

STATISTICAL ANALYSIS PLAN

SEP361-309

AN OPEN-LABEL EXTENSION STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF SEP-363856 IN SUBJECTS WITH SCHIZOPHRENIA SWITCHED FROM TYPICAL OR ATYPICAL ANTIPSYCHOTIC AGENTS

PHASE: PHASE III

AUTHOR: PPD

VERSION NUMBER AND DATE: FINAL VERSION 1.0, 22OCT2024

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		Version Date:	22OCT2024

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Statistical Analysis Plan Version 1.0 (Dated 22OCT2024) for Protocol SEP361-309

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Position:	PPD	Signer Name: PPD Signing Reason: I approve this document Signing Time: 2024/10/21   21:31 EDT 14ADB99AAF714328A4052AC949304CB6
Company:	Magnit, Inc.	
Approved By:	PPD	Signed by: PPD
Position:	PPD	Signer Name: PPD Signing Reason: I approve this document Signing Time: 2024/10/22   22:03 JST 15B689A559B14B98A4BDC5B2D561D369
Company:	IQVIA	
Approved By:	PPD	Signed by: PPD
Position:	PPD, Clinical Trials Management	Signer Name: PPD Signing Reason: I approve this document Signing Time: 2024/10/22   07:43 PDT B93E2D87AD04459FAA901A3F441D4D08
Company:	Sumitomo Pharma America, Inc.	

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Version Date: 22OCT2024

MODIFICATION HISTORY

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
Version 1.0	22OCT2024	PPD	First Version

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1. INTRODUCTION

This document describes the rules and conventions to be used in the presentation and analysis of safety, effectiveness and pharmacokinetic (PK) data for Protocol SEP361-309. It describes the data to be summarized and analyzed, including specifics of the statistical analyses to be performed.

This statistical analysis plan (SAP) is based on protocol version 3.00, dated 28MAR2023.

A Pre-Lock Data Review (PLDR) and Important Protocol Deviation (IPD) Review Plan will be written to describe the process and the outputs to be delivered during the IPD/BDR meetings.

The scope of this SAP does not include calculation and statistical analysis of PK parameters of SEP-363856; individual SEP-363856 PK parameters will be determined using population PK approach and results will not be reported in the clinical study report (CSR).

2. STUDY OBJECTIVES AND ENDPOINTS

2.1. STUDY OBJECTIVES

2.1.1. PRIMARY OBJECTIVE

To evaluate the long-term safety and tolerability of flexibly dosed SEP-363856 (50, 75, 100 mg/day) in adult subjects with schizophrenia who have completed Study SEP361-308 by the incidence of overall adverse events (AEs), serious AEs (SAEs), and AEs leading to discontinuation.

2.1.2. OTHER OBJECTIVES

- To evaluate the long-term safety and tolerability of SEP-363856 by assessing:
  - o 12-lead electrocardiograms (ECG)
  - o Vital sign measurements
  - o Clinical laboratory tests

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- o Columbia – Suicide Severity Rating Scale (C-SSRS)
  - o Simpson-Angus Scale (SAS)
  - o Barnes Akathisia Rating Scale (BARS)
  - o Abnormal Involuntary Movement Scale (AIMS)
- To evaluate the long-term effectiveness of SEP-363856 using:
  - o Positive and Negative Syndrome Scale (PANSS)
  - o Clinical Global Impression-Severity (CGI-S) scale
  - o Clinical Global Impression-Improvement (CGI-I) scale
  - o Brief Negative Symptom Scale (BNSS)
- To evaluate the long-term effects of SEP-363856 on health-related quality of life as measured by the Short Form Health Survey (SF-12)
- To evaluate the long-term effects of SEP-363856 on functional capacity as measured by the Personal and Social Performance Scale (PSP)
- To evaluate long-term medication satisfaction as measured by the Medication Satisfaction Questionnaire (MSQ)
- To evaluate long-term sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI)
- To evaluate the long-term impact of SEP-363856 on healthcare resource utilization (HCRU)

## 2.2. STUDY ENDPOINTS

### 2.2.1. PRIMARY ENDPOINT

- The incidence of overall AEs, SAEs, and AEs leading to discontinuation

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**2.2.2. OTHER SAFETY ENDPOINTS**

- Observed values and changes from Baseline of Study SEP361-308 (pre-switch baseline [PS Baseline]) and Baseline of Study SEP361-309 (open-label extension [OLE] Baseline) in clinical laboratory tests (including hematology, chemistry [including but not limited to lipid parameters and Hemoglobin A1c (HbA1c)], and urinalysis) (See Section 21 in protocol)
- Observed values and changes from PS Baseline and OLE Baseline in vital signs (including temperature, body weight, body mass index [BMI], waist circumference, blood pressure [supine and standing], pulse rate [supine and standing] and respiratory rate) and 12-lead ECG parameters
- Frequency of subjects with suicidal ideation and suicidal behavior based on the C-SSRS
- Change from PS Baseline and OLE Baseline in SAS, BARS and AIMS scores
- Change from PS Baseline and OLE Baseline in PSQI scores

**2.2.3. OTHER ENDPOINTS**

- Changes from PS Baseline and OLE Baseline in:
  - o PANSS total score and subscale scores (positive, negative, and general psychopathology)
  - o PANSS Marder Factor (five-factor) scores (positive, disorganized, negative, hostility, and depression/anxiety),
  - o Uncorrelated PANSS (seven-factor) Score Matrix (UPSM) (positive, disorganized, negative apathy/avolition, negative deficit of expression, hostility, anxiety, and depression)
  - o CGI-S score
  - o CGI-I score
  - o BNSS total score
  - o SF-12 scores
  - o PSP total score
  - o MSQ score
- HCRU (including numbers of physician office visits, emergency room (ER) visits and hospitalizations, length of hospital stays, employment status and average number of hours caregiver spend helping subjects per week)

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- Nicotine use

3. STUDY DESIGN

3.1. GENERAL DESCRIPTION

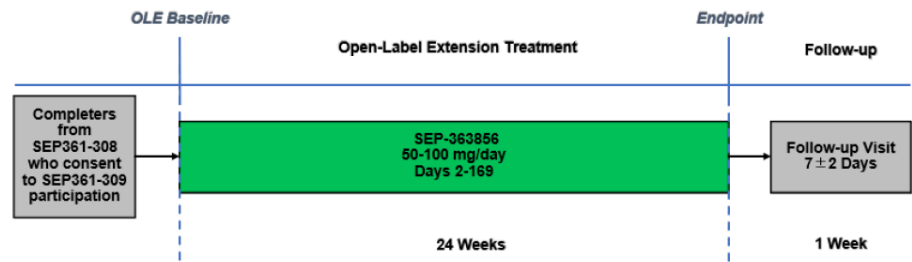
This is a 24-week, outpatient, multicenter, flexible-dose, open-label extension study designed to evaluate the long-term safety and tolerability of SEP-363856 (50 to 100 mg/day) for the treatment of subjects with schizophrenia who have completed Study SEP361-308 treatment period, during which they were switched from a previous antipsychotic treatment to SEP-363856.

The study will consist of two periods: An open-label extension (OLE) Treatment Period (up to 24 weeks), and a Follow-up Period visit at 7 ± 2 days after last study drug dose for subjects who complete the Treatment Period and those who prematurely discontinue from the study (Figure 1).

Subjects who meet the entry criteria and choose to enter the extension study will transition immediately at the End of Treatment (EOT) visit from Study SEP361-308. Subjects who early terminate (ET) from the SEP361-308 study are not eligible to enroll in SEP361-309. The EOT visit from Study SEP361-308 will serve as the OLE Baseline visit for the present study. Informed consent will be obtained from all subjects before any study procedures are performed for the present study.

A study schematic is presented in Figure 1.

Figure 1: Study schematic



Abbreviations: OLE = open-label extension.

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## 3.2. METHOD OF ASSIGNING SUBJECTS TO TREATMENT GROUPS

This is an open label study. There is no randomization planned in this study. All subjects will receive flexible dosing with SEP-363856 (50 to 100 mg/day).

## 3.3. BLINDING

This is an open-label study. All subjects will receive flexible dosing with SEP-363856 (50 to 100 mg/day).

## 3.4. DETERMINATION OF SAMPLE SIZE

All subjects who complete SEP361-308 are eligible to enroll. It is anticipated that approximately 67 subjects will enroll in this study (SEP361-309), assuming 75% of the subjects complete Study SEP361-308 and 75% of the completers will enroll in this study. The sample size is not based on statistical considerations.

## 3.5. CHANGES IN THE CONDUCT OF THE STUDY

The first subject was screened on 19DEC2022 under protocol Version 2.00 (dated 12OCT2022). Additional protocol versions and amendments are listed below.

Protocol version 1.00 (24-Aug-2022)

Protocol version 2.00 (12-Oct-2022); Amendment 1.00 (12-Oct-2022)

Protocol version 3.00 (28-Mar-2023); Amendment 2.00 (28-Mar-2023)

## 3.6. SCHEDULE OF EVENTS

Schedule of events can be found in Section 1, Table 2 of the Clinical Study Protocol (CSP). These tables are also included in APPENDIX 11 of the SAP.

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### 3.7. CHANGES TO ANALYSIS FROM PROTOCOL

There are no changes to analysis from the protocol.

## 4. PLANNED ANALYSES

The following analyses will be performed for this study:

- Final Analysis

### 4.1. DATA AND SAFETY MONITORING BOARD

There is no DSMB planned for this study.

### 4.2. INTERIM ANALYSIS

There is no interim analysis planned for this study.

### 4.3. FINAL ANALYSIS

All final, planned analyses specified in this SAP will be performed by IQVIA following Sumitomo Pharma America, Inc. (SMPA) authorization of this SAP, SMPA authorization of Analysis Populations, Database Lock

Some minor modifications may be necessary to the planned design of tables, figures, and listings to accommodate data collected during the actual study conduct.

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5. ANALYSIS POPULATIONS

Agreement and authorization of subjects included/excluded from each analysis population will be conducted prior to database lock. Enrolled subjects in 361-309 will include all subjects who completed treatment period of Study SEP361-308, signed the informed consent form (ICF) of study 361-309 and were dispensed study medication.

5.1. SAFETY [SAF] POPULATION

The safety population will consist of all subjects who receive at least one dose of study drug during the 24-week OLE treatment period. The Safety Population will be used for the long-term safety, tolerability, and effectiveness analyses.

6. GENERAL CONSIDERATIONS

Study medication refers to SEP-363856 unless otherwise specified.

6.1. REFERENCE START DATE AND STUDY DAY

Study Day will be calculated from the reference start date and will be used to show the start/stop day of assessments and events. Reference start date is defined as the date of the first dose of study medication (Day 1 is the Study Day of the first dose of study medication).

- If the date of assessment or event is prior to the reference start date, then:  
  
Study Day = (date of assessment or event - reference start date).
- If the date of assessment or event is on or after the reference start date, then:  
  
Study Day = (date of assessment or event - reference start date) + 1.

In the situation where the assessment or event date is partial or missing, Study Day and any corresponding durations will appear missing

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in the listings. Partial assessment or event dates will however be presented as is in the listings.

## 6.2. BASELINE

Unless otherwise specified, pre-switch (PS) Baseline is defined as the last non-missing measurement taken prior to the first dose of study medication of study 361-308, including unscheduled assessments. PS Baseline values are essentially the “Baseline” values of study 361-308 and will be directly obtained from the 361-308 ADaM datasets.

Unless otherwise specified, Open-label extension (OLE) Baseline is defined as the last non-missing measurement taken prior to the first dose of OLE study medication of study 361-309, including unscheduled assessments. These values will be derived in 361-309 ADaM datasets using data collected in studies 361-308.

In case no value is available after first dose of PS treatment in 361-308, then PS Baseline and OLE Baseline could coincide.

Whenever available, the time information should be accounted for in the derivation of OLE Baseline values. In the case where time is not available and the date of the last non-missing measurement and the date of the first dose of OLE study medication coincide, that measurement will be considered the OLE Baseline.

OLE Baseline will be derived for the following outcome measures

- PANSS: total score, subscale scores, Marder factor scores, uncorrelated PANSS score matrix (UPSM) factor scores and total factor score, and individual item scores. For a given subject, the OLE Baseline values for all PANSS summary and individual item scores should come from the same assessment (i.e., have the same visit number and assessment start date/time) and it should be the last assessment prior to first dose where PANSS total score is available (i.e., not set to missing). In the rare event where no PANSS total score is available before first dose due to partially completed assessments, the assessment prior to first dose with most PANSS item scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- CGI-S score.
- BNSS: total score, subscale scores, and individual item scores. For a given subject, the OLE Baseline values for all BNSS summary and individual item scores should come from the same assessment and it should be the last assessment prior to first dose where BNSS total score is available. In the rare event where no BNSS total score is available before first dose due to partially completed assessments, the assessment prior to first dose with most BNSS item scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- SF-12 Score.

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- PSP: total score, individual domain scores, and the derived binary variables. For a given subject, the OLE Baseline values for all PSP data should come from the same assessment and it should be the last assessment prior to first dose where PSP total score is available. In the rare event where no PSP total score is available before first dose due to partially completed assessments, the assessment prior to first dose with most PSP individual domain scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- MSQ score.
- C-SSRS: Suicidal ideation categories 1-5 (yes/no) and suicidal behavior categories 6-10 (yes/no); C-SSRS composite endpoints: any suicidal ideation (yes/no), any suicidal behavior (yes/no), any suicidality (yes/no); the suicidal ideation score (0-5). See [Section 17.6.1](#) for the definition of a C-SSRS Baseline.
- SAS: mean score and individual item scores. For a given subject, the OLE Baseline values for all SAS summary and individual item scores should come from the same assessment and it should be the last assessment prior to first dose where SAS mean score is available. In the rare event where no SAS mean score is available before first dose due to partially completed assessments, the assessment prior to first dose with most SAS item scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- BARS: total score and individual item scores. For a given subject, the OLE Baseline values for all BARS summary and individual item scores should come from the same assessment and it should be the last assessment prior to first dose where BARS total score is available. In the rare event where no BARS total score is available before first dose due to partially completed assessments, the assessment prior to first dose with most BARS item scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- AIMS: total score and individual item scores. For a given subject, the OLE Baseline values for all AIMS summary and individual item scores should come from the same assessment and it should be the last assessment prior to first dose where AIMS total score is available. In the rare event where no AIMS total score is available before first dose due to partially completed assessments, the assessment prior to first dose with most AIMS item scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- PSQI: global score, component scores, and individual item scores. For a given subject, the OLE Baseline values for all PSQI summary and individual item scores should come from the same assessment and it should be the last assessment prior to first dose where PSQI global score is available. In the rare event where no PSQI global score is available before first dose due to partially completed assessments, the assessment prior to first dose with most PSQI item scores available should be taken as the OLE Baseline assessment for all raw and derived scores as applicable.
- Clinical laboratory parameters (blood chemistry, hematology, urinalysis, HOMA-IR (if collected)). For a given subject, the OLE Baseline values for the clinical laboratory parameters do not have to all come from the same assessment; the only exception is: the OLE Baseline flag for the counts

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of leukocytes and its differential should be applied to records from the same assessment and it should be the last assessment prior to first dose where counts of leukocytes and its differential are reported. OLE Baseline flag does not need to be derived for RBC morphology findings, WBC morphology findings, and urinalysis microscopic examination findings (excluding urine erythrocytes and leukocytes).

- Urine drug screening: For a given subject, the OLE Baseline values for all urine drug screening parameters should come from the same assessment and it should be the last assessment prior to first dose where a urine drug screening test was administered.
- Vital sign parameters (supine and standing systolic blood pressure [SBP], supine and standing diastolic blood pressure [DBP], supine and standing pulse rate, respiratory rate, oral temperature), height, weight, BMI, and waist circumference. For a given subject, the OLE Baseline values for all vital sign parameters, height, weight, BMI, and waist circumference do not have to come from the same assessment; the only exceptions are: (1) the OLE Baseline flag for weight and BMI should be applied to records from the same assessment and it should be the last assessment prior to first dose where weight is available, (2) the OLE Baseline flag for supine SBP and DBP, standing SBP and DBP, and the derived corresponding orthostatic endpoints (i.e., standing SBP – supine SBP; standing DBP – supine DBP) should be applied to records from the same assessment and it should be the last assessment prior to first dose where all four BP measures are available, (3) the OLE Baseline flag for supine and standing pulse rate and the derived corresponding orthostatic endpoint (i.e., standing pulse rate – supine pulse rate) should be applied to records from the same assessment and it should be the last assessment prior to first dose where both pulse rate measures are available.
- ECG parameters: For a given subject, the OLE Baseline values for all ECG parameters do not have to come from the same assessment. OLE Baseline flag does not need to be derived for ECG parameters in the category of “FINDINGS”.
- Nicotine use data: OLE Baseline of this outcome measure should be taken strictly from the assessment given at week 8 of SEP361-308 without regard to its temporal relationship to the first dose of study medication.
- Healthcare resource utilization data: OLE Baseline of this outcome measure should be taken strictly from the assessment used as the pre-switch baseline of SEP361-308.

The OLE Baseline flag may be derived for additional outcome measures based on the needs during analyses.

### 6.3. DERIVED TIMEPOINTS

The last non-missing post-Baseline (i.e., post-first dose) measurement collected during the study up to and including the Visit 7E (EOT/ET) measurement will be carried forward and defined as the last observation carried forward (LOCF) endpoint. Both scheduled and unscheduled assessments as well as the early termination assessments that are collected during this period will contribute to the

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derivation of the LOCF endpoint. However, unscheduled measurements taken after the Visit 7E (EOT/ET) measurement will not be used in the derivation.

The LOCF endpoint will be derived for the following outcome measures:

- PANSS: total score, subscale scores, Marder factor scores, UPSM factor scores and total factor score, individual item scores, and derived binary variables for PANSS response. For a given subject, the LOCF values for all PANSS summary and individual item scores and derived binary variables should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where PANSS total score is available. In the rare event where no PANSS total score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.
- CGI-S score.
- BNSS: total score, subscale scores, and individual item scores. For a given subject, the LOCF values for all BNSS summary and individual item scores should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where BNSS total score is available. In the rare event where no BNSS total score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.
- SF-12.
- PSP: total score, individual domain scores, and the derived binary variables. For a given subject, the LOCF values for all PSP data should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where PSP total score is available. In the rare event where no PSP total score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.
- MSQ score.
- C-SSRS suicidal ideation score (0-5).
- SAS: mean score and individual item scores. For a given subject, the LOCF values for all SAS summary and individual item scores should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where SAS mean score is available. In the rare event where no SAS mean score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.

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- BARS: total score and individual item scores. For a given subject, the LOCF values for all BARS summary and individual item scores should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where BARS total score is available. In the rare event where no BARS total score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.
- AIMS: total score and individual item scores. For a given subject, the LOCF values for all AIMS summary and individual item scores should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where AIMS total score is available. In the rare event where no AIMS total score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.
- PSQI: global score, component scores, and individual item scores. For a given subject, the LOCF values for all PSQI summary and individual item scores should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where PSQI global score is available. In the rare event where no PSQI global score is available after first dose due to partially completed assessments, the last post-Baseline assessment up to and including Visit 7E should be taken as the LOCF assessment for all raw and derived scores as applicable.
- CGI-I.
- Clinical laboratory parameters (blood chemistry, hematology, urinalysis, HOMA-IR (if collected)). For a given subject, the LOCF values for the clinical laboratory parameters do not have to all come from the same assessment; the only exception is: the LOCF flag for the counts of leukocytes and its differential should be applied to records from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where counts of leukocytes and its differential are reported. LOCF endpoint does not need to be derived for RBC morphology findings, WBC morphology findings, and urinalysis microscopic examination findings (excluding urine erythrocytes and leukocytes).
- Urine drug screening: For a given subject, the LOCF values for all urine drug screening parameters should come from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where a urine drug screening test was administered.
- Vital sign parameters (supine and standing SBP, supine and standing DBP, supine and standing pulse rate, respiratory rate, oral temperature), weight, BMI, and waist circumference. For a given subject, the LOCF values for all vital sign parameters, height, weight, BMI, and waist circumference do not have to come from the same assessment; the only exceptions are: (1) the LOCF flag for weight and BMI should be applied to records from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where weight is available (2) the LOCF flag for supine SBP and DBP, standing SBP and DBP, and the derived corresponding orthostatic endpoints (i.e., standing SBP – supine SBP; standing DBP – supine DBP) should be applied to records from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where all four BP measures are available, (3) the LOCF flag for supine and standing pulse rate and the derived

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corresponding orthostatic endpoint (i.e., standing pulse rate – supine pulse rate) should be applied to records from the same assessment and it should be the last post-Baseline assessment up to and including Visit 7E where both pulse rate measures are available.

- ECG parameters: For a given subject, the LOCF values for all ECG parameters do not have to come from the same assessment. LOCF endpoint does not need to be derived for ECG parameters in the category of “FINDING”.
- Nicotine use data: LOCF of this outcome measure should come from the same assessment and it should be the last assessment post first dose up to and including Visit 7E where any data are reported.
- Healthcare resource utilization data: LOCF of this outcome measure should come from the same assessment and it should be the last assessment post first dose up to and including Visit 7E where any data are reported.

The study visits will be mapped to analysis visits for table summaries and statistical analyses where applicable (Table 1).

