9 STATISTICAL METHODS INTERIM ANALYSIS PLAN

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A Phase 2A Safety and Biomarker Study of EPI-589 in Mitochondrial Subtype and Idiopathic Parkinson's Disease Subjects

Protocol No.: EPI589-15-002

STATISTICAL ANALYSIS PLAN

Version: 1.0
Date: 03-Aug-2018
Biostatistician: [redacted]

Confidentiality Statement

Approval of Statistical Analysis Plan
Protocol No : EPI589-15-002

The undersigned approved the SAP Version 1.0, dated 03-Aug-2018 as final. Programming of the tables, figures and listings based upon the specifications within this document can proceed.

BioElectron Technology Corporation

[redacted] [redacted] 3 Aug 2018

Signature Print Name **Date**

(Title: [redacted] **)**

QPS-Qualitix Approval:

[redacted] [redacted] 06 Aug 2018

Signature [redacted] Print Name **Date**

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TABLE OF CONTENTS

1. INTRODUCTION

This is a phase 2a safety and biomarker study of EPI-589 in mitochondrial subtype and idiopathic Parkinson's disease (PD) subjects. Approximately 40 subjects with PD including 20 subjects with genetically-defined subtypes and 20 subjects with drug-naïve idiopathic PD will be enrolled.

This statistical analysis plan (SAP) is based on protocol amendment 2.0, dated 04-Jan-2016. The SAP provides details of data handling procedures and statistical analysis methods for efficacy and safety evaluations. It also outlines statistical programming specifications for tables and listings, and other details on the analyses not provided in the study protocol. It is noted that in case there is discrepancy between the SAP and the protocol then the SAP will supersede the protocol.

This SAP will include efficacy and safety analysis only. The pharmacokinetic (PK) analysis plan is not part of this SAP.

2. STUDY OBJECTIVE

Primary Objective

The primary objective is to evaluate the effects of EPI-589 on safety as assessed by occurrence of drug-related serious adverse events in subjects with PD.

Secondary Objectives

The secondary objectives are to evaluate the effects of EPI-589 in subjects with PD on:

(1) Redox biomarkers as measured in blood, cerebral spinal fluid, and urine
(2) Clinical disease state as assessed by the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS)
(3) Disease morbidity as assessed by the Non-motor Symptoms Scale (NMSS), PDQ-39 and EQ-5D
(4) Cognitive function as assessed by Montreal Cognitive Assessment (MoCA)
(5) Mood as assessed by the Beck Depression Inventory (BDI) and the Montgomery and Asberg Depression rating scale (MADRS)
(6) Pharmacokinetics
(7) Hematology, blood chemistry, electrocardiogram

3. STUDY DESIGN

This is an open-label, subject-controlled study. Following study enrollment, baseline clinical and biomarker assessments will be performed. Subjects will participate in a 30-day run-in phase to establish biomarker and clinical baseline measurement. EPI-589 will then be administered at a dose of 500-mg twice a day (BID) from Day 1 and up to 3 months (85 days ± 3 days) unless discontinued for safety or tolerability issues. A post-treatment follow-up will be conducted at least 10 days and up to 30 days after last dose to assess for possible adverse events.

