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NEURELIS, INC.

STATISTICAL ANALYSIS PLAN

Section 14 and 16

Protocol No.: DIAZ.001.05

A 12-Month Open-Label, Repeat-Dose Safety Study of NRL-1 in Epilepsy Subjects (DIAZ.001.05)

CONFIDENTIAL

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Document History

Verision	Date of Issue	Summary of Change
1.0	May 26, 2018	Original
1.1	July 8, 2020	Additional analysis has been added (Safety/Tolerability & Effectiveness)

LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
AE	adverse event
$AUC_{(0-6)}$	area under the plasma concentration time-curve to 6 hours post dose
BLQ	below the limit of quantization
C-SSRS	Columbia Suicide Severity Rating Scale
C_{max}	Maximum plasma concentration
ECG	Electrocardiogram
EMU	Epilepsy Monitoring Unit
FDA	US Food and Drug Administration
HEENT	head, ears, eyes, nose, and throat
ICH	International Conference on Harmonization
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram(s)
mL	milliliter
NIH	National Institutes of Health
NRL-1	Diazepam nasal spray
PK	pharmacokinetics
QOLIE	Quality Of Life In Epilepsy
QTcF	Corrected QT interval, Fridericia's formula
SAE	serious adverse event
TEAE	treatment-emergent adverse event
t_{max}	time to maximum plasma concentration
VAS	Visual Analog Scale
WHODD	World Health Organization Drug Dictionary

1. INTRODUCTION

The purpose of this statistical analysis plan (SAP) is to describe the procedures to be used for analyzing and reporting results for study DIAZ.001.05.

This SAP is based on the final protocol version 3 (23-May-2016).

2. STUDY OBJECTIVES AND ENDPOINTS

2.1. Study Objectives

The purpose of this study is to assess the safety of repeat intranasal doses of NRL-1 administered to Epilepsy subjects.

Primary objective

The primary objective of this study is to assess the safety of diazepam after repeat intranasal doses of NRL-1 administered to Epilepsy subjects who experience frequent breakthrough seizures or Acute Repetitive Seizures, over a 12-month period. FDA has requested that analyses be presented by Overall and age group of 6-11 and 12+ dosing in the Diastat labeling.

Secondary objective

- To assess the tolerability of diazepam after repeat intranasal administration of NRL-1.
- To assess the ability of caregivers to administer NRL-1 based on the Directions for Use (DFU).
- To assess an improvement in the Quality of Life with NRL-1 use as compared to Diastat.

2.2. Study Endpoints

2.2.1. Efficacy Endpoints

There are no efficacy endpoints for this study.

2.2.2. Safety Endpoints

Safety data will be summarized by dose group and based on their initial dose level or treatment group (i.e., if a dose reduction occurs they will be considered in their initial group). Overall and age group of 6-11 and 12+ descriptive statistics will be provided for actual values and change from baseline values for vital signs and change from screening for clinical laboratory tests (serum chemistry, hematology, and urinalysis).

A nasal examination and irritation assessments will be conducted to evaluate any effects of the NRL-1 formulation on the nasal mucosa. The following will be assessed on separate scales: nasal Irritation, erythema, edema, nasal discharge, mucosal erythema, mucosal edema, nasal discharge, mucosal crusting and epistaxis. Overall and age group of 6-11 and 12+ descriptive statistics will be provided.

Smell tests and examination of the nasal mucosa will be conducted at screening and at each study visit. The NIH Toolbox for Odor Identification Test will be used as smell tests.

The Columbia-Suicide-Severity Rating Scale (C-SSRS), a measure of suicidal ideation and behavior, will be used to document suicidality in order to classify suicidal events. Suicidality will be assessed at screening for eligibility, day 150 and day 365. The pediatric C-SSRS should be used for subject age 6 to 11. The adult C-SSRS should be used for subjects 12 and greater years of age.

The Quality of Life in Epilepsy will be administered to assess the quality of life while on NRL-1 compared to baseline therapy at time of enrollment, day 30, day 150, day 270 and day 365. QOLIE-AD-48 will be used for subject age 11-18 years with epilepsy. Subjects age 18 years or older should complete the QOLIE-31-P.