**Table 1: Mapping of study visits to analysis visits.**

Study Visit	Analysis Visit Number	Analysis Visit
NA	0	PS Baseline
NA	0.5	OLE Baseline
Visit 1E	1	Visit 1E*
Visit 2E	2	Week 4/Visit 2E
Visit 3E	3	Week 8/Visit 3E
Visit 4E	4	Week 12/Visit 4E
Visit 5E	5	Week 16/Visit 5E
Visit 6E	6	Week 20/Visit 6E
Visit 7E (if representing true EOT visit). For ET visit mapping see Section 6.4)	7	Week 24/Visit 7E

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Study Visit	Analysis Visit Number	Analysis Visit
Visit 8E	8	Week 25/Follow up/Visit 8E

\* Several assessments from that visit are collected in 361-308 study.

Original study visit collected on the case report forms (CRFs) will be displayed in the listings.

6.4. RETESTS, UNSCHEDULED VISITS, AND EARLY TERMINATION DATA

In general, for by-visit summaries, data recorded at the planned visits where assessment is intended to be given will be presented, as well as the derived PS Baseline and OLE Baseline value and the LOCF value.

Unscheduled measurements will not be included in by-visit summaries as a separate time point. However,

- Unscheduled measurements collected prior to the first dose of study medication in 361-308 contributed to the derivation of the PS Baseline value.
- Unscheduled measurements collected in 361-308 or 361-309 prior to the first dose of OLE study medication in 361-309 will contribute to the derivation of the OLE Baseline value.
- Unscheduled measurements collected post-OLE Baseline in 361-309 will contribute to the derivation of the LOCF value, the potential clinically significant (PCS) value, and the best/worst case value where required (e.g., shift table).

In the case of a retest, the assessment recorded under the planned visit will be used for by-visit summaries, and the assessment(s) recorded under unscheduled visit(s) will be presented in listings only.

As per protocol, study Visit 7E can be a Week 24/End of Treatment (EOT) visit or an Early Termination (ET) visit. If a subject terminates early, his/her measurements taken at the ET visit will be mapped to the next planned visit (after the last scheduled visit the subject attended) during which that assessment was expected to be performed as specified by the Schedule of Assessments table in the protocol. This applies to both safety and effectiveness data.

Listings will include scheduled, unscheduled, retest and early discontinuation data with original dates and visits displayed.

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6.5. WINDOWING CONVENTIONS

No visit windowing will be performed during the analysis for this study. Data will be analyzed according to the schedule outlined in the CSP.

6.6. STATISTICAL TESTS

The default significance level will be 5%; confidence intervals (CIs) will be 95%. All CIs will be two-sided, unless otherwise specified in the description of the analyses or the outputs.

6.7. COMMON CALCULATIONS

For quantitative measurements, change from Baseline will be calculated as:

- Test Value at Visit X - Baseline Value

For PANSS total score, percentage change from Baseline will be calculated as:

- (Test Value at Visit X - Baseline Value) × 100 / (Baseline Value - 30)

For other quantitative measurements, percentage change from Baseline will be calculated as:

- (Test Value at Visit X - Baseline Value) × 100 / Baseline Value

6.8. SOFTWARE VERSION

All analyses will be conducted using SAS version 9.4 or later.

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7. STATISTICAL CONSIDERATIONS

7.1. ADJUSTMENTS FOR COVARIATES AND FACTORS TO BE INCLUDED IN ANALYSES

No statistical comparison will be conducted, so no adjustments for covariates and factors are to be considered.

7.2. MULTICENTER STUDIES

This study will be conducted by multiple investigators at multiple centers in the US.  
Center pooling will not be implemented in analyses for this study.

7.3. MISSING DATA

Individual missing items in any scale will not be imputed in any analysis. When calculating a total score, subscale score, or any summary scores based on more than one item, if one or more items are missing at a visit, then the associated summary score will be set to missing. For additional details, see the individual scale description sections.

- Handling of missing effectiveness data, if any, is described in Sections [16.10](#).
- Handling of missing safety data, if any, is described in Sections [17.3](#) and [17.8](#).
- See [APPENDIX 2](#) for details of handling incomplete/missing dates.

7.4. MULTIPLE COMPARISONS/ MULTIPLICITY

No statistical comparison will be conducted, so no multiplicity adjustment will be performed.

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## 7.5. EXAMINATION OF SUBGROUPS

Subgroup analyses will be conducted for subjects as stated in Section [16.1](#) for PANSS, Section [16.2](#) for CGI-S, and Section [17.3.9](#) for Adverse Events.

The following subgroups will be assessed:

- Sex:
  - o Female
  - o Male
- Age group:
  - o ≤40 years
  - o >40 years
- Race (in 3 categories):
  - o White (White)
  - o Black (Black or African American)
  - o Other (All other races combined)
- BMI (kg/m<sup>2</sup>) categories at PS Baseline and OLE Baseline:
  - o Underweight: <18.5 kg/m<sup>2</sup>
  - o Normal: ≥18.5 to <25.0 kg/m<sup>2</sup>
  - o Overweight: ≥25.0 to <30.0 kg/m<sup>2</sup>
  - o Obese: ≥30.0 kg/m<sup>2</sup>
- Baseline patient type based on UPSM factor scores at PS Baseline and OLE Baseline ([Hopkins S. , Ogirala, Loebel, & Koblan, 2020](#)) (only used in the subgroup analysis of PANSS total score):
  - o Type 1: Prominently Disorganized
  - o Type 2: Prominently Negative

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- o Type 3: Prominently Hostile
- o Type 4: Prominently Positive
- o Type 5: Prominently Affective

Subjects will be classified into one of 5 patient types based on their PANSS UPSM factor scores at Baseline. See [APPENDIX 9](#) for details of how the classification will be made.

- Primary Reason for Switch (this will be obtained from study SEP361-308):
  - o Side Effect
  - o Lack of Efficacy
- Duration of Switch (this will be obtained from study SEP361-308):
  - o 2 weeks
  - o 3 weeks
  - o 4 weeks
  - o 5 weeks
  - o 6 weeks
- Type of Pre-switch Antipsychotic (this will be obtained from study SEP361-308):
  - o Partial Agonist
  - o Strong M1/H1 Antagonist
  - o Strong D2/3 Antagonist
  - o Sedating
  - o Non-sedating
- Pre-switch AP Dose Level (this will be obtained from study SEP361-308):
  - o <= 6 mg HAL equivalent

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- > 6 mg HAL equivalent
- Metabolic Status at PS Baseline and OLE Baseline:
  - Metabolic Syndrome
  - No Metabolic Syndrome
- Reason for Clinical Discontinuation
  - Adverse Event
  - Lack of Efficacy

#### 7.5.1. DERIVATION OF SUBGROUPS

Metabolic Status will be derived for both PS Baseline and OLE Baseline using the following:

If a male subject meets at least 3 out of 5 of the characteristics listed below, the subject is considered metabolically impaired at PS Baseline or OLE Baseline.

1. Baseline waist circumference  $\geq 102$  cm
2. Baseline fasting triglycerides  $\geq 150$  mg/dL (1.7 mmol/L) or use of drug treatment for elevated triglycerides at Baseline
3. Baseline fasting HDL  $< 40$  mg/dL (1.0 mmol/L) or use of drug treatment for reduced HDL at Baseline
4. (Baseline supine systolic blood pressure  $\geq 130$  mmHg and/or Baseline supine diastolic blood pressure  $\geq 85$  mmHg) or use of anti-hypertensive medications at Baseline
5. Baseline fasting glucose  $\geq 100$  mg/dL or use of antidiabetic medications at Baseline

If a female subject meets at least 3 out of 5 of the characteristics listed below, the subject is considered metabolically impaired at PS Baseline or OLE Baseline.

1. Baseline waist circumference  $\geq 88$  cm.
2. Baseline fasting triglycerides  $\geq 150$  mg/dL (1.7 mmol/L) or use of drug treatment for elevated triglycerides at Baseline

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3. Baseline fasting HDL < 50 mg/dL (1.3 mmol/L) or use of drug treatment for reduced HDL at Baseline
4. (Baseline supine systolic blood pressure  $\geq$  130 mmHg and/or Baseline supine diastolic blood pressure  $\geq$  85 mmHg) or use of anti-hypertensive medications at Baseline
5. Baseline fasting glucose  $\geq$  100 mg/dL or use of antidiabetic medications at Baseline

## 8. OUTPUT PRESENTATIONS

APPENDIX 1 shows conventions for presentation of data in outputs.

The templates provided with this SAP describe the presentations for this study and therefore the format and content of the summary tables, figures, and listings to be provided by IQVIA.

## 9. DISPOSITION AND WITHDRAWALS

Unless otherwise specified, the disposition summary tables will include the columns: SEP-363856 50 to 100 mg/day.

All subjects who were enrolled will be accounted for in this study.

The number and percentage of subjects who enrolled in study 361-309, received at least one dose of OLE study medication, enrolled but did not receive OLE study medication, and completed or discontinued from the OLE treatment period (including reasons for discontinuation) will be presented.

Discontinuation by visit will be summarized for the enrolled subjects.

The number and percentage of enrolled subjects will also be summarized by Site.

Lastly, the number and percentage of enrolled subjects included in and excluded from the safety population will be summarized, along with the reason for exclusion.

### COVID-19 related analysis updates:

*The number of subjects who failed enrollment due to COVID-19 related reasons, who discontinued early due to COVID-19 related reasons will be summarized in the disposition table.*

*Subjects affected by COVID-19 related study disruptions will be provided in data listings. These subjects will be identified as:*

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- *Subjects who failed enrollment due to COVID-19.*
- *Subjects who were enrolled but discontinued from the OLE treatment period due to COVID-19.*
- *Subjects who experienced a pre-treatment event / adverse event related to COVID-19.*
- *Subjects who had any protocol deviations related to COVID-19.*
- *Subjects who had any investigator comments related to COVID-19.*

A subject may be identified in one or more categories listed above.

9.1. DERIVATIONS

- Time to discontinuation of the treatment in days.

For the purpose of this analysis, a subject’s last dose date will be derived as follows:

- o If a subject’s observed last dose date is before or on the date of Study Day 168, the derived last dose date will be set to the observed last dose date.
- o If a subject’s observed last dose date is after the date of Study Day 168, the derived last dose date will be set to the date of Study Day 168.

Time to discontinuation (days) = Derived last dose date – First dose date + 1.

The event of interest is the discontinuation of treatment. Subjects who completed the treatment will be censored on the derived last dose date.

10. IMPORTANT PROTOCOL DEVIATIONS

Important protocol deviations (IPDs) will be identified and documented based on data listings and the protocol deviations log; the data will be presented separately.

Unless otherwise specified, the IPD summary tables will include the following columns: SEP-363856 50 to 100mg/day.

The IPD categories may include, but may not be limited to:

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- Did not satisfy inclusion and/or exclusion criteria for SEP361-309.
- Received prohibited medication in study SEP361-309.
- Overall compliance rate <75% or >125%.

IPDs will be identified and presented in a data listing. The number and percentage of subjects within each IPD category will be summarized for the SAF population.

A dedicated listing will present protocol deviations related to COVID-19.

## 11. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Unless otherwise specified, the demographic and Baseline characteristics summary tables will include the column: SEP-363856 50 to 100 mg/day.

Demographic data and other Baseline characteristics will be presented for the SAF population. The data will be presented by the treatment group.

No statistical testing will be carried out for demographic or other Baseline characteristics.

The following demographic and other Baseline characteristics will be reported for this study.

Age (years) - calculated relative to date of informed consent in SEP361-308; as a continuous variable

- Age (years) categories:
  - <18 years
  - ≥18 to ≤40 years
  - >40 to ≤65 years
  - >65 years
- Age (years) categories for ClinicalTrials.gov (CTR.GOV):
  - ≤18 years
  - >18 to <65 years
  - ≥65 years

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- Age (years) categories for European Union Drug Regulating Authorities Clinical Trials Database (EudraCT):
  - <12 years
  - ≥12 to <18 years
  - ≥18 to <65 years
  - ≥65 years
- Sex:
  - Female
  - Male
- Race:
  - American Indian or Alaska Native
  - Asian
  - Black or African American
  - Native Hawaiian or Other Pacific Islander
  - White
  - Multiracial
  - Other
- Ethnicity:
  - Hispanic or Latino
  - Not Hispanic or Latino
- Country :
  - United States
- PS Baseline Height (cm), as a continuous variable
- PS Baseline and OLE Baseline Weight (kg), as a continuous variable

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- PS Baseline and OLE Baseline BMI (kg/m<sup>2</sup>), as a continuous variable
- PS Baseline and OLE Baseline BMI (kg/m<sup>2</sup>) category:
  - Underweight: <18.5 kg/m<sup>2</sup>
  - Normal: ≥18.5 to <25.0 kg/m<sup>2</sup>
  - Overweight: ≥25.0 to <30.0 kg/m<sup>2</sup>
  - Obese: ≥30.0 kg/m<sup>2</sup>
- PS Baseline and OLE Baseline Waist Circumference (cm), as a continuous variable
- PS Baseline and OLE Baseline PANSS Total Score, as a continuous variable
- PS Baseline and OLE Baseline PANSS Total Score categories:
  - < Overall median Baseline value
  - ≥ Overall median Baseline value
- PS Baseline and OLE Baseline PANSS Subscale Scores, as continuous variables
- PS Baseline and OLE Baseline PANSS Subscale Score categories:
  - < Overall median Baseline value
  - ≥ Overall median Baseline value
- PS Baseline and OLE Baseline PANSS Positive vs Negative Subscale Score categories:
  - Positive Subscale Score < Negative Subscale Score
  - Positive Subscale Score ≥ Negative Subscale Score
- Patient type based on PS Baseline and OLE Baseline UPSM factor scores:
  - Type 1: Prominently Disorganized
  - Type 2: Prominently Negative
  - Type 3: Prominently Hostile
  - Type 4: Prominently Positive
  - Type 5: Prominently Affective

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- PS Baseline and OLE Baseline CGI-S Score, as a continuous variable
- PS Baseline and OLE Baseline CGI-S Score categories:
  - o <4
  - o ≥4 to ≤5
  - o >5

The following psychiatric history data will be summarized for Safety Population. All values were collected or derived in the 361-308 study:

- Prior Antipsychotic Drug Administration
  - o 1
  - o 2
- Number of subjects who agreed to tokenization
- DSM-5 schizophrenia subtype diagnosis:
  - o 295.90 Schizophrenia
  - o 293.89 Schizophrenia with Catatonia
- Any other current psychiatric disorders:
  - o Yes
  - o No

Diagnosis and DSM-5 code for any other current psychiatric disorders will be summarized in a separate table. These other current psychiatric disorders will be coded using Medical Dictionary for Regulatory Activities (MedDRA) central coding dictionary, Version 22.0, and presented by System Organ Class (SOC) and Preferred Term (PT).

11.1. DERIVATIONS

- BMI expressed in kg/m²:  
  
Weight (kg)/ height (m)².

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All other derivations if applicable are detailed in 361-308 Statistical Analysis Plans, and all derivations are done in 361-308 ADaM datasets.

12. MEDICAL HISTORY

Unless otherwise specified, the medical and surgical history summary tables will include the column: SEP-363856 50 to 100 mg/day.

Medical and surgical history information, including both past and concomitant medical conditions and major surgical history, as collected on the “Medical History” CRF form, will be coded using MedDRA, Version 22.0 or higher, and presented by SOC and PT for the SAF population by the actual treatment group. Data will be sorted by SOC based on the internationally agreed order (APPENDIX 4) and by PT in decreasing frequency.

13. MEDICATIONS

Unless otherwise specified, the medications summary tables will include the following columns: SEP-363856 50 to 100 mg/day.

Medications will be coded to Anatomical Therapeutic Chemical (ATC) Levels and Preferred Names according to World Health Organization Drug (WHODRUG) dictionary, Version 01MAR2019 or later.

Whenever available, the time information should be accounted for in the derivation of prior, concomitant, and post-treatment medications. See APPENDIX 2 for the handling of partial dates for medications. In the case where it is not possible to define a medication as prior, concomitant, or post treatment, the medication will be classified by the worst case; i.e., concomitant.

- Prior medications are medications which stopped prior to the first dose of OLE study medication.
- Concomitant medications are medications which started at the same time of or after the first dose of OLE study medication and at the same time of or before the last dose of OLE study medication; or started prior to and ended at the same time of or after the first dose of OLE study medication; or started at the same time of or prior to the last dose of OLE study medication and marked as ongoing.
- Post-treatment medications are medications which started after the last dose of OLE study medication.

Prior and concomitant medication use will be summarized by ATC Level 3 and Preferred Base Name for the SAF population by the actual treatment group. Medications will be sorted by ATC Level 3 alphabetically and by Preferred Base Name in decreasing frequency in the “SEP-363856 50 to 100 mg/day” column. Similar summary for primary and secondary prior antipsychotic drug administration will also be presented separately.

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Descriptive statistics of primary prior antipsychotic drug dosage at each visit will be presented.

Prior, concomitant, and post-treatment medications will be provided in data listings.

Psychotropic and/or Sedating Medications taken by subjects prior to each visit as collected on the “*Timing of last dose of Psychotropic and/or Sedating Medications*” CRF form will be summarized by ATC Level 3 and Preferred Base Name for the SAF population by visit.

## 14. STUDY MEDICATION EXPOSURE

Unless otherwise specified, the study medication exposure summary tables will include the column: SEP-363856 50 to 100 mg/day.

Exposure to study medication data will be summarized for the SAF population.

Duration of exposure (in days) will be summarized both as a continuous variable for the treatment period and categorically:

- Number and percentage of subjects with exposure  $\geq 1$ ,  $\geq 28$ ,  $\geq 56$ ,  $\geq 84$ ,  $\geq 112$ ,  $\geq 140$ ,  $\geq 168$  days
- Number and percentage of subjects with exposure for 1 - 27, 28 - 55, 56 - 83, 84 - 111, 112 - 139, 140 – 167 and  $\geq 168$  days

Total person-years of exposure will be calculated for all subjects.

Mean daily dose and modal daily dose will be calculated for the treatment period and summarized.

The dose adjustment decision at each visit will be summarized in a shift table.

Lastly, the number of days that a subject received the 50 mg/day dose level, the 75 mg/day dose level and 100 mg/day dose level will be summarized for the SAF population both as a continuous variable and categorically:

- Number and percentage of subjects with exposure to a particular dose level for 1 - 27, 28 - 55, 56 - 83, 84 - 111, 112 - 139, 140 – 197 and  $\geq 198$  days

### 14.1. DERIVATIONS

- Duration of exposure (days) = date of last dose of OLE study drug – date of first dose of OLE study drug + 1. Interruptions in exposure (i.e., missed doses) and dose changes (if any) are not considered in the calculation of overall exposure.
- Total person-years of exposure is the sum of all durations of exposure in days / 365.25.

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- Mean daily dose (mg/day):

$$\frac{\sum \text{Dose per tablet for Visit } j * (\# \text{ Tablets Dispensed for Visit } j - \# \text{ Tablets Returned for Visit } j - \# \text{ Tablets Lost for Visit } j)}{\text{Duration of Exposure}}$$

If the number of tablets dispensed, returned, and/or lost as collected on the “*Study Treatment Administration as Collected / Drug Accountability Log*” CRF form is missing for one or more visits, the mean daily dose will be calculated based on visits with complete drug accountability data available. That is, the numerator of the formula above will only include visits with the number of tablets dispensed, returned, and lost available, and the denominator should be adjusted to exclude dosing periods covered by visits excluded from the calculation (i.e., Duration of Exposure – dosing periods [sum of (EXENDTC – EXSTDTC+1)] covered by visits with missing or incomplete accountability data). If the dose level of a visit is unknown, that visit should be excluded from the calculation as well in both the numerator and the denominator.

- Modal daily dose will be determined as the daily dose that is taken for the most time (in terms of number of days) among all doses taken. A subject’s modal daily dose may fall in one of the categories below:
  - o SEP-363856 50 mg/day
  - o SEP-363856 75 mg/day
  - o SEP-363856 100 mg/day
  - o Tie between xx and yy (i.e. the subject was on xx mg/day and yy mg/day for the same amount of time) (if needed)

## 15. STUDY MEDICATION COMPLIANCE

Unless otherwise specified, the study medication compliance summary tables will include the column SEP-363856 50 to 100 mg/day.

Compliance to study medication will be presented for the SAF population.

Percent compliance will be calculated overall for the treatment period. Non-compliance is defined as less than 75% or more than 125% non-missing compliance for the treatment period. Subjects with missing compliance will not be classified as non-compliant. Compliance will be summarized both as a continuous variable and categorically (i.e., number and percentage of subjects with compliance < 75%, 75% - 125%, > 125%, and missing).

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Overall Compliance (%) to study medication in percentage will be calculated as follows:

$$\frac{\sum(\# \text{ Tablets Dispensed for Visit } j - \# \text{ Tablets Returned for Visit } j - \# \text{ Tablets Lost for Visit } j)}{\# \text{ Tablets should be taken per day} \times \text{Duration of Exposure}} \times 100\%$$

If the number of tablets dispensed, returned, and/or lost as collected on the “*Study Treatment Administration / Drug Accountability Log*” CRF form is missing for one or more visits, the overall compliance will be calculated based on visits with complete drug accountability data available. That is, the numerator of the formula above will only include visits with the number of tablets dispensed, returned, and lost available, and the denominator should be adjusted to exclude dosing periods covered by visits excluded from the calculation (i.e., change “Duration of Exposure” to be Duration of Exposure – dosing periods [sum of (EXENDTC – EXSTDTC+1)] covered by visits with missing or incomplete accountability data).