3.1 Schedule of Assessments and Dosing Schedule

Tests	-2 to -1 Months		Day 0	Month 1	Month 2	Month 3 End of Treatment Visit	Post-Treatment Follow-up
	Screening	Run-in (± 30 days)	Baseline	Day 29 (± 3 days)	Day 57[d] (± 3 days)	Day 85 (± 3 days)	Up to 30 Days after Last Dose[e]
Informed consent	✓						
Inclusion/Exclusion criteria	✓						
Past Medical history	✓						
Previous genetic testing review	✓						
Physical exam & Vital signs	✓		✓	✓		✓	
Height & weight	✓		✓[a]	✓		✓	
12-lead ECG	✓		✓[a]	✓		✓	
Hematology (including coagulation panel)	✓		✓[a]	✓		✓	
Serum Chemistry	✓		✓[a]	✓		✓	
Pregnancy test[b]	✓		✓	✓		✓	
C-SSRS			✓	✓		✓	
Montreal Cognitive Assessment	✓					✓	
DaTscan	✓						
Revised Hamilton Rating Scale for Depression	✓						
Subject enrolls in study		X					
Blood-based glutathione cycle biomarkers		✓	✓	✓		✓	
Lumbar puncture (CNS biomarkers)		✓				✓	
Urine-based biomarkers		✓	✓	✓		✓	
MDS-UPDRS		✓	✓	✓		✓	
Timed motor tests (for subjects on dopamine therapy)		✓	✓			✓	
NMSS, PDQ-39, EQ-5D			✓			✓	
BDI, MADRS			✓			✓	
Drug plasma concentration[c]				✓[c]		✓[c]	
AE/SAE assessment[d]				✓	✓[d]	✓[d]	✓[e]
Concomitant medications assessment	✓	✓	✓	✓	✓[d]	✓[d]	✓[e]
Post-Treatment Assessments[e]							✓[e]
a. Screening values can be used if done within one month of baseline. b. Female subjects of childbearing potential must have a negative pregnancy test. c. Full plasma concentration profile will be obtained at Time = 0, and 0.5, 1, 2, 4, 6, 8, and 12 hours after dosing from the first 10 subjects to complete 1 month of therapy at each site. d. Month 2 assessments can be done by telephone. Any new AEs and associated concomitant medications reported at Month 3 must be followed for 30 days; this follow up may be conducted by telephone. e. AE/SAE and concomitant medication assessments conducted by telephone at least 10 days after last dose. Additional assessments determined at Investigator discretion.							
Dosing Schedule				**Month 1**	**Month 2**	**Month 3**	**Post-Treatment**
EPI-589 500-mg BID				✓	✓	✓	

3.2 Primary Endpoint

To evaluate the effects of EPI-589 on safety as assessed by occurrence of drug-related serious adverse events in subjects with PD.

3.3 Secondary Endpoints

Secondary Endpoints (Efficacy)

(1) Blood-based biomarkers
(2) CNS-based biomarkers
(3) Urine-based biomarkers
(4) MDS-UPDRS
(5) NMSS
(6) PDQ-39
(7) EQ-5D
(8) MoCA
(9) BDI
(10) MADRS
(11) Timed motor tests in ON and OFF state (for subjects on dopamine therapy)
(12) Pharmacokinetics

Secondary Endpoints (Safety)

(1) Routine assessments of AEs and SAEs
(2) Dose limiting toxicities
(3) Routine serum chemistries with liver function tests
(4) C-SSRS
(5) Routine hematology tests with coagulation tests
(6) Electrocardiogram

4. GENERAL STATISTICAL ISSUES

For data listings, all raw data will be displayed exactly as provided. For summaries of quantitative data, the median, minimum and maximum value will be reported exactly as the raw data are reported; measures of central tendency (means will be reported as one decimal more than the raw data and measure of standard deviation (SD) will be reported as the two decimals more than the raw data.) Baseline will be defined as the last value prior to study drug dosing.

4.1 Continuous endpoints

Continuous variables, such as age, will be presented as number of observations (n), mean, median, standard deviation (SD), minimum and maximum for the raw data as well as change from baseline.

4.2 Categorical endpoints

Categorical variables, such as gender, will be presented and summarized as counts and percentages.

4.3 Sample size estimation and power

Approximately 40 subjects (20 with genetically-defined subtypes of PD and 20 PD drug-naïve subjects). Under an adaptive design strategy, additional subjects (up to 20) may be added to increase the number of biomarker-responsive idiopathic PD subjects to achieve a higher number of subjects in whom we could understand the biochemical effects of the investigative drug and its potential clinical impact as assessed by the same study protocol and outcome metrics.

5. DATA HANDLING PROCEDURES

5.1 Coding System

The Adverse Events and Serious Adverse Events will be coded using Medical Dictionary for Regulatory Activities (MedDRA) version 14.3 or higher, and be reported by System Organ Class and Preferred Term.

Concomitant medications will be coded according to the World Health Organization (WHO) Drug Dictionary, March 2014 or higher.

5.2 Missing Data Handling

For missing data related to a safety or efficacy endpoint, no missing data method will be performed.

5.3 Early Termination Data Handling

For early termination data, it will combine to Month 3 measurements.

