STATISTICAL ANALYSIS PLAN
FOR PROTOCOL NTRP-101-203

Sponsor:	**Neurotrope, Inc.** 1185 Avenue of the Americas. 3rd Floor New York, NY 10036	Tel : (973)242-0005 Fax : (973)242-0009
Protocol Number:	NTRP-101-203	
Protocol Title:	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study Assessing the Safety, Tolerability and Efficacy of Bryostatin in the Treatment of Moderately Severe to Severe Alzheimer's Disease Subjects Not Receiving Memantine Treatment	
Protocol Date / Version:	Version 3.0 / 9 May 2019	

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Plan Version:	SAP –Version 1.0		
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I have read and approve the Statistical Analysis Plan specified above and agree with its content:

Statistician, Amarex	Date
Neurotrope, Inc. Representative	Date

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	Adverse event
ANCOVA	Analysis of Covariance
ASA	American Statistical Association
CBC	Complete Blood Count
C.I.	Confidence Interval
CM	Concomitant Medications
CMED	Concomitant Medications
CRO	Contract Research Organization
eCRF	Electronic case report form
EDC	Electronic Data Capture
ECG	Electrocardiogram
EOS	End of study
FAS	Full Analysis Set
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
IA	Interim analysis
ICF	Informed consent form
ICH	International Conference on Harmonization
Kg	Kilogram
MedDRA	Medical Dictionary for Regulatory Activities
µg	Microgram
mITT	Modified Intent-to-Treat
n	Number in sample
PI	Principal Investigator
PK	Pharmacokinetic
PT	MedDRA preferred term
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SIB	Severe Impairment Battery
SD	Standard Deviation
SOC	MedDRA system organ class
SOP	Standard Operating Procedure

TEAE	Treatment Emergent Adverse Event
TESAE	Treatment Emergent Serious Adverse Event
U.S.	United States of America
WHO	World Health Organization

1. INTRODUCTION

This Statistical Analysis Plan describes the planned analyses and reporting for the clinical trial protocol NTRP-101-203, sponsored by Neurotrope, Inc. The reader of this Statistical Analysis Plan (SAP) is encouraged to review the complete protocol as this plan contains only a limited overview of protocol information. The main objective of this plan is to provide details pertaining to statistical methodology, data conventions, and processes used for the analysis of data from this trial.

The format and content of this SAP are structured to provide sufficient detail to meet the requirements specified by the International Conference on Harmonization (ICH) E9: Guidance on Statistical Principles in Clinical Trials. All work planned and presented in this Statistical Analysis Plan will follow the ethical guidelines published by the American Statistical Association (ASA).

The following documents were reviewed in preparation of this Statistical Analysis Plan:

- Version 3.0, protocol 18 April 2019
- ASA Ethical Guidelines for Statistical Practice (2016)
- The Royal Statistical Society: Code of Conduct (2014)
- ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3, 1996)
- ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3(R1), 2013)
- ICH Guideline on General Considerations for Clinical Trials (ICH E8, 1997)
- ICH Guidance on the Statistical Principles for Clinical Trials (ICH E9, 1998)
- ICH Guidance on the Statistical Principles for Clinical Trials (ICH E9(R1), 2017)

2. PROTOCOL DESIGN AND OBJECTIVE

2.1 Design Overview

This is a randomized double-blind Placebo-controlled, Phase 2 study comparing bryostatin to placebo for the treatment of moderately severe to severe Alzheimer's disease in subjects not receiving memantine treatment. The study is 15 weeks in duration, including safety and efficacy evaluation 30 days after the last treatment. Eligible subjects will be stratified based on MMSE-2

scores 4-9 vs. 10-15 and will be randomized 1:1 to treatment with 20µg bryostatin or placebo for 12 weeks of treatment. Study drug is administered IV by continuous infusion. The first two doses of study drug will be a loading dose 20% higher (i.e., 24µg) than the assigned dose and will be administered one week apart. Thereafter, the assigned dose of 20µg will commence with the third dose and be administered every other week. Subjects are scheduled to receive seven doses over 12 weeks.