16. EFFECTIVENESS OUTCOMES

Unless otherwise specified, the effectiveness analysis and summary tables will include the columns: SEP-363856 50 to 100 mg/day.

All analyses of the effectiveness variables will be based on the SAF population.

Descriptive statistics presented for effectiveness outcomes include sample size, mean, standard deviation, minimum, median, maximum, and a 95% confidence interval. Confidence intervals will be based on means and standard deviations estimated without adjustment for any center or baseline effects.

16.1. PANSS

The PANSS (Positive and Negative Syndrome Scale) is an interview-based measure of the severity of psychopathology in adults with psychotic disorders and comprises 30 items and 3 subscales. The positive subscale assesses hallucinations, delusions, and related symptoms (7 items); the negative subscale assesses emotional withdrawal, lack of motivation, and related symptoms (7 items); and the general psychopathology subscale assesses other symptoms such as anxiety, somatic concern, and disorientation (16 items). An anchored Likert scale from 1 to 7 (1 = absent, 7 = extreme, with values of 2 and above indicating the presence of progressively more severe symptoms) is used to score each item.

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Individual items are summed to derive the following scores:

Total score = sum of all 30 items. Total score ranges from 30 to 210.

Subscale scores = sum of items within each of the following subscales:

- Positive subscale: delusions, conceptual disorganization, hallucinatory behavior, excitement, grandiosity, suspiciousness/persecution, hostility. The subscale score ranges from 7 to 49.
- Negative subscale: blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, difficulty in abstract thinking, lack of spontaneity and flow of conversation, stereotyped thinking. This subscale score ranges from 7 to 49.
- General psychopathology subscale: somatic concern, anxiety, guilt feelings, tensions, mannerisms and posturing, depression, motor retardation, uncooperativeness, unusual thought content, disorientation, poor attention, lack of judgment and insight, disturbance of volition, poor impulse control, preoccupation, active social avoidance. This subscale score ranges from 16 to 112.

Marder factor scores = sum of items within each of the following factors (Marder, Davis, Chouinard. 1997):

- Negative symptoms: blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, lack of spontaneity and flow of conversation, motor retardation, active social avoidance. This Marder factor score ranges from 7 to 49.
- Positive symptoms: delusions, hallucinatory behavior, grandiosity, suspiciousness/persecution, stereotyped thinking, somatic concern, unusual thought content, lack of judgment and insight. This Marder factor score ranges from 8 to 56.
- Disorganized thought: conceptual disorganization, difficulty in abstract thinking, mannerisms and posturing, poor attention, disturbance of volition, preoccupation, disorientation. This Marder factor score ranges from 7 to 49.
- Uncontrolled hostility/excitement: excitement, hostility, uncooperativeness, poor impulse control. This Marder factor score ranges from 4 to 28.
- Anxiety/depression: anxiety, guilt feelings, tension, depression. This Marder factor score ranges from 4 to 28.

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UPSM (Uncorrelated PANSS Score Matrix) factor scores = PANSS item scores of each subject at each visit transformed using the UPSM to obtain scores of 7 transformed PANSS factors (Hopkins et al. 2018):

- POS: Positive
- DIS: Disorganized
- NAA: Negative apathy/avolition
- NDE: Negative deficit of expression
- HOS: Hostility
- ANX: Anxiety
- DEP: Depression

The transformation will be done as follows:

- $[\text{Transformed PANSS Factor Data}]_{(N \times 7)} = [\text{PANSS Data}]_{(N \times 30)} * [\text{UPSM}]_{(30 \times 7)}$
- where

$[\text{Transformed PANSS Factor Data}]_{(N \times 7)}$  is the transformed matrix with N sets of scores for the 7 transformed PANSS factors.

$[\text{PANSS Data}]_{(N \times 30)}$  is a matrix with N PANSS assessments and 30 columns containing the scores of 30 PANSS items ordered in the same way as shown in UPSM.

$[\text{UPSM}]_{(30 \times 7)}$  is a matrix with 30 rows (one for each PANSS item) and 7 columns (one for each of the 7 transformed PANSS factors). This matrix is presented in [APPENDIX 3](#).

UPSM total factor score = sum of the 7 UPSM factor scores.

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PANSS is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E.

**16.1.1. PANSS TOTAL SCORE**

PANSS is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E. The PS Baseline and OLE Baseline PANSS total score will be derived as described in [Section 6.2](#). The change from PS Baseline and OLE Baseline in PANSS total score at all the post-Baseline time points, will be derived as described in [Section 6.7](#).

The observed PANSS total score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit.

The observed PANSS total score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit for each subgroup listed in [Section 7.5](#).

**16.1.2. PROPORTION OF SUBJECTS WHO ACHIEVE A RESPONSE**

PANSS response is defined as a 20% or greater improvement (i.e., decrease) in PANSS total score from PS Baseline.

The percent change in PANSS total score from PS Baseline will be calculated by:

$$\frac{\text{PANSS total score at a visit or the LOCF endpoint} - \text{PANSS total score at PS Baseline}}{\text{PANSS total score at PS Baseline} - 30} \times 100\%$$

For each subject, the responder indicator will be set to 1 if the percent change is negative and the magnitude is equal to or greater than 20%. The indicator will be set to 0 if the percentage is negative but the magnitude is less than 20% or if the percentage is non-negative. The indicator will be set to missing if the percentage is missing.

In addition, PANSS response defined by two more stringent thresholds will be assessed; that is, having a 30% or greater, and 50% or greater improvement in PANSS total score from PS Baseline.

PANSS response at all three thresholds will be derived for all scheduled OLE study visits and LOCF.

The number and percentage of subjects who achieve a PANSS response (at each of the three thresholds) will be summarized descriptively

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for each scheduled OLE study visit (starting from Visit 1E) and LOCF.

Lastly, the proportion of subjects achieving a given percentage change threshold in PANSS total score from PS Baseline at the LOCF endpoint will be calculated. This calculation will be performed at multiple thresholds, starting from 100% and increases at 5% increments until all subjects are accounted for.

### 16.1.3. PANSS SUBSCALE SCORES

Individual items from the PANSS scale are summed to derive the following subscale scores:

- Positive subscale: delusions, conceptual disorganization, hallucinatory behavior, excitement, grandiosity, suspiciousness/persecution, hostility. This subscale score ranges from 7 to 49.
- Negative subscale: blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, difficulty in abstract thinking, lack of spontaneity and flow of conversation, stereotyped thinking. This subscale score ranges from 7 to 49.
- General psychopathology subscale: somatic concern, anxiety, guilt feelings, tension, mannerisms and posturing, depression, motor retardation, uncooperativeness, unusual thought content, disorientation, poor attention, lack of judgment and insight, disturbance of volition, poor impulse control, preoccupation, active social avoidance. This subscale score ranges from 16 to 112.

PANSS is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E. The PS Baseline and OLE Baseline PANSS subscale scores will be derived as described in Section 6.2. The change from PS Baseline and OLE Baseline in PANSS subscale scores at each post-Baseline time point will be derived as described in Section 6.7.

The observed values of PANSS subscale scores at PS Baseline and OLE Baseline and each scheduled post-Baseline visit will be summarized descriptively. The PS Baseline and OLE Baseline PANSS subscale scores will be derived as described in Section 6.2.

The change from PS Baseline and OLE Baseline in PANSS subscale scores will be summarized for each scheduled post-Baseline visit. The change from PS Baseline and OLE Baseline in PANSS subscale scores will be derived as described in Section 6.7.

### 16.1.4. PANSS MARDER FACTOR SCORES

Individual items from the PANSS scale are summed to derive the following Marder factors (Marder, Davis, & Chouinard, 1997;58:538–46):

- Negative symptoms: blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, lack of spontaneity and flow of conversation, motor retardation, and active social avoidance. This Marder factor score ranges from 7 to 49.

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- Positive symptoms: delusions, hallucinatory behavior, grandiosity, suspiciousness/persecution, stereotyped thinking, somatic concern, unusual thought content, and lack of judgment and insight. This Marder factor score ranges from 8 to 56.
- Disorganized thought: conceptual disorganization, difficulty in abstract thinking, mannerisms and posturing, poor attention, disturbance of volition, preoccupation, and disorientation. This Marder factor score ranges from 7 to 49.
- Uncontrolled hostility/excitement: excitement, hostility, uncooperativeness, and poor impulse control. This Marder factor score ranges from 4 to 28.
- Anxiety/depression: anxiety, guilt feelings, tension, and depression. This Marder factor score ranges from 4 to 28.

PANSS is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E. The PS Baseline and OLE Baseline PANSS Marder factor scores will be derived as described in Section 6.2. The change from PS Baseline and OLE Baseline in PANSS Marder factor scores at each post-Baseline time point will be derived as described in [Section 6.7](#).

The observed values of PANSS Marder factor scores at PS Baseline and OLE Baseline and each scheduled post-Baseline visit will be summarized descriptively. The PS Baseline and OLE Baseline PANSS Marder factor scores will be derived as described in [Section 6.2](#).

The change from PS Baseline and OLE Baseline in PANSS Marder factor scores will be summarized for each scheduled post-Baseline visit. The change from PS Baseline and OLE Baseline in PANSS Marder factor scores will be derived as described in [Section 6.7](#).

#### 16.1.5. PANSS UPSM FACTOR SCORES AND THE UPSM TOTAL FACTOR SCORE

The PANSS item scores of each subject at each visit will be transformed using the UPSM, to obtain the scores of 7 transformed PANSS factors (Hopkins S. , Ogirala, Loebel, & Koblan, 2018;44(3):593-602):

- POS: Positive
- DIS: Disorganized
- NAA: Negative apathy/avolition
- NDE: Negative deficit of expression
- HOS: Hostility
- ANX: Anxiety

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- DEP: Depression

The transformation will be done as follows:

$$[\text{Transformed PANSS Factor Data}]_{(N \times 7)} = [\text{PANSS Data}]_{(N \times 30)} * [\text{UPSM}]_{(30 \times 7)}$$

where

- o  $[\text{Transformed PANSS Factor Data}]_{(N \times 7)}$  is the transformed matrix with N sets of scores for the 7 transformed PANSS factors.
- o  $[\text{PANSS Data}]_{(N \times 30)}$  is a matrix with N PANSS assessments and 30 columns containing the scores of 30 PANSS items ordered in the same way as shown in UPSM.
- o  $[\text{UPSM}]_{(30 \times 7)}$  is a matrix with 30 rows (one for each PANSS item) and 7 columns (one for each of the 7 transformed PANSS factors). This matrix is presented in [APPENDIX 3](#).

Lastly, the UPSM total factor score will be calculated as the sum of the 7 UPSM factor scores.

PANSS is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E. The PS Baseline and OLE Baseline PANSS UPSM factor scores and UPSM total factor score will be derived as described in Section 6.2. The change from PS Baseline and OLE Baseline in PANSS UPSM factor scores and UPSM total factor score at each post-Baseline time point will be derived as described in [Section 6.7](#).

The observed values of PANSS UPSM factor scores at PS Baseline and OLE Baseline and each scheduled post-Baseline visit will be summarized descriptively. The PS Baseline and OLE Baseline PANSS UPSM factor scores will be derived as described in [Section 6.2](#).

The change from PS Baseline and OLE Baseline in PANSS UPSM factor scores will be summarized for each scheduled post-Baseline visit. The change from PS Baseline and OLE Baseline in PANSS UPSM factor scores will be derived as described in [Section 6.7](#).

The observed values of PANSS UPSM total factor score at PS Baseline and OLE Baseline and each scheduled post-Baseline visit will be summarized descriptively. The PS Baseline and OLE Baseline PANSS UPSM total factor score will be derived as described in [Section 6.2](#).

The change from PS Baseline and OLE Baseline in PANSS UPSM total factor score will be summarized for each scheduled post-Baseline visit. The change from PS Baseline and OLE Baseline in PANSS UPSM total factor score will be derived as described in [Section 6.7](#).

16.2. CLINICAL GLOBAL IMPRESSION-SEVERITY

The CGI-S (Clinical Global Impression-Severity) is a clinician-rated assessment of the subject's current illness state on a 7-point scale, where a higher score is associated with greater illness severity. The CGI-S score takes one of the following values: 1 (normal, not at all ill),

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2 (borderline mentally ill), 3 (mildly ill), 4 (moderately ill), 5 (markedly ill), 6 (severely ill), 7 (among the most extremely ill patients).

CGI-S is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E. The PS Baseline and OLE Baseline CGI-S score will be derived as described in [Section 6.2](#). The change from PS Baseline and OLE Baseline in CGI-S score at all the post-Baseline time points, will be derived as described in [Section 6.7](#).

The observed CGI-S score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit.

The observed CGI-S score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit for each subgroup.

16.3. BRIEF NEGATIVE SYMPTOM SCALE (BNSS) TOTAL SCORE AND SUBSCALE SCORES

The BNSS (Brief Negative Symptom Scale) is a rating scale that measures the current level of severity of negative symptoms in schizophrenia and schizoaffective disorder. The measure is comprised of 13 individual items organized into 6 subscales: blunted affect (items 9, 10, 11), alogia (items 12, 13), avolition (items 7, 8), anhedonia (items 1, 2, 3), asociality (items 5, 6), and distress (item 4). Each of the items are scored on a Likert-type 7-point scale from 0-6, where values of 0 indicates the symptom is absent and a value of 6 means the symptom is a severe form. The subscale scores are calculated by summing the individual items within each scale. The 13 items are also summed to provide a total score which ranges from 0 to 78.

BNSS is assessed at these study visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E.

The observed values of BNSS total score and BNSS subscale scores at PS Baseline and OLE Baseline and each scheduled post-Baseline visit will be summarized descriptively. The PS Baseline and OLE Baseline BNSS total score and BNSS subscale scores will be derived as described In [Section 6.2](#).

The change from PS Baseline and OLE Baseline in BNSS total score and BNSS subscale scores will be summarized for each scheduled post-Baseline visit. The change from PS Baseline and OLE Baseline in BNSS total score and BNSS subscale scores will be derived as described in [Section 6.7](#).

16.4. 12-ITEM SHORT FORM SURVEY (SF-12)

The SF-12 is a 12-item self-reported questionnaire that is a subset of the SF-36 Health Survey. The survey captures physical and mental health. There are 8 subscales including: Physical functioning, Role-physical, Bodily pain, General health, Vitality, Social Functioning, Role emotional, and Mental health. The responses are reported on a 3- or 5-point Likert scale, depending on the question. The SF-12 uses 2-items each to estimate scores for 4 of the 8 health concepts (physical functioning, role-physical, role-emotional, and mental health). Score

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for the remaining 4 healthy concepts (bodily pain, general health, vitality, and social functioning) are estimated using 1 item each. Physical Component Summary (PCS-12) and Mental Component Summary (MCS-12) are computed using the scores of 12 questions and range from 0 to 100, where a zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health. The norm-based subdomain scores are the scores normed to the US population to have a mean of 50 and standard deviation of 10.

The observed values of the SF-12 for each subdomain (both raw and norm-based) such as general health, physical functioning, role physical, bodily pain, vitality, role emotional, mental health, social functioning, and both PCS and MCS composite scores and health utility index score at PS Baseline and OLE Baseline and each scheduled post-Baseline visit will be summarized descriptively.

The change from PS Baseline and OLE Baseline will be summarized for each scheduled post-Baseline visit.

16.5. PSP TOTAL SCORE AND INDIVIDUAL DOMAIN SCORES

The PSP (Personal and Social Performance Scale) is a 100-point single-item rating scale of personal and social functioning. The 100-point rating scale is subdivided into 10 equal intervals (or 10-point categories). The rating is based on the assessment of a patient's functioning in four areas: 1) socially useful activities, 2) personal and social relationships, 3) self-care, and 4) disturbing and aggressive behaviors. Each area is evaluated using the degree of severity: Absent, Mild, Manifest, Marked, Severe and Very Severe. For the purpose of analysis, the following numerical values will be assigned to the degrees of severity:

- 0 = Absent
- 1 = Mild
- 2 = Manifest
- 3 = Marked
- 4 = Severe
- 5 = Very Severe

A PSP total score (range 1 to 100) is assigned by the rater based on the subject's functioning in the four areas.

Higher PSP total scores indicate better functioning. Scores of 1-30 indicate functioning so poor that intensive support or supervision is needed; scores of 31-70 indicate varying degrees of difficulty; and scores of 71-100 reflect only mild difficulties.

PSP is assessed at these study visits: Visit 1E, Visit 4E and Visit 7E. The PS Baseline and OLE Baseline PSP total score will be derived as described in Section 6.2. The change from PS Baseline and OLE Baseline in PSP total score at each post-Baseline time point will be derived as described in Section 6.7.

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In addition, the following binary outcomes based on PSP total score will be derived:

- PSP total score  $\geq 71$  at PS and OLE Baseline and each scheduled visit
- Improvement of  $\geq 1$  PSP 10-point category from PS and OLE Baseline to each scheduled visit

For each subject, the indicator for each of the binary outcomes described above will be set to Y if the subject satisfied the condition, and N if the subject failed to satisfy the condition. The indicator will be set to missing if the data necessary for the derivation is missing (e.g., the PSP total score is missing at a particular time point).

The observed PSP total score and individual domain scores and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by treatment group and visit.

The number and percentage of subjects satisfying each binary outcome listed below at each scheduled OLE study visit (starting from Visit 1E) and LOCF will be summarized descriptively by visit.

- PSP total score  $\geq 71$  at PS and OLE Baseline and each scheduled visit
- Improvement of  $\geq 1$  PSP 10-point category from PS and OLE Baseline to each scheduled visit

In addition, the number and percentage of subjects that fall in each of the following PSP categories will be summarized descriptively by treatment group and visit:

- o Total score 100-71 (mild to no impairment).
- o Total score 70-51 (moderate impairment)
- o Total score 50-31 (marked impairment)
- o Total score 30-1 (severe impairment)

## 16.6. MEDICATION SATISFACTION QUESTIONNAIRE (MSQ)

The MSQ is a single-item, patient-rated, rater administered questionnaire that requires the subject to use a 7-point, Likert-type scale to rate how satisfied they are with their current antipsychotic medication. The subject will be asked the following question: "Overall, how satisfied are you with your current antipsychotic medication".

Subjects will select 1 of 7 potential responses based on their level of satisfaction from extremely dissatisfied (1) to extremely satisfied (7) as follows:

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- (1) Extremely dissatisfied
- (2) Very dissatisfied
- (3) Somewhat dissatisfied
- (4) Neither dissatisfied nor satisfied
- (5) Somewhat satisfied
- (6) Very satisfied
- (7) Extremely satisfied

MSQ is assessed at these study visits: Visit 1E and Visit 7E. The PS Baseline and OLE Baseline MSQ score will be derived as described in [Section 6.2](#). The change from PS Baseline and OLE Baseline in MSQ score at each post-Baseline time point will be derived as described in [Section 6.7](#).

The analysis of MSQ data will be limited to subjects who were being treated with an antipsychotic medication at the time of screening or had been treated with antipsychotic medications within 30 days prior to the Screening visit in study 308. These subjects will be identified at the Data Review meeting prior to database lock.

The observed MSQ score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit. In addition, the frequency distribution of the MSQ score will be summarized descriptively by visit.

16.7. CLINICAL GLOBAL IMPRESSIONS – IMPROVEMENT SCALE (CGI-I)

The CGI-I scale is a standard 7-point scale (Guy-1976) that requires the clinician to assess how much the subject's overall symptoms have improved or worsened relative to a baseline state. CGI-I scale is assessed at these visits: Visit 1E, Visit 2E, Visit 3E, Visit 5E and Visit 7E.

The observed CGI-I score and the change from OLE Baseline values will also be summarized descriptively by visit.

The observed CGI-I score and the change from OLE Baseline values will also be summarized descriptively by visit for each subgroup.

16.8. HEALTHCARE RESOURCE UTILIZATION

Healthcare resource utilization is assessed at these study visits: Visit 1E, Visit 4E and Visit 7E.

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Given Visit 1E contains the same data as PS Baseline, this visit will not be presented as a separate time point in the descriptive summary.

The frequency and percentage of subjects with physician's office visits, ER visits, and hospitalizations (for any reason and those related to schizophrenia) at PS Baseline, OLE Baseline, and at Visits 4E, 7E and LOCF (capturing the information during the past 3 months) will be summarized. The number of physician's office visits, ER visits, and hospitalizations (for any reason and those related to schizophrenia) per month at PS Baseline, OLE Baseline, and at Visit 4E, 7E, and LOCF, as well as the average length of hospital stays (for any reason and those related to schizophrenia) will be summarized. The frequency and percentage of subjects receiving unpaid care at each time point, along with the average number of hours a caregiver spends per week helping the subject, will also be summarized.

Employment status will be summarized at PS Baseline and Visit 4E, 7E, and LOCF.

The change in the number of physician's office visits, ER visits, and hospitalizations per month, the average length of hospital stays, and the average number of hours a caregiver spends per week helping the subject from PS Baseline and from OLE Baseline to Visit 4E, 7E, and LOCF will be summarized.

Shift from PS Baseline to Visit 4E, 7E, and LOCF in whether the subject receive unpaid care will also be summarized.

## 16.9. NICOTINE USE

Nicotine use is assessed at these study visits: Visit 1E, Visit 4E and Visit 7E. Nicotine use data will be summarized descriptively by visit.

