STATISTICAL ANALYSIS PLAN

STUDY NUMBER: INDV-6000-404

PROTOCOL TITLE: An Open-label treatment extension study for eh Rapid Initiation of Extended-Release Buprenorphine Subcutaneous Injection (SUBLOCADE™)

NCT NUMBER: NCT04060654

DATE: 02Jul2020

Title Page

Protocol Title: An Open-label, Treatment Extension Study for the Rapid Initiation Study for Extended-Release Buprenorphine Subcutaneous Injection (SUBLOCADE™)

Protocol Number: INDV-6000-404

Drug: SUBLOCADE™ (extended-release buprenorphine)

Short Title: SUBLOCADE Rapid Initiation Extension Study

Sponsor Name: Indivior Inc.

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Regulatory Agency Identifier Number(s)

Registry	**ID**
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Statistical Analysis Plan Approval

Protocol ID#: INDV-6000-404

Protocol Title: An Open-label, Rapid Initiation Study for Extended-Release Buprenorphine Subcutaneous Injection (SUBLOCADE™)

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1 INTRODUCTION

This statistical analysis plan (SAP) provides the detailed methodology for summary, pharmacokinetic and statistical analyses of the data collected in Study INDV-6000-404.

This SAP supersedes the statistical considerations identified in the protocol; where considerations are substantially different, they will be so identified in Section 6.2. Any deviations from the analyses described below, as well as Post-hoc analyses, will be documented in the clinical study report (CSR).

Specification of tables, listings and figures (TLFs) are provided in a separate document.

1.1 Version History

Table 1 SAP Version History Summary

SAP Version	SAP Approval Date	Associated Protocol	Protocol Amendment Approval Date	Change	Rationale
1.0	08 Apr 2020	Amendment 1	04Dec2019	Not Applicable	Original version
2.0	02 Jul 2020	Amendment 1	04Dec2019	In Section 4 added that all subjects screened received SUBLOCADE, so a screened population was not defined	Clarification.
				Section 5.1.4.5, definition of treatment completion was removed.	Not needed for analysis.
				In Section 5.1.5, removed the statement regarding concomitant medication summary tables being produced	Concomitant medications are only being listed, not summarized, so this statement was not applicable.

				only if there are >6 medications.	
				In Section 5.4.2, removed information about derived variables.	The prior and concomitant medication data is only being listed and not summarized, so derived variables are not necessary.
				In Section 5.5.1, removed adverse events of special interest from the adverse event overall summary table.	A flag for adverse events of special interest was not derived since there were no adverse events reported in the study.
				In Section 5.5.5, correct the description of the IV opioid use analysis.	Data is from study 403 screening, not each visit.
				In Section 6.2, removed 'the reporting of concomitant medications as a listing only and no summary table in the case of ≤ 6 medications' as a change from the	The protocol states prior and concomitant medications will only be listed, so there was no change to the protocol planned analysis regardless of number of medications reported.

				protocol planned analysis.	
				Removed Section 6.5.2 regarding partial prior/concomitant medication start/stop dates and assignment of prior and concomitant medication flags.	The prior and concomitant medication data is only being listed and not summarized, so derived variables are not necessary.
				In Section 6.7, remove variables not being summarized	COWS and OC-VAS were not transferred and analysis of UDS is described in Section 5.5.7.

1.2 Objectives and Endpoints

Table 2 Objectives and Endpoints

Objectives	Endpoints
Primary	
• The objective of this study is to assess the longer-term safety of an abbreviated initiation protocol of SUBLOCADE in subjects who have completed INDV-6000-403. It is also to provide treatment to these individuals while they seek longer-term care arrangements, as it (on average) takes an individual with OUD 6 months between seeking treatment and achieving an appointment at a provider within the US.	• The proportion of subjects with treatment emergent adverse events (TEAEs) at any time during the treatment period.
Other Safety Endpoints	
	• Assessment of study medication-related TEAEs, serious TEAEs, study medication-related serious TEAEs, TEAEs leading to treatment discontinuation and concomitant medications.

1.3 Study Design

Only subjects who have completed the End of Treatment (EOT) procedures for Study INDV-6000-403, have signed the INDV-6000-404 informed consent form (ICF), and meet all the enrolment criteria may be considered for inclusion in this study.

