary Efficacy Variables

Total hair count after 24 weeks of treatment

3.2 Secondary Efficacy Variables

- Total hair count after 12 weeks of treatment
- Hair width after 12 and 24 weeks of treatment
- Patient assessment in Male Hair Growth questionnaire (MHGQ) at Weeks 12 and 24:
    - Bald spot getting smaller

- Appearance of your hair
- Growth of hair
- Effectiveness in slowing down hair loss
- The hair line at the front of your head
- The hair line at the top of your head
- Overall assessed by a patient

- Score of Investigator Assessment of Improvement from Baseline to Week 12 and from Baseline to Week 24, assessed for vertex
- Score of Blind Assessment of Improvement from Baseline to Week 12 and from Baseline to Week 24, assessed for vertex

3.3 Safety Variables

- Adverse events (AEs)
- Physical examination
- Vital signs
- Clinical laboratory tests
  - Hematology

    Hemoglobin concentration, hematocrit, red blood cell count and white blood cell count with differential and platelet count
  - Clinical Chemistry

    Transaminases (Aspartate aminotransferase [AST], Alanine aminotransferase [ALT]), total serum bilirubin (direct and indirect), gamma glutamyl transferase, alkaline phosphatase, serum creatinine, blood urea nitrogen, uric acid, glucose, potassium, calcium, chloride, testosterone, protein and albumin
  - Urinalysis

    Protein content, glucose content, hemoglobin content, white blood cell content in sediment, red blood cell content in sediment, crystals content in sediment, casts content in sediment
- Local Tolerability/skin irritation
- Assessment of potential Sexual Dysfunction (IIEF-2):
  - Erectile function score
  - Orgasmic function score
  - Sexual desire score
  - Intercourse satisfaction score
  - Overall satisfaction score

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I [redacted]

- CCI [redacted]

5 ANALYSIS POPULATIONS

A patient will be defined as screened after the signature of the informed consent, regardless of the completion of all the screening procedures.
A patient will be defined as eligible if he meets all the inclusion/exclusion criteria. Otherwise he will be defined as a screening failure.
A patient will be defined as enrolled in the study if he is included in the interventional phase of the study. Enrolment will be performed through randomized allocation to a treatment arm/treatments sequence.

5.1 All Randomized Population

All enrolled patients who are randomized to a treatment group.

5.2 Safety Population

All randomized patients who receive at least one application of the investigational drug.

5.3 Intent to Treat (ITT) Population

All patients who have measurements in regards to hair count both at baseline and on treatment.

5.4 Per Protocol Population (PPP)

All patients in the ITT population

- who did not take forbidden medications;
- who complete the entire study without any major protocol violations.

Analysis done on the PPP will be considered supportive.

5.4.1 Important Protocol Violation Leading to Exclusion from the PPP Analysis

A blinded data review meeting will be set up when 100% of patients with clean data before last patient last visit are available but before unblinding. The meeting will focus on defining the final PPP for PPP analysis. Detail of exclusion criteria will be documented in the blinding review meeting report.

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- CCI [redacted]

6 DATA HANDLING

6.1 Time points and Visit Windows

Day 1 is defined as the day of first treatment dose. Relative days after Day 1 are calculated as (assessment date – Day 1 date) + 1. Relative days prior to Day 1 are calculated as (assessment date – Day 1 date). The day prior to Day 1 is Day -1.

All relevant safety data will be analyzed using nominal study visits as defined in the Study Schedule and electronic case report form (eCRF). A visit window of 28 days will be applied to all efficacy endpoints at visit 5 and 15 days at visit 6. A scheduled assessment/photo shooting with valid readings will be used if it is available. If there is no valid efficacy assessment/photo shooting at a scheduled visit, the analysis window below (Table 1) will be applied to re-allocate a post baseline unscheduled assessment/photo re-shoot with valid readings to a scheduled assessment/photo shooting.

Table 1 – Analysis window definition

Scheduled visit post baseline	Targeted study day	Analysis window in study days
Week 12 (Visit 5)	84	81 to 112
Week 24 (Visit 6)	168	165 to 183

6.2 Handling of Drop-outs or Missing Data

Assuming missing data follows Missing Completely At Random (MCAR) or a Missing At Random (MAR) mechanism, a maximum likelihood analysis on available data should theoretically induce less bias compared to commonly used and naïve imputation method such as LOCF. So, the mixed linear models for the main analyses described in section 7.6.1 will represent a suitable choice in handling missing data and correcting for the bias potentially caused by drop-outs in this study.

To assess the sensitivity of the results due to the presence of missing values; three supplemental analyses will be performed on the primary endpoint analysis:

1. Last Observation Carried Forward (LOCF)[1]: Missing outcomes will be replaced by the last non-missing, post-baseline value. For example, if a patient withdraw from the study before Visit 6 (Week 24) but has available hair count data at the early withdrawal visit, then the data from the early withdrawal visit will be carried forward to Visit 6 (Week 24).
2. Best Case Analysis (BCA)[1]: Missing post-baseline outcomes will be replaced by the best outcome (maximum hair count) within the same treatment group at any post-baseline measurement (including follow-up visit) during the study period.
3. Worst Case Analysis (WCA)[1]: Missing post-baseline outcomes will be replaced by the worst outcome (minimum hair count) within the same treatment group at any post-baseline measurement (including follow-up visit) during the study period.

Handling of missing/incomplete AE start/stop date will be documented in Section 7.7.2 Adverse Events. .

7 STATISTICAL METHODS

7.1 General Principles

All data processing, summarization and analyses will be performed using the Hosted SAS Environment Version 9.3 (or later) of the SAS® statistical software package.

Unless specified otherwise, data will be displayed using the following treatment group labels, in the order presented:

- P-3074 + P
- Vehicle + P
- Vehicle + FNS

Where "P-3074 + P" represents P-3074 o.d. + placebo of oral Finasteride 1 mg o.d, "Vehicle + P" represents P-3074 Vehicle + placebo of oral Finasteride 1 mg o.d., and "Vehicle + FNS" represents Finasteride 1 mg o.d. + P-3074 Vehicle.

All data collected will be presented in listings by treatment group, country, subject, and visit (where applicable), unless otherwise specified.

Data will be presented in summary tables by treatment group and visit (where applicable). The category "Missing" will be presented if the number missing is greater than zero for at least one treatment group.

Descriptive summary statistics for continuous variables will include the number of subjects (N), mean, standard deviation (SD), median, first (Q1) and third (Q3) quartiles, minimum (Min) and maximum (Max).
Descriptive summary statistics for categorical variables will include frequency counts and percentages [n (%)]. Unless stated otherwise in the table shells, the denominator for percentage calculations will be the number of subjects in the analysis population.

Dates will be displayed as DDMMMYYYY.

All significance tests will be two-sided and use a 5% significance level accompanied with 95% confidence interval.

7.2 Subject Disposition and Data Sets Analyzed

Subject disposition will be based on all enrolled subjects and will be listed and summarized by treatment group and overall, and will include the number and percentage of subjects:

- with inform consent;
- screened;
- randomized;
- included in each study population (All Randomized, ITT, Safety, PPP, CCI).

The number and percentage of subjects who complete the study and who discontinue early (before follow up visit), including a breakdown of the primary reasons for discontinuation, will be presented for the All Randomized Population.

A summary of the reasons for screen failure as well as the number of subjects screened but not randomized will be produced. No other information for screen failures will be presented.

The number and percentage of subjects in each country and each site will be presented for the Randomized Population.

7.3 Protocol Violations

All protocol violations will be listed and summarized by treatment group for the Randomized Population.

All important protocol violations from the ITT population leading to exclusion from the PPP (see Section 5.4.1) will be listed and summarized by treatment group.

7.4 Demographics and Other Baseline Characteristics

Demographic and baseline characteristics will be listed and summarized by treatment group and overall for ITT and Safety populations. Descriptive statistics will be presented for the continuous variables of:

- age (years) [calculated as (year of informed consent signed – year of birth) and reported as integer;
- weight (kg);
- height (cm);
- body mass index (kg/m^2) [calculated as ($weight/height^2$) where weight is in kg and height is in m];

The total counts and percentages of subjects will be presented for the categorical variables of:

- race;
- ethnicity;
- current alcohol use;
- current smoking/tobacco use;
- smoke >=10 cigarettes/day
- drink >5 cups coffee/tea/day

No formal tests of statistical significance will be performed on the demographic and baseline data.

Other baseline measurements, such as vital signs and laboratory data will be summarized by treatment group with the post-baseline measurements.

7.4.1 Medical History

Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) [Version 19.0]. All medical history will be listed, and the number and percentage of subjects with any medical history and the frequency and percentage of a medical history episode will be summarized for All Randomized Population by system organ class (SOC) and preferred term (PT) for each treatment group and overall.

Vertex pattern hair loss according to Norwood/Hamilton scale will also be listed and the number and percentage of subjects in each type will be summarized for both ITT and Safety Populations.

7.4.2 Prior and Concomitant Medications

Medications received prior to or concomitantly with treatment will be coded by PPD using the WHODrug Dictionary [Version MAR16B2E].

Prior medications and concomitant medications are defined as follows:

Prior medications are those taken with a start and stop date prior to the first day of study treatment.

Concomitant medications are those with a start date on or after the first dose date of treatment, or those with a start date before the first dose date of treatment and a stop date on or after the first dose date of treatment or ongoing at the end of the study period.

If there are missing/partial medication start/end dates, The following rule will be used to determine whether the medication is a concomitant medication:

- If month/year of the start date is after the month/year of Day 1, the medication will be considered as concomitant medication;
- If month/year of the start date is equal or before the month/year of Day 1, and the end date is present, the end date will be used to determine whether the medication is prior or concomitant. If the end date is on or after Study Day 1, the medication will be considered as concomitant medication. Otherwise, if the medication stopped before Study Day 1, then the medication is a prior medication.

If month/year of the start date is equal to the month/year of Day 1, and the end date is a partial date, the medication will be considered as concomitant medication.

If a medication cannot be classified as "prior" or "concomitant" after applying imputation rules for missing/incomplete dates, it will be classified as concomitant.

Prior medications and concomitant medications will be listed together and summarized separately by treatment for the ITT and Safety Populations.

The number and percentage of subjects using each medication will be displayed together with the number and percentage of subjects using at least one medication within each therapeutic class (ATC-Level 2) and generic term.

7.5 Measurements of Treatment Compliance

Based on the protocol, patient compliance should be 80-120%, based on the number of days treated. The percentage of compliant subjects will be presented for the ITT and Safety Populations.

7.5.1 Compliance via Diary

The patients enrolled will be asked to keep a diary to record their drug compliance on a daily basis. Data will be summarized by treatment group using descriptive statistics. Boxplots will be produced for treatment arm and methods of compliance calculations.

7.5.1.1 Compliance via Tablet

Compliance in percentage based on number of days treated with tablets will be calculated as follows:

$$\frac{\text{Number of tablets actually taken based on the diary}}{\text{Number of tablets expected to be taken}} \times 100\%$$

Where number of tablets expected to be taken is calculated as:

(date of treatment discontinuation/date of treatment completion – date of first dose + 1) × 1

7.5.1.2 Compliance via Spray

Compliance in percentage based on number of days treated on spreads will be calculated as follows:

$$\frac{\text{Actual number of spray shots based on the diary}}{\text{Total number of spray shots expected}} \times 100\%$$

Where number of spray expected shots is calculated as:

(date of treatment discontinuation/date of treatment completion – date of first dose + 1) × Number of spray shots recommended per day

Summary statistics on the compliance via spray will be based on the number of spray instructed at the randomization visit.

7.5.2 Compliance via Return of Plastic Bottles/Capsules

7.5.2.1 Compliance via Tablets Returned

Compliance in percentage is based on the number of tablets dispensed and the number of tablets returned. On the eCRF compliance will be calculated as follows:

$$\frac{\text{Number of tablets taken based on the eCRF}}{\text{Number of tablets expected to be taken}} \times 100\%$$

Where number of tablets taken based on eCRF is calculated as:

Sum of (number dispensed – number returned)

Where number of tablets expected taken is calculated as:

(date of discontinuation/date of treatment completion – date of first dose + 1) × 1

7.5.2.2 Compliance via Bottles Returned

Compliance in percentage based on weight of bottles dispensed and returned recorded from vendor data will be calculated as follows:

$$\frac{\text{Net weight of solution used}}{\text{Expected weight solution used}} \times 100\%$$

Where expected weight of solution used is calculated as:

(date of discontinuation/date of treatment completion – date of first dose + 1) × Number of spray shots recommended per day × 0.05 ml × 0.91 g/cm^3

Summary statistics on the compliance via bottle returned will be based on the number of spray instructed at the randomization visit.

Note: Missing returned bottle(s) is considered as not used and cannot be included in the net weight of solution used for compliance calculation.
Unused kits will have net weight of solution used as 0.
The percentage of compliance will then be summarized in the following categories:

- <80%
- ≥80% and ≤120%
- >120%

7.6 Efficacy

All primary, secondary efficacy analyses as well as sensitivity analysis will be summarized and analyzed for the ITT and PPP.