For each nicotine type, the amount being used at each scheduled OLE post-baseline visit and LOCF in comparison with the amount being used at PS Baseline and OLE Baseline will be classified as "increased", "decreased", or "unchanged" for every subject, based on the reported amount used in a given period. If a subject quit using a particular type of nicotine since Baseline, the amount used for that nicotine type will be classified as "decreased". If a subject newly started or restarted using a particular type of nicotine since Baseline, the amount used for that nicotine type will be classified as "increased".

Then for subjects whose changes in amount for all nicotine types between PS Baseline/ OLE Baseline and each scheduled OLE post-Baseline visit are not in opposite directions, a subject's overall nicotine consumption at each scheduled post-Baseline visit in comparison with PS Baseline and OLE Baseline will be classified as "increased", "decreased", or "unchanged" based on the following:

- If the change in amount for each nicotine type is either "increased" or "unchanged", the subject's overall consumption will be classified as "increased".
- If the change in amount for each nicotine type is either "decreased" or "unchanged", the subject's overall consumption will be classified as "decreased".
- If the change in amount for all nicotine types is "unchanged", the subject's overall consumption will be classified as "unchanged".

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The number and percentage of subjects in each overall consumption amount change category will be summarized.

In addition, for subjects who reported using “Cigarettes” at either PS Baseline and OLE Baseline or each scheduled OLE post-Baseline visit or at both time points, the number of cigarettes used per day will be derived for both time points. The following conversion will be applied if necessary:

- Amount: 1 Pack = 20 Cigarettes.
- Time period: 1 Week = 7 Days; 1 Month = 30 Days.

The amount of cigarette used per day and the change from Baseline values will be summarized by visit.

## 16.10. MISSING DATA METHOD

Any individual missing item in any scale will not be imputed.

For derived scores that depend on more than one individual item (e.g., PANSS total score, PANSS subscale scores, PANSS Marder factor scores, PANSS UPSM factor scores and UPSM total factor score, BNSS total score, BNSS subscale scores, MADRS total score), if one or more items are missing at a visit, the derived score will be set to missing. The corresponding change from Baseline value at a given post-Baseline time point will be set to missing if the Baseline derived score is missing or if the derived score at that time point is missing.

For PANSS response, any subject with a missing PANSS total score at Baseline or at any post-Baseline time point will have their PANSS response set to missing for that time point.

For PSP binary variables based on the PSP total score, if the PSP total score is missing at Baseline or at any post-Baseline time point, the affected binary variable will be set to missing.

## 17. SAFETY OUTCOMES

Unless otherwise specified, the safety analysis and summary tables will include the column SEP-363856 50 to 100 mg/day.

All analyses of the safety outcomes will be based on the SAF Population.

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17.1. ADVERSE EVENTS AND PRE-TREATMENT EVENTS

Adverse events (AEs) and pre-treatment events will be coded using MedDRA central coding dictionary, Version 22.0 or higher. Any COVID-19 related Adverse Events and pre-treatment events will be identified using a pre-defined search:

Table 2: Predefined search criteria for COVID-19 related adverse events or pre-treatment events.

Lower Level Term	Lower Level Term Code	Preferred Term	Preferred Term Code	Search Criteria for COVID-19 Related Adverse Events or Pre-treatment Events
Coronavirus test positive	1007025	Coronavirus test positive	10070255	Preferred Term Code = 10070255 or 10053983
Coronavirus infection	10051905	Corona virus infection	10053983	

The concept of “pre-treatment events” only applies to studies 361-308. Pre-treatment events are untoward medical occurrences that started prior to the first dose of study medication in 361- 308. Adverse events of studies 361-308 are untoward medical occurrences that started at the same time of or after the first dose of study medication in 361-308, but before the first dose of OLE study medication in 361-309. These events will be recorded in the 361-308 databases.

AEs of study 361-309 are defined as untoward medical occurrences that started at the same time of or after the first dose of the OLE study drug. These events will be recorded in the 361- 309 database.

AEs (and pre-treatment events) that started in study 361-308 and are ongoing at the time of subject rollover will be re-entered into the 361-309 database and continue to be followed. These events will not be included in any AE summary table of 361-309. They will only be listed in a separate data listing.

Whenever available, the time information should be accounted for to determine if a record in the 361- 309 AE database belongs to study 361-308 or 361-309. In the case where time is not available, untoward medical occurrences that started prior to the day of the first OLE dose will be considered to belong to study 361-308; those that started after the day of the first OLE dose will be considered to belong to study 361-309. Events that started on the same day of the first OLE dose will be assigned to study 361-308 or 361-309 depending on whether this AE record also exists in the 361-308 database (based on a comparison of subject ID, preferred term, AE start date (and time if available), severity, and seriousness).

See [APPENDIX 2](#) for handling of partial dates for AEs. In the case where it is unclear whether an untoward medical occurrence is an AE or a pre-treatment event, the algorithm uses a conservative approach where the untoward medical occurrence is classified by the worst

case; i.e., AE.

AEs (including serious adverse events (SAEs)) are collected into the clinical database until the last study visit. For subjects continuing into study 361-309, the last 361-308 study visit will be Visit 10 (the end of treatment visit). If an AE (or a pre-treatment event) started in 361-308 and was ongoing at rollover, this adverse event (pre-treatment event) will be marked Ongoing in the 361-308 database. It will also be re-entered into the 361-309 database and its outcome will be monitored and updated in the 361-309 database.

Overall summary of the incidence of all AEs, AEs related to COVID-19, study medication-related AEs, severe AEs, serious AEs, AEs leading to discontinuation from study, AEs leading to study medication withdrawal, AEs leading to study medication interruption, and AEs leading to death will be provided by treatment group. This overall incidence summary will also be separately presented for the following subgroups: country, sex, age group, and BMI category.

Listings will be provided for all AEs, AEs related to COVID-19, study medication-related AEs, severe AEs, serious AEs, AEs leading to discontinuation from the study, AEs leading to study medication withdrawal, AEs leading to study medication interruption, AEs leading to death, AEs of potential drug abuse and dependence and extrapyramidal AEs. A listing of 361-308 events (pre-treatment events and AEs) present in the 361-309 database will also be presented. When complete event start date and complete event end date are available, duration of AEs from 361-301/302/303 and pre-treatment events from 361-308 will be calculated as: event end date – event start date + 1. Duration will be presented in data listings.

For all summaries, each subject will be counted only once within each category (e.g., an AE type, a severity level, a relationship category, a SOC, a high level term (HLT), and a PT). If not otherwise specified, all summaries will present the number and percentage of subjects as well as the number of events. For summaries by SOC and PT, AEs will be sorted by SOC based on the internationally agreed order (see [APPENDIX 4](#)) and then by PT in decreasing frequency in the “SEP-363856 50 to 100 mg/day” column. For summaries by SOC, HLT, and PT, AEs will be sorted by SOC based on the internationally agreed order and then by HLT and PT in decreasing frequency in the “SEP-363856 50 to 100 mg/day” column.

COVID-19 related pre-treatment events related pre-treatment events and AEs will be displayed similarly as any other pre-treatment events and AEs.

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**17.1.1. All AEs**

All AEs will be summarized by PT, by SOC and PT, as well as by SOC, HLT, and PT. The summary by SOC and PT will also be presented for the following subgroups: sex, age group and BMI category.

Summary tables (by SOC and PT) will be generated for those AEs starting after the last dose of study drug and those AEs starting more than 1 day after the last dose of study drug.

AEs reported by  $\geq 2.0\%$  (without rounding) of subjects in any treatment group will be summarized by SOC and PT.

Non-serious AEs reported by  $> 5.0\%$  (without rounding) of subjects will be summarized by SOC and PT.

The summary by SOC and PT will be broken down further by maximum severity and by strongest relationship to study medication. These summaries are described in the sections below.

**17.1.1.1. Severity**

Severity is classed as mild/ moderate/ severe (increasing severity). AEs with a missing severity will be classified as severe.

If a subject reported an AE more than once within the same SOC/ PT with different severity levels, the subject will be assigned to a severity level for that SOC/ PT based on the worst case severity (i.e., maximum severity). Event counts will not be included in this summary.

In a separate table, severe AEs will be summarized by SOC and PT.

**17.1.1.2. Relationship to study medication**

Relationship to study medication, as indicated by the Investigator, is classed as “not related”/ “possible”/ “probable”/ “definite” (increasing strength of relationship). A “related” AE is defined as an AE with a relationship to study medication as “possible”, “probable” or “definite”. AEs with a missing relationship to study medication will be regarded as related to the study medication. For this summary, AEs will be presented in 2 categories, related and not related.

If a subject reported an AE more than once within the same SOC/ PT in different relationship categories, the subject will be assigned to a category for that SOC/ PT based on the worst case relationship (i.e., strongest relationship). Event counts will not be included in this summary.

In a separate table, study medication-related AEs will be summarized by SOC and PT.

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**17.1.2. AEs LEADING TO DISCONTINUATION FROM STUDY**

AEs leading to discontinuation from the study are those AEs with “Caused Study Discontinuation” = “Yes” on the “*Adverse Events*” CRF form.

AEs leading to discontinuation from the study will be summarized by SOC and PT.

**17.1.3. AEs LEADING TO STUDY MEDICATION WITHDRAWAL**

AEs leading to permanent withdrawal from the study medication are those AEs with “Action Taken with Study Treatment” = “Drug Withdrawn” on the “*Adverse Events*” CRF form.

AEs leading to study medication withdrawal will be summarized by SOC and PT.

**17.1.4. AEs LEADING TO STUDY MEDICATION INTERRUPTION**

AEs leading to study medication interruption are those AEs with “Action Taken with Study Treatment” = “Drug Interrupted” on the “*Adverse Events*” CRF form.

AEs leading to study medication interruption will be summarized by SOC and PT.

**17.1.5. SERIOUS ADVERSE EVENTS**

SAEs are those AEs recorded as “Serious” on the “*Adverse Events*” CRF form.

SAEs will be summarized by SOC and PT. The summary will also be presented for the following subgroups: country, sex, age group, number of prior hospitalizations for treatment of schizophrenia, duration of schizophrenia, and BMI category.

In a separate table, SAEs starting within 7 days, after the last dose of study drug will be summarized by SOC and PT as well.

**17.1.6. ADVERSE EVENTS LEADING TO DEATH**

AEs leading to death are those AEs with “Outcome” = “Fatal” on the “*Adverse Events*” CRF form.

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AEs leading to death will be summarized by SOC and PT.

**17.1.7. ADVERSE EVENTS OF POTENTIAL DRUG ABUSE AND DEPENDENCE**

AEs associated with potential drug abuse and dependence will be identified as described in [APPENDIX 5](#).  
These AEs will be summarized by PT only.

**17.1.8. EXTRAPYRAMIDAL ADVERSE EVENTS**

Extrapyramidal AEs will be identified by MedDRA SMQ 20000095 Extrapyramidal syndrome as described in [APPENDIX 6](#).  
These AEs will be summarized by PT only.

**17.1.9. ADVERSE EVENTS BY SUBGROUPS**

The subgroup factors of interest for AE summaries include: country, sex, age group and BMI category (see [Section 7.5](#)). AE by subgroup summaries are described in the individual sections above.

**17.1.10. PSYCHIATRIC ADVERSE EVENTS LEADING TO DISCONTINUATION FROM STUDY (PAEDCs)**

Additional information is collected for the non-serious psychiatric AEs that led to discontinuation from the study as well as for all serious psychiatric AEs within the study. The information is recorded in separate trackers and not part of the CRF. This information will be presented in separate data listings only.

**17.2. LABORATORY EVALUATIONS**

Results from the central laboratory to be reported for this study include Hematology, Chemistry (including lipid panel and thyroid panel), Urinalysis, Urine drug screening, Rapid Urine Drug Screening, Serology panel, Serum pregnancy (β-HcG) (in female subjects only), Urine pregnancy (in female subjects only), Rapid Urine Pregnancy Test (in female subjects only).

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Serum and urine pregnancy results in female subjects, serology panel in subjects, and any unexpected lab parameters not specified in protocol Section 22 (APPENDIX IV. CLINICAL LABORATORY TESTS) will only be listed. Laboratory parameters prespecified in protocol Section 22 under the categories of “HEMATOLOGY”, “BLOOD CHEMISTRIES” (plus HOMA-IR if collected), “URINALYSIS”, and “URINE DRUG SCREENING/ RAPID URINE DRUG SCREENING” will be summarized in tables as well as presented in listings.

Listing presentations will use both standard international (SI) Units and conventional units (CV). Table summaries will also be provided using both SI units and conventional units.

Quantitative laboratory measurements reported as “< X”, i.e., below the lower limit of quantification (BLQ), or “> X”, i.e., above the upper limit of quantification (ULQ), will be converted to X for the purpose of quantitative summaries, but they will be presented as recorded, i.e., as “< X” or “> X” in the listings.

The following summaries will be provided:

- By-visit summary of observed values and change from PS Baseline and OLE Baseline values for quantitative measurements in hematology, chemistry, and urinalysis. Serum prolactin results will be summarized overall and separately by sex. Glucose, insulin and lipid panel results (total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides) will be summarized by fasting status: fasting only and overall (fasting, non-fasting, or fasting status unknown combined). Change from PS Baseline and OLE Baseline for glucose, insulin and lipid panel results will only be calculated if OLE post-Baseline fasting status is matching Baseline fasting status.
- By-visit summary of the number and percentage of subjects in each outcome category for qualitative measurements in urinalysis (as applicable) and for urine drug screening results. Urine drug screening results will be reported as “Positive” / “Negative”.
- Shift in laboratory results (chemistry, hematology, urinalysis) from PS Baseline and OLE Baseline to each scheduled OLE post-Baseline and LOCF Endpoint according to the reference range criteria. The existing reference range indicators provided by the central laboratory will be mapped as needed to categories of “Normal” (within the reference range) / “Abnormal” (outside the reference range) for urinalysis non-pH results, and to categories of “Low” (below the reference range) / “Normal” (within the reference range) / “High” (above the reference range) for chemistry and hematology results as well as urinalysis pH results.
- Number and percentage of subjects with at least one potentially clinically significant (PCS) laboratory value (see [APPENDIX 7](#)) post OLE Baseline. The period of evaluation includes the follow-up period, including unscheduled visits. Subjects will be counted in a particular PCS category if they met that PCS criteria at least once post OLE Baseline, regardless of their Baseline value.

All laboratory data will be provided in data listings, with the values outside the reference ranges flagged. In addition, separate listings will be provided to present the laboratory data that met the PCS criteria.

Boxplots will be created to present PS Baseline and OLE Baseline and each scheduled OLE post-Baseline values for lipid parameters

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(total cholesterol, LDL, HDL, and triglycerides), glucose, insulin by fasting status: fasting only and overall (fasting, non-fasting, or fasting status unknown combined). In addition, boxplots will be created to present PS Baseline and OLE Baseline and each scheduled OLE post-Baseline prolactin values group by sex: Overall, males, females. Lastly, the values of HbA1c will be presented for PS Baseline and OLE Baseline and each scheduled OLE post-Baseline by treatment group in boxplots as well. Each of these boxplots will be repeated to present the change from PS Baseline and OLE Baseline values.

17.2.1. LABORATORY SPECIFIC DERIVATIONS

No applicable derivations.

17.2.2. LABORATORY REFERENCE RANGES

Laboratory reference range indicators will be provided by the laboratory vendor and used in statistical analyses. Only if a reference range indicator is missing in the data transfer will it be derived in the analysis step as described below.

- Quantitative laboratory measurements (that are not urinalysis erythrocytes or urinalysis leukocytes) will be compared with the relevant laboratory reference ranges in original units and categorized as:
  - Low: Below the lower limit of the laboratory reference range.
  - Normal: Within the laboratory reference range (upper and lower limit included).
  - High: Above the upper limit of the laboratory reference range.
- For laboratory parameters with categorical outcomes as well as urinalysis erythrocytes and urinalysis leukocytes, if the result is within the reference range, the indicator is “NORMAL”; if the result is not within range, the indicator is “ABNORMAL”.

17.3. ECG EVALUATIONS

Data from the centrally over-read ECG (Electrocardiogram) results will be included in the reporting of this study.

The following ECG parameters will be reported for this study:

- PR Interval (msec)
- RR Interval (msec)

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- QRS Duration (msec)
- QRS Axis (deg)
- QT Interval (msec)
- QTcF Interval (msec) (Fridericia's Correction of QT interval)
- QTcB Interval (msec) (Bazett's Correction of QT interval)
- Heart Rate (bpm)
- Overall assessment of ECG as determined by the central over-read:
  - o Normal
  - o Abnormal, Insignificant
  - o Abnormal, Potentially Significant
  - o Abnormal, Significant
  - o Exclusion Alert (only given for the Screening visit). In table summaries, the category of "Exclusion Alert" will be combined into the category of "Abnormal, Significant".
  - o Category of Incomplete Analysis, Not Applicable, Uninterpretable, Not Evaluable will be combined into Not Evaluable
- ECG findings

ECG findings will only be listed. Other ECG data will be summarized in tables as well as presented in listings.

The following summaries will be provided:

- By-visit summary of observed values and change from PS Baseline and OLE Baseline values for quantitative measurements.
- By-visit summary of ECG overall assessment results as determined by the central over-read ("Normal", "Abnormal, Insignificant", "Abnormal, Potentially Significant", "Abnormal, Significant", "Not Evaluable").
- Shift in ECG overall assessment as determined by the central over-read from PS Baseline and OLE Baseline to each scheduled OLE post-baseline visit, and LOCF endpoint.

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- Number and percentage of subjects who met each of the QTc interval prolongation criteria (see [Section 17.3.1](#)). The period of evaluation includes both the treatment period and the follow-up period, including unscheduled visits.
- Number and percentage of subjects with at least one PCS ECG value (see [Section 17.3.2](#)) post OLE Baseline. The period of evaluation includes both the treatment period and the follow-up period, including unscheduled visits. Subjects will be counted in a particular PCS category if they met that PCS criteria at least once post OLE Baseline, regardless of their PS Baseline or OLE Baseline value.

All ECG parameters, overall assessment as determined by the central over-read, and findings will be provided in a data listing. In addition, separate listings will be generated to present the QTc interval data of subjects who met at least one QTc prolongation criterion and the ECG data that met the PCS criteria.

### 17.3.1. QTc INTERVAL PROLONGATION CRITERIA

QTc interval prolongation will be identified in accordance with the following predefined criteria (same criteria apply to both QTcF and QTcB):

- > 450 msec at any post-OLE Baseline time point (including unscheduled visit) not present at PS Baseline
- > 450 msec at any post-OLE Baseline time point (including unscheduled visit) not present at OLE Baseline
- > 480 msec at any post-OLE Baseline time point (including unscheduled visit) not present at PS Baseline
- > 480 msec at any post-OLE Baseline time point (including unscheduled visit) not present at OLE Baseline
- > 500 msec at any post-OLE Baseline time point (including unscheduled visits) not present at PS Baseline
- > 500 msec at any post-OLE Baseline time point (including unscheduled visits) not present at OLE Baseline
- $\geq 30$  msec increase from PS Baseline for at least one post-OLE Baseline measurement (including unscheduled visits) and  $< 60$  msec increase from PS Baseline for all post-OLE Baseline measurements (including unscheduled visits)
- $\geq 30$  msec increase from OLE Baseline for at least one post-OLE Baseline measurement (including unscheduled visits) and  $< 60$  msec increase from OLE Baseline for all post-OLE Baseline measurements (including unscheduled visits)

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- ≥ 60 msec increase from PS Baseline for at least one post-OLE Baseline measurement (including unscheduled visits)
- ≥ 60 msec increase from OLE Baseline for at least one post-OLE Baseline measurement (including unscheduled visits)

**17.3.2. ECG POTENTIALLY CLINICALLY SIGNIFICANT CRITERIA**

Potentially clinically significant ECG measurements will be identified in accordance with the following predefined PCS criteria:

**Table 3: Predefined ECG PCS criteria.**

ECG Parameter	PCS Low	PCS High
Heart Rate (beats/min)	--	≥ 100
PR Interval (msec)	--	≥ 210
QRS Interval (msec)	--	≥ 120

**17.4. VITAL SIGNS**

The following vital sign measurements will be reported for this study:

- Supine and Standing Systolic Blood Pressure (mmHg)
- Supine and Standing Diastolic Blood Pressure (mmHg)
- Supine and Standing Pulse Rate (bpm)
- Respiratory Rate (breaths/min)
- Temperature (°C)
- Height (cm)

- Weight (kg)
- BMI (kg/m<sup>2</sup>)
- Waist Circumference (cm)

Height will be summarized as part of the Baseline characteristics only.

The following summaries will be provided:

- By-visit summary with 95% CI of the mean of observed values and change from Baseline values for vital sign measurements, including Week 25/Follow-up/Visit 8E.
- Number and percentage of subjects with at least one PCS vital sign value (see [Section 17.4.2](#)) post OLE Baseline. The period of evaluation includes both the treatment period and the follow-up period, including unscheduled visits. Subjects will be counted in a particular PCS category if they met that PCS criteria at least once post OLE Baseline, regardless of their PS Baseline or OLE Baseline value.
- Number and percentage of subjects with orthostatic hypotension and/or orthostatic tachycardia (see [Section 17.4.1](#)). The data will be summarized for PS Baseline and OLE Baseline and the overall post OLE Baseline period (which covers both the treatment period and the follow-up period, including unscheduled visits), as well as by visit, including Week 25/Follow-up/Visit 8E.
- By-visit summary of BMI category (see [Section 7.5](#)) and shift in BMI category from PS Baseline and OLE Baseline to each post OLE Baseline time point.
- By-visit summary with 95% CI of the mean of observed values and change from PS Baseline and OLE Baseline values for vital signs measurements by BMI category (see [Section 7.5](#)).