2.2 Treatment *Groups*

There are two treatment groups in this trial. The two treatment groups to be evaluated in this trial are described below

Table 2-2-1: Treatment Groups

Group	Description
Active Treatment	20 µg bryostatin
Control Treatment	placebo

2.3 Randomization

Once all eligibility criteria for the study have been met, and the site has received approval by the Medical Monitor (MM) and Clinical Assessment Technologies (CAT) group, via the EDC system, the subject can be randomized via Interactive Response Technology (IRT) system. A randomization number will be assigned, and drug for that randomization number will be shipped to the site for twelve weeks of treatment. Randomization and scheduling of the first study drug infusion should be timed to allow for receipt of study drug prior to the scheduled study treatment. The drug kits will be shipped to the individual who will be responsible for kit storage and drug preparation.

2.4 Blinding

All subjects, PIs, and investigational clinical site personnel will be blinded to dose assignment.

Since there is no known antidote to bryostatin, the blind should only be broken in exceptional circumstances and is at the discretion of the PI. The Medical Monitor should be contacted as soon as possible to discuss the situation, but this should not delay any treatment.

In a non-emergency situation, when unblinding is requested, the site should discuss the clinical

circumstances with the Medical Monitor to determine if breaking the blind will alter the subject's treatment. The decision to break the blind is ultimately the decision of the PI. If the blind is broken for a subject, the PI will record the date and reason for breaking the blind in the electronic case report form (eCRF) and study drug treatment will be discontinued. However, the subject will continue to be monitored per protocol for safety and efficacy.

2.5 Study Objective

The primary objective of this study is to evaluate the safety, tolerability and efficacy of bryostatin for the treatment of moderately severe to severe Alzheimer's disease in subjects not receiving concurrent memantine treatment.

2.6 Efficacy Assessments

2.6.1 Primary Efficacy Endpoint

The primary efficacy endpoint is defined as the change from baseline to Week 13 in the SIB total score.

2.6.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints are:

- The changes from baseline at Weeks 5, 9 and 15 in the SIB total score
- The changes from baseline at Weeks 5, 9, 13 and 15 in the SIB total score for subjects in the MMSE-2 4-9 stratification group
- The changes from baseline at Weeks 5, 9, 13 and 15 in the SIB total score for subjects in the MMSE-2 10-15 stratification group
- Individual patient's slope over time in SIB total score evaluated via Weeks 0, 5, 9 and 13.

2.6.3 Exploratory Endpoints:

The exploratory endpoints for this study are:

- Change from baseline in Alzheimer's Disease Cooperative Study - Activities of Daily Living – Severe Impairment Version (ADCS-ADL-Sev) total score
- Change from baseline in Mini Mental State Examination, 2nd edition (MMSE-2) total score

- Change from baseline in 10-point Neuropsychiatric Inventory (NPI) total score
- Clinical Global Impression of Improvement Scale (CGI-I) score

2.7 Safety Assessments

- Treatment emergent AEs and SAEs
- Vital signs, hematology, blood chemistry, and physical examination including body weight
- ECG parameters
- C-SSRS

3. SAMPLE SIZE DETERMINATION AND RATIONALE, STATISTICAL POWER, AND SIGNIFICANCE LEVEL

Based on post hoc analyses of the NTRP 101-202 study for patients not treated with memantine, the SIB for the 20ug bryostatin group demonstrated a mean (SD) increase of 4.5 (6.8) points from baseline by Week 13. In contrast, patients not treated with memantine in the placebo arm showed a decrease in SIB scores at the 13-week time-point from baseline, giving a mean (SD) SIB change of -0.9 (6.7) points. This resulted in group difference in means of the 13-week SIB measure from baseline SIB changes of 5.4 points.

Guided by these post hoc results, power analyses were performed based on 50 patients per treatment arm, and assuming differences of between 4.0 to 5.5 points in the treatment arm-specific means of the primary outcome (e.g. the treatment effect). Table 3-1 below gives the estimated power to detect various treatment effects, assuming a two-sided alpha of 0.05. Based on these analyses, 50 patients per group will give an approximate 83% power to detect a treatment effect of 4.0 points, and an estimated power of 98% to see a treatment effect of 5.5 points. Power calculation was based the two-sample t-test of the group difference in the mean 13-week SIB changes from baseline SIB.

Table 3-1: Power to detect treatment effect sizes of between 4.0 to 5.5 points; 50 patients per group with an available primary efficacy endpoint.