Adverse event (AE) collection will begin on Day 0 after baseline assessments are complete prior to the initial treatment with NRL-1 and continue for 28-days after Day 365. AE may be either spontaneously reported or elicited during questioning and examination of a subject. Adverse event information will be elicited at appropriate intervals by indirect questioning using a non-leading question. Adverse events that occur after dosing in a home setting will be recorded in a diary and reported at the next study visit. Subjects will receive follow-up telephone contact approximately 28 days (± 3 days) after Day 365 to determine if any AE has occurred and to follow-up on any treatment-emergent AEs (TEAE[s]) ongoing since last communication with the subject.

The incidence and severity of TEAEs reported during the study and their relationship to study drug will be tabulated. TEAEs will be coded using the MedDRA and will be presented by body system.

The World Health Organization Drug Dictionary (WHODD) will be used to classify prior and concomitant medications by therapeutic class and preferred term. Prior and concomitant medication usage will be summarized by the number and percentage of subjects receiving each medication within each therapeutic class by dose cohort.

3. STUDY DESIGN

This is a Phase 3, repeat dose, open-label, safety study in Epilepsy subjects who have frequent breakthrough seizures or Acute Repetitive Seizures (ARS). NRL-1 will be administered as needed to treat bouts of those seizures over a 12-month period of time. Doses will be defined as 5 mg, 10 mg, 15 mg, or 20 mg based on the subject's body weight. A diary will be used to record the seizure and NRL-1 administration.

The study consists of a screening phase, a baseline, a 12-month treatment period and a follow-up telephone contact 28-days after the last dose of NRL-1 or study termination. The primary purpose of this study is to assess the safety of repeat doses of NRL-1 as intermittent chronic therapy to treat frequent break through seizures or ARS.

Safety assessments include physical and neurological examination including head, ears, eyes, nose, and throat (HEENT), vital signs, laboratories (hematology, serum chemistry, and urinalysis), 12-lead electrocardiograms (ECGs), and adverse event assessment. Concomitant medications will be recorded. Columbia-Suicide Severity Rating Scale (C-SSRS for adults or pediatric), Nasal Irritation Assessment, Sedation Score Assessment, and Smell Test (NIH Toolbox Odor Identification Test) and examination of nasal mucosa will be conducted at each visit. A targeted physical examination may be used to evaluate any potentially related side effects.

Subjects and caregivers will be trained on the proper use of the NRL-1 nasal sprayer at screening period and as needed during treatment period. The ability of caregivers to administer NRL-1 based on the Directions for Use (DFU) will be assessed.

The Quality of Life in Epilepsy (QOLIE) questionnaire will be administered to assess the quality of life while on NRL-1 compared to baseline therapy at time of enrollment.

Naïve subjects may be entered into this study as well as those subjects completing the protocol DIAZ.001.04 are eligible for the long-term safety study (DIAZ.01.05) and may receive treatment with NRL-1 under DIAZ.01.05 protocol.

Study Procedure	**Screening[a]**	**Baseline[b]**	**Treatment period and Visit Days**							**Follow Up telephone contact[c]**
Study Day	**Day -21 to Day -1**	**Day -3 to Day 0**	**Day 30[d]**	**Day 90[d]**	**Day 150[d]**	**Day 210[d]**	**Day 270[d]**	**Day 330[d]**	**Day 365[d]**	**Day 393 or termination visit**
Signed informed consent	X									
Inclusion/Exclusion Criteria	X	X								
Medical history including seizure history	X	X								
Columbia-Suicide Severity Rating Scale (C-SSRS)[e]	X				X				X	
Physical and Neurological exam (including HEENT)[f]	X								X	
Vital signs[g]	X	X	X	X	X	X	X	X	X	
Height and Weight	X	X[h]							X	
Hematology, Serum Chemistry and Urinalysis	X				X		X		X	
Serum or urine ß-hCG (Pregnancy)[i]	X	X	X	X	X	X	X	X	X	
HIV Antibody and Hepatitis Test[j]	X									
Urine Drug, Alcohol and Cotinine Screen[k]	X									
Prior and Concomitant medication assessment	X	X	X----------→							X
Adverse event assessment[l]		X	X----------→							X
ECG (12-Lead in triplicate)[m]	X	X								
Smell Test[n]		X	X	X	X	X	X	X	X	
Assessment of the ability of caregivers to administer NRL-1[o]		X	X		X		X		X	
Nasal Examination and Irritation Assessment[p]		X	X	X	X	X	X	X	X	
Quality of Life in Epilepsy questionnaire (QOLIE)[q]		X	X		X		X		X	
NRL-1 administration[r]		X	X----------→							
Diary to record seizure and NRL-1 administration		X	X----------→							
Subject/caregiver training[s]	X		X----------→							