7.6.1 Primary Efficacy Analysis

The primary efficacy variable, i.e. the change in the hair count from baseline, will be summarized by visit and by treatment group using descriptive statistics. The primary efficacy variable will then be analyzed using the SAS PROC MIXED procedure.

The null hypothesis is that there is no difference between P-3074 and placebo in the mean change from baseline for the hair count at Visit 6 (Week 24).

The alternative hypothesis will be that there is a difference between P-3074 and placebo in the mean change from baseline for the hair count at Visit 6 (Week 24).

The primary efficacy data will be fitted by a mixed linear model for repeated measures with treatment (P-3074 or placebo), center, visit and the treatment-by-visit interaction as fixed effects and baseline hair count as a covariate. The variance-covariance matrix of unstructured form will be used in order to model the correlation between the two repeated measurements (over the post-baseline visits). In the case of a convergence problem with the unstructured covariance matrix, the following structures with robust sandwich estimator for the standard error of the fixed effect estimates will be assessed in a sequential fashion: heterogeneous Toeplitz, heterogeneous first-order autoregressive, Toeplitz, and compound symmetry. Maximum likelihood estimates of the treatment mean difference will be computed at Visit 6 (Week 24) together with the associated two-sided 95% confidence interval (CI) that will be calculated by using the Newton-Raphson algorithm implemented in the SAS® Mixed Procedure. A two-sided test with a p-value less than or equal to 0.05 will be considered statistically significant. The interaction between treatment and center will be assessed. A two-sided p-value less than or equal to 0.10 will be considered statistically significant for the test of interaction between treatment and center. If a statistically significant interaction is observed, efforts will be made to determine whether and how the interaction may affect the treatment comparisons.

The pooling centers strategy to be used for the above mentioned models will be the following: Those centers with less than 10 patients that wererandomized within the same country will be grouped as one big site for analysis to ensure the convergence of the. If the combined group is still less than 10 patients, it will then be grouped to the site with minimum number of patients randomized within the same country. In

case that the model does not converge and after replacing the variance-covariance matrix as described in the paragraph above, sites with less than 15 patients will be gathered following the same strategy described. If the model failed to converge, the center effect will be replaced by the country effect (in case of not converging, any country with less than 15 patients, that country would be gathered with the niebougrhood country).

Same approach will be applied to all secondary efficacy analysis and sensitivity analysis.

Below is an SAS syntax example for primary analysis and secondary analyses.

```
proc mixed;
   class trt usubjid visit center;
   model chg = trt base visit center visit*trt;
   repeated visit/ type = un subject = usubjid ;
   lsmeans visit*trt/diff e cl;
quit;
```

Note: `chg` is change from baseline

The main analysis will be based on observed cases using the above mixed model only on ITT population. Supportive analysis will be based on observed cases only on PPP population. Detail of sensitivity analyses are described in section 7.6.3.

7.6.2 Secondary Efficacy Analysis

- **Total hair count after 12 weeks of treatment:**
  Data will be summarized by visit by treatment group using descriptive statistics. The maximum likelihood estimate of the treatment mean difference at Visit 5 (Week 12) together with the associated two-sided 95% CI and p-value will be obtained through the mixed linear model employed for the primary endpoint analysis (see above).
  Data will also be displayed graphically. Both the unadjusted and adjusted mean change from baseline over time by treatment will be presented.
- **Hair width after 12 and 24 weeks of treatment:**
  Data will be summarized by visit by treatment group using descriptive statistics. Adjusted and Unadjusted mean hair width over time will also be plotted. Data will be fitted by a mixed linear model for repeated measures with treatment group, center, visit and treatment-by-visit interaction as fixed effects, baseline hair width as covariate, and with an unstructured variance-covariance matrix to take into account correlations among repeated measures within patient. Results will be reported as maximum likelihood estimates of the treatment difference at Weeks 12 and 24 together with associated two-tailed 95% CI. A two-sided test with a p-value less than or equal to 0.05 will be considered statistically significant.
- **Self-administered MHGQ as assessed by the patient at Weeks 12 and 24:**
  No summary score is calculated. Each question is scored and analyzed individually. Data will be summarized by visit by treatment group using descriptive statistics for each question. Each question will be fitted by a mixed linear model for repeated measures with treatment group, center,

visit and treatment-by-visit interaction as fixed effects, and with an unstructured variance-covariance matrix to take into account correlations among repeated measures within patients. Results will be reported as maximum likelihood estimates of the treatment difference at Weeks 12 and 24 together with associated two-tailed 95% CI. A two-sided test with a p-value less than or equal to 0.05 will be considered statistically significant

- **Blind assessor assessment of patient hair growth/loss change from baseline:**
  Data will be fitted by a mixed linear model for repeated measures with treatment group, center, visit and treatment-by-visit interaction as fixed effects and with an unstructured variance-covariance matrix to take into account correlations among repeated measures within patients. Results will be reported as maximum likelihood estimates of the treatment difference at Weeks 12 and 24 together with associated two-tailed 95% CI. A two-sided test with a p-value less than or equal to 0.05 will be considered statistically significant.
- **Change from baseline in Investigator Assessment at 12 and 24 weeks:**
  Data will be summarized by visit by treatment group using descriptive statistics, and both adjusted unadjusted mean score over time will be plotted. Data will be fitted by a mixed linear model for repeated measures with treatment group, center, visit and treatment-by-visit interaction as fixed effects and with an unstructured variance-covariance matrix to take into account correlations among repeated measures within patients. Results will be reported as maximum likelihood estimates of the treatment difference at Weeks 12 and 24 together with associated two-tailed 95% CI. A two-sided test with a p-value less than or equal to 0.05 will be considered statistically significant.

7.6.3 Sensitivity Analysis

Sensitivity analyses will be based on the ITT and PPP and performed on the change in the hair count in 3 different approaches on missing data imputation as described in Section 6.2.

For each of the three sensitivity analyses (LOCF, BCA and WCA), the change in the hair count from baseline to Visit 5 (Week 12) will be fitted by a linear model with treatment arm (P-3074 or placebo), center and baseline value as covariates (analysis of covariance).

7.6.4 Subgroup Analysis

No Subgroup analysis will be performed for this study.

CCI [redacted]

[redacted]

CCI [redacted]

CCI [redacted]

[redacted]

7.7 The SAS syntax example can is shown in 7.6.5.Safety

7.7.1 Extent of Exposure

Duration of overall exposure will be defined in days as for both tablets and spray use:

(date of last dose/spray shot whichever comes later – date of first dose/spray shot whichever comes earlier) + 1 – off-drug (where both form of drugs were not used) days

If the date of first dose date is missing, then date of first dose dispensed will be used. If last dose date is missing, then last known date of study treatment taken/shot will be used.

Duration of overall exposure will be listed and summarized using descriptive statistics for each treatment group for the ITT and Safety Populations.

Duration of tablet exposure will be defined in days as:

(date of last dose – date of first dose) + 1 – off-drug (tablets were not used) days

Duration of spray exposure will be defined in days as:

(date of last spray – date of first spray) + 1 – off-drug (spray were not used) days

7.7.2 Adverse Events

All AEs recorded on the eCRF will be coded using the MedDRA dictionary [Version 19.0] and classified as either pre-treatment AEs (PTAEs) or treatment – emergent AEs (TEAEs) as follows:

- PTAEs: all AEs occurring before the first dose of the investigational medicinal product (IMP)
- TEAEs: all AEs occurring or worsening on or after the first dose of the IMP

In case of missing/partial AE start/end dates. The following decision rule will be performed:

- If month/year of the onset date is after the month/year of Day 1, the AE will be considered as a TEAE.
- If month/year of the onset date is equal to the month/year of Day 1, and the end date is present, the end date will be used to determine when the AE resolved. If the end date is on or after Study Day 1, the AE will be considered as TEAE; otherwise, if the AE stopped before Study Day 1, then it will be categorized as PTAE.
- If the month/year of the onset date is equal to the month/year of Day 1, and the end date is a partial date, the AE will be considered as TEAE.

If after implementing the above conventions, the onset date of the AE cannot be placed before, on, or after Day 1, then the event will be considered as TEAE.

All AE data will be listed by treatment group where treatment-emergence status will be flagged in the listing. Corresponding listings of serious TEAEs (SAEs), TEAEs leading to discontinuation of treatment and TEAEs resulting in death will be produced.

No summary table will be provided for PTAEs.

Summary tables of TEAEs by treatment group and overall will be produced for the Safety Population.

The intensity of all AEs is recorded as mild, moderate, or severe. If intensity is missing for a TEAE, it will be considered severe in the summary tables.

The relationship between an AE and treatment is assessed as related, possibly related, unlikely to be related, or not related. A treatment-related AE is an AE considered by the investigator as related or possibly related to treatment or with unknown/missing relationship to treatment.

An overview table will summarize the number and percentage of subjects with at least one of the following TEAEs, where subjects with more than one TEAE in a particular category are counted only once in that category:

- any TEAE;
- any TEAE by intensity (mild, moderate, severe);
- any TEAE leading to discontinuation from the study;
- Treatment-related TEAEs;
- Treatment-related TEAEs leading to discontinuation from the study;
- Treatment-emergent SAEs (TESAE);
- Treatment-related TESAEs;
- TESAEs leading to death;

- Treatment-related TESAEs leading to death;
- TESAEs leading to discontinuation from the study;
- Treatment-related TESAEs leading to discontinuation from the study;

The number and percentage of subjects reporting each AE and the frequency and percentage of each reported AE will be summarized by SOC and PT for the Safety Population. Tables will be sorted alphabetically by SOC. PTs will be sorted by descending overall total. The following summaries will be produced:

- TEAEs, by SOC and PT;
- TEAEs related to treatment, by SOC and PT;
- TEAEs by relationship to treatment, by SOC and PT;
- TEAEs by maximum intensity, by SOC and PT;
- TEAEs related to treatment by maximum intensity, by SOC and PT;
- TEAEs causing discontinuation from the study, by SOC and PT;
- TEAEs related to treatment causing discontinuation from the study, by SOC and PT;
- TESAEs, by SOC and PT;
- TESAEs related to treatment, by SOC and PT;
- TEAEs leading to death, by SOC and PT.

In the above summaries, subjects with more than one AE within a particular SOC are counted only once for that SOC. Similarly, subjects with more than one AE within a particular PT are counted only once for that PT. For summaries by maximum intensity, subjects with multiple AEs within a particular SOC or PT will be counted under the category of their most severe AE within that SOC or PT. AEs with missing intensity will be included (as severe) with AEs within a particular SOC or PT.

No statistical comparisons of AEs between treatment groups will be performed.

7.7.3 Skin Irritation

The number and percentage of subjects reporting severity score for skin irritation will be listed displayed by treatment at Week 4, Week 8, Week 12, Week 24, Week 28 and early termination visit for the Safety Population in a summary table.

Event incidence rate will also be reported by treatment group during the treatment period as well as during the study period. Anything other than “No evidence of irritation” under Dermal Response will be considered as an Dermal Responsed Skin Irritation event. Anything other than “No other eveffects” under Other Effects will be considered as an Other Effects of Skin Irritation event.

Treatment period is considered as the duration between the first date and the last date of the study treatment. Events observed during the study treatment period will be summarized as the event incidence rate during the study treatment period.

Study period is considered as the duration between the first date of the study treatment and patient's last date of contact. Events observed during the study period will be summarized as the event incidence rate during the study period.

A person may have more than 1 skin irritation events and number of events will be used to calculate the event incidence rate. A person may have more than one skin irritation events where number of events are used to calculate the event incidence rate.

Event incidence rate is calculated as the number of events interest devided by total personal time in years.

7.7.4 Laboratory Evaluations

Data for the hematology, blood chemistry, and urinalysis analyses listed below received from central laboratory will be listed and summarized in shift table by treatment group. If data for any additional analyses are also received then these will be listed only.

Hematology	Serum Chemistry	Urinalysis
Hematocrit Hemoglobin White Blood Cell Count with Differential (Eosinophils Basophils Lymphocytes Neutrophils Monocytes) Erythrocytes Thrombocytes Mean Corpuscular Volume (MCV) Mean Corpuscular hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration(MCHC)	Alanine aminotranferase (ALT) Aspartate aminotranferase (AST) Total Bilirubin Total Cholesterol Triglycerides Gamma-Glutamyltransferase (GGT) Alkaline phosphatase Albumin Total protein Glucose Creatinine Globulin Calcium Potassium Chloride Testosterone Sodium Inorganic Phosphorus Uric acid Urea	**Macroscopic analysis:** pH specific weight appearance colour nitrites proteins glucose urobilinogen bilirubin ketones haematic pigments leukocytes **Microscopic analysis**: leukocytes Erythrocytes flat cells round cells crystals cylinders mucus bacteria

All laboratory data will be reported in SI units. Out-of-reference-range values will be flagged as high (H) or low (L) in the listings.

Shift tables (i.e., cross-tabulations of below the lower limit of the normal range, within the limits of the normal range and above the upper limit of the normal range at baseline versus scheduled visits) will be presented where the reference ranges are available by treatment group for the Safety Population for each laboratory test including urinalysis test parameters that are reported qualitatively (e.g. glucose, proteins and urobilinogen). In addition, shift tables on urinalysis test parameters that are reported qualitatively will be presented by treatment group for the ITT Population.