Diff. in Deltas	Power	N1	N2	Two-sided Alpha
4	83%	50	50	0.05
4.5	91%	50	50	0.05

5	95%	50	50	0.05
5.5	98%	50	50	0.05

Power analyses were also performed to determine detectable effect sizes that assume an estimated dropout rate of 25% (e.g. 50 patients per group at a baseline, dropping to 37 patients per group by Week 13). Table 3-2 gives the estimated powers for treatment effects of between 4.5 and 5.5 points, assuming a 25% dropout rate. Note that a minimum treatment effect of 4.5 points can be statistically detected with at least 80% power, given 37 patients per group with a primary efficacy endpoint.

Table 3-2: Power to detect treatment effect sizes of between 4.5 to 5.5 points; 37 patients per group with an available primary efficacy endpoint.

Diff. in Deltas	Power	N1	N2	Two-sided Alpha
4.5	80%	37	37	0.05
5	88%	37	37	0.05
5.5	93%	37	37	0.05

4. INTERIM ANALYSIS

No interim analyses are planned.

5. PRIMARY HYPOTHESIS TO BE TESTED

The primary hypothesis to be tested for this study is below:

H_0: $\mu_{Active} = \mu_{Control}$ (i.e. mean change from baseline in SIB total score between the two groups is the same)

H_1: $\mu_{Active} \neq \mu_{Control}$ (i.e. mean change from baseline in SIB total score between the two groups is different)

6. ANALYSIS POPULATIONS

6.1 Full Analysis Set

The Full Analysis Set (FAS) used for efficacy analyses is defined as all randomized subjects who received at least one dose of study medication and who have at least one post-baseline efficacy assessment.

6.2 Safety Analysis Set

The Safety Analysis Set (SAS) is defined as all randomized subjects who received any study medication (either partial or completed infusions of bryostatin or placebo).

6.3 Completer Analysis Set

The Completer Analysis Set (CAS) is defined as all randomized subjects who completed 12 weeks of treatment, and who have a week 13 SIB assessment.

7. DATA CONVENTION AND RELATED DEFINITIONS

7.1 Baseline Definition

For all parameters, baseline will be defined as the last available value before the randomized treatment.

7.2 Duplicate Data

For unplanned duplicate data within a protocol-specified visit, the last measured value will be used for the analysis. If it is not possible to identify the "last measured value" the average of the duplicate values will be used. No data will be excluded. All collected data will be listed.

7.3 Handling of Missing Data

Every effort will be made to obtain required data at each scheduled evaluation from all subjects who have been randomized to minimize missing data. However, in the event when there is missing data the following imputation methods will be used.

7.3.1 Handling of Missing Data for Efficacy Evaluations

For efficacy evaluations, multiple imputation methods will be used to handle missing data. The imputation will be carried out in SAS version 9.4 or later using PROC MI. Each imputation model will include the stratification factor (i.e., MMSE-2 score (4-9 vs. 10-15)) as a covariate in the model.

7.3.1.1 Multiple Imputation for Continuous variables

If the **missing data point is continuous in nature with monotone pattern**, predictive mean matching will be used in the model.

This method imputes a value randomly from a set of observed values whose predicted values are closest to the predicted value for the missing value from the simulated regression model.

If the **missing data point is continuous in nature with arbitrary pattern**, a fully conditional specification (FCS) will be used, using the predictive mean matching method with joint distribution for all variables.

7.3.1.2 Multiple Imputation for Categorical variables

If the **data point is categorical in nature with monotone pattern**, logistic method will be used in the model. With this method, a logistic regression model is fitted for a categorical variable with covariates. All the categorical endpoints in the study have binary classification variables, and for these based on the fitted regression model, a new logistic regression model is simulated from the posterior predictive distribution of the parameters and is used to impute the missing values for each variable.

If the **data point is categorical in nature with arbitrary pattern**, a fully conditional specification (FCS) will be used using logistic regression approach with joint distribution for all variables.

7.4 Multicenter Clinical Trials

This is a randomized study with multiple centers.

7.5 Multiple Comparisons and Multiplicity

There will be no need to adjust for multiple testing or multiplicity for this phase 2 trial. For all effectiveness endpoints, inference will be based on type I error rate of 0.05.

7.6 Covariates and Prognostic Factors

In the efficacy analysis, the stratification factors and baseline values such as age, sex, or disease severity may be used as covariates in the analysis of all the primary, secondary, and additional efficacy endpoints.

7.7 Stratification Factors and Subgroups

This is a randomized study and stratified so that the groups have similar distribution of MMSE-2 score (4-9 vs. 10-15). The stratification will ensure balance between each treatment group in each stratum.