a. Screening evaluations must be performed within 21 days prior to dosing on Day 0. Screening evaluations performed within 24 hours (Day -1 to Day 0) of dosing do not need to be repeated.
b. Baseline evaluations will be performed within 72 hours prior to study initiation on Day 0. Baseline assessment may be conducted at clinic.
c. Subjects will receive follow-up telephone contact approximately 28 days (± 3 days) after Day 365
d. Study window at visits from Days 30 to 365 is ± 7 days.
e. C-SSRS, a measure of suicidal ideation and behavior, will be used to document suicidality in order to classify suicidal events. The pediatric C-SSRS should be used for subjects age 6 to 11. The adult C-SSRS should be used for subjects 12 and greater years of age (see APPENDIX B).
f. Targeted physical examinations may be used during the treatment period to evaluate potentially related adverse events.
g. Vital signs (temperature, pulse, and blood pressure) are to be obtained.
h. Weight only.
i. A serum (ß-hCG) pregnancy test will be administered to females of childbearing potential at screening. Pregnancy test will be done with urine at baseline and at the visits during the treatment period. If a serum pregnancy test is done on Day -1, urine pregnancy test does not have to be repeated if done within 72 hours of study initiation (baseline).
j. Hepatitis B surface antigen (HbSAg), or Hepatitis C

k. When marijuana was prescribed for medical reason by a licensed practitioner, it is not considered as drug abuse and the patient can be enrolled even if the marijuana metabolites in the urine revealed as positive. In this case, information about marijuana prescription should be entered in the CRF page for concomitant medication.
l. Adverse event assessment is continuous from Day 0 after baseline assessments are complete. Events that occur after dosing in a home setting will be recorded in a diary and reported at the next study visit.
m. ECG is to be performed in triplicate. Three consecutive ECGs (each approximately 1-2 minutes apart) are performed.
n. Smell tests will be conducted at baseline and at each visit. The NIH Toolbox Odor Identification Test will be used as smell tests.
o. Ability of caregivers to administer NRL-1 will be assessed.
p. Nasal examination and scoring for nasal irritation, mucosal erythema, mucosal edema, nasal discharge, mucosal crusting and mucosal epistaxis will be performed at baseline and at each site visit.
q. QOLIE questionnaire will be administered to assess the quality of life while on NRL-1 compared to baseline therapy at time of enrollment (see APPENDIX D).
r. NRL-1 administration will be as needed to treat bouts of uncontrolled seizures (frequent break through seizures or ARS) after baseline procedures completed.
s. Subjects and caregivers will be trained based on the Direction for Use (DFU) for the proper use of the NRL-1 nasal sprayer. Training may be given as needed during the treatment period.

4. PLANNED ANALYSES

4.1. Interim Analysis

One interim analysis will be performed done using soft lock data (cut off date : April 30, 2018) for regulatory approval.

4.2. Final Analysis

Final analyses will be completed following database lock in the study. Any changes from the planned analyses described in this section will be stated in the final study report.

5. SAMPLE SIZE CONSIDERATIONS

5.1. Sample Size Determination

Up to 100 subjects, at least 30 age 6 to 11 years and up to 70 over 12 years of age, are to be enrolled.

5.2. Sample Size Re-estimation

A re-estimation of sample size will not be performed on this study.

6. ANALYSIS POPULATIONS

Safety Population

Subjects who have taken at least one dose of NRL-1will be included in the safety analyses.

7. GENERAL CONSIDERATIONS FOR DATA ANALYSES

In general, the sort order for listings will be dose level (ascending dose levels of NRL-1), subject and assessment time, while summaries will be presented by dose level (ascending dose levels of NRL-1) and assessment time. A separate but identical analysis will be performed by age groups (6-11 and 12+).

Unless stated otherwise, descriptive summaries will include n(Number of subjects), mean, standard deviation, median, range for continuous variables and n(Number of subjects) and percent for categorical variables. For planned ECG parameter assessments that are done in triplicate, the mean value will be used in the calculation of all descriptive statistics. If there are repeated assessments at a scheduled time point, the assessment closest to the scheduled time will be used in the calculation of all descriptive statistics. Any unscheduled or unplanned readings will be presented within the subject listings, but only the scheduled readings will be used in any summaries. Version 9.4 of the SAS™ system (SAS is a registered trademark of the SAS Institute, Inc., Cary, NC, USA) will be used to analyze the data as well as to generate tables, figures, and listings.