The INDV-6000-403 EOT visit is 28 days after the subject's first dose of SUBLOCADE in INDV-6000-403, therefore the INDV-6000-403 EOT and the INDV-6000-404 screening and Day 1 visit for this study will occur within 2 days, thus the INDV-6000-403 EOT assessments will serve as the screening assessments for the Screening Visit (Day 1) of this study.

Any AEs and concomitant medications ongoing at the INDV-6000-403 EOT will be re-recorded for this study. In addition, demographics, height, medical/psychiatric, substance and drug of abuse history will not be re-collected and will be taken from the INDV-6000-403 screening assessments. As per protocol amendment 1, a detailed detox and MOUD (medication for opioid use disorder) treatment history will be collected at screening. For those subjects who have enrolled in the study prior to approval of protocol amendment 1, their detox and MOUD treatment history will be collected retrospectively at their next visit.

On Day 1, eligible subjects will receive a subcutaneous injection of 300mg SUBLOCADE. Before departing the site, any new adverse events (AEs) or concomitant medications will be recorded.

Subjects will return to the site for monthly injection visits every 4 weeks (-2 / +7 days) for a total of up to 5 injections. At Injection Visits 2 through 5, subjects will be evaluated in accordance with local standard of care and results for the following procedures will be recorded: urine pregnancy test (to be performed before SUBLOCADE administration for all female subjects who are of childbearing potential); urine drug screen (UDS) and evaluation of previous injection site for potential reaction and evidence of attempts to remove the depot. For injections 2 to 5, subjects may receive either a dose of 100 mg SUBLOCADE or 300 mg SUBLOCADE, based on the medical judgment of the Investigator, per the SUBLOCADE United States Prescribing Information (USPI). During each visit the subject will be assessed for AEs and use of concomitant medications.

All subjects will receive counselling as determined by local standard of care throughout the study from Day 1 through EOT.

All subjects who receive SUBLOCADE (including those who wish to discontinue early), will be encouraged to attend the EOT/ET visit 4 weeks after SUBLOCADE administration.

At the EOT/ET Visit, results for the following procedures and assessments will be recorded: urine pregnancy test for all female subjects who are of childbearing potential; evaluation of previous injection site for potential reaction and evidence of attempts to remove the depot; UDS; use of concomitant medications and assessment for AEs. At every visit, options for continued care should be discussed with the subject.

Any subject with ongoing AEs or concomitant medications at the EOT Visit will also be followed up by telephone 4 weeks later for a safety follow up to assess the ongoing AEs or concomitant medications only.

Table 3 Schedule of Assessments – Overview of Study

Procedure/Assessment	Screening	Injection 1	Injection 2	Injection 3	Injection 4	Injection 5	ET / EOT[9]	Safety Follow up[10]
Visit Number	**1**		**2**	**3**	**4**	**5**	**6**	**7**
Day(s)		**1**	**29**	**57**	**85**	**113**	**141**	**169**
Window (days)		+2	-2 / +7	-2 / +7	-2 / +7	-2 / +7	-2 / +7	-7 / +7
Informed Consent[1]	X							
Inclusion/Exclusion Criteria	X							
Demographics[2]	403[2]							
Medical/Psychiatric History[2]	403[2]							
Substance/Drug Use History[2]	403[2]							
Height[2]	403[2]							
Weight/BMI[3]	403 EOT[3]							
Urine Pregnancy Test[5]	403 EOT[3]		X	X	X	X	X	
UDS[6]	403 EOT[3]		X	X	X	X	X	
Injection Site Evaluation[7]	403 EOT[3]		X	X	X	X	X	
AE Assessment	X[4]		X	X	X	X	X	
Concomitant Medications	X[4]		X	X	X	X	X	X
Study Drug Administration		X	X	X	X	X		
MOUD and treatment History[11]	X							
Counselling[8]	X							

AE=adverse event; BMI=body mass index; EOT=End-of-Treatment; ET=Early Termination; OUD=opioid use disorder; UDS=urine drug screen; MOUD=medication for opioid use disorder