7.8 Standard Calculations

7.8.1 Age

Age will be calculated as the number of completed years between the date of informed consent and the subject's birth date.

Age (years) = integer of [(date of informed consent – date of birth)/ 365.25]

7.8.2 Height

For summary purposes height will be expressed in centimeters. Entries made in inches will be converted to centimeters using the formula noted below.

Height (cm) = Height (in)*2.54

7.8.3 Weight

For summary purposes weight will be expressed in kilograms. Entries made in pounds will be converted to kilograms using the formula noted below.

Weight (kg) = Weight (lb)/ 2.2046

7.8.4 Change from Baseline

For any of the effectiveness measurements change from baseline will be calculated using the formula noted below.

Change from baseline = Post Baseline Measurement – Baseline Measurement

8. STATISTICAL METHODS

All data collected during this study will be presented in subject data listings.

All statistical analyses will be performed using SAS® for Windows, version 9.4 or later. For continuous variables, descriptive statistics (n, mean, standard deviation, median, minimum and maximum) will be presented by treatment group. For categorical variables both frequencies and percentages will be presented by treatment group.

8.1 Disposition and Baseline Characteristics

8.1.1 Subject Disposition and Withdrawals

There will be a detailed accounting of all subjects that signed the informed consent to participate in this trial. The following will be summarized by treatment group:

- The number of subjects who signed the informed consent
- The number of subjects who are screen failures
- The number of subjects who are randomized
- The number of randomized subjects in each stratum
- The number of subjects who received at least one study treatment
- The number of subjects who completed the study
- The number of subjects who discontinued
    - Reasons for discontinuation prior to completion will also be summarized descriptively by treatment group.

In addition, there will also be a listing of all discontinued subjects, which will provide the clinical trial center, treatment group and the specific reason for discontinuation.

8.1.2 Demographics and Baseline Characteristics

Demographic (age, sex, race, ethnicity, height and body weight) and other basic baseline characteristics will be summarized and/or listed, descriptively, by treatment group.

Medical history and Rosen-modified Hachinski Scale results will be provided as by-subject listings.

8.1.3 Prior and Concomitant Medications

Prior and concomitant medications will be summarized.

All prior and concomitant medications recorded in the case report form will be coded to the drug substance level (*i.e.,* generic term) using the most recent version of WHO Drug dictionary.

Descriptive summaries, by treatment group, will be prepared using the coded terms. All prior and concomitant medications recorded in the case report form will be listed.

8.1.4 Treatment Administration and Compliance

All treatment administration and compliance data will be listed and summarized.

8.2 Analysis of Efficacy Data

The primary analysis will be conducted on FAS population. The CAS population will be used as a supportive analysis. All statistical tests for efficacy will be two-sided tests, with α=0.05.

8.2.1 Primary Efficacy Endpoint

The primary endpoint for this study is the change from baseline to Week 13 in the SIB total score.

The change from baseline to Week 13 in the SIB total score will be summarized descriptively and compared using Analysis of Covariance (ANCOVA) adjusted for baseline SIB total score.

If the normality assumption is not met, a non-parametric method or a rank-ANCOVA analysis (i.e., an ANCOVA analysis on rank-transformed data) will be used.

8.2.2 Secondary Efficacy Endpoints

8.2.2.1 The changes from baseline at Weeks 5, 9 and 15 in the SIB total score

The change from baseline at Week 5, 9 and 15 in the SIB total score will be summarized descriptively and compared using ANCOVA adjusted for baseline SIB total score.

If the normality assumption is not met, a non-parametric method or a rank-ANCOVA analysis will be used.

8.2.2.2 The changes from baseline at Weeks 5, 9, 13 and 15 in the SIB total score for subjects in the MMSE-2 4-9 stratification group

The change from baseline at Week 5, 9, 13 and 15 in the SIB total score for subjects in the MMSE-2 4-9 stratification group will be summarized descriptively. Similar analysis methods as the primary endpoint will be used for analysis of this endpoint.

8.2.2.3 The changes from baseline at Weeks 5, 9, 13 and 15 in the SIB total score for subjects in the MMSE-2 10-15 stratification group

The change from baseline at Week 5, 9, 13 and 15 in the SIB total score for subjects in the MMSE-2 10-15 stratification group will be summarized descriptively. Similar analysis methods as the primary endpoint will be used for analysis of this endpoint.