7.1. Multicenter Studies

Multi center will participate in the study.

7.2. Other Strata and Covariates

There are no other strata and covariates.

7.3. Examination of Subgroups

There is subgroup analysis of safety data by age group of 6-11 and 12+ will be provided.

7.4. Multiple Comparisons and Multiplicity

No adjustments for multiple comparisons are planned.

8. DATA HANDLING CONVENTIONS

8.1. Premature Withdrawal and Missing Data

All subjects who withdraw from the study prematurely will be documented and the reason for their withdrawal will be reported in the final study report. Subjects who discontinue participation in the study prior to receiving study drug for a given dose level will be replaced, if possible. Missing data will not be imputed.

8.2. Derived and Transformed Data

8.2.1. ECG

QTc intervals will be calculated by Fridericia's (QTcF) formulas.

Fridericia's formula is:

$$\text{QTcF interval (msec)} = \text{QT interval (msec)} / (\text{RR interval (sec)})^{1/3}$$

where RR interval (sec) = 1/(heart rate (bpm)/60)

8.2.2. QOLIE

Following component summary will be populated following each scoring manuals.

- QOLIE31: Quality of Life In Epilepsy QOLIE-31 (Version 1.0) Scoring manual will be used to calculate sub-scale parameters for version 1 of QOLIE-31.
    e. Energy
    f. Mood
    g. Daily Activities
    h. Cognition
    i. Medication effects
    j. Seizure Worry
    k. Overall Quality of Life
    l. Final QOLIE-31-P Score

- QOLIE-31-P : Patient-Weighted Quality of Life in Epilepsy (v.2) will be used to calculate sub-scale parameters for version 2 of QOLIE-31-P.
    a. Seizure worry
    b. Overall quality of life
    c. Emotional well-being
    d. Energy/fatigue
    e. Cognitive functioning
    f. Medication effects
    g. Social functioning
    h. Overall scores

- QOLIE-AD-48. Quality of Life in Epilepsy for Adolescents (version 1.0) will be used to calculate sub-scale parameters and Total (Summary) Score.
    a. Epilepsy Impact
    b. Memory/Concentration
    c. Physical Functioning
    d. Stigma
    e. Social Support
    f. School Behavior
    g. Attitudes Toward Epilepsy
    h. Health Perceptions
    i. Total (Summary) Score

8.3. Values of Clinical Concern

Values that exceed the lower/upper limits of clinical lab values, all abnormal or "not clinically significant" and all changes in vital signs will be reviewed for clinical relevance by the Medical Monitor (PLC).

9. STUDY POPULATION

Subjects with a clinical diagnosis of frequent break through seizures or ARS with bouts of uncontrolled seizures, who, in the opinion of the Investigator, may need a benzodiazepine for seizure control.

9.1. Disposition of Subjects

All data from enrolled subjects will be summarized to provide the number of subjects who complete the study within each treatment and the number of subjects withdrawn and the reasons for withdrawal will be summarized. Also, subject listing will be provided.

9.2. Protocol Deviations

Protocol deviations will be reported to Neurelis, Inc and will be documented in the clinical study report. Any changes from the analyses described within this statistical analysis plan will be stated in the final study report.

9.3. Demographic and Baseline Characteristics

Demographic and baseline characteristics for the subject population will be listed and summarized using the safety population. Descriptive summaries (n(Number of subjects), mean, standard deviation, minimum, median, and maximum and n(Number of subjects) and percent for categorical variables) will be provided by treatment group.

10. EFFICACY ANALYSES

No efficacy measures will be assessed during this study.

11. SAFETY ANALYSES

No formal statistical comparisons of the safety data will be conducted.

11.1. Extent of Exposure

The exposure data will be a by-subject listing, including the treatment administered with the dates and times of treatment administration.

11.2 Analysis of Seizure Events

A seizure event is defined as the initial event of a 24-hour period. For example, consider the following hypothetical data from a subject with 5 records:

Record	Date/time of seizure record
1	2019-07-08T13:00
2	2019-07-09T14:00
3	2019-07-10T01:00
4	2019-07-10T02:00
5	2019-07-19T05:00

This subject has three seizure events (records 1, 2, and 5). Because records 3 and 4 occur within 24 hours of record 2, these are retreatment records.