1. Written informed consent must be obtained after completion of all INDV-6000-403 EOT procedures and before any INDV-6000-404 study-specific assessments/procedures are initiated.
2. This data will not be re-collected; the data from the INDV-6000-403 screening visit will be used.
3. This data will not be re-collected; the data from the INDV-6000-403 EOT visit will be used.
4. Any ongoing (at the INDV-6000-403 EOT) or new AEs or concomitant medications in this study will be recorded.
5. Required for female subjects of childbearing potential only, to be performed before SUBLOCADE dosing at Visits 1 to 6.
6. Qualitative test to be performed before SUBLOCADE dosing at Visits 1 to 6.
7. Injection site will be evaluated for signs of attempted removal before SUBLOCADE dosing at Visits 1 to 6. Any injection site reactions or infections will be recorded as AEs.
8. All subjects will receive counselling as determined by local standard of care throughout the study from Day 1 through EOT.
9. All subjects who receive SUBLOCADE (including those who wish to discontinue early), will be encouraged to attend the EOT visit 4 weeks after SUBLOCADE administration.
10. Any subject with ongoing AEs or concomitant medications at the EOT/ET Visit will also be followed up by telephone 4 weeks later for a safety follow up to assess the ongoing AEs or concomitant medications only.
11. A detailed detox and MOUD treatment history will be collected at screening. For those subjects who have enrolled in the study prior to approval of protocol amendment 1, their detox and MOUD treatment history will be collected retrospectively at their next visit.

2 STATISTICAL HYPOTHESES

For this single arm study, the analysis methods are descriptive. Therefore, statistical testing and hypotheses are not applicable.

2.1 Multiplicity Adjustment

There is no multiplicity adjustment.

3 SAMPLE SIZE DETERMINATION

Up to 25 adult subjects with moderate to severe OUD are planned to be enrolled into the study.

4 POPULATIONS FOR ANALYSIS

The safety population will consist of all subjects who received at least 1 dose of SUBLOCADE in this study and will be the primary population for all analyses. All subjects who were screened received SUBLOCADE. Therefore, a screened population was not defined as it would comprise the same set of subjects.

5 STATISTICAL ANALYSES

5.1 General Considerations

5.1.1 INDV-6000-403 Data

Per the Schedule of Assessments (**Table 3**), some data will not be re-collected in this study, as the INDV-6000-403 data will be used. Further details of the transfer of these data into the INDV-6000-404 database are described in the analysis sections below.

5.1.2 Statistical Analyses and Coding

Statistical analyses will be performed using version 9.4 (or higher) of SAS.

The AEs and medical/psychiatric conditions will be coded using the process and MedDRA version per the study coding guidelines.

The final analysis will occur after the database lock.

5.1.3 Treatment Label

The treatment label will be presented in the tables, listings and figures (TLFs) as SUBLOCADE.

5.1.4 Study Definitions

5.1.4.1 Subject Screening

Study screening begins once written informed consent is obtained; the same subject identification number from INDV-6000-403 will be assigned.

5.1.4.2 Enrolled

A subject will be considered enrolled if he/she receives at least 1 dose of SUBLOCADE in this study.

5.1.4.3 Not Enrolled

A subject will be considered not enrolled if written informed consent is obtained but the subject does not receive SUBLOCADE in this study. Reasons for not enrolling (e.g., withdrawal of consent, does/not meet specified inclusion or exclusion criteria) will be recorded in the case report form (CRF).

5.1.4.4 Treatment Period

Treatment period begins when the SUBLOCADE injection is given on Day 1 and ends after all assessments have been made at the EOT Visit.

5.1.4.5 Study Completion

A subject will be considered to have completed the study if they have completed the last injection visit (Injection 5) and the scheduled EOT visit.

5.1.4.6 Early Termination

A subject will be considered an Early Termination (discontinued) if he/she is dosed with SUBLOCADE and does not complete the study (did not complete the last injection visit [Injection 5]) and the scheduled EOT visit.

5.1.5 General Conventions for Analysis

Continuous variables will be summarised using the descriptive statistics mean, standard deviations (SD), median, minimum and maximum, unless other statistics are specified. Categorical variables will be reported as frequency counts (including number missing) and the percentage of subjects in corresponding categories.

Individual subject data will be presented by subject in data listings. Data listings will include all data collected from the initial screening visit to the Safety follow-up visit (including unscheduled visits).

The derivation of Study Day will be made relative to the date/time of the first administration of SUBLOCADE in this study.