For each laboratory analyte, the baseline value will be defined as the last scheduled or unscheduled value collected prior to the first dose of treatment. Assessments carried out on the day of first treatment administration are considered to have taken place before the treatment administration, if the corresponding times have not been recorded. For post-baseline, only data from scheduled visits and final visit will be included in the shift tables.

7.7.5 Vital Signs

The following vital signs will be listed and summarized by treatment group and visit:

- systolic and diastolic blood pressure (mmHg);
- heart rate (bpm);
- weight (kg);
- body temperature (°C).

Vital signs data will be listed and changes from baseline in vital signs will be summarized by visit and final visit using standard descriptive statistics for the ITT and Safety Populations. Body temperature will be recorded in both Celsius and Fahrenheit on the eCRF. For the reporting purpose, body temperature will be reported in Celsius. The baseline value will be defined as the last scheduled or unscheduled value collected prior to the first dose of treatment. Assessments carried out on day of first treatment administration are considered to have taken place before the treatment administration, if the corresponding times have not been recorded. For post-baseline, only data from scheduled visits will be included in the summary tables.

7.7.6 Physical Examination

The number and percentage of patients with physical examination abnormalities will be listed and presented by treatment at screening, Week 24, Week 28 and early termination visits for the ITT and Safety Populations in summary tables.

7.7.7 Self-administered Sexual Dysfunction Questionnaire (IIEF-2)

A score of 0-5 is awarded to each of the 15 questions that examine the 4 main domains of male sexual function: erectile function, orgasmic function, sexual desire and intercourse satisfaction. The table below shows the association between each domain and its corresponding questions.

Function Domain	Associate Questions	Max Score
Erectile Function	1, 2, 3, 4, 5, 15	30
Orgasmic Function	9, 10	10
Sexual Desire	11, 12	10
Intercourse Satisfaction	6, 7, 8	15
Overall Satisfaction	13, 14	10

Data will be listed and summarized for the ITT for each domain by treatment at each visit.

Each domain will be analysed through a mixed linear model for repeated measures with treatment group, center and visit and treatment-by-visit interaction as fixed effects, and with an unstructured variance-covariance matrix.

7.8 Interim Analysis

No interim analysis is planned.

8 CHANGES IN PLANNED ANALYSES

Not applicable

9 REFERENCES

1 CPMP. Points to Consider on Missing Data. EMEA: London, 2001. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003641.pdf

10 APPENDICES

Appendix I - Schedule of Events

	Screening	Treatment Phase					Follow up Phase (End of Study)	Early Termination Visit
Visit	**Visit 1**	**Random Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	
	-Week 2	**Day 1± 5d**	**Week 4±3d**	**Week 8±3d**	**Week 12±3d**	**Week 24±3d**	**Week 28±3d**	
Patient's Informed Consent Form signature	X							
Demographic and habits information	X							
Physical examination§	X					X	X	X
Medical history/current diseases	X							
Prior and concomitant medication	X							
Vital signs	X					X	X	X
Check all Inclusion/exclusion criteria	X	X						
Enrolment	X							
Dispense patient's card	X							
Global Photograph	X				X	X		X
Investigator assessment	X*				X	X		X
Blind Assessor (entry eligibility)	X							
Blind Assessor (efficacy)	X*				X	X		X
Safety Laboratory examinations	X			X		X		X
Check record		X	X	X	X	X	X	X

concomitant medication								
CCI [redacted] CCI								
Macrophotography (hair count)		X			X	X		X
MHGQ Questionnaire					X	X		X
Sexual Dysfunction Questionnaire (IIEF-2)			X	X	X	X	X	X
Randomization		X						
Dispense study medication		X			X			
Collect / return study medication			X#	X#	X	X		X
Drug Application at site			X	X	X	X		
Drug Compliance					X	X		X
Dispense study diary to the patient		X						
Check of patient's study diary			X	X	X	X	X	X
Collect / return study diary							X	X
Severity score for skin irritation			X	X	X	X	X	X
Record AEs		X	X	X	X	X	X	X

* Assessment of hair growth will be performed by investigator and blinded assessor at visits 5 and 6/EOT using global photographs as baseline

CCI [redacted]

§ Height will be measured only at screening

Appendix II - Table, Figure and Listing Shells

The table, figure and listing shells and corresponding Table of Contents will be created in separate file but can be appended here for the paper copy of the SAP.

TABLES, FIGURES, AND LISTINGS SHELLS

A Multicenter, Randomized, Double-blind, Parallel-Group, Controlled Study, to Assess The Efficacy and Safety of P-3074 Cutaneous Spray, Solution, In The Treatment of Male Pattern Baldness

TFL Status: Final 1.0
TFL Date: 2018-01-22T13:53:00

Study Drug: P-3074

Sponsor Reference:
PPD

1. INTRODUCTION

The table, figure, and listing (TFL) shells presented in this document are mock-ups and may be subject to minor format modifications once the actual data are used. The data represented in this document are used for example purposes only and do not reflect the actual study data captured. The overall contents in any individual TFL shell will not change, although additional tables may be added if necessary, thus changing the table number scheme. Significant changes will be approved by the responsible PPD Clinical Pharmacology project team member and communicated to the Sponsor.

1.1 General Programming Specifications

All TFLs will follow the following rules:

Papersize will be A4, with the following margins in Inches:

Landscape			
top	1	left	1
bottom	1	right	1

Every TFL will have a footnote containing program location, name, run date and run time (optional).
Every TFL will have a header containing client name, protocol number and the status of the output.
Dry run – Draft – Final Draft – Final (others as needed)

Dates will be presented in the format DDMMMYYYY
The presentation order of the statistics will be:
n, Mean, SD, median, minimum, maximum. The abbreviations Med, Min, Max may be used, if necessary.
Rules for significant digits in safety data tables are as follows: if the raw value has x decimal places, then the mean, the median and the Q1 and Q3 will have x+1 decimal places, the standard deviation will have x+2 decimal places. A maximum if 5 decimal places will be displayed if it is a derived value or the raw value has more than 5 decimal places.

N will be presented as whole numbers.

Percentages will always be displayed with 1 decimal place.

All TFLs will be delivered in .pdf format.

1.2 Derived Parameters

Individual derived parameters (e.g. CCI [redacted] parameters) and appropriate summary statistics will be reported to three significant figures.

1.3 Tables Summarizing Categorical Data

Tables that summarize categorical data will be created per these specifications:

1. If the number of events is zero, data will be presented as “No event”.
2. All categories of a parameter will be included and displayed. If the categories of a parameter are ordered, all categories between the maximum possible category and the minimum category will be included, even if n=0 for a given category. If the categories are not ordered, all categories will be included even if n=0 for a given category.
3. A “missing” category will be included for any parameter for which information is missing. This will ensure that the population size totals are consistent across different parameters.

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CCI [redacted]

Overall Preface
Tables, Figures and Listings

@	Patient Excluded from Safety Population
$	Patient Excluded from Intent-to-Treat Population (ITT)
&	Patient Excluded from Per-Protocol Population
(R)	Repeat Visit
(W)	Patient Withdrew
(M)	Patient Misrandomized
NA	Not Applicable
NC	Not Calculated
ND	Not Done
NK	Not Known
NR	Not Recorded

Program Name: Date Generated: Page x of y

Table 14.1.1
Summary of Disposition of Patients Overall

	P-3074 + P	Vehicle + P	Vehicle + FNS	Overall Total
Patients with Informed Consent				xxx
Patients Screened				xxx
Patients Randomized	xxx	xxx	xxx	xxx
Safety Population	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
ITT Population	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Per Protocol Population	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
CCI [redacted]	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Completed Study	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Primary Reason for Early Discontinuation:				
Adverse Event	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Death	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Lack of Efficacy	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Lost to Follow-Up	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Non-Compliance with Study Drug	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Physician Decision	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Protocol Deviation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Study Terminated by Sponsor	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Site Terminated by Sponsor	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Technical Problems	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Withdrawal by Patient	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

The denominator for percentages is the number of patients in the All Randomized Population for each treatment group.
Programming Notes:
Obtain reasons for early discontinuation from CRF. Counts for screened patients will only be presented in the total column.
Program Name: Date Generated: Page x of y

Table 14.1.2
Disposition of Patients by Country and Trial Site
Randomized Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
German				
Site 1 name	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Site 2 name	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Site 3 name	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
…	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Total	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Grouped sites: xxx, yyy, zzz	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Hungary				
Site 1 name	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Site 2 name	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Site 3 name	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
…	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Total	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note: Sites with less than 8 patients who are randomized within the same country will be grouped as one big site for analysis to ensure model converging. If the combined group is still less than 8 patients, it will then be grouped to the site with minimum number of patients randomized in the neighboring country.

Programming Notes:

Only include "Grouped site" if number of patient in each individual site is less than 8 and grouping is required for modelling.

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Table 14.1.3
Summary of Protocol Violations
Randomized Population

Protocol Violation	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Patients with at Least 1 Major Protocol Violation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Major Protocol Violation 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
etc				

The violations and deviations were identified prior to data unblinding.
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Table 14.1.4.1
Summary of Demography
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Age (Years) [a]				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
Height (cm)				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
Weight (kg)				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx

Note: Denominators for percentages are based on the number of patients with non-missing data in each treatment group for the relevant variable.
[a] Age is calculated as calendar years from birth to informed consent
[b] Body Mass Index
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Table 14.1.4.1
Summary of Demography
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
BMI (kg/m2) [b]				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
Race, n (%)				
n	xxx	xxx	xxx	xxx
Asian	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Black/African American	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Caucasian/White	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Native Hawaiian/Pacific Islander	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
American Indian/Alaska Native	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Ethnicity, n (%)				
n	xxx	xxx	xxx	xxx
Hispanic or Latino	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not Hispanic or Latino	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not Provided or Unknown	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note: Denominators for percentages are based on the number of patients with non-missing data in each treatment group for the relevant variable.
[a] Age is calculated as calendar years from birth to informed consent
[b] Body Mass Index
Program Name: Date Generated: Page x of y

Table 14.1.4.1
Summary of Demography
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Current Alcohol Use, n(%)				
n	xxx	xxx	xxx	xxx
None	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Less Than or Equal to 2 Drinks Per Day	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
More Than 2 Drinks Per Day	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Current Smoke/Tobacco Use, n (%)				
n	xxx	xxx	xxx	xxx
Never Smoked/Never Used Tobacco Products	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Currently Smokes/Uses Tobacco Products	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Formally Smoked/Used Tobacco Product	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Smoke >=10 Cigarettes/Day, n (%)				
n	xxx	xxx	xxx	xxx
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Drink > 5 Cup Coffee/Tea/Day, n (%)				
n	xxx	xxx	xxx	xxx
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note: Denominators for percentages are based on the number of patients with non-missing data in each treatment group for the relevant variable.
[a] Age is calculated as calendar years from birth to informed consent
[b] Body Mass Index
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.1.4.2 Summary of Demography Safety Population

Table 14.1.5.1
Summary of Medical History
ITT Population

	P-3074 + P (N = xxx) n (%)/e (%)	Vehicle + P (N = xxx) n (%)/e (%)	Vehicle + FNS (N = xxx) n (%)/e (%)	Overall Total (N = xxx) n (%)/e (%)
Vertex Pattern Hair Loss According to Norwood/Hamilton Scale				
Type III Vertex	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Type IV	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Type V	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Other	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Patients with Any Current Medical History?				
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Medical History				
System Organ Class 1	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 1	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 2	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 3	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 4	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
System Organ Class 1	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
:	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
:	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)

n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)
Note: This table contains counts of patients. If a patient had more than one medical history within a preferred term, the patient is counted only once within a preferred term. If a patient had more than one medical history within a system organ class, the patient is counted once for each preferred term and once for the system organ class.
Note: MedDRA Version MAR16B2E used for coding.

Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.1.5.2 Summary of Medical History Safety Population

Table 14.1.6.1
Summary of Prior Medications
ITT Population

WHO ATC Level 2 (Therapeutic Class) Generic Term ([a])	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Patients with Any Prior Medication?	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
ATC Level 2 Term 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 2	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 3	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 4	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
ATC Level 2 Term 2	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 2	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 3	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 4	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

The denominator for percentages is the number of patients in the ITT Population for each treatment group.
Note: Prior medications are defined as medications taken with a start and stop date prior to the first day of study treatment.
Note: A patient may have taken more than one medication. Therefore, the sum of medication counts and percentages may not equal the total counts.
If a patient had more than one medication in a category, the patient is counted once in that category.
[a] WHO Drug Dictionary (Version MAR16B2E) was used for coding.

Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.1.6.2 Summary of Prior Medications Safety Population
Add:
Footnote: The denominator for percentages is the number of patients in the Safety Population for each treatment group.

Delete:
Footnote: The denominator for percentages is the number of patients in the ITT Population for each treatment group.