8.2.2.4 Individual patient's slope over time in SIB total score evaluated via Weeks 0, 5, 9 and 13

Individual-specific SIB slopes will be estimated for all patients over each person's available SIB outcome measures. An indicator will be assigned to each patient depending on the sign of the SIB slope β (i.e. I=-1 if β <0; 1 if β >0; no value otherwise). The proportions of patients with I=1 and, respectively, -1 will be compared using logistic regression to assess the overall trend between treatments. In addition, an overall population averaged slope will be estimated for each treatment arm, and two-sample t-test will be used to assess the difference between treatments.

8.2.3 Exploratory Endpoints

The exploratory endpoints will be analyzed as follows:

8.2.3.1 Change from baseline in ADCS-ADL-Sev total score

The change from baseline in ADCS-ADL-Sev total score will be calculated for each subject using the formula in Section 7.8.4. Similar analysis methods as the primary endpoint will be used for analysis of this endpoint.

8.2.3.2 Change from baseline in MMSE-2 total score

The change from baseline in MMSE-2 total score will be calculated for each subject using the formula in Section 7.8.4. Similar analysis methods as the primary endpoint will be used for analysis of this endpoint.

8.2.3.3 Change from baseline in NPI total score

The change from baseline in NPI total score will be calculated for each subject using the formula in Section 7.8.4. Similar analysis methods as the primary endpoint will be used for analysis of this endpoint.

8.2.3.4 CGI-I score

CGI-I score will be summarized descriptively. Similar analysis methods as the primary endpoint will be used for analysis of this endpoint.

8.3 Analysis of Safety Data

For continuous variables, data will be summarized by treatment using n, mean, SD, minimum and maximum values. For categorical variables, data will be summarized by treatment using frequency and percentage.

8.3.1 Adverse Events

Adverse events will be coded using the most recent version of Medical Dictionary for Regulatory Activities (MedDRA). Treatment Emergent AE's (TEAE) are defined as events with an onset on or after the first randomized treatment. TEAEs will be summarized by treatment group, System Organ Class, and preferred term. The following TEAE summaries will be provided:

- Overall (*i.e.,* regardless of severity or relationship to treatment)
- By severity grade (mild, moderate, severe, life threatening or death for SAEs)

  By relationship to clinical trial treatment (definitely related, probably related, possibly related, unlikely related, unrelated)

Unless otherwise specified, at each level of subject summarization, a subject will be counted only once. If there is more than one occurrence of an event, the event of the worst severity or the worst-case relationship category will be summarized.

In addition, separate summaries of serious adverse events, and adverse events resulting in discontinuation of study treatment will be presented.

AEs leading to premature discontinuation of clinical trial treatment, AEs that lead to study discontinuation, AEs that lead to death and Serious Adverse Events (SAEs) will also be summarized by treatment group and relationship.

8.3.2 Clinical Laboratory Evaluations

All available results of the clinical laboratory evaluations will be listed and summarized as follows:

8.3.2.1 Laboratory Values over Time

Summary statistics of raw data and change from baseline values for each laboratory parameter will be presented by treatment group and time point. Data will be summarized as appropriate for the variable type.

- For continuous data, summaries will include the number of observations, mean, SD, median, minimum, and maximum values.
- For categorical data, frequency counts and percentages will be used.

For change from baseline summaries, subjects with an undefined change from baseline, because of missing data, will be excluded.

8.3.2.2 Individual Subject Changes (Shift Tables)

Individual subject changes will be identified through shift tables. Shift tables will be presented for each laboratory parameter with counts and percentages of subjects, by treatment group and time point, for shift (change) from baseline, using the normal ranges from the laboratory.

8.3.2.3 Individual Clinically Significant Abnormalities

Clinically significant laboratory abnormalities (i.e., those laboratory abnormalities recorded as AEs) will be listed.

All results of laboratory evaluations will be presented as by-subject listings.

8.3.3 Physical Examination

All physical examination findings will be listed and/or summarized by treatment group. Shift tables will also be presented to show any abnormality shifts from baseline to post baseline visits.

8.3.4 Vital Signs

Tabulations of raw data and change from baseline values will be presented by time point for each vital sign parameter.

Tabulations will include the number of observations, mean, standard deviation, median, and minimum and maximum values. For change from baseline summaries, subjects with an undefined change from baseline, because of missing data, will be excluded.

8.3.5 ECG

All ECG findings will be listed and/or summarized. Shift tables will also be presented to show any abnormality shifts from baseline to post baseline visits.