Observed data is used for analysis, unless handling of missing data is described otherwise within the analysis description or in Section 6.5.

If there are ≤ 6 AEs reported, only a listing and no AE summary tables will be produced, except for the table of AE occurrences used for public disclosure. The table of AE occurrences for public disclosure will only be produced if there are ≥ 1 AEs reported.

5.2 Subject Dispositions

The number and percentage of subjects who were screened and were enrolled or not enrolled (See Sections 5.1.4.2 and 5.1.4.3), and the reasons for not enrolling (if applicable), will be summarized for the screened population. The number and percentage of enrolled subjects who completed the study, discontinued and the reasons for discontinuing will be summarized.

The number and percentage of subjects failing entry criteria will be summarized overall and by individual criterion for the screened population.

The number and percentage of subjects in each analysis set will be summarized.

5.3 Primary Endpoint Analysis

The analysis will be performed using the safety population. See Section 6.5 for methods to handle missing data.

5.3.1 Treatment Emergent Adverse Events – Definition of Endpoint

A TEAE is defined as an AE observed after starting, that is having a start date/time on or after the date/time of the first administration of SUBLOCADE in this study. Any AEs ongoing at the INDV-6000-403 EOT were to be recorded in this study; however, note that these are not TEAEs in this study per this definition.

If subject experiences an event both prior to starting administration of SUBLOCADE and ongoing during the treatment, the event will be considered a TEAE (of the treatment) only if it has worsened in severity (i.e., it is reported with the date of worsening as the new start date/time) after starting administration of SUBLOCADE in this study.

Adverse events will be coded using the MedDRA dictionary and grouped by primary system organ class. The Investigator determines the intensity of AEs and the relationship of AEs to study therapy.

5.3.2 Treatment Emergent Adverse Events – Main Analysis Approach

If > 6 AEs are reported, the summaries will be produced as described below. Otherwise, no summaries and only the AE listing will be produced.

The number and percentage of subjects reporting TEAEs at any time during the treatment period (**Section 5.1.4.4**) will be presented by MedDRA system organ class (SOC) and preferred term (PT), each in descending order of frequency (then alphabetically in case of ties).

All TEAEs collected during the treatment period will be presented by system organ class and preferred term, each in descending order of frequency, unless otherwise specified.

If more than one TEAE is coded to the same PT for the same subject, the subject will be counted only once for that PT using the most severe and most related occurrence for the summarizations by severity and by relationship to the study medication.

5.4 Analysis of Other Safety Endpoints

Other safety endpoints include study-medication-related TEAEs, serious TEAEs, study medication-related serious TEAEs, TEAEs leading to treatment discontinuation and concomitant medications (see **Section** Error! Reference source not found.).

The analyses will be performed using the safety population if > 6 AEs are reported. See Section 6.5 for methods to handle missing safety data (e.g., partial dates).

5.4.1 Study Medication-related Adverse Events, Serious Adverse Events and Adverse Events Leading to Study Medication Discontinuation

The number and percentage of subjects reporting study medication-related TEAE, serious TEAE, study medication-related serious TEAE and TEAE leading to study medication discontinuation will be summarised by system organ class and preferred term, as described above in **Section 5.3.2**.

5.4.2 Prior and Concomitant Medications

Any medications ongoing at the INDV-6000-403 EOT were to be recorded in this study. The prior and concomitant medications will be listed.

5.5 Analysis of Other Safety Variables

The analyses will be performed using the safety population. See Section 6.5 for methods to handle missing safety data (e.g., partial dates).

5.5.1 Adverse Events – Additional Analyses

If > 6 AEs are reported, the summaries described below will be produced. If there are ≥1 but ≤ 6 AEs reported, only the AE occurrences summary will be produced.