Table 14.1.7.1
Summary of Concomitant Medications
ITT Population

WHO ATC Level 2 (Therapeutic Class) Generic Term ([a])	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Patients with Any Concomitant Medication?	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
ATC Level 2 Term 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 2	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 3	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 4	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
ATC Level 2 Term 2	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 1	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 2	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 3	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Generic Medication 4	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

The denominator for percentages is the number of patients in the ITT Population for each treatment group.
Note: Concomitant medications are defined as medications taken with a start date on or after the first dose date of treatment, or those with a start date before the first dose date of treatment and a stop date on or after the first dose date of treatment or ongoing at the end of the study period.
Note: A patient may have taken more than one medication. Therefore, the sum of medication counts and percentages may not equal the total counts. If a patient had more than one medication in a category, the patient is counted once in that category.
[a] WHO Drug Dictionary (Version MAR16B2E) was used for coding.

Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.1.7.2 Summary of Concomitant Medications Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients in the Safety Population for each treatment group.

  Delete:
    Footnote: The denominator for percentages is the number of patients in the ITT Population for each treatment group.

Table 14.1.8.1
Summary of Treatment Compliance
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Compliance Via Diary(%)				
Tablets Count				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
<80%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
80% to 120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
>120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Actual spray count for those prescribed with 1 Spray				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
<repeat for 2 sprays, 3 sprays and 4 sprays>				

The denominator for percentages is the number of patients with non-missing data in the ITT Population for each treatment group.
Compliant is defined as percentage compliance between 80.0% and 120.0%, inclusive.
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Table 14.1.8.1
Summary of Treatment Compliance
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Spray Compliance				
Compliance among with those with 1 Spray prescribed				
<80%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
80% to 120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
>120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<repeat for 2 sprays, 3 sprays and 4 sprays>				
Compliance among with those with 1-4 Spray prescribed				
<80%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
80% to 120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
>120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

The denominator for percentages is the number of patients with non-missing data in the ITT Population for each treatment group.
Compliant is defined as percentage compliance between 80.0% and 120.0%, inclusive.
Program Name: Date Generated: Page x of y

Table 14.1.8.1
Summary of Treatment Compliance
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Compliance Via Drug Accountability(%)				
Tablets Count				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
<80%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
80% to 120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
>120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Bottle Weight-1 Spray				
n	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x	xx.xx
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x	xx.xx
Max	xx.x	xx.x	xx.x	xx.xx
<Repeat for Bottle Weight-2 Spray, 3 sprays and 4 sprays>				

The denominator for percentages is the number of patients with non-missing data in the ITT Population for each treatment group.
Compliant is defined as percentage compliance between 80.0% and 120.0%, inclusive.
Program Name: Date Generated: Page x of y

Table 14.1.8.1
Summary of Treatment Compliance
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Compliance Bottle Weight-1 Spray				
<80%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
80% to 120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
>120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<Repeat for Bottle Weight-2 Spray, 3 sprays and 4 sprays>				
Compliance Bottle Weight-1-4 Spray				
<80%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
80% to 120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
>120%	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

The denominator for percentages is the number of patients with non-missing data in the ITT Population for each treatment group.
Compliant is defined as percentage compliance between 80.0% and 120.0%, inclusive.
Program Name: Date Generated: Page x of y

Repeat for the following displays:
Table 14.1.8.2 Summary of Treatment Compliance Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients with non-missing data in the Safety Population for each treatment group.
  Delete:
    Footnote: The denominator for percentages is the number of patients with non-missing data in the ITT Population for each treatment group.

Table 14.1.9.1
Summary of Treatment Exposure
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Duration (days)			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Duration of tablets exposure(days)			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Duration of spray exposure(days)			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x

Duration of overall exposure is calculated as (date of last dose/spray shot whichever comes later – date of first dose/spray shot whichever comes earlier) + 1 – off-drug (where both form of drugs were not used) days.
Duration of table exposure is calculated as (date of last dose – date of first dose) + 1 – off-drug (tablets were not used) days.
Duration of spray exposure is calculated as (date of last spray – date of first spray) + 1 – off-drug (spray were not used) days.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.1.9.2 Summary of Treatment Exposure Safety Population
Add:
Footnote: The denominator for percentages is the number of patients with non missing data in the Safety Population for each treatment group.
Duration of overall exposure is calculated as (date of last dose/spray shot whichever comes later – date of first dose/spray shot whichever comes earlier) + 1 – off-drug (where both form of drugs were not used) days.
Delete:
Footnote: Duration of overall exposure is calculated as (date of last dose/spray shot whichever comes later – date of first dose/spray shot whichever comes earlier) + 1 – off-drug (where both form of drugs were not used) days.

Table 14.2.1.1
Summary of Total Hair Count by Visit
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Baseline			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
<Visit>			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Change from Baseline			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
[Repeat for all scheduled visits]			

Program Name: Date Generated: Page x of y

Repeat for the following displays:

Table 14.2.2.1 Summary of Total Hair Count by Visit PP Population

Table 14.2.3.1 Summary of Hair Width by Visit ITT Population

Table 14.2.4.1 Summary of Hair Width by Visit PP Population

Table 14.2.6.1 Summary of Patient Hair Growth/Loss Assessed by Blind Assessor by Visit ITT Population

Table 14.2.7.1 Summary of Patient Hair Growth/Loss Assessed by Blind Assessor by Visit PP Population

Table 14.2.1.2
Analysis of Change in Total Hair Count from Baseline after 12 and 24 Weeks of Treatment
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Number of patients	xxx	xxx	xxx
Baseline Unadjusted Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
12 Weeks Visit			
Unadjusted Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Unadjusted Mean Change from Baseline(SE)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Adjusted Mean Change from Baseline(SE)[a]	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Versus P-3074 + P			
LS Mean Difference (SE) [a]		x.xx (x.xxx)	
95% Confidence Interval [a]		(x.xx , x.xx)	
p-value [a]		x.xxx	

[a] The analysis uses a covariance pattern model adjusted for treatment group, center, visit and treatment-by-visit interaction as fixed effects and baseline hair count as a covariate with an unstructured covariance structure. Change from Baseline by Visit is the reported result.

Program Name: Date Generated: Page x of y

Table 14.2.1.2
Analysis of Change in Total Hair Count from Baseline after 12 and 24 Weeks of Treatment
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
24 Weeks Visit			
Unadjusted Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Unadjusted Mean Change from Baseline(SE)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Adjusted Mean Change from Baseline(SE)[a]	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Versus P-3074 + P			
LS Mean Difference (SE) [a]		x.xx (x.xxx)	
95% Confidence Interval [a]		(x.xx , x.xx)	
p-value [a]		x.xxx	

[a] The analysis uses a covariance pattern model adjusted for treatment group, center, visit and treatment-by-visit interaction as fixed effects and baseline hair count as a covariate with an unstructured covariance structure. Change from Baseline by Visit is the reported result.

Program Name: Date Generated: Page x of y

Repeat for the following displays:

Table 14.2.2.2 Analysis of Change in Total Hair Count from Baseline after 12 and 24 Weeks of Treatment PP Population

Table 14.2.3.2 Analysis of Change in Hair Width from Baseline after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.4.2 Analysis of Change in Hair Width from Baseline after 12 and 24 Weeks of Treatment PP Population

Table 14.2.5.2.1 Analysis of Self-administered (MHGQ) Score - Bald Spot Getting Smaller as assessed by the Patient after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.5.2.2 Analysis of Self-administered (MHGQ) Score - Appearance of Your Hair as assessed by the Patient after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.5.2.3 Analysis of Self-administered (MHGQ) Score - Growth of Hair as assessed by the Patient after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.5.2.4 Analysis of Self-administered (MHGQ) Score - Effectiveness in Slowing Down Hair Loss as assessed by the Patient after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.5.2.5 Analysis of Self-administered (MHGQ) Score - The Hair Line at the Front of Your Head as assessed by the Patient after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.5.2.6 Analysis of Self-administered (MHGQ) Score - The Hair on Top of Your Head as assessed by the Patient after 12 and 24 Weeks of Treatment ITT Population

Table 14.2.5.4.1 Analysis of Self-administered (MHGQ) Score - Bald Spot Getting Smaller as assessed by the Patient after 12 and 24 Weeks of Treatment PP Population

Table 14.2.5.4.2 Analysis of Self-administered (MHGQ) Score - Appearance of Your Hair as assessed by the Patient after 12 and 24 Weeks of Treatment PP Population

Table 14.2.5.4.3 Analysis of Self-administered (MHGQ) Score - Growth of Hair as assessed by the Patient after 12 and 24 Weeks of Treatment PP Population

Table 14.2.5.4.4 Analysis of Self-administered (MHGQ) Score - Effectiveness in Slowing Down Hair Loss as assessed by the Patient after 12 and 24 Weeks of Treatment PP Population

Table 14.2.5.4.5 Analysis of Self-administered (MHGQ) Score - The Hair Line at the Front of Your Head as assessed by the Patient after 12 and 24 Weeks of Treatment PP Population

Table 14.2.5.4.6 Analysis of Self-administered (MHGQ) Score - The Hair on Top of Your Head as assessed by the Patient after 12 and 24 Weeks of Treatment PP Population

Table 14.2.6.2 Analysis of Change in Patient Hair Growth/Loss Assessed by Blind Assessor ITT Population

Table 14.2.7.2 Analysis of Change in Patient Hair Growth/Loss Assessed by Blind Assessor PP Population

Table 14.2.8.2 Analysis of Change in Patient Hair Growth/Loss Assessed by Investigator ITT Population

Table 14.2.9.2 Analysis of Change in Patient Hair Growth/Loss Assessed by Investigator PP Population

Table 14.2.10.2.1 Analysis of Change in Self-administered (IIEF-2) Erectile Function Score ITT Population

Table 14.2.10.2.2 Analysis of Change in Self-administered (IIEF-2) Orgasmic Function Score ITT Population

Table 14.2.10.2.3 Analysis of Change in Self-administered (IIEF-2) Sexual Desire Score ITT Population

Table 14.2.10.2.4 Analysis of Change in Self-administered (IIEF-2) Intercourse Satisfaction Score ITT Population

Table 14.2.10.2.5 Analysis of Change in Self-administered (IIEF-2) Overall Satisfaction Score ITT Population

Table 14.2.10.4.1 Analysis of Change in Self-administered (IIEF-2) Erectile Function Score PP Population

Table 14.2.10.4.2 Analysis of Change in Self-administered (IIEF-2) Orgasmic Function Score PP Population

Table 14.2.10.4.3 Analysis of Change in Self-administered (IIEF-2) Sexual Desire Score PP Population

Table 14.2.10.4.4 Analysis of Change in Self-administered (IIEF-2) Intercourse Satisfaction Score PP Population

Table 14.2.10.4.5 Analysis of Change in Self-administered (IIEF-2) Overall Satisfaction Score PP Population

Table 14.2.5.1
Summary of Self-administered (MHGQ) Score by Visit
ITT Population

Bald Spot Getting Smaller as Assessed by the Patient	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
<Visit>			
Since the start of the study, I can see my bald spot getting smaller.			
Strongly agree (1)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Agree (2)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No Opinion either way (3)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Disagree (4)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Strongly disagree (5)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Score			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
[Repeat for all scheduled visits]			

Note: A higher score indicates a worse outcome.
Programming Notes:
Include Bald Spot Getting Smaller as Assessed by the Patient, Appearance of My Hair as Assessed by the Patient, Growth of Hair as Assessed by the Patient , Effectiveness in Slowing Down Hair Loss as Assessed by the Patient , The Hair Line at the Front of Your Head as Assessed by the Patient, The Hair on Top of Your Head as Assessed by the Patient, and Overall as Assessed by the Patient. Start with a new page with a new a new question from the questionnaire to be summarized.
Please note, each question has it own number of options to be choosen and wording to be displayed. Please cross check with the original questionnaire with correct wording and number selection options.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.2.5.3 Summary of Self-administered (MHGQ) Score by Visit PP Population
Delete:
Note to Programmer: Please note, each question has it own number of options to be choosen and wording to be displayed. Please cross check with the original questionnaire with correct wording and number selection options.

Table 14.2.8.1
Summary of Patient Hair Growth/Loss Assessed by Investigator by Visit
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
<Visit>			
Assessment of hair growth			
Greatly decreased (-3)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Moderately decreased (-2)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Slightly decreased (-1)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No change (0)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Slightly increased (1)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Moderately increased (2)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Greatly increased (3)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Score			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x

[Repeat for all scheduled visits]

Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.2.9.1 Summary of Patient Hair Growth/Loss Assessed by Investigator by Visit PP Population

Table 14.2.10.1
Summary of Self-administered (IIEF-2) Score by Visit
ITT Population

IIEF-2 Erectile Function Score	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Week 4			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Week 8			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x

[Repeat for all IIEF-2 scheduled visits]

Programming Notes:
Include IIEF-2 Erectile Function Score, IIEF-2 Orgasmic Function Score, IIEF-2 Sexual Desire Score, IIEF-2 Intercourse Satisfaction score, and IIEF-2 Overall Satisfaction Score. Start with a new page with a new function domain from the IIEF-2 questionnaire to be summarized.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.2.10.3 Summary of Self-administered (IIEF-2) Score by Visit PP Population
Add:
Note to Programmer: Include IIEF-2 Erectile Function Score, IIEF-2 Orgasmic Function Score, IIEF-2 Sexual Desire Score, IIEF-2 Intercourse Satiscation score, and IIEF-2 Overall Satisfaction Score. Start with a new page with a new function domain from the IIEF-2 questionnaire to be summarized.
Delete:
Note to Programmer: Include IIEF-2 Erectile Function Score, IIEF-2 Orgasmic Function Score, IIEF-2 Sexual Desire Score, IIEF-2 Intercourse Satisfaction score, and IIEF-2 Overall Satisfaction Score. Start with a new page with a new function domain from the IIEF-2 questionnaire to be summarized.