6. ANALYSIS OF STUDY POPULATIONS

In this study, there will be two populations, efficacy intent-to-treat (EITT) population and

safety population. The EITT population will be used in the efficacy analysis, and the safety population will be used in the safety analysis. Demographic characteristics and baseline efficacy data will be presented and summarized by treatment group for all subjects in the EITT population and safety population. No formal statistical comparisons will be made for either the EITT or Safety populations. The populations for analysis applied in this study are defined as follows:

6.1 Efficacy Intent-to-treat (EITT) Population

The efficacy intent-to-treat (EITT) population will consist of any subject receiving at least one dose of EPI-589 and has minimum of the month 3 assessment.

6.2 Safety Population

The safety population will consist of any subject receiving at least one dose of EPI-589.

The analysis of study population will be summarized as Table 14.1.1. Besides, subjects excluded from the analysis will be listed as Listing 16.2.3.

7. DISPOSITION OF PATIENTS AND STUDY COMPLETION

A total of 40 subjects are anticipated to be enrolled. Data on the completion status and primary reason for study discontinuation will be listed in Listing 16.2.1.1 and Listing 16 2.1.2. All subjects' disposition and completion status will be summarized in Table 14.1.1.

Subject eligibility will be listed in Listing 16.2.1.3. All protocol deviation(s) will be listed in Listing 16.2.2.

8. DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS

Subject demographics will be listed in Listing 16.2.4.1. Demographics and baseline characteristics will be summarized by treatment group in Table 14.1.2.

8.1 Medical History

Medical history and concurrent medical conditions data will be listed by subject in Listing 16 2.4.2.

9. EFFICACY ANALYSIS

9.1 Primary Efficacy Variable

The primary endpoint of this study is to evaluate the effects of EPI-589 on safety as assessed by occurrence of drug-related serious adverse events in subjects with PD. No primary efficacy variable is defined on protocol.

9.2 Secondary Efficacy Variables

Secondary efficacy endpoints included:

(1) Blood-based biomarkers

Individual subject Blood-based redox biomarkers will be listed in Listing 16.2.6.1 and the results at Baseline, Month 1, Month 3 / End of Treatment and change from baseline will be summarized in Table 14.2.1.

(2) CNS-based biomarkers

Individual subject CNS-based redox biomarkers will be listed in Listing 16.2.6.2 and the results at Month 3 / End of Treatment will be summarized in Table 14.2.2.

(3) Urine-based biomarkers

Individual subject Urine-based redox biomarkers will be listed in Listing 16.2.6.3 and the results at Baseline, Month 1, Month 3 / End of Treatment and change from baseline will be summarized in Table 14.2.3.

(4) Parkinson's Disease Rating (MDS-UPDRS)

The MDS-UPDRS is a tool for monitoring the impact of PD, the degree of disability caused, and complications from treatment. Part I evaluates non-motor experiences of daily living and will be listed in Listing 16.2.6.4; Part II evaluates motor experiences of daily living and will be listed in Listing 16.2.6.5; Part III is a motor examination including the Hoehn and Yahr scale and will be listed in Listing 16.2.6.6; Part IV examines motor complications (e.g., motor fluctuations and dyskinesias) and will be listed in Listing 16.2.6.7. Total score for all parts of MDS-UPDRS at Baseline, Month 1, Month 3 / End of Treatment and changed from baseline will be summarized in Table 14.2.4.

(5) Non-motor Symptoms (NMSS)

Totally 30 questions in the NMSS are listed by subject and 9 different domains including such symptoms as dribbling saliva, constipation, depression, sleep disorders, apathy, hallucinations and dementia in Listing 16.2.6.8. Symptoms are quantified based on their severity (using a scale of 0 to 3) and frequency (using a scale of 0 to 4). The final cumulative scores are derived from adding up the product of the frequency score times severity score for each of the 30 questions at Baseline, Month 3 / End of Treatment and

changed from baseline will be summarized in Table 14.2.5.

(6) Parkinson's Disease Questionnaire (PDQ-39)

PDQ-39 is a self-administered questionnaire for patients with PD that has 39 questions relating to eight key areas of health and daily activities, including both motor and non-motor symptoms. It is scored on a scale of 0 to 100, with lower scores indicating better health, and high scores more severe symptoms.

Individual subject PDQ-39 score will be listed in Listing 16.2.6.9 and total score of 39 questions at Baseline, Month 1 and change from baseline will be summarized in Table 14 2.6.

(7) EQ-5D

EQ-5D is a questionnaire designed to provide measures of health-related quality of life states, consisting in five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/ depression).