All vital signs data will be provided in a data listing. In addition, a separate listing will be generated to present the vital signs data that met the PCS criteria. All occurrences of orthostatic hypotension and orthostatic tachycardia will also be presented in a listing.

Boxplots will be created to present weight data by time point. The boxplots will be repeated to present the change from PS Baseline and OLE Baseline values.

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**17.4.1. VITAL SIGN SPECIFIC DERIVATIONS**

- BMI expressed in  $\text{kg/m}^2 = \text{Weight (kg)} / \text{height (m)}^2$ .

The height collected at Visit 1 in study 308 will be used to derive BMI where needed throughout the study.

- Orthostatic hypotension is defined as a decrease of  $\geq 20$  mmHg in systolic blood pressure or  $\geq 10$  mmHg in diastolic blood pressure after a subject has been standing for at least 2 to 4 minutes, compared to the systolic blood pressure and diastolic blood pressure measured in the supine position, respectively.
- Orthostatic tachycardia is defined as a heart rate increase of  $\geq 20$  bpm after a subject has been standing for at least 2 to 4 minutes compared to the heart rate measured in the supine position, and a heart rate of  $> 100$  bpm after the subject has been standing for at least 2 to 4 minutes.

**17.4.2. VITAL SIGN POTENTIALLY CLINICALLY SIGNIFICANT CRITERIA**

Potentially clinically significant vital sign measurements will be identified in accordance with the following predefined PCS criteria:

**Table 5: Predefined vital sign PCS criteria.**

Vital Sign Parameter	PCS Low	PCS High
Systolic Blood Pressure (Supine, Standing) (mmHg)	Value $\leq 90$ and $\geq 20$ decrease from PS/ OLE Baseline	Value $\geq 180$ and $\geq 20$ increase from PS/ OLE Baseline
Diastolic Blood Pressure (Supine, Standing) (mmHg)	Value $\leq 50$ and $\geq 15$ decrease from PS/ OLE Baseline	Value $\geq 105$ and $\geq 15$ increase from PS/ OLE Baseline
Pulse Rate (Supine, Standing) (beats/min)	Value $\leq 50$ and $\geq 15$ decrease from PS/ OLE Baseline	Value $\geq 120$ and $\geq 15$ increase from PS/ OLE Baseline
Weight (kg)	$\geq 7\%$ decrease from PS/ OLE Baseline	$\geq 7\%$ increase from PS/ OLE Baseline
Temperature ( $^{\circ}\text{C}$ )	NA	Value $\geq 38.3^{\circ}\text{C}$ and $\geq 0.8^{\circ}\text{C}$ increase from PS/ OLE Baseline

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17.5. PHYSICAL EXAMINATION

As all physical and neurological findings will be recorded as medical history or AEs, no specific analysis of physical and neurological examination will be performed.

17.6. OTHER SAFETY ASSESSMENTS

17.6.1. COLUMBIA SUICIDE SEVERITY RATING SCALE (C-SSRS)

The C-SSRS is a tool designed to systematically assess and track suicidal behavior and suicidal ideation for lifetime, one month prior to the screening visit for suicidal ideation and 6 months prior to the screening visit for suicidal behavior, and throughout the study. The strength of this suicide classification system is in its ability to comprehensively identify suicidal events while limiting the over-identification of suicidal behavior. The C-SSRS Baseline/Screening Version is used at the screening visit and the C-SSRS Since Last Visit Version is used from Visit 2 and onward. Subjects with Type 4 (active suicidal ideation with some intent to act, without specific plan) or Type 5 (active suicidal ideation with specific plan and intent) suicidal ideation during the study will be discontinued from the study and referred to a mental health professional.

C-SSRS includes two main sections: Suicidal Ideation and Suicidal Behavior.

The following outcomes are C-SSRS categories and have binary responses (yes/no). The categories are re-ordered from the scale to facilitate the definitions of the C-SSRS endpoints, and to provide clarity in the presentation of the results.

- Suicidal ideation is measured by 5 categories, representing 5 subtypes of suicidal ideation with increasing severity:
  - o Category 1: Wish to be Dead
  - o Category 2: Non-specific Active Suicidal Thoughts
  - o Category 3: Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act
  - o Category 4: Active Suicidal Ideation with Some Intent to Act, without Specific Plan
  - o Category 5: Active Suicidal Ideation with Specific Plan and Intent
- Suicidal behavior is measured by 5 categories, representing 5 subtypes of suicidal behavior:
  - o Category 6: Preparatory Acts or Behavior
  - o Category 7: Aborted Attempt

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- o Category 8: Interrupted Attempt
- o Category 9: Actual Attempt (non-fatal)
- o Category 10: Completed Suicide

The 10 categories above are not mutually exclusive. Subjects will be counted in each category for which they have an event.

Self-injurious behavior without suicidal intent is a non-suicide-related C-SSRS outcome, and also has a binary response (yes/no).

For the purpose of C-SSRS analysis, “Baseline” and the overall “post-Baseline” periods are defined as follows.

Time point	Study Visit	C-SSRS Version	Derivation Rule
PS Baseline	Visit 1 of study 361-308	Baseline/Screening – Past 1 Month for Suicidal Ideation / Past 6 Months for Suicidal Behavior	Most severe outcome
	Visit 2* of study 361-308	Since Last Visit	
OLE Baseline	Week 8/Visit 10 ** of study 361-308	Since Last Visit	As collected for that visit
Post OLE Baseline	All post-Baseline visits up to and including Visit 8E (the follow-up visit), including unscheduled visits	Since Last Visit	Most severe outcome

\* Note: The Visit 2 C-SSRS assessment must be administered prior to the first dose of 361-308 study medication in order to be used in the C-SSRS PS Baseline derivation.

\*\*Note: The Visit 10 C-SSRS assessment must be administered prior to the first dose of 361-309 extension study medication in order to be used as the C-SSRS OLE Baseline. In the rare event where the Visit 10 assessment is administered after the first dose of 361-309 extension study medication, take the assessment from the previous visit as the OLE Baseline.

The following C-SSRS composite endpoints will be derived for each time point of interest (i.e., PS Baseline, OLE Baseline, overall post OLE Baseline, and each scheduled visit including Week 25/Follow-up/Visit 8E) as follows:

- Any suicidal ideation: A “yes” answer to any one of the 5 suicidal ideation questions on C-SSRS (Categories 1-5).

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- Any suicidal behavior: A “yes” answer to any one of the 5 suicidal behavior questions on the C-SSRS (Categories 6-10).
- Any suicidality: A “yes” answer to any one of the 10 suicidal ideation and behavior questions on the C-SSRS (Categories 1-10).

For each subject, the suicidal ideation score at each time point of interest (i.e., PS Baseline, OLE Baseline, overall post OLE Baseline, the LOCF endpoint, and each scheduled visit including Week 25/Follow-up/Visit 8E) is defined as the maximum suicidal ideation category (1-5) present for the time point of interest. If no ideation is present a score of 0 is assigned.

The number and percentage of subjects with any suicidality, any suicidal ideation and subtypes of ideation, any suicidal behavior and subtype of behavior, and any non-suicidal self-injurious behavior will be presented for:

- PS Baseline (as defined above)
- OLE Baseline (as defined above)
- The overall post OLE Baseline period (as defined above)
- Each scheduled visit (starting from Visit 1E).

Shift in suicidal ideation score from PS Baseline to the overall post OLE Baseline period, to each of the scheduled visits (starting from Visit 1E), and to the LOCF, and shift from OLE Baseline to each scheduled post OLE Baseline extension study visit (starting from Visit 2E), and LOCF, will be presented endpoint will be presented.

Intensity of ideation for the most severe ideation subtype is measured in terms of frequency, duration, controllability, deterrents, and reasons for ideation. Each is measured with responses ranging from 1 to 5 for frequency and duration, and from 0 to 5 for controllability, deterrents, and reasons for ideation. The ideation intensity total score is the sum of responses to the five items and can range from 2 to 25 for subjects with endorsed suicidal ideation. For subjects with endorsed suicidal ideation, if one or more of these five items are missing at an assessment, the total score will be set to missing. If a subject did not endorse any suicidal ideation, a score of 0 for the ideation intensity total score will be given.

Actual lethality associated with actual attempts is rated on a 6-point scale from 0 = ‘No physical damage or very minor physical damage’ to 5 = ‘Death’. Potential lethality of actual attempts (if actual lethality = 0) is rated on a 3-point scale from 0 = ‘Behavior not likely to result in injury’ to 2 = ‘Behavior likely to result in death despite available medical care’.

Responses to each C-SSRS question will be listed. The ideation intensity total score and the actual lethality and potential lethality of actual attempts will only be presented in data listings.

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### 17.6.2. ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)

The AIMS is a clinician-rated assessment of abnormal movements consisting of unobtrusive observation of the subject at rest (with shoes removed) and several questions or instructions directed toward the subject. It contains seven items related to: facial, lip, jaw, and tongue movements (items 1 -4), upper and lower extremity movements (items 5 - 6), and trunk movements (item 7). Three other items assess the subject at a global level (items 8 - 10), and two items assess dental status (items 11 - 12).

The (non-global) AIMS total score is the sum of items 1 through 7. (Items 8 through 12 are not used in AIMS total score calculation.) The possible range for AIMS total score is 0 to 28. Higher values of the AIMS total score indicate increased severity in abnormal movement. If one or more of the 7 items contributing to AIMS total score calculation are missing at a visit, the total score will be set to missing for that visit.

AIMS total score at each visit is classified as 'abnormal' if: either at least two items (out of items 1 - 7) have a response of 'Mild' or higher (i.e., item score  $\geq 2$ ); or at least one item (out of items 1 - 7) has a response of 'Moderate' or higher (i.e., item score  $\geq 3$ ). Otherwise, the non-missing AIMS total scores is classified as 'normal'.

Item 8 of AIMS represents the global severity score. Post-Baseline AIMS global severity scores will be classified as 'worsened', 'unchanged', or 'improved', relative to a subject's Baseline response to item 8. A higher score than that of the Baseline would be classified as 'worsened'. Conversely, a lower score would be classified as 'improved'. If the score is equal to that of Baseline, the score will be classified as 'unchanged'. Relative to PS Baseline, the classification will be made for each OLE study visit. Relative to OLE Baseline, the classification will be made for each post OLE Baseline extension study visit.

AIMS is assessed at these study visits: Visit 1E, Visit 2E and Visit 7E.

The observed AIMS total score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit. In addition, the observed AIMS total score and the change from PS Baseline and OLE Baseline values will be summarized descriptively by the subgroups of concomitant medication use for treatment of movement disorders.

Shift from PS Baseline and OLE Baseline in AIMS total score category (Normal/Abnormal) to each post OLE Baseline scheduled visit and to the overall post OLE Baseline period (including both the treatment period and the follow-up period) will be summarized descriptively.

The observed AIMS global severity score and the change from PS Baseline and OLE Baseline values will be summarized descriptively by visit. In addition, the frequency distribution of the AIMS global severity item will be summarized descriptively by visit. Post OLE Baseline changes in AIMS global severity score (Worsened/Unchanged/Improved) will also be summarized descriptively by visit.

### 17.6.3. BARNES AKATHISIA RATING SCALE (BARS)

The BARS is a rating scale geared toward assessment of neuroleptic-induced akathisia, though it can be used to measure akathisia

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associated with other drugs as well. The BARS consists of four items, including one item assessing objective restlessness (item 1), two items targeting subjective restlessness (awareness and related distress; items 2 - 3), and one global clinical assessment of akathisia item (item 4). The objective and subjective items are anchored and utilize a 4-point scale. The global assessment item has a 6-point scale (from absence of akathisia through severe akathisia).

The BARS total score is the sum of items 1 through 3 and ranges from 0 to 9. Higher values of the BARS total score indicate higher severity of akathisia. If one or more of items 1 to 3 are missing at a visit, the BARS total score will be set to missing for that visit.

The post-Baseline BARS Global Clinical Assessment of Akathisia responses will be classified as 'worsened', 'unchanged', or 'improved', relative to a subject's Baseline response to this item. A higher score than that of the Baseline would be classified as 'worsened'. Conversely, a lower score would be classified as 'improved'. If the score is equal to that of Baseline, the score will be classified as 'unchanged'.

BARS is assessed at these study visits: Visit1E, Visit 2E and Visit 7E.

The PS Baseline and OLE Baseline BARS total score and BARS item scores will be derived as described in [Section Error! Reference source not found.](#). The change from PS Baseline and OLE Baseline in BARS total score and BARS item scores will be derived as described in [Section Error! Reference source not found.](#).

The observed BARS total score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit including LOCF. In addition, the observed BARS total score and the change from PS Baseline and OLE Baseline values will be summarized descriptively by the subgroups of concomitant medication use for treatment of movement disorders.

Post OLE Baseline changes from PS Baseline and OLE Baseline in BARS global clinical assessment score (Worsened/Unchanged/Improved) will be summarized descriptively by visit including LOCF.

Lastly, the observed BARS item scores and the change from Baseline values will be summarized descriptively by treatment group and visit. In addition, the frequency distribution of each BARS item will be summarized descriptively by treatment group and visit.

**17.6.4. SIMPSON-ANGUS SCALE (SAS)**

The SAS is a clinician-rated assessment of neuroleptic-induced Parkinsonism consisting of 10 items. Items are anchor-based, rated on a 5-point scale (ranging between 0 and 4), and address rigidity, gait (bradykinesia), tremor, akathisia, shoulder shaking, glabellar tap, and salivation.

SAS mean score is defined as the average of all 10 items and ranges between 0 and 4. Lower values of the SAS mean score indicate milder symptoms. If one or more of the SAS items are missing at a visit, the SAS mean score will be set to missing for that visit.

The SAS mean score at each visit will be classified as 'abnormal' if it exceeds 0.3 ([Rush, et al., 2000](#)). Otherwise, the non-missing SAS mean score will be classified as 'normal'.

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SAS is assessed at these study visits: Visit 1E, Visit 2E and Visit 7E.

The PS Baseline and OLE Baseline SAS mean score will be derived as described in [Section Error! Reference source not found.](#). The change from PS Baseline and OLE Baseline in SAS mean score will be derived as described in [Section Error! Reference source not found.](#).

The observed SAS mean score and the change from PS Baseline and OLE Baseline values will also be summarized descriptively by visit including LOCF. In addition, the observed SAS mean score and the change from PS Baseline and OLE Baseline values will be summarized descriptively by the subgroups of concomitant medication use for treatment of movement disorders.

Shift from PS Baseline and OLE Baseline in SAS mean score category (Normal/Abnormal) to each post OLE Baseline scheduled visit including LOCF and to the overall post OLE Baseline period (including both the treatment period and the follow-up period) will be summarized descriptively.

#### 17.6.5. PITTSBURGH SLEEP QUALITY INDEX

The Pittsburgh Sleep Quality Index (PSQI) consists of 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one is available). It is used to measure the quality and patterns of sleep in adults. Only self-rated questions are included in the scoring. It differentiates “poor” from “good” sleep quality by measuring seven “component” scores, each of which has a range of 0-3 points: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction due to sleepiness over the last month.

The seven component scores are then summed to yield one global PSQI score, with a range of 0-21 points, “0” indicating no difficulty and “21” indicating severe difficulties in all areas ([Buysse, Reynolds, Monk, Berman, & Kupfer, 1989](#)).

The PSQI scoring algorithm as downloaded from the University of Pittsburgh Sleep and Chronobiology Center is inserted in [APPENDIX 8](#). The seven component scores and the PSQI global score will be derived according to this algorithm. If one or more of the component scores are missing at a visit, the PSQI global score will be set to missing for that visit.

PSQI is assessed at these study visits: Visit 1E, Visit 4E and Visit 7E.

The PS Baseline and OLE Baseline PSQI global score will be derived as described in [Section Error! Reference source not found.](#). The change from PS Baseline and OLE Baseline in PSQI global score will be derived as described in [Section Error! Reference source not found.](#).

The observed PSQI global score and the change from PS Baseline and OLE Baseline values will be summarized descriptively by visit including LOCF.

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## 17.7. SUBGROUP ANALYSIS OF SAFETY VARIABLE(S)

The subgroup analyses for AE data, vital signs data, and AIMS/BARS/SAS scales are described in their respective sections.

## 18. PHARMACOKINETIC ANALYSIS

Plasma concentrations of SEP-363856 and SEP-363854 (metabolite of SEP-363856) of all enrolled subjects will be presented in a data listing.

## 19. DATA NOT SUMMARIZED OR PRESENTED

The variables and/or domains not summarized or presented are:

- Subject initials
- Any data collected on screen failures other than disposition, basic demographics, and pre-treatment events.
- Any data collected during previously failed screening(s) for enrolled subjects who were screened more than once except Adverse Events.

These domains and/or variables will not be summarized or presented but will be available in the clinical study database and SDTM datasets.

## 20. REFERENCES

Buyse, D., Reynolds, C., Monk, T., Berman, S., & Kupfer, D. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. *Psychiatry Research*, 28(2), 193-213.

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Rush, A., Pincus, H., First, M., Blacker, D., Endicott, J., Keith, S., . . . Zarin, D. (2000). *Handbook of Psychiatric Measures*. American Psychiatric Association.

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## APPENDIX 1. PROGRAMMING CONVENTIONS FOR OUTPUTS

### IQVIA OUTPUT CONVENTIONS

The following output conventions are to be followed:

- General presentation:
  - o The first row in the body of the table or listing should be blank
  - o Rounding should be done with the SAS function ROUND.
  - o Numbers in tables should be rounded, not truncated.
  - o The first letter of a text entry should be capitalized.
- Univariate Statistics: If the raw data has N decimal places, then the summary statistics should have the following decimal places:
  - o Minimum and maximum: N
  - o Mean, median, Q1, and Q3: N + 1
  - o SD: N + 2
  - o For lab data only, in the rare case where raw data has more than 3 decimal places, summary statistics will be presented for the scenario of N = 3. All decimals will be presented in Listings.
  - o For CGI-S score, 2 decimal places will be presented for mean, median, Q1, Q3, LS mean, LS mean difference, and 95% CI; 3 decimal places will be presented for SD and SE; 0 decimal places will be presented for min and max. 0 decimal places will be presented in listings.
  - o For UPSM scores, 3 decimal places will be presented for mean, median, Q1, Q3, LS mean, LS mean difference, and 95% CI; 4 decimal places will be presented for SD and SE; 2 decimal places will be presented for min and max. Up to 2 decimal places will be presented in Listings. No rounding will be applied in the ADaM datasets.
- Frequencies and percentages (n and %):
  - o Percentages will be reported to one decimal place, except cases where percent <100.0% but >99.9% will be presented as '>99.9%' (e.g., 99.99% is presented as >99.9%); and cases where percent < 0.1% will be presented as '<0.1%' (e.g., 0.08% is presented as <0.1%). Rounding will be applied after the <0.1% and >99.9% rule.
  - o Where counts are zero, no percentage should appear in the output.
- Confidence Intervals:

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- o Confidence intervals and estimates are presented to one place more than the raw data, and standard errors to two places more than the raw data.
  - o Boundary values of confidence intervals should be separated by a comma.
- P-values should be reported to three decimal places, except values <1.000 but >0.999 will be presented as ‘>0.999’ (e.g., 0.9998 is presented as >0.999); and values <0.001 will be presented as ‘<0.001’ (e.g., 0.0009 is presented as <0.001). Rounding will be applied after the <0.001 and >0.999 rule.
- Ratios should be reported to one more decimal place than the raw data.
- Missing values:
  - o A “0” should be used to indicate a zero frequency.
  - o A “-” will be used to indicate missing data in an end-of-text table or subject listing.

**DATES & TIMES**

Depending on data available, dates and times will take the form yyyy-mm-ddThh:mm:ss .

**SPELLING FORMAT**

English US.

**PRESENTATION OF TREATMENT GROUPS**

For outputs, treatment groups will be represented as follows and in that order:

Treatment Group	For Tables (Column Order)	For Listings and Graphs (Order)
SEP-363856 50 to 100 mg/day	SEP-363856 50 to 100 mg/day	SEP-363856 50 to 100 mg/day

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**LISTINGS**

All listings will be ordered by the following (unless otherwise indicated in the template):

- Enrolled subjects who did not receive any study medication will be presented at the end and labelled “Not Treated”.
- Subject ID.
- Visit (where applicable)
- Original date/time (where applicable).

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## APPENDIX 2. PARTIAL DATE CONVENTIONS

The actual dates as collected on the CRF will be presented in the listings. Imputed dates will not be presented in the listings unless otherwise specified.

### ALGORITHM FOR ADVERSE EVENTS

The algorithm below applies to all 361-308/309 AEs and 361-308 pre-treatment event records collected in the 361-309 clinical database.

Step 1) For events that exist in the 361-308 databases and have a missing or partial start date, retrieve imputed event start dates from the respective ADaM dataset.

Events in the 361-309 database which also exist in the 361-308 databases will be identified based on a comparison of subject ID, PT, AE start date (and time if available), severity, and seriousness.

Step 2) For events that do not exist in the 361-308 databases yet the known part of the event start and/or end dates show that the event unambiguously started before first OLE dose in 361-309, impute missing or partial event start and/or end dates (if not ongoing) using the algorithm below.

If an event has some missing components in both the start and end dates, first impute the end date.