Table 14.2.11.1
Summary of Total Hair Count at Baseline to Week 12 (LOCF)
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Baseline			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Week 12			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Change from Baseline			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x

Program Name: Date Generated: Page x of y

Repeat for the following displays:

Table 14.2.12.1 Summary of Total Hair Count at Baseline to Week 12 (LOCF) PP Population

Table 14.2.13.1 Summary of Total Hair Count at Baseline to Week 12 (BCA) ITT Population

Table 14.2.14.1 Summary of Total Hair Count at Baseline to Week 12 (BCA) PP Population

Table 14.2.15.1 Summary of Total Hair Count at Baseline to Week 12 (WCA) ITT Population

Table 14.2.16.1 Summary of Total Hair Count at Baseline to Week 12 (WCA) PP Population

Table 14.2.11.2
Analysis of Change in Total Hair Count from Baseline after 12 Weeks of Treatment (LOCF)
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Number of patients	xxx	xxx	xxx
Baseline Unadjusted Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
12 Weeks Visit			
Unadjusted Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Unadjusted Mean Change from Baseline(SE)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Adjusted Mean Change from Baseline(SE)[a]	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Versus P-3074 + P			
LS Mean Difference (SE) [a]		x.xx (x.xxx)	
95% Confidence Interval [a]		(x.xx , x.xx)	
p-value [a]		x.xxx	

[a] The analysis uses an ANCOVA model adjusted for treatment group, center, as fixed effects and baseline hair count as a covariate. Change from Baseline by Visit is the reported result.

Program Name: Date Generated: Page x of y

Repeat for the following displays:

Table 14.2.12.2 Analysis of Change in Total Hair Count from Baseline after 12 Weeks of Treatment (LOCF) PP Population

Table 14.2.13.2 Analysis of Change in Total Hair Count from Baseline after 12 Weeks of Treatment (BCA) ITT Population

Table 14.2.14.2 Analysis of Change in Total Hair Count from Baseline after 12 Weeks of Treatment (BCA) PP Population

Table 14.2.15.2 Analysis of Change in Total Hair Count from Baseline after 12 Weeks of Treatment (WCA) ITT Population

Table 14.2.16.2 Analysis of Change in Total Hair Count from Baseline after 12 Weeks of Treatment (WCA) PP Population


CCI

CCI [redacted]


CCI


CCI

Table 14.3.1.1
Overall Frequency of Patients with Adverse Events
Safety Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Patients with any TEAE	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with Mild TEAEs	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with Moderate TEAEs	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with Severe TEAEs [a]	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any Study Drug Related TEAEs [a]	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any TEAE Leading to Discontinuation of Study	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any Study Drug Related TEAE Leading to Discontinuation of Study	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any Treatment Emergent Serious Adverse Events (TESAE)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any Study Drug Related TESAE [b]	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any TESAE Leading to Death	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any Study Drug Related TESAE Leading to Death	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any TESAE Leading to Discontinuation from Study	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Patients with any Study Drug Related TESAE Leading to Discontinuation from Study	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

The denominator for percentages is the number of patients in the Safety Population
[a] Cases with unknown intensity were assumed to be severe
[b] Included are AEs considered relataed or possibly related to study drug and AEs with unknown or missing relationship to study drug

Program Name: Date Generated: Page x of y

Table 14.3.1.2
Summary of Treatment Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	P-3074 + P (N = xxx) n (%)/e (%)	Vehicle + P (N = xxx) n (%)/e (%)	Vehicle + FNS (N = xxx) n (%)/e (%)	Overall Total (N = xxx) n (%)/e (%)
Patients with any TEAE	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
System Organ Class 1	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 1	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 2	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 3	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
.. etc.				
System Organ Class 2	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 1	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 2	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 3	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
.. etc.				

n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)
Note: This table contains counts of patients. If a patient experienced more than one episode of an adverse event, the patient is counted only once within a preferred term. If a patient experienced more than one adverse event within a system organ class, the patient is counted once for each preferred term and once for the system organ class.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.3.1.3 Summary of Treatment-Related Treatment Emergent Adverse Events by MedDRA System Organ Class and Preferred Term Safety Population

Table 14.3.1.7 Summary of Treatment Emergent Adverse Events Causing Discontinuation from Study by MedDRA System Organ Class and Preferred Term Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients in the Safety Population
  Delete:
    Footnote:
n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)

Table 14.3.1.8 Summary of Treatment-Related Treatment Emergent Adverse Events Causing Discontinuation from Study by MedDRA System Organ Class and Preferred Term Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients in the Safety Population
  Delete:
    Footnote:
n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)

Table 14.3.1.9 Summary of Treatment-Related Treatment Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients in the Safety Population
  Delete:
    Footnote:
n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)

Table 14.3.1.10 Summary of Adverse Events Leading to Death by MedDRA System Organ Class and Preferred Term Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients in the Safety Population
  Delete:
    Footnote:
n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)

Table 14.3.1.4
Summary of Treatment Emergent Adverse Events by Relationship to Study Treatment by MedDRA System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term Relationship to Study Drug	P-3074 + P (N = xxx) n (%)/e (%)	Vehicle + P (N = xxx) n (%)/e (%)	Vehicle + FNS (N = xxx) n (%)/e (%)	Overall Total (N = xxx) n (%)/e (%)
Patients with Any TEAE				
Overall	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not Related	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Unlikely Related	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Possibly Related	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Related	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
System Organ Class 1				
Overall	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Not Related	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Unlikely Related	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Possibly Related	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Related	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 1				
Overall	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Not Related	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
:	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 2				
Overall	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Not Related	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
:	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
etc	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)

n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)
Note: Patients with missing relationship to study drug are counted in the Overall category only.
Note: This table contains counts of patients. If a patient experienced more than one episode of an adverse event, the patient is counted only once within a preferred term and for the episode that is most related to study drug. If a patient experienced more than one adverse event within a system organ class, the patient is counted once for each preferred term and once for the system organ class.

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Table 14.3.1.5
Summary of Treatment Emergent Adverse Events by Maximum Intensity System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term Maximum Severity	P-3074 + P (N = xxx) n (%)/e (%)	Vehicle + P (N = xxx) n (%)/e (%)	Vehicle + FNS (N = xxx) n (%)/e (%)	Overall Total (N = xxx) n (%)/e (%)
Patients with Any Maximum Intensity TEAE				
Overall	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Mild	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Moderate	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
System Organ Class 1				
Overall	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Mild	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Moderate	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Severe	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 1				
Overall	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
:	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
Preferred Term 2				
Overall	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
:	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)
etc	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)	xxx(xx.x%)/xxx(xx.x%)

n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)
Note: Patients with missing maximum severity are considered as severe in this table.
Note: This table contains counts of patients. If a patient experienced more than one episode of an adverse event, the patient is counted only once within a preferred term and for the episode with the maximum severity. If a patient experienced more than one adverse event within a system organ class, the patient is counted once for each preferred term and once for the system organ class.

Program Name: Date Generated: Page x of y
Repeat for the following displays:

Table 14.3.1.6 Summary of Treatment-Related Treatment Emergent Adverse Events by Maximum Intensity, System Organ Class and Preferred Term Safety Population
  Add:
    Footnote: The denominator for percentages is the number of patients in the Safety Population
    Footnote: Note: Patients with missing maximum severity are counted in the Overall category only.

  Delete:
    Footnote:
n = number of patients in each category; The percentage is calculated as 100 x (n/N)
e = number of episodes in each category; the percentage is calculate as 100 x (e/Total number of episodes)
    Footnote: Note: Patients with missing maximum severity are considered as severe in this table.

Table 14.3.1.11
Summary of Severity Score for Skin Irritation
Safety Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
<Visit>			
Dermal Response			
No evidence of irritation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Minimal erythema, barely perceptible	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Definite erythema, readily visible; minimal oedema or minimal papular response	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Erythema and papules	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Definite oedema	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Erythema, oedema and papules	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Vescicular eruption	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Strong reaction spreading beyond test site	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other Effects			
No other effects	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Slightly glazed appearance	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Marked glazing	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Glazing with peeling and cracking	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Glazing with fissures	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Film of dried serour exudate covering all or part of the patch site	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Small petechial erosions or scabs	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

[Repeat for all scheduled visits]

The denominator for percentages is the number of patients with non-missing data in the Safety Population for each treatment group.
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Table 14.3.1.12
Incidence Rate of Severity Score for Skin Irritation
Safety Population

	P-3074 + P (N = xxx)			Vehicle + P (N = xxx)			Vehicle + FNS (N = xxx)		
Incidence Rate of Skin Irritation	N Events	Total Time (Years)	Incidenc Rate	N Events	Total Time (Years)	Incidence Rate	N Events	Total Time (Years)	Incidence Rate
Dermal Response									
Treatment Period	xxx	xxx	xxxx	xxx	xxx	xxxx	xxx	xxx	xxxx
Overall Study Period	xxx	xxx	xxxx	xxx	xxx	xxxx	xxx	xxx	xxxx
Other Effects									
Treatment Period	xxx	xxx	xxxx	xxx	xxx	xxxx	xxx	xxx	xxxx
Overall Study Period	xxx	xxx	xxxx	xxx	xxx	xxxx	xxx	xxx	xxxx

Event incidence rate is calculated as the number of events interest devided by total personal time in years.
Program Name: Date Generated: Page x of y

Table Listing 14.3.2
Serious Treatment Emergent Adverse Events
Safety Population

Treatment group: *Treatment 1*

Site	Patient/ Age	AE Line No./ System Organ Class/ Preferred Term/ Verbatim [a]	Start Date (day) Stop Date (day)[b] / Duration (days)	Intensity/ Frequency	Relationship to Study Drug/ Action Taken[c]	Outcome/ Discontinue?	Medically Important but not SAE	SAE Type [d]	Comments
xx	xxx/xx	1/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/	DDMMMYYYY (xx) DDMMMYYYY (xx) /xx	Mild/ Single Event	Not Related/ xxx	Resolved/ No	No	2	
		2/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/xx	Moderate/ Single Event	Unlikely/ xxx	Death/ Yes	No	3, 1	
xx	xxx/xx	1/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/	DDMMMYYYY (xx)/ Ongoing	Severe/ Single Event	Possibly/ xxx	Ongoing/ No	No	3	

[a] Coded using MedDRA Dictionary (Version 19.0)
[b] Relative to the day of first dose of study treatment group
[c] Action Taken: Inc=Dose increased; No Chg=Dose not changed; Red=Dose reduced; Int=Drug interrupted; Withd=Drug withdrawn; NA=Not applicable; Un=Unknown; Oth=Other.
[d] SAE Type: 1=Death; 2=Life Threatening; 3=Initl or Prolonged Hospitalization; 4=Persistent or Significant Disability or Incapacity; 5=Congenital Anomaly or Birth Defect.

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient, start date and SOC.

Program Name: Date Generated: Page x of y

Table 14.3.4.1
Shift Table of Hematology Test Results
Safety Population

Parameter (unit) Time point	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Hematocrit (unit)				
Week 8	xxx	xxx	xxx	xxx
Baseline Low to Low	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline Low to Normal	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline Low to High	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline Normal to Low	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline Normal to Normal	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline Normal to High	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline High to Low	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline High to Normal	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Baseline High to High	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<Repeat for Week 24>				
<Continue for Early Termination Visit>				

Note: This table only presents results for patients with non-missing data at baseline and the time point of interest.
Note: Low = below lower limit of normal range, Normal = within normal limits, High = above upper limit of normal range.
Programming Notes:
Include hemoglobin, Hematology, Eosinophils, Eosinophils(%), Basophils, Basophils(%), Lymphocytes, Lymphocytes(%), Neutrophils, Neutrophils(%), Monocytes, Monocytes(%), Erythrocytes, Thrombocytes, Mean Corpuscular Volume (MCV), Mean Corpuscular hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration(MCHC) in the same table. Start with a new page with an analyte to be summarized.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.3.4.2 Shift Table of Serum Chemistry Test Results Safety Population
Add:
Note to Programmer: Include Alanie aminotranferase (ALT), Aspartate aminotranferase (AST), Total Bilirubin, Total Cholesterol, Triglycerides, Gamma-Glutamyltransferase (GGT), Alkaline phosphatase, Albumin, Total protein, Glucose, Creatinine, Globulin, Calcium, Potassium, Chloride, Testosterone, Sodium, Inorganic Phosphorus, Uric acid, Urea in the same table. Start with a new page with an analyte to be summarized.
Delete:
Note to Programmer: Include hemoglobin, Hematology, Eosinophils, Eosinophils(%), Basophils, Basophils(%), Lymphocytes, Lymphocytes(%), Neutrophils, Neutrophils(%), Monocytes, Monocytes(%), Erythrocytes, Thrombocytes, Mean Corpuscular Volume (MCV), Mean Corpuscular hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration(MCHC) in the same table. Start with a new page with an analyte to be summarized.