The TEAE summary table will present the number and percentage of subjects reporting a TEAE in the categories listed in **Table 4.**

Table 4 TEAE Summary Categories

Category
Subjects with Any TEAEs
With Study Medication-Related TEAEs
With Serious TEAEs (SAE)
With Study Medication-Related Serious TEAEs
With Severe TEAEs
With TEAE Leading to Death
With TEAE Leading to Study Medication Discontinuation
With TEAE Leading to Study Medication Interruption
With TEAE Leading to Study Medication Dose Decrease
With TEAE Leading to Study Medication Dose Increase
With Serious TEAE Leading to Study Medication Discontinuation
With Serious TEAE Leading to Study Medication Interruption
With Serious TEAE Leading to Study Medication Dose Decrease
With Serious TEAE Leading to Study Medication Dose Increase

The additional categories of TEAE listed above in Table 4 will be summarized in the same manner as TEAEs **(Section 5.3.2)** if > 6 AEs are reported. TEAEs will also be summarized by maximum intensity, system organ class and preferred term. The number of occurrences of TEAEs and study medication-related TEAEs will be summarized by PT. In addition, the number and percentage of fatal and fatal study medication-related treatment-emergent SAEs will be summarized separately by PT.

If more than one TEAE is coded to the same SOC/PT for the same subject, the subject will be counted only once for that SOC/PT using the most severe and most related occurrence for the summarizations by severity and by relationship to the study medication.

If > 6 AEs are reported, listings will be presented for subjects with AEs, SAEs, AEs leading to discontinuation, and subjects who died (if any). Otherwise, the only listing of AEs presented will be all the AEs listing.

AEs that are not treatment emergent (i.e., AEs that were ongoing at the time of completion of the feeder study INDV-6000-403 and recorded in this study database) will be listed.

5.5.2 Extent of Exposure

The number and percentage of subjects who received at least 1 dose of SUBLOCADE and who received 1, 2, 3, 4 or 5 doses of SUBLOCADE will be summarized. The number and percentage of subjects who received SUBLOCADE 300mg and 100mg will be summarized by injection. The data will be listed.

5.5.3 Adverse events of special interest (AESI)

Adverse events of special interest are:

- SUBLOCADE depot removal
- Occurrences of ALT >3 × ULN and bilirubin >2 × ULN (> 35% direct)

The AESI will be included in the AE and SAE summaries and listings as reported.

5.5.4 Pregnancy Tests

The pregnancy test result data will be listed.

5.5.5 Drug Use History

The screening visit drug use history results will be transferred from the INDV-6000-403 database to serve as the screening visit results for this study.

The following information describes the transferred data:

- Dates of drug use history were collected as month and year.
- The overall lifetime drug use across all substances in years was derived by subject as (the latest Stop Date – the earliest Start Date +1)/12.
- The lifetime use in years was derived for each drug class by subject, as the sum of the [(Stop Date – Start Date +1) / 12] for each drug in the class used by the subject. Where use of individual drugs within a class overlapped, this overlapped time was not be double-counted in the derivation.
- For these derivations, missing end dates (month and year are missing) were set to the month and year of first study medication dose of transmucosal buprenorphine for

induction from the INDV-6000-403 study. Partial dates (i.e., only year is collected) will be imputed as follows:

- Partial start dates were set to the first month of the year.
- Partial end dates were set to the last month of the year.

The number and percentage of subjects reporting each drug class, the years of lifetime use overall and for each drug class, and the use in the last 30 days will be summarized using observed data.

An additional analysis will summarize the number and percentage of subjects who use any opioid via the I.V route.

The drug use history data will be listed.

5.5.6 Medication for Opioid Use Disorder Treatment History

The MOUD treatment history data will be listed.

5.5.7 Urine Drug Screen Results

For each visit, data from the urine drug screen (UDS) results will be assessed to derive the number and percentage of subjects with positive opioid use, using observed data.

For this analysis, opioids will include the results for opioids, methadone, fentanyl, oxycodone, and morphine. If the result for any of these are positive, the subject will be considered positive for opioids.

The usage of individual substances collected via the UDS will be listed.

5.6 Interim Analyses

No formal interim analyses are planned for this study.

6 SUPPORTING DOCUMENTATION

6.1 Appendix 1 List of Abbreviations

Table 5 List of Abbreviations

Abbreviation	Term
AE	adverse event
AESI	adverse event of special interest
ALT	alkaline aminotransferase
BMI	body mass index
CRF/eCRF	case report form/electronic case report form
CSR	clinical study report
ECG	electrocardiogram
EOT	end-of-treatment
ET	early termination
ICF	informed consent form
INDV	Indivior

Abbreviation	Term
MedDRA	Medical Dictionary for Regulatory Activities
MOUD	medication for opioid use disorder
OUD	opioid use disorder
PT	preferred term
SAE	serious adverse event
SAP	statistical analysis plan
SC	subcutaneous
SD	standard deviation
SOC	System Organ Class
TEAE	treatment-emergent adverse event
TLF	tables, listings and figures
UDS	urine drug screen
ULN	upper limit of normal
USPI	United States Prescribing Information

6.2 Appendix 2: Changes to Protocol-Planned Analyses

The definitions of completion of the treatment period versus completing treatment were clarified.