#### AE end date imputation

- If year and month (YYYY-MM) of AE end date are known, then impute the missing day to be the earlier of (last day of the month; date of 361-308 last contact).
- If only year (YYYY) of AE end date is known, then impute the missing month and day to be the earlier of (31<sup>st</sup> December; date of 361-308 last contact).
- If AE end date is completely missing and AE is not ongoing, then impute AE end date to be date of 361-308 last contact.

#### AE start date imputation

- If year and month (YYYY-MM) of AE start date are known and YYYY-MM = year and month of 361- 308 study med start date, then impute AE start date to be the earlier of (361-308 study med start date; full or imputed AE end date [if non-missing]).

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- If year and month (YYYY-MM) of AE start date are known and YYYY-MM  $\neq$  year and month of 361- 308 study med start date, then impute AE start date to be YYYY-MM-01.
- If only year (YYYY) of AE start date is known and YYYY = year of 361-308 study med start date, then impute AE start date to be the earlier of (361-308 study med start date; full or imputed AE end date [if non-missing]).
- If only year (YYYY) of AE start date is known and YYYY  $\neq$  year of 361-308 study med start date, then impute AE start date to be YYYY-01-01.
- If AE start date is completely missing, then impute AE start date to be the earlier of (361-308 study med start date; full or imputed AE end date [if non-missing]).

Step 3) For the remaining events in 361-309 database, impute missing or partial event start and/or end dates (if not ongoing) using the algorithm below.

If an event has some missing components in both the start and end dates, first impute the end date.

#### **AE end date imputation**

- If year and month (YYYY-MM) of AE end date are known, then impute the missing day to be the earlier of (last day of the month; date of 361-309 last contact).
- If only year (YYYY) of AE end date is known, then impute the missing month and day to be the earlier of (31st December; date of 361-309 last contact).
- If AE end date is completely missing and AE is not ongoing, then impute AE end date to be date of 361-309 last contact.

#### **AE Start date imputation**

- If year and month (YYYY-MM) of AE start date are known and YYYY-MM = year and month of OLE study med start date, then impute AE start date to be the earlier of (OLE study med start date; full or imputed AE end date [if non-missing]).
- If year and month (YYYY-MM) of AE start date are known and YYYY-MM  $\neq$  year and month of OLE study med start date, then impute AE start date to be YYYY-MM-01.
- If only year (YYYY) of AE start date is known and YYYY = year of OLE study med start date, then impute AE start date to be the earlier of (OLE study med start date; full or imputed AE end date [if non-missing]).

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- If only year (YYYY) of AE start date is known and  $YYYY \neq$  year of OLE study med start date, then impute AE start date to be YYYY-01-01.
- If AE start date is completely missing, then impute AE start date to be the earlier of (OLE study med start date; full or imputed AE end date [if non-missing]).

Step 4) Using the full or imputed event dates, assign events into 361-308pre-treatment event, 361- 308AE, or 361-309 AE as described below.

If both event start date/time and 361-309 OLE study med start date/time are available:

- If event start date/time < 361-309 OLE study med start date/time, then 361-308 pre-treatment event or 361-308 AE\*.
  - If event start date/time  $\geq$  361-309 OLE study med start date/time, then 361-309 AE.
- If (event start date is available and time is not available) and/or (361-309 OLE study med start date is available and time is not available):
- If event start date < 361-309 OLE study med start date, then 361-308 pre-treatment event or 361- 308 AE\*.
  - If event start date > 361-309 OLE study med start date, then 361-309 AE.
  - If event start date = 361-309 OLE study med start date and the event record exists in 361-308 databases<sup>§</sup>, then 361-308 pre-treatment event or 361-308 AE\*.
  - If event start date = 361-309 OLE study med start date and the event record does not exist in 361- 308 databases<sup>§</sup>, then 361-309 AE.

\*The distinction between 361-308 pre-treatment event and 361-308 AE should be performed as specified in the 361-308 SAP.

<sup>§</sup>Based on a comparison of subject ID, PT, AE start date (and time if available), severity, and seriousness.

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**ALGORITHM FOR PRIOR / CONCOMITANT / POST-TREATMENT MEDICATIONS**

In case of partial or missing medication start and/or stop dates, impute the partial or missing dates using the algorithm below.

If a medication has some missing components in both the start and stop dates, first impute the stop date.

**Impute stop date as latest possible date**

- If only day unknown, impute to the earlier of (last day of the month; date of 361-309 last contact).
- If month and day unknown, impute to the earlier of (31<sup>st</sup> December; date of 361-309 last contact).
- If stop date is completely unknown and medication is not ongoing, impute to date of 361-309 last contact.

**Impute start date as earliest possible date**

*CRF questions: 'Started prior to first dose?' = Yes; 'Started after last dose of study medication?' = No.*

- If only day unknown, impute to the later of (first day of the month; date of birth [if full date is available]).
- If month and day unknown, impute to the later of (1<sup>st</sup> January; date of birth [if full date is available]).
- If start date is completely unknown, impute to the earlier of (date of informed consent\*; full or imputed medication stop date [if not missing]).

*CRF questions: 'Started prior to first dose?' = No; 'Started after last dose of study medication?' = Yes.*

- If only day unknown, impute to the later of (first day of the month; 361-309 study med end date + 1).
- If month and day unknown, impute to the later of (1<sup>st</sup> January; 361-309 study med end date + 1).
- If start date is completely unknown, impute to 361-309 study med end date + 1.

*CRF questions: 'Started prior to first dose?' = No; 'Started after last dose of study medication?' = No.*

- If only day unknown, impute to the later of (first day of the month; 361-309 study med start date).
- If month and day unknown, impute to the later of (1<sup>st</sup> January; 361-309 study med start date).
- If start date is completely unknown, impute to 361-309 study med start date.

**Then assign a medication into prior, concomitant, or post-treatment**

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The concept of “date” below should also include time information whenever time is available for both comparators.

- If medication stop date < 361-309 study med start date, assign as prior.
- If (medication stop date ≥ 361-309 study med start date or medication is ongoing) and medication start date ≤ 361-309 study med end date, assign as concomitant.
- If medication start date > 361-309 study med end date, assign as post-treatment.

**Overriding rule**

For the case where the medication start date is known and is equal to 361-309 study med end date and the medication start time is unknown, or the case where the imputed medication start date is equal to 361-309 study med end date:

- If CRF question ‘*Started after last dose of study medication?*’ = No, then assign as concomitant.
- If CRF question ‘*Started after last dose of study medication?*’ = Yes, then assign as post-treatment.

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**PARTIAL DATE IMPUTATION RULES FOR INITIAL ONSET OF SCHIZOPHRENIA**

For subjects with partial onset date of schizophrenia, impute the onset date using the following rules:

- If only day unknown, impute as the earlier of: 15<sup>th</sup> of the month, or date of ICF\*.
- If both month and day unknown, impute as the earlier of: June 30<sup>th</sup> of the year, or date of ICF\*.

**PARTIAL DATE IMPUTATION RULES FOR CURRENT ONSET OF ACUTE EXACERBATION**

For subjects with partial onset date of acute exacerbation, impute the onset date using the following rules:

- If only day unknown and the known year and month is earlier than the year and month of ICF\*, impute as the later of: 15<sup>th</sup> of the month, or date of initial onset of schizophrenia (actual or imputed).
- If only day unknown and the known year and month is the same as the year and month of ICF\*, impute as the later of: earlier of (date of ICF\*, 15<sup>th</sup> of the month), or date of initial onset of schizophrenia (actual or imputed).
- If both month and day unknown and the known year is earlier than the year of ICF\*, impute as the later of: June 30<sup>th</sup> of the year, or date of initial onset of schizophrenia (actual or imputed).
- If both month and day unknown and the known year is the same as the year of ICF\*, impute as the later of: earlier of (date of ICF\*, June 30<sup>th</sup> of the year), or date of initial onset of schizophrenia (actual or imputed).

**PARTIAL DATE IMPUTATION RULES FOR FIRST HOSPITALIZATION**

For subjects with partial date of first hospitalization for treatment of schizophrenia, impute the date using the following rules:

- If only day unknown, impute as the earlier of: 15<sup>th</sup> of the month, or date of ICF\*.
- If both month and day unknown, impute as the earlier of: June 30<sup>th</sup> of the year, or date of ICF\*.

For subjects whose date of first hospitalization for treatment of schizophrenia is completely missing AND the number of prior

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hospitalizations for treatment of schizophrenia is 0, impute the date of first hospitalization to be the “*Date of admission for this study hospitalization*” collected on the “*Psychiatric Hospitalization (HOSP)*” CRF form.

**PARTIAL DATE IMPUTATION RULES FOR FIRST ANTI-PSYCHOTIC DRUG THERAPY**

For subjects with partial start date for the first anti-psychotic drug therapy of at least 2 weeks duration intended for treatment of schizophrenia, impute the start date using the following rules:

- If only day unknown, impute as the earlier of: 15<sup>th</sup> of the month, or date of ICF\*.
- If both month and day unknown, impute as the earlier of: June 30<sup>th</sup> of the year, or date of ICF\*.

**PARTIAL DATE IMPUTATION RULES FOR ONSET OF INITIAL BEHAVIORAL DISTURBANCE**

For adolescent subjects with partial onset date of initial behavioral disturbance, impute the onset date using the following rules:

- If only day unknown, impute as the earlier of: 15<sup>th</sup> of the month, or the later of (date of ICF and date of IAF).
- If both month and day unknown, impute as the earlier of: June 30<sup>th</sup> of the year, or the later of (date of ICF and date of IAF).

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**RULES FOR ASSIGNING DOSEON/DOSEA**

- In general, DOSEON/DOSEA should be the dose level immediately before the start of an AE or an assessment. In case the AE or the assessment start date/time coincides with the first dosing start date/time of the study, the DOSEON/DOSEA should be assigned to the dose level associated with that first dosing start date/time. In case the AE or the assessment start date/time coincides with a dosing start date/time other than the first dosing start date/time, the DOSEON/DOSEA should be assigned to the dose level associated with the previous dosing start date/time.
- In case of missing AE start time, missing assessment (start) time, and/or missing dosing start time, DOSEON/DOSEA should be assigned using the algorithm in the table below.

Scenario	Data	Rules
Dosing start date and start time both available	Adverse Events	If AE start date is available and AE start time is missing, dose on the same day as AE start should be assigned as DOSEON.
	Scales/Questionnaires, Vitals, Labs, ECG	If assessment start date is available and assessment start time is missing, dose on the previous day of the assessment should be assigned as DOSEA.
Dosing start date available but start time missing	Adverse Events	Regardless of whether AE start time is available, dose on the same day as AE start should be assigned as DOSEON.
	Scales/Questionnaires, Vitals, Labs, ECG	Regardless of whether assessment start time is available, dose on the previous day of the assessment should be assigned as DOSEA.

- In case of partial or missing AE start date, the imputed AE start date will be used for the purpose of assigning DOSEON.

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## APPENDIX 3. UNCORRELATED PANSS SCORE MATRIX (UPSM)

PANSS	UPSM-POS	UPSM-DIS	UPSM-NAA	UPSM-NDE	UPSM-HOS	UPSM-ANX	UPSM-DEP
PANSS01	0.5792730597	-0.1547126840	-0.0828932650	0.0071927220	-0.0593031510	-0.0735449620	0.0020484408
PANSS02	0.0292444390	0.1975824582	-0.0260173260	-0.0234753800	-0.0368756010	-0.0012396240	-0.0361645050
PANSS03	0.2065788330	-0.0179419820	-0.0250663450	-0.0133031880	-0.0300507070	0.0001506005	0.0293001724
PANSS04	-0.0336790630	0.0115284348	0.0011652392	-0.0723891460	0.1379358628	0.1108194656	-0.1045224460
PANSS05	-0.0341508580	-0.0301875430	-0.0041019560	-0.0233459100	-0.0069204000	-0.0313277060	0.0308288417
PANSS06	0.3537254634	-0.0626270750	0.0477329954	0.0012126712	0.0192067437	-0.0161398140	0.0063264235
PANSS07	-0.0383468990	-0.1767919370	-0.0299340700	0.0314652864	0.5025411101	-0.0997121200	0.0573604084
PANSS08	-0.0054230270	-0.0291400280	0.0568702938	0.2474176209	-0.0388464000	0.0188235393	-0.0091524870
PANSS09	-0.0315765690	-0.0243925850	0.3317907576	-0.0228204580	-0.0507096280	-0.0145653830	0.0112689069
PANSS10	-0.0742072890	-0.0401313020	-0.0097485120	0.0161513666	0.0245536353	-0.0176161520	-0.0172218040
PANSS11	-0.0943532590	-0.0856364190	0.4611503804	-0.0286825100	-0.0189062390	-0.0185825180	-0.0130433890
PANSS12	0.0043338689	0.1062496353	0.0255910591	-0.0301470410	-0.0133497570	0.0096065791	-0.0686802390
PANSS13	0.0041274699	0.0051521898	0.0009558861	0.2576813501	-0.0085004640	0.0194235006	-0.1037459520
PANSS14	-0.0111267300	0.1462268689	-0.0276416260	0.0023017188	-0.0055291270	-0.0118427800	0.0040128786
PANSS15	-0.0356272010	0.0552508287	-0.0382627720	0.0110152489	-0.0309176290	0.0444944076	0.1059845189
PANSS16	-0.0331052830	-0.0821894470	-0.0327376640	-0.0533178140	-0.0386473380	0.4576579818	0.1197800301
PANSS17	-0.0368854600	-0.0004363100	-0.0020681500	-0.0407976460	-0.0272172130	-0.0253163640	0.2459654614
PANSS18	-0.0931367690	-0.0332617600	-0.0132943930	0.0231904701	-0.0287529750	0.5123850161	-0.0312522560
PANSS19	-0.0455199430	0.0494113554	-0.0324174560	0.1026255664	-0.0136676190	0.0293507269	-0.0441735260
PANSS20	-0.0344751890	-0.0688197670	-0.0412738350	0.0381793764	0.0042219619	-0.0635101090	0.4514426846
PANSS21	-0.0348890020	-0.0366137810	-0.0779782830	0.4409895205	-0.0073240410	-0.0192655290	0.0464131877
PANSS22	-0.0803690920	0.0334025939	-0.0088488890	-0.0200483170	0.2858700784	-0.0567167860	-0.0531076130
PANSS23	0.1428966744	0.0939213700	-0.0326143600	-0.0367524640	-0.0675856980	-0.0209072840	-0.0177890070
PANSS24	-0.0383047770	-0.0324584080	-0.0255393890	-0.0180115340	-0.0266180700	-0.0210068530	-0.0176029110
PANSS25	-0.1036311520	0.2814367260	-0.0478918640	0.0029986238	0.0037656449	-0.0226520240	0.0401351054
PANSS26	0.0142987589	0.1548635741	-0.0306089330	-0.0331581690	0.0262295986	-0.0576293550	-0.0626180490
PANSS27	-0.0573513270	0.1867914227	-0.0143489160	0.0581534153	-0.0145494330	-0.0371788310	0.0455412078
PANSS28	-0.0748387810	0.0166272025	-0.0267498020	-0.0031632780	0.2546669938	-0.0201249190	-0.0076420280
PANSS29	-0.0520812460	0.2912295497	0.0029775475	-0.0324350460	-0.0442337350	-0.0047991290	0.0567191230

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PANSS30	-0.0112030990	-0.0007246980	0.2860136812	-0.0606201430	0.0183598393	-0.0302347770	0.0370748725
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APPENDIX 4.      **INTERNATIONALLY AGREED ORDER FOR SYSTEM ORGAN CLASS**

Internationally Agreed Order
Infections and infestations
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Blood and lymphatic system disorders
Immune system disorders
Endocrine disorders
Metabolism and nutrition disorders
Psychiatric disorders
Nervous system disorders
Eye disorders
Ear and labyrinth disorders
Cardiac disorders
Vascular disorders
Respiratory, thoracic and mediastinal disorders
Gastrointestinal disorders
Hepatobiliary disorders
Skin and subcutaneous tissue disorders
Musculoskeletal and connective tissue disorders
Renal and urinary disorders
Pregnancy, puerperium and perinatal conditions
Reproductive system and breast disorders
Congenital, familial and genetic disorders
General disorders and administration site conditions
Investigations
Injury, poisoning and procedural complications
Surgical and medical procedures
Social circumstances
Product issues

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## APPENDIX 5. ADVERSE EVENTS OF POTENTIAL DRUG ABUSE AND DEPENDENCE

To ensure comprehensive and consistent selection of terminology used for analyses of drug abuse and dependence in ongoing / planned studies of SEP-363856, MedDRA preferred terms were identified from the following sources:

FDA Guidance for Industry: Assessment of Abuse Potential of Drugs (CDER, 2017; noted that the Guidance reflects MedDRA version 20.0 terminology)

MedDRA version 22.0 SMQ: Drug abuse and dependence [20000101], Broad

FDA FMQ: Study Agent Abuse Potential, Broad (released at FDA public workshop “Advancing Premarket Safety Analytics”, held September 14, 2022)

### Description:

Preferred terms were tabulated using MedDRA version 22.0 from the sources listed above. All preferred terms (PTs) within the FDA Abuse Potential Guidance were included. All PTs listed in the MedDRA version 22.0 SMQ for Drug abuse and dependence [20000101] were included. For the FDA Study Agent Abuse Potential FMQ: No associated MedDRA PT was found for the term “Hypnogogic hallucination”, and this is therefore not included. SMPA evaluates ‘Drug withdrawal’ as a unique medical concept using MedDRA version 22.0 SMQ for Drug withdrawal [20000102] (Broad); any overlapping PTs from the Drug withdrawal SMQ which are listed in the FDA Study Agent Abuse Potential FMQ are not included. All other PTs listed in the FDA FMQ were included.

The table below depicts the preferred terms by source.

**Table 7: Drug Abuse and Dependence Preferred Terms Using MedDRA v 22.0**

FDA Guidance 2017		SMQ 20000101		FDA FMQ	
PT	Code	PT	Code	PT	Code
-	-	Accidental overdose	10000381	Accidental overdose	10000381
-	-	-	-	Acute psychosis	10001022
Aggression	10001488	-	-	-	-
Behavioural addiction	10081939	-	-	-	-
Confusional state	10010305	-	-	-	-
-	-	-	-	Delusion of grandeur	10012241
-	-	-	-	Delusional perception	10012258
Dependence	10012335	Dependence	10012335	Dependence	10012335
-	-	-	-	Depersonalisation	10012357
-	-	-	-	Derealisation disorder	10077810
-	-	-	-	Detoxification	10061814
-	-	-	-	Disinhibition	10013142
Disorientation	10013395	-	-	-	-
-	-	Disturbance in social behaviour	10061108	-	-
Dizziness	10013573	-	-	-	-
Dopamine dysregulation syndrome	10067468	Dopamine dysregulation syndrome	10067468	-	-

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FDA Guidance 2017		SMQ 20000101		FDA FMQ	
PT	Code	PT	Code	PT	Code
-	-	Drug abuse	10013654	Drug abuse	10013654
-	-	Drug abuser	10061111	Drug abuser	10061111
-	-	Drug dependence	10013663	Drug dependence	10013663
Drug dependence, antepartum	10013675	Drug dependence, antepartum	10013675	Drug dependence, antepartum	10013675
Drug dependence, postpartum	10013676	Drug dependence, postpartum	10013676	Drug dependence, postpartum	10013676
-	-	Drug detoxification	10052237	Drug detoxification	10052237
-	-	Drug diversion	10066053	Drug diversion	10066053
-	-	Drug level above therapeutic	10061132	-	-
-	-	Drug level increased	10013722	-	-
-	-	Drug screen	10050837	-	-
-	-	Drug screen positive	10049177	-	-
Drug tolerance	10052804	Drug tolerance	10052804	-	-
Drug tolerance decreased	10052805	Drug tolerance decreased	10052805	-	-
Drug tolerance increased	10052806	Drug tolerance increased	10052806	-	-
Drug use disorder	10079381	Drug use disorder	10079381	Drug use disorder	10079381
-	-	Drug use disorder, antepartum	10079382	Drug use disorder, antepartum	10079382
-	-	Drug use disorder, postpartum	10079383	Drug use disorder, postpartum	10079383
-	-	-	-	Energy increased	-
Euphoric mood	10015535	-	-	Euphoric mood	10015535
Feeling abnormal	10016322	-	-	-	-
Feeling drunk	10016330	-	-	Feeling drunk	10016330
-	-	-	-	Feeling jittery	10016338
Feeling of relaxation	10016352	-	-	Feeling of relaxation	10016352
-	-	-	-	Flight of ideas	10016777
Hallucination	10019063	-	-	Hallucination	10019063
Hallucination, auditory	10019070	-	-	Hallucination, auditory	10019070
Hallucination, gustatory	10019071	-	-	Hallucination, gustatory	10019071
Hallucination, olfactory	10019072	-	-	Hallucination, olfactory	10019072
Hallucination, synaesthetic	10062824	-	-	Hallucination, synaesthetic	10062824
Hallucination, tactile	10019074	-	-	Hallucination, tactile	10019074
Hallucination, visual	10019075	-	-	Hallucination, visual	10019075
Hallucinations, mixed	10019079	-	-	Hallucinations, mixed	10019079
Inappropriate affect	10021588	-	-	Hallucination, gustatory	10019071
-	-	-	-	Hypersomnia	10020765
-	-	-	-	Hypervigilance	10048533
-	-	-	-	Hypnagogic hallucination	10020927