Health status measured in terms of five dimensions (5D) and the Visual analogue scale (VAS) scored on a scale of 0 to 100 for each subject will be listed in Listing 16.2.6.10. The health state involves having no problem will score 1, some problems score 2, and extreme score 3. The 'Total score', which simply adds up the levels on each dimension and the VAS score at Baseline, Month 3 / End of Treatment and change from baseline will be summarized in Table 14.2.7.

(8) Montreal Cognitive Assessment (MoCA)

MoCA is a 30-point questionnaire for cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Severity ranges are approximately: 26 to 30 normal; 18 to 26 mild cognitive impairment; 10-17 moderate cognitive impairment; < 10 severe cognitive impairment.

Individual subject MoCA report will be listed in Listing 16.2.6.11 and total score of 30-point questionnaire at Month 3 will be summarized in Table 14.2.8.

(9) Beck Depression Inventory (BDI)

The BDI is a self-reporting inventory that measures characteristic attitudes and symptoms of depression, including physical symptoms. Twenty-one questions have four responses each (rated 0 to 3) with a total cumulative score scale ranging from 1-10 considered normal) > 40 (extreme depression).

Individual subject BDI report will be listed in Listing 16.2.6.12 and total score at Baseline, Month 3 / End of Treatment and change from baseline will be summarized in Table 14.2.9.

(10) Montgomery and Asberg Depression Rating Scale (MADRS)
The MADRS is a clinician-rated tool for measuring changes in depressive symptom severity. Ten core symptoms and cognitive features are rated on a severity scale of 0 to 6. Higher scores indicate increasing depressive symptoms.

Individual subject MADRS report will be listed in Listing 16.2.6.13 and the cumulative scores for 10 questions at Baseline, Month 3 / End of Treatment and change from baseline will be summarized in Table 14.2.10.

(11) Timed Motor Tests in ON and OFF State (for Subjects on Dopamine Therapy)
Timed motor tests are simple, objective, quantitative measures for the assessment of Parkinson's disease. They include, in on-medication and off-medication state, timed recorded physical movements.

Time Up and Go Test (TUG) is one of timed motor tests which is used to assess a person's mobility and requires both static and dynamic balance. Listing 16.2.6.14 will list the measurement of the time in seconds for a subject to complete TUG test and checking records of subject's postural stability, gait, stride length, and sway. The total time will be summarized under ON and OFF state by group with subjects on dopamine therapy for Baseline, Month 3 / End of Treatment and change from baseline in Table 14.2.11. While subjects on dopamine therapy is defined as the answer 'Yes' to question '3c Is the patient on Levodopa'.

No formal statistical comparisons will be made for all secondary efficacy variables. All secondary endpoints will be summarized descriptively as number of observation, mean, median, standard deviation, minimum and maximum for continuous variables; and count and percentages for categorical variables.

10. EXTENT OF EXPOSURE AND DRUG COMPLIANCE

The dosing compliance and missed dose data be listed by subject in Listing 16.2.5.1 and Listing 16.2.5.2.
Listing 16.2.5.1: Dosing Compliance

Listing 16.2.5.2: Missed Dose

Besides, the drug concentration data will be listed in Listing 16.2.5.4.

11. SAFETY ANALYSIS

11.1 Adverse Events

Clinical AEs will be monitored throughout the study. All AEs, whether observed by the Investigator, reported by the subject, from clinically significant laboratory findings, or other means, will be recorded in the CRF. The listing of all AEs will be provided in Listing 16.2.7.1. The listing of all AEs leading to discontinuation will be provided in Listing 16.2.7.4.

All AEs will be graded if possible by Common Terminology Criteria for Adverse Events (CTCAE) v4.03. The severity of AEs that cannot be graded by CTCAE v4.03 will be categorized as follows:

Grade 1 – Transient of mild discomfort; no limitation in activity; no medical intervention/therapy indicated.

Grade 2 – Moderate limitation in activity, some assistance may be needed; minimal noninvasive medical intervention/therapy indicated.

Grade 3 – Severe limitation in activity, assistance usually required; medical intervention/therapy required; hospitalization or prolongation of hospitalization indicated; disabling.

Grade 4 – Extreme limitation in activity, significant assistance required; urgent medical intervention/therapy required; life-threatening consequences.