Table 14.3.4.3.2.1 Shift Table of Urinalysis Test Results ITT Population
Add:
Note to Programmer: Include Specific Weight, pH, Leukocytes, and Erythrocytes Start with a new page with an analyte to be summarized.
Delete:
Note to Programmer: Include hemoglobin, Hematology, Eosinophils, Eosinophils(%), Basophils, Basophils(%), Lymphocytes, Lymphocytes(%), Neutrophils, Neutrophils(%), Monocytes, Monocytes(%), Erythrocytes, Thrombocytes, Mean Corpuscular Volume (MCV), Mean Corpuscular hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration(MCHC) in the same table. Start with a new page with an analyte to be summarized.
Footnote: Note: This table only presents results for patients with non-missing data at baseline and the time point of interest.
Footnote: Note: Low = below lower limit of normal range, Normal = within normal limits, High = above upper limit of normal range.

Table 14.3.4.3.2.2 Shift Table of Urinalysis Test Results Safety Population
Add:
Note to Programmer: Include Specific Weight, pH, Leukocytes, and Erythrocytes Start with a new page with an analyte to be summarized.
Delete:
Note to Programmer: Include hemoglobin, Hematology, Eosinophils, Eosinophils(%), Basophils, Basophils(%), Lymphocytes, Lymphocytes(%), Neutrophils, Neutrophils(%), Monocytes, Monocytes(%), Erythrocytes, Thrombocytes, Mean Corpuscular Volume (MCV), Mean Corpuscular hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration(MCHC) in the same table. Start with a new page with an analyte to be summarized.
Footnote: Note: This table only presents results for patients with non-missing data at baseline and the time point of interest.
Footnote: Note: Low = below lower limit of normal range, Normal = within normal limits, High = above upper limit of normal range.

Table 14.3.4.3.1.1
Shift Table of Urinalysis Test Results
ITT Population

Glucose	P-3074 + P (N = xxx) Baseline							Vehicle + P (N = xxx) Baseline							Vehicle + FNS (N = xxx) Baseline							Overall Total (N = xxx) Baseline						
	N	T	1+	2+	3+	4+	Tot	N	T	1+	2+	3+	4+	Tot	N	T	1+	2+	3+	4+	Tot	N	T	1+	2+	3+	4+	Tot
Week 8																													
Normal (N)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Trace (T)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
1+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
3+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
4+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total (Tot)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Week 24																													
Normal (N)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Trace (T)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
1+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
3+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
4+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total (Tot)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

<Continue for Early Termination Visit>

Programming Notes:
Include Proteins, Glucose, Urobilinogen, and Ketones. Start with a new page with an analyte to be summarized.
For glucose, the readings are “Normal (N)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For proteins and ketones, the readings are “Negative (-)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For urobilinogen, the readings are “Normal (N)”, “1+”, “2+”, “3+”, “4+”.
Programmers need to update the reading ranges accordingly. If there is only 5 options instead of 6 move up if display vertically and move left if displays horizontally.

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Table 14.3.4.3.1.1
Shift Table of Urinalysis Test Results
ITT Population

Protein	P-3074 + P (N = xxx) Baseline							Vehicle + P (N = xxx) Baseline							Vehicle + FNS (N = xxx) Baseline							Overall Total (N = xxx) Baseline						
	N	T	1+	2+	3+	4+	Tot	N	T	1+	2+	3+	4+	Tot	N	T	1+	2+	3+	4+	Tot	N	T	1+	2+	3+	4+	Tot
Week 8																													
Negative (-)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Trace (T)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
1+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
3+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
4+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total (Tot)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Week 24																													
Negative (-)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Trace (T)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
1+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
3+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
4+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total (Tot)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

<Continue for Early Termination Visit>

Programming Notes:
Include Proteins, Glucose, Urobilinogen, and Ketones. Start with a new page with an analyte to be summarized.
For glucose, the readings are “Normal (N)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For proteins and ketones, the readings are “Negative (-)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For urobilinogen, the readings are “Normal (N)”, “1+”, “2+”, “3+”, “4+”.
Programmers need to update the reading ranges accordingly. If there is only 5 options instead of 6 move up if display vertically and move left if displays horizontally.

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Table 14.3.4.3.1.1
Shift Table of Urinalysis Test Results
ITT Population

Protein	P-3074 + P (N = xxx) Baseline						Vehicle + P (N = xxx) Baseline						Vehicle + FNS (N = xxx) Baseline						Overall Total (N = xxx) Baseline					
	N	1+	2+	3+	4+	Tot	N	1+	2+	3+	4+	Tot	N	1+	2+	3+	4+	Tot	N	1+	2+	3+	4+	Tot
Week 8																								
Normal (N)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
1+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
3+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
4+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total (Tot)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Week 24																								
Normal (N)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
1+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
2+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
3+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
4+	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total (Tot)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

<Continue for Early Termination Visit>

Programming Notes:
Include Proteins, Glucose, Urobilinogen, and Ketones. Start with a new page with an analyte to be summarized.
For glucose, the readings are “Normal (N)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For proteins and ketones, the readings are “Negative (-)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For urobilinogen, the readings are “Normal (N)”, “1+”, “2+”, “3+”, “4+”.
Programmers need to update the reading ranges accordingly. If there is only 5 options instead of 6 move up if display vertically and move left if displays horizontally.

Program Name: Date Generated: Page x of y

Repeat for the following displays:

Table 14.3.4.3.1.2 Shift Table of Urinalysis Test Results Safety Population
Delete:
Note to Programmer: For glucose, the readings are “Normal (N)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For proteins and ketones, the readings are “Negative (-)”, “Trace (T)”, “1+”, “2+”, “3+”, “4+”.
For urobilinogen, the readings are “Normal (N)”, “1+”, “2+”, “3+”, “4+”.
Programmers need to update the reading ranges accordingly. If there is only 5 options instead of 6 move up if display vertically and move left if displays horizontally.

Table 14.3.4.3.3.1
Shift Table of Urinalysis Test Results
ITT Population

Nitrites	P-3074 + P (N = xxx)			Vehicle + P (N = xxx)			Vehicle + FNS (N = xxx)			Overall Total (N = xxx)		
	Baseline			Baseline			Baseline			Baseline		
	Pos	Neg	Tot	Pos	Neg	Tot	Pos	Neg	Tot	Pos	Neg	Tot
Week 8												
Positive (Pos)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Negative (Neg)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Total (Tot)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Week 24												
Positive (Pos)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Negative (Neg)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Total (Tot)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

<Continue for Early Termination Visit>

Programming Notes:
Include Specific Nitrites and Bilirubin. Start with a new page with an analyte to be summarized.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.3.4.3.3.2 Shift Table of Urinalysis Test Results Safety Population

Table 14.3.5.1
Summary of Vital Signs
ITT Population

Weight (unit)	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)
Baseline			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
<Visit>			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
Change from Baseline			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.xx (xx.xx)
Median	xx.x	xx.x	xx.x
Q1, Q3	xxx, xxx	xxx, xxx	xxx, xxx
Min	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x
[Repeat for all scheduled visits]			

Programming Notes:
Include Weight, Systolic Blood Pressure, Diastolic Blood Pressure, Heart Rate, and Temperature. Start with a new page with an analyte to be summarized.

Program Name: Date Generated: Page x of y

Repeat for the following displays:

Table 14.3.5.2 Summary of Vital Signs Safety Population

Table 14.3.6.1
Summary of Physical Exam
ITT Population

	P-3074 + P (N = xxx)	Vehicle + P (N = xxx)	Vehicle + FNS (N = xxx)	Overall Total (N = xxx)
Screening	xxx	xxx	xxx	xxx
Any Abnormality?[a]				
Normal	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal not clinically significant	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal clinically significant	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormalities by Body System				
Body System 1				
Normal	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal not clinically significant	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal clinically significant	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Body System 2				
Normal	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal not clinically significant	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal clinically significant	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Body System 3				
:				

<Repeat for all visits>

[a] Count are based on the worst severity documented on the CRF at the visit.
The denominator for percentages is the number of patients with non-missing data in theITT Population for each treatment group.
Program Name: Date Generated: Page x of y
Repeat for the following displays:
Table 14.3.6.2 Summary of Physical Exam Safety Population
Add:
Footnote: The denominator for percentages is the number of patients with non-missing data in theSafety Population for each treatment group.
Delete:
Footnote: The denominator for percentages is the number of patients with non-missing data in theITT Population for each treatment group.

Listing 16.2.1.1
Patients Screened
All Screened Patients

Treatment group: *Treatment 1*

Site	Patient/ Age	Date of Informed Consent	Date of Screen Failure	Reason(s) for Screen Failure
xx	xxx/xx	DDMMMYYYY	DDMMMYYYY	*Reason 1; Reason 2*
xx	xxx/xx	DDMMMYYYY	DDMMMYYYY	*Reason 1*
xx	xxx/xx	DDMMMYYYY	DDMMMYYYY	

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient

Program Name: Date Generated: Page x of y

Listing 16.2.1.2
Patients Disposition
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient	Age (year)	Completed Study	Primary Reason for Withdrawal	Date of 1st Dose of Study Treatment group/ Date of 1st Spray of Study Treatment group	Date of Withdrawal (Day)[a]	Date of Last Dose of Study Treatment group (Day)[a]/ Date of Last Spray of Study Treatment group
xx	xxx	xx	No	*Reason 1*	DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY (xx)	DDMMMYYYY (xx)/ DDMMMYYYY (xx)
xx	xxx	xx	No	*Reason 2*	DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY (xx)	DDMMMYYYY (xx)/ DDMMMYYYY (xx)
xx	xxx	xx	Yes		DDMMMYYYY/ DDMMMYYYY		DDMMMYYYY (xx)/ DDMMMYYYY (xx)

[a] Relative to date of first dose of study treatment group

Programming Notes:

Repeat for all treatment groups. Sort by treatment group, site and patient

Program Name: Date Generated: Page x of y

Listing 16.2.1.3
Patients Disposition
All Randomized Population

Treatment group Group: P-3074 + P

Site	Patient/ Age	Visit	Date Visit (Day) [a]
xx	xxx/xx	Screening	DDMMMYYYY (xx)
		Randomization	DDMMMYYYY (xx)
		Week 4	DDMMMYYYY (xx)
		Week 8	DDMMMYYYY (xx)
		Week 12	DDMMMYYYY (xx)

[a] Relative to date of first dose of study treatment group
Programming notes: Repeat for all treatment group groups. Sort by treatment group group, site and patient
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Program Name: Date Generated: Page x of y

Listing 16.2.1.4
Patients Treatment Allocation
All Randomized Population

Site	Patient/Age	Randomized Treatment Group	Date of Randomization
xx	xxx/xx	Treatment x	DDMMMYYYY

Programming Notes:
Repeat for all treatment groups. Sort by site and patient

Program Name: Date Generated: Page x of y

Listing 16.2.1.5
Protocol Violations
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient/Age	Any Violations?	Date	Violation Category	Details of Violation
xx	xxx/xx	Yes	DDMMMYYYY	xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx
		No			

Note: Violations were identified and categorized prior to unblinding. Patients may have more than one violation leading to exclusion from All Randomized Population

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient

Program Name: Date Generated: Page x of y

Listing 16.2.2.1
Inclusion Criteria
All Screened Patients

Treatment group: T*reatment 1*

Site	Patient/Age	Protocol Version	I1	I2	I3	I4	I5	I6	I7
xx	xxx/xx	1	Yes	Yes	Yes	Yes	Yes	Yes	Yes
xx	xxx/xx	1	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Refer to Preface A for full descriptions of the Inclusion and Exclusion Criteria.
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Program Name: Date Generated: Page x of y

Listing 16.2.2.2
Exclusion Criteria
All Screened Patients

Treatment group: T*reatment 1*

Site	Patient /Age	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12	E13	E14	E15	E16	E17	E18
xx	xxx/xx	Yes	Yes	NA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
xx	xxx/xx	No	Yes	NA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						

Refer to Preface A for full descriptions of the Inclusion and Exclusion Criteria.
[a] Relative to the day of first dose of study treatment group
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Program Name: Date Generated: Page x of y

Listing 16.2.3
Study Population
All Screened Patients

Treatment group: *Treatment 1*

Site	Patient/ Age	All Screened Patient	All Randomized Population	Safety Population	ITT Population	Per Protocol Population	CCI
xx	xxx/xx	Yes	Yes	Yes	Yes	Yes	
xx	xxx/xx	Yes	Yes	Yes	No	No	

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient

Program Name: Date Generated: Page x of y

Listing 16.2.4.1
Demographics
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Year of Birth	Race	Ethnicity	Current Tobacco Use/ Smoke>=10 cigerretts per day	Current Alocohol Use	Drink>5 Cups of coffee/tea per day
xx	xxx/xx	YYYY	*Race1*	Ethnicity1	Never/No	None	Yes
xx	xxx/xx	YYYY	*Race2*	Ethnicity2	Current/No	<=2 drinks per day	Yes
xx	xxx/xx	YYYY	*Other: xxxx*	Ethnicity3	Former/Yes	> 2 drinks per day	No