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FDA Guidance 2017		SMQ 20000101		FDA FMQ	
PT	Code	PT	Code	PT	Code
-	-	-	-	Hypnagogic hallucination	No such code
-	-	-	-	Hypnopompic hallucination	10020928
-	-	-	-	Inappropriate affect	10021588
-	-	-	-	Infant sedation	10082187
-	-	-	-	Intentional misuse of drug delivery system	10081675
-	-	Intentional overdose	10022523	Intentional overdose	10022523
-	-	Intentional product misuse	10074903	Intentional product misuse	10074903
-	-	Intentional product use issue	10076308	-	-
-	-	-	-	Mania	10026749
-	-	Maternal use of illicit drugs	10026938	-	-
-	-	Medication overuse headache	10072720	-	-
-	-	-	-	Mixed delusion	10076429
Mood altered	10027940	-	-	Mood altered	10027940
Mood swings	10027951	-	-	-	-
-	-	Narcotic bowel syndrome	10072286	-	-
-	-	Needle track marks	10028896	-	-
-	-	Neonatal complications of substance abuse	10061862	-	-
-	-	-	-	Neonatal oversedation	10050395
-	-	Overdose	10033295	-	-
-	-	-	-	Paranoia	10033864
-	-	-	-	Post-injection delirium sedation syndrome	10072851
-	-	Prescription drug used without a prescription	10076639	-	-
-	-	Prescription form tampering	10067669	Prescription form tampering	10067669
-	-	-	-	Psychomotor hyperactivity	10037211
Psychotic disorder	10061920	-	-	-	-
-	-	Reversal of opiate activity	10039004	-	-
-	-	-	-	Sedation	10039897
-	-	-	-	Sedation complication	10079741
Somnolence	10041349	-	-	Somnolence	10041349
-	-	-	-	Somnolence neonatal	10041350

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FDA Guidance 2017		SMQ 20000101		FDA FMQ	
PT	Code	PT	Code	PT	Code
-	-	-	-	Stupor	10042264
-	-	Substance abuse	10066169	Substance abuse	10066169
-	-	Substance abuser	10067688	Substance abuser	10067688
-	-	Substance dependence	10076595	Substance dependence	10076595
-	-	Substance use	10070964	-	-
Substance use disorder	10079384	Substance use disorder	10079384	Substance use disorder	10079384
-	-	Substance-induced mood disorder	10072387	Substance-induced mood disorder	10072387
-	-	Substance-induced psychotic disorder	10072388	Substance-induced psychotic disorder	10072388
-	-	-	-	Suspected product tampering	10079404
Thinking abnormal	10043431	-	-	-	-
-	-	Toxicity to various agents	10070863	-	-
-	-	-	-	Transient psychosis	10056326
-	-	-	-	Withdrawal hypertension	10048007

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## APPENDIX 6. EXTRAPYRAMIDAL ADVERSE EVENTS

To ensure comprehensive and consistent selection of terminology used for analyses of extrapyramidal signs and symptoms in ongoing / planned studies of SEP-363856, MedDRA preferred terms were identified from the following source:

MedDRA version 22.0 SMQ: Extrapyramidal syndrome [20000095], Broad, including all 4 sub-SMQs (Akathisia [20000096], Dyskinesia [20000097], Dystonia [20000098], and Parkinson-like events [20000099])

### Description:

All preferred terms listed in the MedDRA version 22.0 SMQ for Extrapyramidal syndrome [20000095] were included. The table below depicts the preferred terms by sub-SMQ.

**Table 8: Extrapyramidal Syndrome SMQ Using MedDRA v 22.0**

Akathisia		Dyskinesia		Dystonia		Parkinson-like	
PT	Code	PT	Code	PT	Code	PT	Code
Akathisia	10001540	-	-	-	-	-	-
-	-	-	-	-	-	Akinesia	10001541
-	-	Athetosis	10003620	-	-	-	-
-	-	Ballismus	10058504	-	-	-	-
-	-	-	-	-	-	Bradykinesia	10006100
-	-	Buccoglossal syndrome	10006532	-	-	-	-
-	-	Chorea	10008748	-	-	-	-
-	-	Choreoathetosis	10008754	-	-	-	-
-	-	-	-	-	-	Cogwheel rigidity	10009848
-	-	Dopamine dysregulation syndrome	10067468	-	-	-	-
-	-	-	-	Dopa-responsive dystonia	10080034	-	-
-	-	Dyskinesia	10013916	-	-	-	-
-	-	Dyskinesia neonatal	10013922	-	-	-	-
-	-	Dyskinesia oesophageal	10013924	-	-	-	-
-	-	-	-	Dystonia	10013983	-	-
-	-	-	-	Dystonic tremor	10073210	-	-
-	-	-	-	Early onset primary dystonia	10076668	-	-
-	-	-	-	Emprosthotonus	10014566	-	-
-	-	-	-	-	-	Freezing phenomenon	10060904
-	-	Grimacing	10061991	-	-	-	-
-	-	-	-	-	-	Hypertonia	10020852

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Akathisia		Dyskinesia		Dystonia		Parkinson-like	
PT	Code	PT	Code	PT	Code	PT	Code
-	-	-	-	-	-	Hypertonia neonatal	10048615
-	-	-	-	-	-	Hypokinetic dysarthria	10082243
-	-	-	-	Meige's syndrome	10027138		
-	-	-	-	-	-	Muscle rigidity	10028330
-	-	Oculogyric crisis	10030071	Oculogyric crisis	10030071		
-	-	-	-	-	-	On and off phenomenon	10030312
-	-	-	-	Opisthotonus	10030899	-	-
-	-			Oromandibular dystonia	10067954	-	-
-	-	-	-	-	-	Parkinsonian crisis	10048868
-	-	-	-	-	-	Parkinsonian gait	10056242
-	-	-	-	-	-	Parkinsonian rest tremor	10056437
-	-	-	-	-	-	Parkinsonism	10034010
-	-	-	-	-	-	Parkinsonism hyperpyrexia syndrome	10071243
-	-	-	-	-	-	Parkinson's disease	10061536
-	-	-	-	-	-	Parkinson's disease psychosis	10074835
-	-	Pharyngeal dyskinesia	10070912	-	-	-	-
-	-	-	-	Pharyngeal dystonia	10081226	-	-
-	-	-	-	Pleurothotonus	10035628	-	-
-	-	-	-			Propulsive gait	10082328
-	-	Protrusion tongue	10037076	-	-	-	-
-	-	Rabbit syndrome	10068395	-	-	-	-
-	-	Respiratory dyskinesia	10057570	-	-	-	-
-	-	-	-	-	-	Resting tremor	10071390
-	-	-	-	Spasmodic dysphonia	10067672	-	-
-	-	Tardive dyskinesia	10043118	-	-	-	-
-	-	-	-	Torticollis	10044074	-	-
-	-	-	-	Trismus	10044684	-	-
-	-	-	-	Writer's cramp	10072249	-	-

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Akathisia		Dyskinesia		Dystonia		Parkinson-like	
PT	Code	PT	Code	PT	Code	PT	Code
-	-	Abnormal involuntary movement scale	10075002	-	-	-	-
-	-	-	-	-	-	Action tremor	10072413
-	-	-	-	Blepharospasm	10005159	-	-
-	-	-	-	-	-	Bradyphrenia	10050012
-	-	Chronic tic disorder	10076661	Chronic tic disorder	10076661	-	-
-	-	Complex tic	10076663	Complex tic	10076663	-	-
-	-	Drooling	10013642	Drooling	10013642	Drooling	10013642
-	-	-	-	-	-	Dysphonia	10013952
Extrapyramidal disorder	10015832	Extrapyramidal disorder	10015832	Extrapyramidal disorder	10015832	Extrapyramidal disorder	10015832
-	-	-	-	Facial spasm	10063006	-	-
-	-	-	-	-	-	Fine motor skill dysfunction	10076288
-	-	-	-	-	-	Gait disturbance	10017577
-	-	-	-	Gait inability	10017581	-	-
Hyperkinesia	10020651	-	-	-	-	-	-
Hyperkinesia neonatal	10020652	-	-	-	-	-	-
-	-	-	-	-	-	Hypokinesia	10021021
-	-	-	-	-	-	Hypokinesia neonatal	10021022
-	-	-	-	-	-	Laryngeal tremor	10078751
-	-	-	-	Laryngospasm	10023891	-	-
-	-	-	-	-	-	Micrographia	10057333
-	-	-	-	-	-	Mobility decreased	10048334
Motor dysfunction	10061296	Motor dysfunction	10061296	Motor dysfunction	10061296	Motor dysfunction	10061296
Movement disorder	10028035	Movement disorder	10028035	Movement disorder	10028035	Movement disorder	10028035
-	-	Muscle twitching	10028347	-	-	-	-
-	-	-	-	Muscle contractions involuntary	10028293	-	-
-	-	-	-	Muscle spasms	10028334	-	-
-	-	-	-	Muscle spasticity	10028335	-	-
-	-	-	-	Muscle tightness	10049816	-	-
-	-	-	-	Muscle tone disorder	10072889	Muscle tone disorder	10072889
-	-	-	-	Muscle twitching	10028347	-	-

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Akathisia		Dyskinesia		Dystonia		Parkinson-like	
PT	Code	PT	Code	PT	Code	PT	Code
-	-	-	-	Musculoskeletal stiffness	10052904	Musculoskeletal stiffness	10052904
-	-	-	-	Oesophageal spasm	10030184	-	-
-	-	-	-	Oropharyngeal spasm	10031111	-	-
-	-	-	-	Posture abnormal	10036436	-	-
-	-	-	-	-	-	Postural reflex impairment	10067206
-	-	-	-	-	-	Postural tremor	10073211
-	-	-	-	Posturing	10036437	-	-
-	-	Provisional tic disorder	10076694	Provisional tic disorder	10076694	-	-
Psychomotor hyperactivity	10037211	-	-	-	-	-	-
-	-	-	-	-	-	Reduced facial expression	10078576
Restlessness	10038743	-	-	-	-	-	-
-	-	-	-	Risus sardonicus	10039198	-	-
-	-	Secondary tic	10076702	Secondary tic	10076702	-	-
-	-	Tic	10043833	Tic	10043833	-	-
-	-	-	-	Tongue spasm	10043981	-	-
-	-	-	-	Torticollis psychogenic	10044076	-	-
-	-	-	-	-	-	Tremor	10044565
-	-	-	-	-	-	Tremor neonatal	10044575
-	-	-	-	Uvular spasm	10050908	-	-
-	-	-	-	-	-	-	-
-	-	-	-	-	-	Walking disability	10053204

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## APPENDIX 7. PREDEFINED POTENTIALLY CLINICALLY SIGNIFICANT (PCS) CRITERIA IN SI UNITS

### STANDARD PCS CRITERIA FOR LABORATORY PARAMETERS – SI UNITS

Category Parameter Name Age/Sex Restriction, if any	PCS Low	PCS High
<b>HEMATOLOGY</b>		
<b>WBC</b>	$\leq 2.8 \times 10^9/L$	$\geq 16 \times 10^9/L$
<b>Neutrophils (abs)</b>	$< 0.5 \times 10^9/L$	$> 13.5 \times 10^9/L$
<b>Lymphocytes (abs)</b>	N/A	$> 12 \times 10^9/L$
<b>Monocytes (abs)</b>	N/A	$> 2.5 \times 10^9/L$
<b>Eosinophils (abs)</b>	N/A	$> 1.6 \times 10^9/L$
<b>Basophils (abs)</b>	N/A	$> 1.6 \times 10^9/L$
<b>Neutrophils (relative)</b>	$\leq 0.15$	$> 0.85$
<b>Lymphocytes (relative)</b>	N/A	$\geq 0.75$
<b>Monocytes (relative)</b>	N/A	$\geq 0.15$
<b>Eosinophils (relative)</b>	N/A	$\geq 0.10$
<b>Basophils (relative)</b>	N/A	$\geq 0.10$
<b>Hemoglobin</b>		
Male	$\leq 115 \text{ g/L}$	$\geq 190 \text{ g/L}$
Female	$\leq 95 \text{ g/L}$	$\geq 175 \text{ g/L}$
<b>Hematocrit</b>		
Male	$\leq 0.37$	$\geq 0.60$
Female	$\leq 0.32$	$\geq 0.54$
<b>RBC</b>	$\leq 3.5 \times 10^{12}/L$	$\geq 6.4 \times 10^{12}/L$
<b>Platelet Count</b>	$\leq 75 \times 10^9/L$	$\geq 700 \times 10^9/L$
<b>SERUM CHEMISTRY</b>		
<b>Sodium</b>	$< 130 \text{ mmol/L}$	$> 150 \text{ mmol/L}$
<b>Potassium</b>	$< 3 \text{ mmol/L}$	$> 5.5 \text{ mmol/L}$
<b>Chloride</b>	$\leq 90 \text{ mmol/L}$	$\geq 118 \text{ mmol/L}$
<b>Calcium</b>	$< 1.75 \text{ mmol/L}$	$\geq 3.1 \text{ mmol/L}$
<b>Phosphate</b>	$< 0.65 \text{ mmol/L}$	$> 1.65 \text{ mmol/L}$
<b>Bicarbonate</b>	$< 15.1 \text{ mmol/L}$	$> 34.9 \text{ mmol/L}$
<b>Magnesium</b>	$< 0.4 \text{ mmol/L}$	$> 1.23 \text{ mmol/L}$
<b>AST</b>	N/A	$\geq 3 \times \text{ULN}$
<b>ALT</b>	N/A	$\geq 3 \times \text{ULN}$
<b>Alkaline Phosphatase</b>	N/A	$\geq 1.5 \times \text{ULN}$
<b>CK</b>	N/A	$> 2.5 \times \text{ULN}$
<b>Creatinine</b>	N/A	$\geq 177 \text{ umol/L}$
<b>BUN</b>	N/A	$\geq 10.7 \text{ mmol/L}$
<b>Total bilirubin</b>	N/A	$\geq 34.2 \text{ umol/L}$ OR $> 2 \times \text{ULN}$
<b>Total protein</b>	$\leq 45 \text{ g/L}$	$\geq 100 \text{ g/L}$
<b>Albumin</b>	$\leq 25 \text{ g/L}$	N/A
<b>Total Cholesterol</b>	N/A	$> 7.76 \text{ mmol/L}$
<b>HDL-Cholesterol</b>	$< 0.78 \text{ mmol/L}$	N/A
<b>LDL-Cholesterol</b>	N/A	$> 4.9 \text{ mmol/L}$
<b>Triglycerides</b>	N/A	$> 3.42 \text{ mmol/L}$

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Uric acid		
Male	N/A	> 595 umol/L
Female	N/A	> 476 umol/L
Glucose	< 2.78 mmol/L	> 13.9 mmol/L
HbA1c	N/A	≥ 0.075
Prolactin	N/A	≥ 5 × ULN
URINALYSIS		
RBC	N/A	> 25 hpf
WBC	N/A	> 25 hpf



**APPENDIX 8. PSQI SCORING SHEET**

PSQI scoring reference as defined by BUYSSE is provided in following website:

<https://www.sleep.pitt.edu/instruments/#psqi>

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Author:	PPD	Version Number:	1.0
		Version Date:	22OCT2024

Pittsburgh Sleep Quality Index (PSQI)

Form Administration Instructions, References, and Scoring

Form Administration Instructions

The range of values for questions 5 through 10 are all 0 to 3.

Questions 1 through 9 are not allowed to be missing except as noted below. If these questions are missing then any scores calculated using missing questions are also missing. Thus it is important to make sure that all questions 1 through 9 have been answered.

In the event that a range is given for an answer (for example, ‘30 to 60’ is written as the answer to Q2, minutes to fall asleep), split the difference and enter 45.

Reference

Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Research* 28:193-213, 1989.

Scores – reportable in publications

On May 20, 2005, on the instruction of Dr. Daniel J. Buysse, the scoring of the PSQI was changed to set the score for Q5j to 0 if either the comment or the value was missing. This may reduce the DISTB score by 1 point and the PSQI Total Score by 1 point.

PSQIDURAT

DURATION OF SLEEP

IF Q4 ≥ 7, THEN set value to 0  
IF Q4 < 7 and ≥ 6, THEN set value to 1  
IF Q4 < 6 and ≥ 5, THEN set value to 2  
IF Q4 < 5, THEN set value to 3  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIDISTB

SLEEP DISTURBANCE

IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) = 0, THEN set value to 0  
  
IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) ≥ 1 and ≤ 9, THEN set value to 1  
  
IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) > 9 and ≤ 18, THEN set value to 2  
  
IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) > 18, THEN set value to 3  
  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQILATEN

SLEEP LATENCY

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**First, recode Q2 into Q2new thusly:**  
IF  $Q2 \geq 0$  and  $\leq 15$ , THEN set value of Q2new to 0  
IF  $Q2 > 15$  and  $\leq 30$ , THEN set value of Q2new to 1  
IF  $Q2 > 30$  and  $\leq 60$ , THEN set value of Q2new to 2  
IF  $Q2 > 60$ , THEN set value of Q2new to 3  
**Next**  
IF  $Q5a + Q2new = 0$ , THEN set value to 0  
IF  $Q5a + Q2new \geq 1$  and  $\leq 2$ , THEN set value to 1  
IF  $Q5a + Q2new \geq 3$  and  $\leq 4$ , THEN set value to 2  
IF  $Q5a + Q2new \geq 5$  and  $\leq 6$ , THEN set value to 3  
  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIDAYDYS

**DAY DYSFUNCTION DUE TO SLEEPINESS**  
IF  $Q8 + Q9 = 0$ , THEN set value to 0  
IF  $Q8 + Q9 \geq 1$  and  $\leq 2$ , THEN set value to 1  
IF  $Q8 + Q9 \geq 3$  and  $\leq 4$ , THEN set value to 2  
IF  $Q8 + Q9 \geq 5$  and  $\leq 6$ , THEN set value to 3  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIHSE

**SLEEP EFFICIENCY**  
Diffsec = Difference in seconds between day and time of day Q1 and day Q3  
Diffhour = Absolute value of diffsec / 3600  
newtib =IF diffhour > 24, then newtib = diffhour – 24  
          IF diffhour  $\leq 24$ , THEN newtib = diffhour  
(NOTE, THE ABOVE JUST CALCULATES THE HOURS BETWEEN GNT (Q1)  
AND GMT (Q3))  
tmphse = (Q4 / newtib) \* 100  
  
IF tmphse  $\geq 85$ , THEN set value to 0  
IF tmphse < 85 and  $\geq 75$ , THEN set value to 1  
IF tmphse < 75 and  $\geq 65$ , THEN set value to 2  
IF tmphse < 65, THEN set value to 3  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQISLPQUAL

**OVERALL SLEEP QUALITY**  
Q6  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIMEDS

**NEED MEDS TO SLEEP**  
Q7  
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQI

**TOTAL**  
DURAT + DISTB + LATEN + DAYDYS + HSE + SLPQUAL + MEDS  
Minimum Score = 0 (better); Maximum Score = 21 (worse)  
Interpretation: TOTAL  $\leq 5$  associated with good sleep quality  
                  TOTAL > 5 associated with poor sleep quality

**APPENDIX 9. CLASSIFICATION OF PATIENT TYPE FROM UPSM FACTOR SCORES**

Guided machine learning via linear support vector machine (L-SVM) algorithm in MATLAB will be used to classify subjects into 5 patient types based on UPSM factor scores. There are 5 distinct patient types described in the table below.

TYPE	PATIENT TYPE
1	Prominently Disorganized
2	Prominently Negative
3	Prominently Hostile
4	Prominently Positive
5	Prominently Affective

The classification will occur in two steps:

- Step 1: Train L-SVM in MATLAB to classify subjects into 1 of 5 patient types using 7 columns of UPSM data. Training dataset is given in the table below.
- Step 2: Use the now trained classifier function in MATLAB to classify subjects into 1 of 5 patient types using 7 columns of UPSM data.