Grade 5 – Death

Association or relatedness to the study medication will be graded as either “probably”, “possibly”, or “unlikely”. Determination of relatedness includes:

PROBABLY – The adverse event:
1. Follows a reasonable temporal sequence from drug administration
2. Abates upon discontinuation of the drug and reappears with re-introduction of the drug
3. Cannot be reasonably explained by the known characteristics of the subject’s clinical state

POSSIBLY – The adverse event:
1. Follows a reasonable temporal sequence from drug administration
2. Could have been produced by the subject's clinical state or by other modes of therapy administered to the subject

UNLIKELY – The adverse event:
1. Does not follow a reasonable temporal sequence from drug administration
2. Is readily explained by the subject's clinical state or by other modes of therapy administered to the subject

All AEs will be coded by system organ class and preferred term for analysis. Treatment-emergent adverse event (TEAE) is defined as AEs occur after the first administration of study drug, or AEs occur before the first administration of study drug and worsen in severity after first dose. Unless otherwise specified, all adverse event summaries will include the TEAEs only. For purposes of the summary tables, AEs will be classified as either related or not related to study drug. The drug-related AEs are assessed as ' Probably', or 'Possibly' related to study treatment. This summary will present the number and percentage of subjects, as well as number of events.

A general summary of all TEAEs will be provided in Table 14.3.1.1.1 according to the following categories:
- Subject with any AE
- Subject with any SAE
- Subject with any drug-related AE
- Subject with any drug-related SAE

Also, a general summary of all TEAEs with the most severity and most causal relationship will be applied while combined multiple AEs for analysis will be provided in Table 14.3.1.1.2 according to the following categories:
- CTCAE Grade
- Relationship to Study Medication
- Serious AE
- Alternate Causality
- Action Taken with Study Medication
- Dose Limiting Toxicity
- Medication Given for AE
- Outcome

Other summary tables for adverse events will include:
Table 14.3.1.2: Treatment-Emergent Adverse Events - MedDRA
Table 14.3.1.3: Treatment-Emergent Adverse Events by Severity - MedDRA
Table 14.3.1.4: Treatment-Emergent Adverse Events by Severity and Relationship to Study Drug - MedDRA
Table 14.3.1.5: Treatment-Emergent Adverse Events Leading to Discontinuation

11.2 Serious Adverse Event

A serious adverse event (SAE) is one that at any dose results in any of the following:

1. Death
2. A life-threatening adverse drug experience
3. Inpatient hospitalization or prolongation of existing hospitalization
4. A persistent or significant disability/incapacity
5. A congenital anomaly/birth defect

A listing of all serious adverse events will be provided in Listing 16.2.7.2 and Listing 16 2.7.3, and the summary of SAEs will be presented:
Table 14.3.1.6: Treatment-Emergent Serious Adverse Events - MedDRA
Table 14.3.1.7: Treatment-Emergent Serious Adverse Events by Severity and Relationship to Study Drug - MedDRA

11.3 Laboratory Evaluations

Clinical laboratory tests, including standard hematology, serum chemistry, urinalysis, pregnancy test and genetic analysis:

Hematology

1. Erythrocytes: red blood cell (RBC) count, hematocrit, hemoglobin, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV), red cell distribution width (RDW)
2. Leukocytes: white blood cell count (WBC) and differential (basophils, eosinophils, lymphocytes, monocytes, and neutrophils) reported as absolute values and percentage.
3. Platelets: platelet count, mean platelet volume (MPV)
4. Coagulation: prothrombin time (PT) with INR, partial thromboplastin time (PTT), activated (aPTT)

Serum Chemistry

1. Liver: Alkaline Phosphatase (ALP), ALT (serum glutamic-pyruvic transaminase [SGPT]), AST (serum glutamic-oxaloacetic transaminase [SGOT]), bilirubin (total, and direct), gamma-glutamyl transferase (GGT), and lactate dehydrogenase (LDH)
2. Renal: blood urea nitrogen (BUN), creatinine
3. Electrolytes: sodium, potassium, chloride, and carbon dioxide (CO_2) as bicarbonate
4. General: creatine phosphokinase (CPK), creatine kinase (CK), and troponin (at baseline only); total protein, albumin, calcium, magnesium, glucose, phosphate
5. Lipids: cholesterol (total), high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, cholesterol/HDL Ratio (calculated), non-HDL cholesterol (calculated) and triglycerides

The cholesterol/HDL Ratio is calculated as cholesterol (total)/ high-density lipoprotein (HDL) cholesterol; and non-HDL cholesterol is calculated as cholesterol (total) - high-density lipoprotein (HDL) cholesterol.