The MOUD treatment history data will be listed only and not summarized.

The reporting of AEs was specified as a listing only and no summary tables in the case of ≤ 6 AEs.

6.3 Appendix 3: Definition and Use of Visits and Visit Windows in Reporting

Nominal visits will be used for the analysis without regard to visit windows. The nominal visits will be labelled in TLFs as Injection 1 – Injection 5 and ET/EOT.

Unscheduled visits will be given an analysis visit number in sequential order according to chronological date/time following the most recent scheduled visit.

6.4 Appendix 4: Definition of Protocol Deviations

A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol. Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy and/or reliability of the study data or that may significantly impact a subject's rights, safety, or wellbeing.

The important deviations will not be considered in the statistical analyses or in the definitions of analysis populations. All deviations will be listed.

6.5 Appendix 5: Methods to Manage Missing Data

Observed data is used for analysis, unless handling of missing data is described otherwise within the analysis description or in the sections below.

6.5.1 Missing Date Information for Adverse Events

If the AE start date is missing, and the AE stop date is on or after the first dose of study medication, then the AE start date will be imputed as the date of the first dose of study medication.

If the AE start date is missing, and the AE stop date is not missing and before the first dose of study medication, then the AE start date will be imputed as the stop date.

Partial AE Start Date

Missing day and month

- If the year is the same as the year of the date of the first dose of study medication, then the day and month of the date of the first dose of study medication will be assigned to the missing fields.

- If the year is before the year of the date of the first dose of study medication, then December 31 will be assigned to the missing fields.

- If the year is after the year of the date of the first dose of study medication, then January 1 will be assigned to the missing fields.

Missing month only

- The day will be treated as missing and both month and day will be replaced according to the above procedure.

Missing day only

- If the month and year are the same as the month and year of the date of the first dose of study medication, then the day of the first dose of study medication will be assigned to the missing day.

- If either the year is before the year of the date of the first dose of study medication or if both years are the same but the month is before the month of the date of the first dose of study medication, then the last day of the month will be assigned to the missing day.

- If either the year is after the year of the date of the first dose of study medication or if both years are the same but the month is after the month of the date of the first dose of study medication, then the first day of the month will be assigned to the missing day.

If the imputed AE start date is after the AE stop date, then the imputed AE start date will be set to the AE stop date.

6.6 Appendix 6: Data Transferred from Study INDV-6000-403

Some data will be transferred from the INDV-6000-403 study database to serve as the screening visit results, as these data are not being re-collected in this extension study (see **Table 3**).

- Demographic data (age, age category, sex, race ethnicity, child-bearing potential, and height) will be transferred from the screening visit of the INDV-6000-403 database. Weight, and BMI will be transferred from the EOT visit of the INDV-6000-403 database. Together, these data will serve as the demographic data at the screening visit for this study.

- Medical/psychiatric history and substance use history (tobacco use, caffeine use, drug use history) will be transferred from the screening visit of the INDV-6000-403 database to serve as the data for the screening visit of this study. The medical/psychiatric history conditions will be coded using the process and MedDRA version per the study coding guidelines.

- The EOT urine pregnancy test result (from the eCRF entry) will be transferred from the INDV-6000-403 database to serve as the screening visit result for this study.

- The EOT UDS test results (from the eCRF entry) will be transferred from the INDV-6000-403 database to serve as the screening visit results for this study.

6.7 Appendix 7: Demographic and Baseline Characteristics

The demographic and disease characteristics at screening (age, age category, sex, race, ethnicity, weight, height, BMI, BMI category, tobacco use, caffeine use) will be summarised for the safety population using descriptive statistics.

The number and percentage of subjects reporting medical/psychiatric history events will be tabulated by SOC and PT, by decreasing frequency, using observed data.

7 REFERENCES

No references.