**Table 9: Training Dataset**

UPSM-HOS	UPSM-DIS	UPSM-POS	UPSM-NAA	UPSM-ANX	UPSM-NDE	UPSM-DEP	TYPE
0.110138	1.960813	0.478927	3.298293	1.382828	2.114771	0.391504	1
1.431769	1.616874	3.310726	2.225812	0.541127	1.542821	0.22721	4
0.537462	2.293898	3.358519	2.713077	2.582309	1.584137	2.762624	5
1.458801	0.51371	3.162632	4.179415	2.367169	0.687056	2.014098	5
0.491282	1.47429	0.583566	2.633944	4.227873	1.12837	3.735909	5
2.124307	2.621508	2.553096	1.81619	1.463642	0.857061	1.801388	3
0.229749	4.356682	3.900132	2.980611	1.59104	2.825456	2.487569	1
0.65872	1.492003	3.98728	1.558729	1.721153	1.716735	2.567419	4
4.311785	3.13258	3.26397	-0.53456	3.583895	0.246863	3.063737	3
1.673673	2.982224	2.381804	0.168301	2.017634	2.223616	2.420761	3
-0.28911	1.117716	3.325504	4.394722	0.710643	2.619891	1.77449	4
-0.40258	1.164411	3.68884	2.699136	3.395212	2.032147	2.131544	5
0.120462	2.660464	3.395254	2.078197	2.900268	0.261296	2.725002	4
1.361992	3.411795	4.64508	0.18819	1.223746	2.532468	1.366811	4
3.667904	3.136446	2.321715	2.125103	3.409371	1.537432	-0.2218	3
4.879887	3.475862	2.076838	-0.59349	1.113849	1.688076	0.123996	3
-0.02164	2.41729	2.779121	3.079331	2.108443	1.951256	1.676715	1
-0.3092	2.157215	2.674034	2.803489	1.084307	0.996332	1.994321	4
0.196083	2.475004	2.878793	1.351682	1.201559	0.816825	2.181635	4
0.030238	3.526967	4.532129	0.380547	0.326149	1.986222	1.517082	4
2.275873	2.640193	3.251667	0.839343	2.051567	0.58417	2.170745	3
0.664909	2.042059	2.76595	2.366495	1.440192	0.733822	2.402925	5
1.243306	1.337145	4.074218	2.793057	2.698381	2.51747	3.318289	5
3.22947	2.860181	3.577492	3.502082	2.628584	0.298051	3.390157	5
0.901195	1.663412	2.142304	3.688469	1.330552	2.56257	2.640387	5
2.593164	3.648882	3.709823	3.206283	1.011247	1.094186	3.558644	3
-0.51118	2.448093	2.437806	1.15006	2.797663	3.063268	2.065887	1
-0.11226	1.666885	2.743509	1.415346	0.850013	2.305111	1.401516	4
0.461343	2.627467	4.224476	0.273361	1.87481	0.626399	1.981483	4
2.984818	3.119943	1.817018	0.766638	2.093436	1.529787	0.320228	3
3.77918	4.634406	1.565869	3.283619	0.239241	1.954698	0.044583	2

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2.144653	2.782737	3.498727	0.538967	1.545457	0.710868	0.792113	3
0.894321	4.51713	0.328192	4.038478	0.461848	4.202648	0.153093	2
-0.36753	4.43122	3.945508	3.314841	3.447207	2.09228	1.277813	1
-0.54075	4.778543	0.863248	4.518782	2.584591	3.675675	1.102248	1
0.567503	3.24148	3.050335	3.616151	2.485309	1.23559	1.194027	1
-0.14361	3.811718	1.934878	4.106673	2.496619	1.883645	1.255909	1
2.074899	4.309083	3.67494	2.931829	2.158336	1.564656	0.532635	2
-0.19755	3.56726	2.443049	2.469007	2.522924	2.551866	4.876176	1
1.77413	1.53753	2.847139	1.882985	0.272108	1.812518	3.542881	5
1.620442	2.629055	2.66762	-0.09426	2.112038	0.781558	3.528088	3
0.284396	1.770956	2.033619	2.009207	3.469858	0.528655	2.227344	5
3.932854	4.528324	2.861762	1.430475	2.837778	1.200249	2.254885	3
-0.56969	0.692111	4.179689	2.437995	1.95239	1.874127	3.146663	5
4.750689	2.427282	4.856594	3.187711	1.452157	-0.41915	0.793141	3
3.405697	1.355663	3.002656	3.832785	3.044058	1.05007	2.012123	5
3.246586	1.094777	3.274349	3.670523	2.797322	0.536438	3.19334	5
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2.207155	1.517604	2.625454	1.804154	0.763335	0.901574	1.873668	3
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0.021092	1.402188	2.331655	1.812051	2.72359	0.272525	2.258971	5
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0.443037	2.964066	1.915887	2.678915	1.792021	2.577074	1.45575	1
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2.078746	2.558682	3.375823	2.666212	0.672835	2.323415	1.714464	2
2.272887	3.299781	2.934946	3.415632	1.601629	2.553767	1.538921	2
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1.554845	3.411567	3.696475	1.814908	2.144365	0.424043	1.026569	3
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2.24989	0.822324	3.131529	2.802165	1.135157	0.648374	2.308554	5
2.111609	1.90889	2.584371	2.77702	1.595925	0.485008	2.907262	5
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0.745193	1.490097	3.379798	2.22975	2.245205	1.51202	1.55745	4
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1.884125	2.075508	2.16487	1.55485	2.294037	1.421776	2.021908	3
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1.339493	2.1716	2.640416	1.643363	1.890265	0.862075	2.452216	5
1.411204	1.768375	2.509155	2.071366	1.069819	1.270294	2.138543	5
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1.637491	2.60536	2.78299	3.176663	3.185908	0.945942	1.681183	1

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2.397302	1.887024	1.91816	2.197268	2.581808	1.771002	2.369984	5
2.328269	2.27798	2.125474	3.005204	0.099046	1.713398	1.026657	2
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1.819873	2.572002	1.843449	1.60919	3.013846	0.301808	1.919204	3
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0.018361	2.910309	2.608297	1.602254	2.228515	-0.1038	2.327382	4
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1.137828	1.970334	4.54537	1.77048	0.962424	1.676055	0.879076	4

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1.321311	2.063387	2.163432	2.908879	1.330973	1.88362	2.361532	5
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0.858277	2.789032	2.675953	3.975471	2.940192	3.199923	1.756495	1
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0.736881	2.07327	3.906554	3.063998	1.881051	1.369881	0.160261	4
0.665234	2.183043	2.941374	2.995214	1.14126	3.139709	0.670783	2

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1.431209	2.102447	2.877089	3.272383	1.528063	1.667444	0.597345	2
0.48805	2.199462	2.791748	3.053477	1.218693	3.241743	0.81835	2
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0.473393	1.823634	2.603832	3.244876	2.472785	2.388323	0.70335	1
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2.809199	2.201564	3.268227	2.439596	2.217548	2.20399	0.443276	3
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2.891285	1.89644	4.433179	2.19465	1.006817	1.09154	0.498398	3
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2.253494	0.88575	4.05183	1.474706	3.073917	0.406476	3.763321	5
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0.682774	4.503063	1.489453	2.222444	1.302957	2.698368	1.259985	1
2.663757	3.054066	3.250958	2.184488	2.114672	1.565751	0.71493	3
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0.176902	3.363572	1.788922	2.632445	2.046902	1.661218	1.862941	1
1.665005	3.096207	1.841999	2.76653	2.242893	2.006812	0.692106	1
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2.414456	2.360334	2.306623	2.052518	1.905444	2.084339	1.41141	3
1.548719	2.645218	2.647588	3.017119	1.307344	2.603688	1.402963	2
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2.75563	2.346252	3.231356	2.059784	2.305691	0.999648	2.35069	3
1.618229	1.55903	2.663824	2.071062	1.269606	2.184555	2.946364	5
1.927056	2.062933	2.708249	2.422282	0.670938	1.652872	0.78742	2
1.888032	1.739451	3.022219	0.731892	0.901051	1.484288	2.493283	3
1.373058	3.726288	2.173993	1.611522	1.419764	1.355206	1.332446	1
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1.107882	4.1896	0.662106	3.017648	2.54298	3.18947	1.811624	1
0.80748	4.128602	3.05368	0.753182	1.523971	2.218486	1.551826	1
1.792069	5.297029	-1.4584	4.517665	0.420555	3.75568	-0.2235	2
0.29681	2.154562	4.291881	-0.71309	3.192156	4.1492	2.884095	1
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-0.56891	4.003578	3.196236	3.384194	0.419863	2.238542	0.05731	2
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5.269156	3.595336	1.57854	4.563517	3.322321	2.0089	2.253221	3
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0.789672	3.383044	3.337881	3.451955	2.680502	1.791768	-0.33461	1
5.565368	3.181652	3.711348	1.365467	3.165442	0.633596	1.577293	3
0.669129	2.118351	2.117884	2.709941	1.785749	2.353919	1.396308	1

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2.122874	2.370528	4.039168	0.044906	1.404239	0.054061	1.210217	3
-0.31367	1.429249	3.608487	3.153238	3.435385	2.595252	1.562	1
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4.973196	1.25845	3.181555	1.930606	1.754247	0.502145	0.808431	3
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1.235974	1.308576	2.981051	2.429463	1.928441	2.464002	2.952178	5
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0.40928	3.185794	2.623647	1.940549	1.825407	1.698621	1.568015	1
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3.921003	3.011791	1.363058	2.752717	2.051352	2.988232	2.550854	2
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0.989795	3.025333	2.064807	1.322011	2.195479	2.639946	1.743527	1
0.748755	2.27195	2.717904	3.103542	2.114782	3.677446	1.694106	1
-0.54808	3.454881	2.794786	0.243503	2.598806	2.136147	2.934898	1
1.73608	2.049779	2.363716	2.801236	2.019415	1.639227	1.9725	5
2.540272	3.227549	3.596597	2.319795	1.413479	2.179313	0.192601	2
4.283287	3.240125	2.663105	2.760057	0.818601	1.64212	1.574151	3
1.391141	2.810916	2.450279	2.953166	2.210613	2.323273	1.154374	1

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## APPENDIX 10. MARDER PANSS NEGATIVE SYMPTOMS (MPNS) HETEROGENEITY INDEX METHOD

Subject-level PANSS item scores between two assessments (e.g., Screening and Baseline) are encoded in a variance-covariance difference (VCD) vector. The VCD vector captures the intra-item variance, between-item covariance, and between-item differences of PANSS items between two assessment time points from a single subject.

Briefly, for each subject  $h$ , a variance-covariance matrix of the 30 PANSS items is defined as

$$V = \begin{bmatrix} \sigma_{s_1}^2 & \cdots & \sigma_{s_1,30} \\ \vdots & \ddots & \vdots \\ \sigma_{s_{30},1} & \cdots & \sigma_{s_{30}}^2 \end{bmatrix},$$

where

$$\sigma_{s_j}^2 = \sum_{t=1}^2 (s_t^j - \bar{s}^j)^2,$$

is the unbiased estimator of the variance of  $s^j$  (score of PANSS item  $j$ ),  $j = 1, 2, \dots, 30$ , and

$$\sigma_{s_i,j} = \sum_{t=1}^2 (s_t^i - \bar{s}^i)(s_t^j - \bar{s}^j),$$

is the unbiased estimator of the covariance of  $s^i$  and  $s^j$  (scores of PANSS items  $i$  and  $j$ ), and

$$\bar{s}^j = \frac{\sum_{t=1}^2 s_t^j}{2}; \quad \bar{s}^i = \frac{\sum_{t=1}^2 s_t^i}{2}.$$

Note that the denominators of  $\sigma_{s_j}^2$  and  $\sigma_{s_i,j}$  are  $2 - 1 = 1$ , for two time points.

The unique elements of  $V$  for subject  $h$  are kept in vector  $u_{cov_h}$ , consisting of the elements of  $V$  on and below the main diagonal.

Separately, for each subject  $h$  and each timepoint  $t$ , a different matrix for the 30 PANSS items is defined as

$$D = \begin{bmatrix} d_{s_{1,1}} & \cdots & d_{s_{1,30}} \\ \vdots & \ddots & \vdots \\ d_{s_{30},1} & \cdots & d_{s_{30},30} \end{bmatrix},$$

where  $d_{s_i,j} = s^i - s^j$  for scores of items  $i$  and  $j$ . Note that the diagonal elements of  $D$  are 0.

The unique elements of  $D$  for subject  $h$  at timepoint  $t$  are kept in vector  $d_{t(h)}$ , consisting of elements of  $D$  below the main diagonal.

Together, the VCD vector of subject  $h$  for 2 timepoints (e.g., Screening and Baseline) is defined as

$$VCDV_{h(t=1,t=2)} = [u_{cov_h} \quad d_{1(h)}, d_{2(h)}] \rightarrow \mathbb{R}^{1,1335},$$

and the VCD vector for  $N$  subjects is

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$$VCDV_{(t=1,t=2)} = \begin{bmatrix} VCDV_{h_1(t=1,t=2)} \\ VCDV_{h_2(t=1,t=2)} \\ \vdots \\ VCDV_{h_N(t=1,t=2)} \end{bmatrix} \rightarrow \mathbb{R}^{N,1335}.$$

Using the PANSS-defined VCD vector, and the 7 items of the Marder PANSS Negative Symptoms factor, a new vector of 84 elements per subject is used to define a Marder Negative Heterogeneity Index (MNHI). Table 7 lists the parameters used to derive the MNHI.

Table 10: Parameters Used to Derive the Marder Negative Heterogeneity Index (MNHI)

$\sigma_{s_i}^2$	Variance of PANSS item $i$ between Screening and Baseline for subject $h$
$\Delta\sigma_{s(i,j)t}^2$	$\sigma_{s_i}^2 - \sigma_{s_j}^2$ at visit $t$ for subject $h$
$\sigma_{s_{i,j}}$	Covariance of PANSS item $i$ and PANSS item $j$ between Screening and Baseline for subject $h$
$d_{s_{i,j}}$	Difference between PANSS item $i$ and PANSS item $j$ at a given timepoint for subject $h$
$P$	Set of combinations of two Marder PANSS Negative Symptoms factor items
$C(x)$	Count of $x$

The 7 items of the Marder PANSS Negative Symptoms factor are congruent based on the Marder factor model. Therefore,  $\sigma_{s_i}^2 - \sigma_{s_j}^2$  is expected to be small for all  $p$  combinations. Similarly,  $\Delta\sigma_{s(i,j)t}^2$  is expected to be small for all  $p$  combinations, at  $t$  = Screening and  $t$  = Baseline. Furthermore,  $C\left(\sigma_{s_{i,j}}| < 0\right)$  is expected to be small for all  $p$  combinations. Hence, the raw Marder Negative Heterogeneity Index (rMNHI) of subject  $h$  is defined as the sum of L1 norm of variance differences, count of negative covariance, L1 norm of between item differences at Screening and Baseline. It can be expressed as

$$rMNHI = \|\Delta\sigma_{s_p}^2\|_1 + \sum_{p=1}^{21} C\left(\sigma_{s_p}| < 0\right) + \|d_{s_p,t=1}\|_1 + \|d_{s_p,t=2}\|_1.$$

The min-max scaling (min = 0, max = 223) is then applied to rMNHI to derive the MNHI for subject  $h$ .

The optimal threshold to classify MPNS enriched subjects is determined by fitting the one-factor Marder Negative model through computing confirmatory factor analysis (CFA) statistics (comparative fit index [CFI], Tucker Lewis index [TLI], and root mean square error of approximation [RMSEA]) iteratively. The first iteration draws samples from the range of MNHI from the lowest to the lowest + 0.01 point. The range expands incrementally by 0.01 point for each iteration until the upper bound of the range is above the observed maximum MNHI. The smallest upper bound MNHI corresponds to the median CFI (>0.95), TFI (>0.95), and/or RMSEA (<0.08) and is identified as 0.113. It is used to classify subjects into MPNS enriched (MNHI ≤ 0.113) or de-enriched (MNHI > 0.113) groups.

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## APPENDIX 11. SCHEDULE OF EVENTS

Procedures	Treatment Period							Follow-up Period
	V1E	V2E	V3E	V4E	V5E	V6E	V7E	V8E
	OLE Baseline <sup>a</sup>	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24 EOT/ ET <sup>b</sup>	Follow-up EOS <sup>c</sup>
Study Day	Day 1	Day 29 ±3 days	Day 57 ±3 days	Day 85 ±3 days	Day 113 ±3 days	Day 141 ±3 days	Day 169 ±3 days	7±2 days after last dose
Informed consent	X							
Inclusion/exclusion criteria	X							
Concomitant medication review <sup>d</sup>	X	X	X	X	X	X	X	X
Dispense study drug <sup>e</sup>	X	X	X	X	X	X	X	
Study drug accountability		X	X	X	X	X	X	
Telephone contacts <sup>f</sup>		Telephone calls to the subjects will be made at Weeks 1, 2, 3, 5, 6, 7, 9, 10, 11, 13, 14, 15, 17, 18, 19, 21, 22, and 23. Unscheduled visits may occur at the discretion of the Investigator.						
Physical/neurological examination	Core	X		X			X	X
Nicotine use information	Core			X			X	
Vital signs <sup>g</sup>	Core	X	X	X	X	X	X	X
Weight (including BMI) <sup>h</sup>	Core	X	X	X	X	X	X	
Height <sup>i</sup>	Core Pre-switch screening							
Waist circumference	Core	X		X			X	
12-lead Electrocardiogram (ECG)	Core	X		X			X	
Hematology, chemistry, urinalysis <sup>j</sup>	Core	X		X			X	
Blood sample for PK <sup>k</sup>	Core	X		X			X	
Urine drug screen <sup>l</sup>		X		X			X	
Rapid urine drug screen <sup>1</sup>	Core							
Serum β-hCG, females only	Core							
Urine β-hCG, females only <sup>m</sup>		X	X	X	X	X	X	X
Rapid urine β-hCG, females only <sup>m</sup>	Core							
Positive and Negative Syndrome Scale (PANSS)	Core	X	X		X		X	
Clinical Global Impression – Severity (CGI-S)	Core	X	X		X		X	

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Procedures	Treatment Period							Follow-up Period
	V1E	V2E	V3E	V4E	V5E	V6E	V7E	V8E
	OLE Baseline <sup>a</sup>	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24 EOT/ ET <sup>b</sup>	Follow-up EOS <sup>c</sup>
Study Day	Day 1	Day 29 ±3 days	Day 57 ±3 days	Day 85 ±3 days	Day 113 ±3 days	Day 141 ±3 days	Day 169 ±3 days	7±2 days after last dose
Clinical Global Impression – Improvement (CGI-I)	Core	X	X		X		X	
Brief Negative Symptom Scale (BNSS)	Core	X	X		X		X	
Columbia Suicide Severity Rating Scale (C-SSRS)	Core	X	X	X	X	X	X	X
Simpson-Angus Scale (SAS) <sup>a</sup>	Core	X					X	
Barnes Akathisia Rating Scale (BARS) <sup>a</sup>	Core	X					X	
Abnormal Involuntary Movement Scale (AIMS) <sup>a</sup>	Core	X					X	
Pittsburgh Sleep Quality Index (PSQI)	Core			X			X	
Personal and Social Performance Scale (PSP)	Core			X			X	
Short Form Health Survey (SF-12)	Core						X	
Medication Satisfaction Questionnaire (MSQ)	Core						X	
Healthcare Resource Utilization (HCRU), since last assessment	Pre-switch Baseline visit of Core			X			X	
Adverse events (AE) monitoring <sup>d</sup>	X	X	X	X	X	X	X	X

Abbreviations: AE = adverse event; BARS = Barnes Akathisia Rating Scale; β-hCG = human chorionic gonadotropin; BMI = Body Mass Index; BNSS = Brief Negative Symptom Scale; C-SSRS = Columbia Suicide Severity Rating Scale; eCRF = electronic case report form; EDC = electronic data capture; EOS = end of study; EOT = end of treatment; ET = early termination; HCRU = healthcare resource utilization; MSQ = Medication Satisfaction Questionnaire; OLE = open-label extension; PANSS = Positive and Negative Syndrome Scale; PK = pharmacokinetic; PSP = Personal and Social Performance Scale; SAS = Simpson-Angus Scale; SF-12 = Short Form Health Survey.

<sup>a</sup> The Week 8 (EOT) visit of Study SEP361-308 serves as the Baseline visit for the present study. “Core” indicates assessments that were conducted at the EOS Visit of Study SEP361-308, unless otherwise indicated, and do not need to be repeated for this study.

<sup>b</sup> If a subject discontinues from the study, all ET procedures should be performed at the ET visit, within 48 hours of last study dose.

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- <sup>c</sup> All subjects should have a safety Follow-up Visit 7 ( $\pm$  2) days after their last dose of study drug. While every effort should be made to complete the Follow-up Visit in the clinic, administration of the C-SSRS, and collection of AEs and concomitant medications may occur by telephone contact if the subject is unable to come to the clinic for the Follow-up Visit.
- <sup>d</sup> Medications with onset during the Core study (SEP361-308) and ongoing at the start of the current study (SEP361-309) will be entered into the eCRF.
- <sup>e</sup> All study drug will be taken once daily in the evening at bedtime by mouth, with or without food.
- <sup>f</sup> Telephone calls will be made by a qualified member of the research staff to the subject weekly between scheduled study visits to administer the C-SSRS, collect AEs and concomitant medications, as well as to remind the subject about adherence to study drug administration and upcoming visits.
- <sup>g</sup> Vital signs will include respiratory rate, oral body temperature and supine and standing measurements of blood pressure and pulse rate.
- <sup>h</sup> BMI will be derived in the EDC system and during statistical analysis.
- <sup>i</sup> Height collected at the Core study (SEP361-308) Screening Visit will be re-entered into EDC at Visit 2E of this study.
- <sup>j</sup> Subjects must be fasted (no food or drink except water at least 8 hours prior to clinical laboratory tests). A list of clinical laboratory tests is provided in [Section 21](#).
- <sup>k</sup> Blood samples for plasma concentrations of SEP-363856 will be collected on Day 29, Day 85 and Day 169/EOT/ET. The time and date of the previous dose of study drug prior to blood sampling and the time and date of blood sampling must be recorded. The remaining plasma samples, after PK measurement is completed, **CCI**
- <sup>l</sup> Urine drug screen may be ordered at other visits as deemed clinically appropriate. These results should be discussed with the Medical Monitor.
- <sup>m</sup> Any positive urine  $\beta$ -hCG test should be confirmed by a serum  $\beta$ -hCG test.
- <sup>n</sup> Unscheduled SAS, BARS and AIMS scales should be administered if a subject develops extrapyramidal symptoms requiring treatment.
- <sup>o</sup> Any new AEs occurring after signing the informed consent form for this study (SEP361-309) at V1E will be collected. Adverse events with onset during the Core study (SEP361-308) and ongoing at the start of the current study (SEP361-309) will be entered into the eCRF.

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