The number and percentage of seizure events for which retreatment was required will be summarized for all events and by dose level for the following time intervals of retreatment:

- 0-10 minutes
- 10-30 minutes
- 30 minutes-1 hour
- 1-2 hours
- 2-3 hours
- 3-4 hours

- 0-4 hours
- 0-6 hours
- 0-8 hours
- 0-12 hours
- 0-16 hours
- 0-20 hours
- 0-24 hours

In addition to the overall summary, results will be provided for the following subgroups:

- 6-11 year olds
- 12-17 year olds
- 18 years of age and older
- Subjects with seasonal allergies/rhinitis
- Subjects without seasonal allergies/rhinitis

- Subjects with concomitant use of other benzodiazepines
- Subjects without concomitant use of other benzodiazepines

11.2. Adverse Events

All adverse events (AEs) will be coded and classified according to System Organ Class (SOC) and Preferred Term (PT) using MedDRA(Version 16.1or more). TEAE(treatment emergent Adverse Event) will be populated. All AEs (non-serious and serious) will be listed. A summary, by treatment group, of the number and percent of subjects reporting each event at least once will be generated for all AEs and also for drug-related AEs. Adverse events by System Organ Class, Preferred Term, and Severity will be summarized by Treatment group. A listing of the relationship with study drug by System Organ Class and Preferred Term will also be produced.

11.2.1. Additional Adverse Events Tables

Summary AE table, Incidence of TEAE by MedDRA system Organ Class, PT term, by strongest relationship, maximum severity, Seriousness will be produced. Similar tables will be produced by following subgroups.

a. By age group (12-17 years, >= 18 years)what about 6-11?
b. By gender (Female, Male)
c. By subjects whose mean dose is <1 dose/month, 1-2 doses/month, 3-5 doses/month, > 5 doses/month
d. By Subjects whose second dose of NRL-1 was used prior to 4 hours, second doses given 4-24 hours after first dose
e. By subject's the NRL-1 treatment was sooner than the 5 days in-between events
f. By subject who have used more than 5 doses within a 30 days period, don't have used more than 5 doses within a 30 days period
g. By subjects who used benzodiazepines as Concomitant medication
h. By subjects who has seasonal allergies/rhinitis history vs. don't have seasonal allergies/rhinitis
i. By subjects whose AE onset month is Winter : Jan-Mar, Spring : Apr-Jun, Summer : Jul-Sep, Winter : Oct-Dec
j. By subjects who has AE PT are Cardiorespiratory/, Nasal/nasopharyngeal
k. By subjects who had AE Requires/Prolongs Hospitalization
l. By subjects who had Status Epilepticus, Recurrent Seizures – which led to ER/Hospitalization and within the 48 hours after first NRL-1 dose
m. By subjects who were SELF-ADMINISTRATORS from the survey

11.3. Deaths and Serious Adverse Events

Any deaths and other serious adverse events will be summarized and listed as appropriate to the data.

11.4. Adverse Events Leading to Discontinuation of Investigational Product and/or Withdrawal from the Study and Other Significant Adverse Events

If any subject withdraws due to an AE, then a listing and a summary will be provided for these subject(s).

11.5. Pregnancies (as applicable)

If any female subject becomes pregnant during the course of the study, this information will be tabulated and listed.

11.6. Clinical Laboratory Evaluations

All laboratory data will be listed for each subject. Summary statistics (n(Number of subjects), mean, standard deviation, median, range for continuous variables and n(Number of subjects) and percent for categorical variables) will be displayed for laboratory parameters. Clinically significant abnormalities, if they occur, will also be listed. To assess changes in laboratory parameters occurring during treatment, a shift summary of change from baseline to time-point (visit) and summary of change from baseline will be produced. Urine analysis for categorical variables will be categorized by treatment, class variable (*e.g.,* negative or positive) and visit.

11.7. Other Safety Measures

11.7.1. Concomitant Medication

Prior and concomitant medication will be coded and classified to according Preferred Term (PT) and modified drug name using The World Health Organization Drug Dictionary (WHODRL). Prior and concomitant medication by Preferred Term and modified drug name will be summarized by Treatment group.

11.7.2. Vital Signs

All vital sign data will be listed for each subject. Summary statistics (n(Number of subjects), mean, standard deviation, minimum, median, and maximum)for vital parameter(temperature, breathing rate, radial pulse, systolic blood pressure, diastolic blood pressure, height and weight) will be presented by treatments and visit. And also summary of the change from baseline will be summarized.