8.3.6 Columbia Suicide Severity Rating Scale (C-SSRS)

All data from C-SSRS will be listed. Descriptive summaries will be presented for each of the

subscales (i.e. Suicidal Ideation and Suicidal Behavior).

9. APPENDIX 1: SCHEDULE OF ASSESSMENTS

	NTRP101-203											
Week	**Screening**		**0**	**1**	**2**	**3**	**5**	**7**	**9**	**11**	**13**	**15/ET**
Day (±2 days)	**(Days -28 to -2)[d]**		**0**	**7**	**14**	**21**	**35**	**49**	**63**	**77**	**91**	**105**
Dose		**Rand**	**1**	**2**		**3**	**4**	**5**	**6**	**7**		
Informed Consent	X											
Medical history	X											
Demographics	X											
Rosen-modified Hachinski Scale	X											
SIB	X[Δ]						X*		X*		X	X
MMSE-2	X						X*		X*		X	X
ADCS-ADL-Sev[b]	X						X*		X*		X	X
NPI[b]	X						X*		X*		X	
CGI-I							X*		X*		X	
CSSRS	X				X			X*			X	
Labs^^	X				X			X*			X	
ECG	X (x3)				X			X			X	
PE	X							X*[+]			X	
Vitals	X		X[c]	X[c]	X	X[c]	X[c]	X[c]	X[c]	X[c]	X	X
Randomization		X[a]										
Confirm Eligibility	X[◊]	X										
Study Drug Dosing			X	X		X	X	X	X	X		
Adverse Events	X		X	X	X	X	X	X	X	X	X	X
Con meds	X		X	X	X	X	X	X	X	X	X	X

[Δ]Baseline SIB administered during screening must be done within 3 weeks of the first dose of study drug. If the screening period exceeds 3 weeks, the SIB should be repeated on the day of first dose, prior to dosing;* before dose; ^^Labs: CBC including differential, coagulation, clinical chemistry, TSH at screening (B12, T-3 and T-4 if TSH abnormal), CPK at screening and event of myalgia, βhCG if indicated, HbA1C if clinically indicated; [◊] CT scan if necessary per inclusion criterion #6; [+] abbreviated physical examination; [a] Randomization after initial screening procedures indicate eligibility; [b] The ADCS-ADL-Sev and NPI may be administered via telephone at the discretion of the investigator, within the allowed time window for the scheduled visit;[c] Vital signs prior to infusion, then at 30, 60 and 90 minutes from start of the infusion (+/- 5min). [d]The visit window of ±2 Days does not apply to the Screening and Randomization period which is a maximum of 28 days.

10. APPENDIX 2 – PLANNED TLG

10.1 Planned by-subject listings

DISPOSITION/WITHDRAWALS (LISTINGS 16.2.1.X)

ELIGIBILITY (LISTINGS 16.2.2.X)

EXCLUDED SUBJECTS (LISTINGS 16.2.3.X)

DEMOGRAPHICS, POPULATION, AND BASELINE CHARACTERISTICS (LISTINGS 16.2.4.X)

DRUG COMPLIANCE AND DRUG CONCENTRATION LISTINGS (LISTINGS 16.2.5.X)

EFFICACY RESPONSE (LISTINGS 16.2.6.X)

ADVERSE EVENT DATA (LISTINGS 16.2.7.X)

SAFETY DATA (LISTINGS 16.2.8.1.X)

10.2 Planned Summary Tables

POPULATION DISPOSITION

POPULATION DEMOGRAPHICS AND BASELINE CHARACTERISTICS

CONCOMITANT MEDICATION USAGE

EFFICACY SUMMARIES

SAFETY SUMMARIES

- ADVERSE EVENT SUMMARIES
- SERIOUS ADVERSE EVENTS
- LABORATORY
- VITAL SIGNS AND PE
- OTHER SAFETY

11. VERSION HISTORY

This is the first version of this document.

12. REFERENCES

1. ASA. (2016) Ethical Guidelines for Statistical Practice. Prepared by the Committee on Professional Ethics, April, 2016.
2. The Royal Statistical Society: Code of Conduct (2014).
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6. Guideline for Industry: Structure and Content of Clinical Study Reports (ICH E3), July 1996.
7. Yuan, Yang. "Sensitivity analysis in multiple imputation for missing data." Proceedings of the SAS Global Forum 2014 Conference:[http://support. sas. com/resources/papers/proceedings14/SAS270-2014. pdf]. 2014.