Urinalysis

The urinalysis items included: Color, Clarity, Specify Gravity, pH, Leukocytes, Blood, Nitrite, Ketones, Billrubin, Urobillinogen, Protein and Glucose.

Urine Pregnancy Test

Human chorionic gonadotropin (HCG) beta subunit will be measured on all female subjects of childbearing potential.

Genetic Analysis

Mutation will be recorded for subjects with genetically diagnosed.

By-subject listings of measured values for clinical laboratory test data (hematology, chemistry and urinalysis) will be prepared in Listing 16.2.8.3 to Listing 16.2.8.5. A listing of pregnancy test and genetic analysis will be provided in Listing 16.2.8.6 and Listing 16.2.8.7. Observations outside the normal range will be flagged. The abnormal values will be recorded as ‘Low’ for values below the lower limit of the laboratory’s normal range, ‘High’ for values above the upper limit of the laboratory’s normal range or ‘Normal’ for values within laboratory’s normal range. All clinically significant laboratory results will be marked as well. All original and repeated values will be listed.

Abnormal laboratory values of hematology, serum chemistry, urinalysis, urine pregnancy

test and genetic analysis will be listed in Listing 16.2.8.1. The record with observed value of clinical laboratory data below or above the detection limit will be imputed with the detection limit for analysis. The summary results of laboratory assessment (hematology and chemistry) will be presented as Table 14.3.5.1 and Table 14.3.5.2, respectively. The shift table with the counts and percentages of the actual number of subjects whose judgments including 'Normal', 'Abnormal NCS', and 'Abnormal CS' shifted among categories will be presented as Table 14.3.5.3.

11.4 Vital Signs and Physical Examination

Vital Signs

Individual subject vital signs (Height, Weight, Systolic Body Pressure, Diastolic Blood Pressure, Heart Rate and Respirations) will be listed in Listing 16.4.1.

The observed value of vital signs at Baseline, Month 1, Month 3 / End of Treatment and change from baseline values will be summarized in Table 14.3.6.1. The shift table with the counts and percentages of the actual number of subjects whose judgments including 'Normal' and 'Abnormal' shifted among categories will be presented as Table 14.3.6.2.

Physical Exam

Physical exam data (HEENT, Skin, Respiratory, Abdominal/GI, Pulmonary, Cardiovascular, Endocrine, Musculoskeletal, Neurologic/CNS, Psychiatric, Immunologic/Allergy and Gynecologic/Urologic) will be listed in Listing 16.4.2, and will be summarized for Baseline, Month 1, Month 3 in Table 14.3.7.1. The shift table with the counts and percentages of the actual number of subjects whose judgments including 'Normal', 'Abnormal NCS', and 'Abnormal CS' shifted among categories will be presented as Table 14.3.7.2.

11.5 Other Variables Related to Safety

Concomitant Medications

Individual subject concomitant medications will be listed in Listing 16.2.5.3.

12-Lead ECG

Individual subject 12-Lead ECG data (Ventricular rate, PR interval, RR interval, QRS duration, QT, QTc (Bazette) and Overall Interpretation) will be listed in Listing 16.4.3, and will be summarized at Baseline, Month 1, Month 3 / End of Treatment and change from baseline in Table 14.3.8.1. The shift table with the counts and percentages of the actual number of subjects whose judgments including 'Normal', 'Abnormal NCS', and 'Abnormal CS' shifted among categories for overall Interpretation will be presented as Table 14.3.8.2.

DaTscan

Individual subject DaTscan data will be listed in Listing 16.4.5.

Columbia Suicide Severity Rating Scale (C-SSRS)

Individual subject Columbia Suicide Severity Rating Scale (C-SSRS) data will be listed in Listing 16.4.6, and will be summarized as suicidal ideation and suicidal behavior in Table 14 3.9.

Revised Hamilton Rating Scale (RHRSD)

Individual subject RHRSD report will be listed in Listing 16.4.7.

Telephone Contact

Individual subject telephone Contact data will be listed in Listing 16.4.8.

12. COMPUTER METHODS

All statistical analyses will be conducted using SAS® software, Version 9.3 of the SAS System for Windows 7. Copyright© 2013 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.