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Program Name: Date Generated: Page x of y

Listing 16.2.4.2
Medical History
All Randomized Population

Treatment group: *Treatment 1*

Site	Patient/ Age	Vertex Pattern	System Organ Code (SOC)/ Preferred Term (PT)[a]/ Verbatim/ MMH Line No.	Start Date/ Stop Date[b]
xx	xxx/xx	Type III	xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ 1	DDMMMYYYY/ DDMMMYYYY
xx	xxx/x	Type IV	xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ 1	DDMMMYYY/ Ongoing
xx	xxx/xx	Other: xxxxx	None	

[a] MedDRA Dictionary (Version 19.0) was used for coding
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient, SOC and preferred term.
Program Name: Date Generated: Page x of y

Listing 16.2.4.3
Prior and Concomitant Medication
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient /Age	Therapeutic Class Chemical Subgroup Generic Term [a]	Dose/Unit/ Frequency/ Route	Indication CM Number	Start Date (day) Stop Date (day)[b] / Duration (days)
xx	xxx/xx	xxxxxxxxxx xxxxxxxxxxxxxx (xxxxxxxxxxxx)	xx/units/ xx/ xx	xxxxxxxxxx xx, xx /1	DDMMMYYYY (xx) DDMMMYYYY (xx) /xx
		xxxxxxxxxx xxxxxxxxxxxxxx (xxxxxxxxxxxx)	xx/units/ xx/ xx	xxxxxxxxxx xx, xx /2	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/xx
xx	xxx/xx	xxxxxxxxxx xxxxxxxxxxxxxx (xxxxxxxxxxxx)	xx/units/ xx/ xx	xxxxxxxxxx xx, xx /1	DDMMMYYYY (xx)/ Ongoing
xx	xxx/xx	None			

[a] WHO Drug Dictionary (Version MAR16B2E) was used for coding
[b] Relative to date of first dose of study treatment group
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient, start date and drug class.
Program Name: Date Generated: Page x of y

Listing 16.2.5.1
Study Drug Administration (Tablet)
All Randomized Population

Treatment group Group: P-3074 + P

Site	Patient/ Age	Start Date Time of Treatment	Last Date Time of Treatment	Start Date of Interruption (day) [a]	End Date of Interruption (day) [a]	Actual Treatment Received
xx	xxx/xx	DDMMMYYYY HH:MM	DDMMMYYYY HH:MM	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xxxxx

[a] Relative to the day of first dose of study treatment group
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Program Name: Date Generated: Page x of y

Listing 16.2.5.2
Study Drug Administration (Spray)
All Randomized Population

Treatment group Group: P-3074 + P

Site	Patient/ Age	Start Date Time of Treatment	Last Date Time of Treatment	Start Date of Interruption (day) [a]	End Date of Interruption (day) [a]	Actual Treatment Received
xx	xxx/xx	DDMMMYYYY HH:MM	DDMMMYYYY HH:MM	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xxxxxx

[a] Relative to the day of first dose of study treatment group
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Program Name: Date Generated: Page x of y

Listing 16.2.5.3
Study Treatment Compliance/Exposure
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Compliance Based on Diary		Compliance Based Accountability		Duration of Exposure (days)
		Tablets (%)	Spray Shot (%)	Tablets (%)	Spray Shot (%)	
xx	xxx/xx	xx.x%	xx.x%	xx.x%	xx.x%	xxxx

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient and visit.

Program Name: Date Generated: Page x of y

Listing 16.2.6.1
Hair Assessment Results
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient/Age	Visit	Date (day) [a]	Hair Count	Hair Width (unit)						
xx	xxx/xx			10	10.36	12.23	13.15	8.33	6.45	9.32	6.88
					7.55	8.65	8.99				

[a] Relative to the day of first dose of study treatment group

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site and patient
Please include all measured hair width in this listing.

Program Name: Date Generated: Page x of y

Listing 16.2.6.2
MHGQ Questionnaire
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Visit	Collection Data(day) [a]	Question	Patient's Response/Score
xx	xxx/xx	Week 12	DDMMMYYYY(xx)	Bald spot getting smaller?	Agree/2
				Appreance of my hair is:	A littie better/3
				Growth of my hair	Slightly increased/3
				Effctive of the treatment	Somehow effective/2
				Hairline at the frond	I am very satisfied/1
				Hair on top	I am satisfied/2
				Overall	I am satisfied/2

[a] Relative to the day of first dose of study treatment group

Program Name: Date Generated: Page x of y

Listing 16.2.6.3
Blind Assessor Assessment of Patient Hair Growth/Loss Change from Baseline
All Randomized Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Visit	Assessment Data(day) [a]	Assessment of Hair Growth
xx	xxx/xx	Week 12	DDMMMYYYY(xx)	Greatly Increased
		Week 24	DDMMMYYYY(xx)	Greatly Increased

[a] Relative to the day of first dose of study treatment group

Program Name: Date Generated: Page x of y

Repeat for the following displays:
Listing 16.2.6.4 Investigator's Assessment of Patient Hair Growth/Loss Change from Baseline All Randomized Population
Delete:
Footnote: [a] Relative to the day of first dose of study treatment group


CCI

Listing 16.2.7.1
Adverse Events
Safety Population

Treatment group: *Treatment 1*

Site	Patient/ Age	AE Line No./ System Organ Class/ Preferred Term/ Verbatim [a]	TEAE or PTAE/ Start Date (day) Stop Date (day)[b] / Duration (days)	Intensity/ Frequency	Relationship to Study Drug/ Action Taken[c]	Outcome/ Discontinue?	Medically Important but not SAE	SAE[d]	Comments
xx	xxx/xx	1/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/	TEAE/ DDMMMYYYY (xx) DDMMMYYYY (xx) /xx	Mild/ Single Event	Not Related/ xxx	Resolved/ No	No	No	
		2/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/	TEAE/ DDMMMYYYY (xx)/ DDMMMYYYY (xx)/xx	Moderate/ Single Event	Unlikely/ xxx	Death/ Yes	No	Yes:1	
xx	xxx/xx	1/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/	PTAE/ DDMMMYYYY (xx)/ Ongoing	Severe/ Single Event	Not Related/ xxx	Ongoing/ No	No	Yes:3	

[a] Coded using MedDRA Dictionary (Version 19.0)
[b] Relative to the day of first dose of study treatment group
[c] Action Taken: Inc=Dose increased; No Chg=Dose not changed; Red=Dose reduced; Int=Drug interrupted; Withd=Drug withdrawn; NA=Not applicable; Un=Unknown; Oth=Other
[d] SAE Type: 1=Death; 2=Life Threatening; 3=Initl or Prolonged Hospitalization; 4=Persistent or Significant Disability or Incapacity; 5=Congenital Anomaly or Birth Defect

Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient, start date and SOC.

Program Name: Date Generated: Page x of y

Repeat for the following displays:
Listing 16.2.7.2 Treatment Emergent Adverse Events Leading to Discontinuation of Treatment Safety Population

Listing 16.2.7.3 Death Safety Population

Listing 16.2.7.4
Severity Score for Skin Irritation
Safety Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Visit	Collection Data(day) [a]	Dermal Response	Other Effects
xx	xxx/xx	Week 4	DDMMMYYYY(xx)	No evidence of irritation	No other effetcs
		Week 8	DDMMMYYYY(xx)	Erythema and papules	Marked glazing
		Week 12	DDMMMYYYY(xx)	Erythema, oedema and papules	Marked glazing
		Week 24	DDMMMYYYY(xx)	Vescicular eruption	Slight glazed appearance
		Week 28	DDMMMYYYY(xx)	Strong reaction spreading beyond test site	No other effetcs
xx	xxx/xx	Week 4	DDMMMYYYY(xx)	No evidence of irritation	No other effetcs
			:	:	:
			:	:	:
			:	:	:

Program Name: Date Generated: Page x of y

Listing 16.2.8.1
Preface to Laboratory Findings
Safety Population

Laboratory Test	Sex	Age	Reference Ranges	Unit
Hematology			xxxxxxx - xxxxxxx	
Hematocrit				(unit)
Hemoglobin				(unit)
. . .				
Serum Chemistry				
ALT				(unit)
AST				(unit)
. . .				

Program Name: Date Generated: Page x of y

Listing 16.2.8.2
Laboratory Findings - Hematology
Safety Population

Treatment group: *Treatment 1*

Site	Patient/ Age	Nominal Visit	Laboratory Parameter (unit)	Collection Date (day) [a]	Was Blood Sample Collected?	Value [b]	Normal Range	Overall Evaluation
xx	xxx/xx	Screening	Hematocrit	DDMMMYYYY (xx)	Yes	xxx.xxx B	xxx - xxx	Normal
		Week 8	Hematocrit	DDMMMYYYY (xx)	Yes	xxx.xxx	xxx - xxx	Normal
		Week 24	Hematocrit	DDMMMYYYY (xx)	Yes	xxx.xxx	xxx - xxx	Abnormal not clinically significant
		ETV	:	:	:	:	:	:
		:	:	:	:	:	:	:
		Screening	Hemoglobin	DDMMMYYYY (xx)	Yes	xxx.xxx A	xxx - xxx	:
		Week 8	Hemoglobin	DDMMMYYYY (xx)	Yes	xxx.xxx	xxx - xxx	:
		Week 24	Hemoglobin	DDMMMYYYY (xx)	Yes	xxx.xxx	xxx - xxx	Abnormal not clinically significant
		:	:	:	:	:	:	:
		:	:	:	:	:	:	
			Continue for all Hematology parameters					

[a] Relative to the day of first dose of study treatment group
[b] B=Below, A=Above the normal limits
Programming Notes:
Include Hematocrit, Hemoglobin, White Blood Cell Count with Differential (Eosinophils, Basophils, Lymphocytes, Neutrophils, Monocytes), Erythrocytes, Thrombocytes, Mean Corpuscular Volume (MCV), Mean Corpuscular hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration(MCHC)
Program Name: Date Generated: Page x of y

Repeat for the following displays:
Listing 16.2.8.3 Laboratory Findings - Serum Chemistry Safety Population
Add:
Note to Programmer: Include Alanine aminotranferase (ALT), Aspartate aminotranferase (AST), Total Bilirubin, Total Cholesterol, Triglycerides, Gamma-Glutamyltransferase (GGT), Alkaline phosphatase, Albumin, Total protein
Glucose, Creatinine, Globulin, Calcium, Potassium, Chloride,Testosterone, Sodium, Inorganic Phosphorus, Uric acid, Urea
Delete:
Note to Programmer: Include Hematocrit, Hemoglobin, White Blood Cell Count with Differential (Eosinophils, Basophils, Lymphocytes, Neutrophils, Monocytes), Erythrocytes, Thrombocytes, Mean Corpuscular Volume (MCV), Mean Corpuscular hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration(MCHC)

Listing 16.2.8.4
Laboratory Findings - Urinalysis
Safety Population

Treatment group: T*reatment 1*

Site	Patient/Age	Nominal Visit	Laboratory Parameter (unit)	Collection Date (day) [a]	Was Urine Sample Collected?	Value	Overall Inspection
xx	xxx/xx	Screening	PH	DDMMMYYYY (xx)	Yes	xxx	Normal
		Week 8	PH	DDMMMYYYY (xx)	Yes	xxx	Normal
		Week 24	PH	DDMMMYYYY (xx)	Yes	xxx	Abnormal not clinically significant
		ETV	:	:	:	:	:
		:	:	:	:	:	:
		Screening	Color	DDMMMYYYY (xx)	Yes	xxx	:
		Week 8	Color	DDMMMYYYY (xx)	Yes	xxx	:
		Week 24	Color	DDMMMYYYY (xx)	Yes	xxx	Abnormal not clinically significant
		:	:	:	:	:	:
		:	:	:	:	:	
			Continue for all Urinalysis parameters				

[a] Relative to the day of first dose of study treatment group
Programming Notes:
Include Macroscopic analysis: pH, specific weight, appearance, colour, nitrites, proteins, glucose,urobilinogen, bilirubin, ketones, haematic pigments, leukocytes
Microscopic analysis: leukocytes, Erythrocytes, flat cells, round cells, crystals, cylinders, mucus, bacteria

Program Name: Date Generated: Page x of y

Listing 16.2.8.5
Vital Signs
Safety Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Nominal Visit	Collection Date (day) [a]	Height (cm)	Weight (kg)	BMI (kg/m^2)	SBP (mmHg)	DBP (mmHg)	Pulse (bpm)	Temperature (C)
xx	xxx/xx	Screening	DDMMMYYYY(xx)	xxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxx
		Week 24	DDMMMYYYY(xx)	xxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxx
		Week 28	DDMMMYYYY(xx)	xxxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxx

[a] Relative to the day of first dose of study treatment group
Note: Body temperature is reported in Celsius. For those patients who reported their body temperature in Fahrenheit. The following coversion will be used: T(°C) = (T(°F) - 32) × 5/9
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient and visit.
Temperature is collected in 2 units. Please convert F to C. T(°C) = (T(°F) - 32) × 5/9
Program Name: Date Generated: Page x of y

Listing 16.2.8.6
Physical Examination Results
Safety Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Visit	Assessment Date (day) [a]	Body System Abnormalities	Findings
xx	xxx/xx	Baseline	DDMMMYYYY (xx)	Cardiovascular	xxxxxxxxxxxxxxxxxx
				Respiratory	xxxxxxxxxxxxxxxxxx
				Gastrointestinal	xxxxxxxxxxxxxxxxxx
				Skin	xxxxxxxxxxxxxxxxxx
				Musculoskeletal	xxxxxxxxxxxxxxxxxx
				Endocrine	xxxxxxxxxxxxxxxxxx
				Neurological	xxxxxxxxxxxxxxxxxx
				HEENT	xxxxxxxxxxxxxxxxxx
				Genitourinary	xxxxxxxxxxxxxxxxxx
		Week x	DDMMMYYYY (xx)	None	Patient refusal

[a] Relative to the day of first dose of study treatment group

Programming Notes:

Repeat for all treatment groups. Sort by treatment group, site, patient and visit. Only present abnormal body systems. If all body systems are normal at a visit, output “None” in Body System Abnormalities column for the visit.

If PE is not performed, please display "No PE performed" under Body System Abnormalities column and report reason not performed under "Findings" column.

Program Name: Date Generated: Page x of y

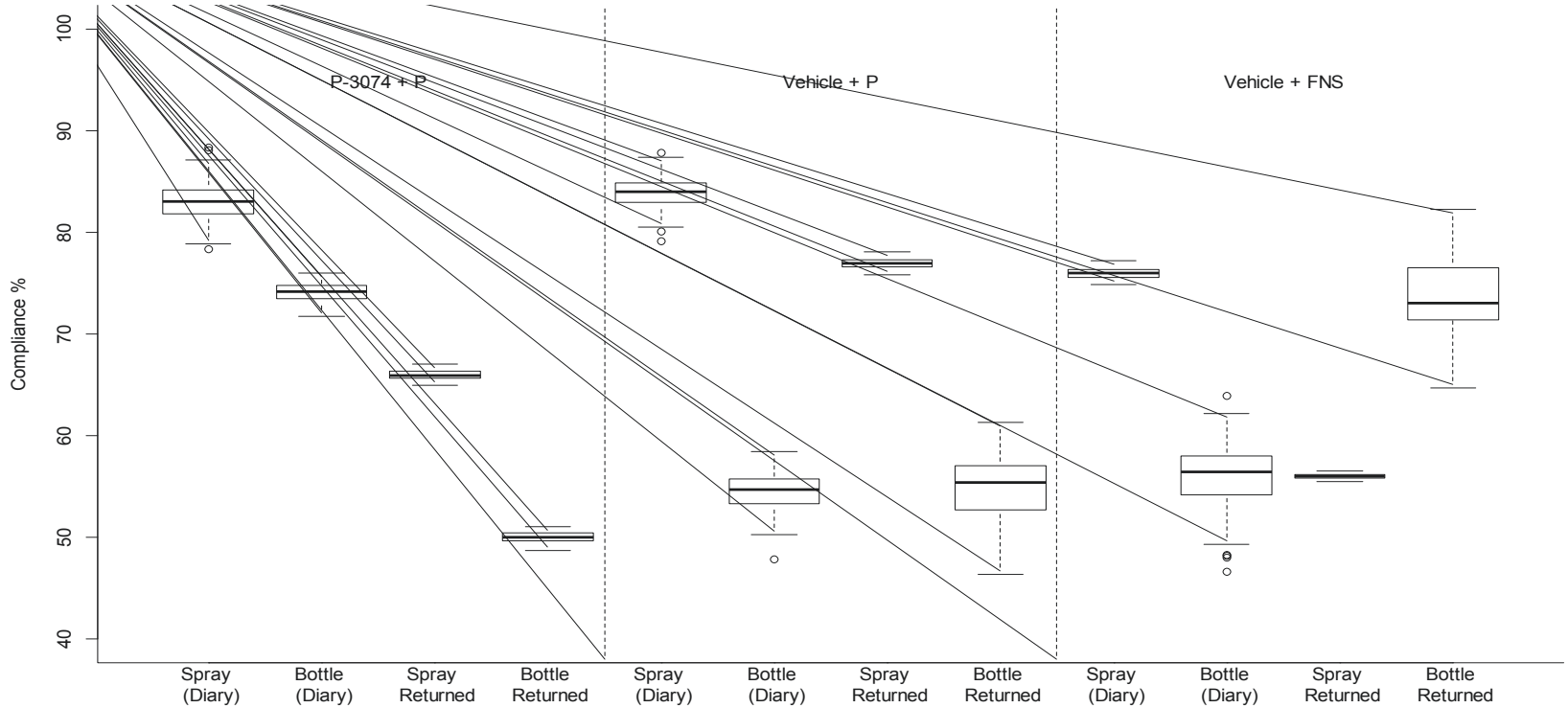
Listing 16.2.8.7
Self-administered Sexual Dysfunction Questionnaire
Safety Population

Treatment group: T*reatment 1*

Site	Patient/ Age	Visit	Assessment Date (day) [a]	Question: Over the past 4 weeks	Answer
xx	xxx/xx	Week 4	DDMMMYYYY (xx)	How often were you able to get an erection during sexual activity?	No sexual activity
				When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost always or always
				When you attempted sexual intercourse how often were you able to penetrate (enter) your partner?	Most times
				During sexual intercourse how often were you able to maintain your erection after you had penetrated (entered) your partner?	Did not attempt intercourse
				During sexual intercourse how difficult was it to maintain your erection to completion of intercourse?	Slightly difficult
				:	:
				:	:
		Week 8	DDMMMYYYY (xx)	How often were you able to get an erection during sexual activity?	No sexual activity
				:	:
				:	:

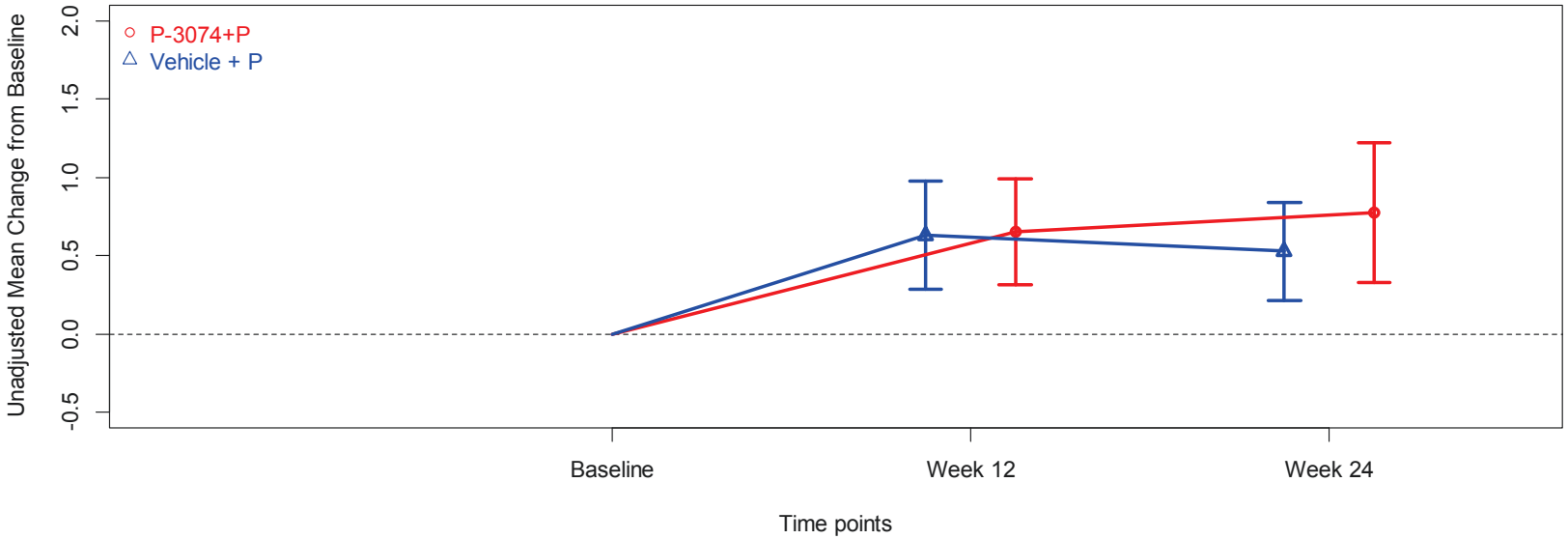
[a] Relative to the day of first dose of study treatment group
Programming Notes:
Repeat for all treatment groups. Sort by treatment group, site, patient and visit.
Program Name: Date Generated: Page x of y

Figure 14.1.6
Study Treatment Compliance
ITT Population



Program Name: Date Generated: Page x of y

Figure 14.2.1.1
Hair Count Unadjusted Mean Change From Baseline by Treatment Over Time
ITT Population



Note: Vertical bar represents 95% CI.

Program Name: Date Generated: Page x of y
Repeat for the following displays:
Figure 14.2.1.2 Hair Count Adjusted Mean Change From Baseline by Treatment Over Time ITT Population

Figure 14.2.2.1 Hair Count Unadjusted Mean Change From Baseline by Treatment Over Time PP Population

Figure 14.2.2.2 Hair Count Adjusted Mean Change From Baseline by Treatment Over Time PP Population

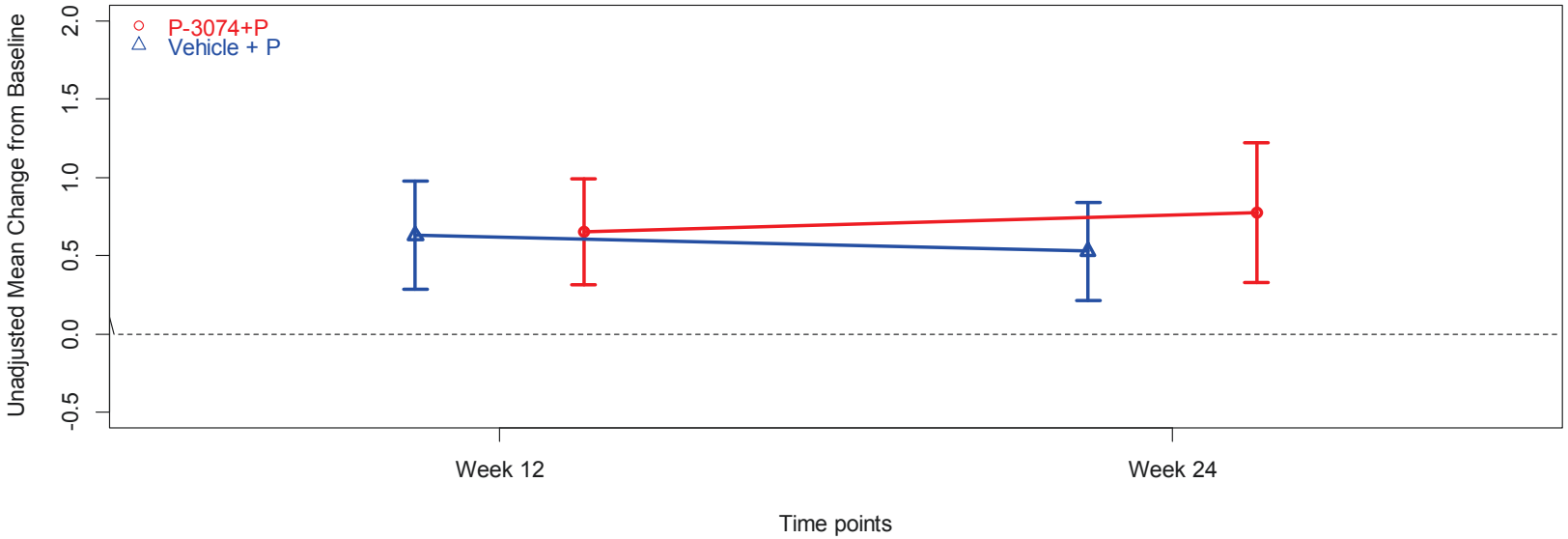
Figure 14.2.3.1 Hair Width Unadjusted Mean Change From Baseline by Treatment Over Time ITT Population

Figure 14.2.3.2 Hair Width Adjusted Mean Change From Baseline by Treatment Over Time ITT Population

Figure 14.2.4.1 Hair Width Unadjusted Mean Change From Baseline by Treatment Over Time PP Population

Figure 14.2.4.2 Hair Width Adjusted Mean Change From Baseline by Treatment Over Time PP Population

Figure 14.2.8.1
Unadjusted Investigator Assessment of Improvement Patient Hair Growth/Loss Mean Score from Baseline by Treatment Over Time
ITT Population



Program Name: Date Generated: Page x of y
Repeat for the following displays:
Figure 14.2.8.2 Adjusted Investigator Assessment of Improvement Patient Hair Growth/Loss Mean Score from Baseline by Treatment Over Time
ITT Population

Figure 14.2.9.1 Unadjusted Investigator Assessment of Improvement Patient Hair Growth/Loss Mean Score from Baseline by Treatment Over Time
PP Population

Figure 14.2.9.2 Adjusted Investigator Assessment of Improvement Patient Hair Growth/Loss Mean Score from Baseline by Treatment Over Time
PP Population


CCI