11.7.3. Electrocardiograms

In order to assess the effect of treatment on cardiac intervals, triplicate 12-lead digital ECGs will be collected. ECG sign data will be listed for each subject. A descriptive summary (n(Number of subjects), mean, standard deviation, minimum, median, and maximum and n(Number of subjects) and percent for categorical variables)for ECG parameter will be presented by treatments.

11.7.4. Physical examination

All physical examination data will be listed for each subject. Frequency and percent by treatment group will be displayed for physical examination parameters. A shift summary of change from screening to time-point (visit) will be produced.

11.7.5. C-SSRS assessments (children and adult)

C-SSRS assessments (children and adult) data will be listed for each treatment and subject by visit.

11.7.6. QOLIE (children and adult)

QOLIE assessments data will be listed for each treatment and subject by visit.

The descriptive statistics (mean, SD, maximum value, minimum value, median, two sided 95% CI) for the populated QOLIE scores and changed from baseline value per visit will be summarized per visit (baseline, day30, day150, day270, day365) by treatment groups.

For Adult (Age 18 Years old), QOLIE-31 and QOLIE-31-P have been used in this trial. For the descriptive statistics table, formula in the QOLIE-31 (version 1.0) scoring manual will be used for both QOLIE-31 & QOLIE-31-P results to calculate sub-scale parameter and overall score, due to lack of distress item score obtained in QOLIE-31-P questionnaires but not in QOLIE-31 questionnaires.

11.7.7. Nasal Irritation, Mucosal Erythema, Mucosal Edema, Nasal Discharge, Mucosal Crusting and Mucosal Epistaxis

Nasal examination and irritation assessments (Nasal Irritation, Mucosal Erythema, Mucosal edema, Nasal discharge, Mucosal crusting and Mucosal epistaxis) data will be listed for each subject. Frequency and percent by treatment group will be displayed for Nasal examination and irritation assessments.

Assessment will be dichomized for each assessment (Nasal Irritation, Mucosal Erythema, Mucosal edema, Nasal discharge, Mucosal crusting and Mucosal epistaxis). One category will be Grade 0 or Score 0 and other category will be combination of any Non Grade 0 or Non Score 0 assessments. A shift summary of change from screening to time-point (visit) will be produced. A figure showing each assessment (Nasal Irritation, Mucosal Erythema, Mucosal edema, Nasal discharge, Mucosal crusting and Mucosal epistaxis) mean and standard deviation by visit will be provided. Same tables and figures by age group of 6-11 and 12+ will be provided.

11.7.8. NIH Toolbox Odor Identification Test

NIH Toolbox Odor Identification Test will be listed for each subject. Summary statistics (n(Number of subjects), mean, standard deviation, minimum, median, and maximum)for NIH Toolbox Odor Identification Test will be presented by treatments and visit. A figure showing mean and standard deviation by visit will be provided. Same tables and figures by age group of 6-11 and 12+ will be provided.

11.7.9. Sedation Score Assessment

Sedation Score Assessment will be summarized for each subject. Summary statistics (n(Number of subjects), mean, standard deviation, minimum, median, and maximum)for Sedation Score Assessment will be presented by treatments and visit.

11.8. Exploratory Analysis

Table for Diurnal Pattern of Seizure Cluster treated with NRL-1 - first seizure that occurred time will be presented by age group (6-11, 12-17, 18 < years old), by gender (female, male), by super users vs. infrequent user and by subject with concomitant use of other benzodiazepines.

Table for Diurnal Pattern of Seizure Cluster treated with NRL-1 - required a second dose will be presented by age group (6-11, 12-17, 18 < years old), by gender (female, male) by super users vs. infrequent user and by subject with concomitant use of other benzodiazepines.

Tables for Mean doses use per patient per month by treatment will be presented by age group (6-11, 12-17, 18 < years old) and by gender (female, male).

Table for Pattern of use for Single -> Second Dose by TIME-POINT (0-10 minutes, 10-30 minutes, 30 minutes-1 hour, 1-2 hours, 2-3 hours,3-4 hours, 0-4 hours, 0-6 hours, 0-8 hours, 0-12 hours, 0-16 hours, 0-20 hours, 0-24 hours) by Treatment will be present by Subject with concomitant use of other benzodiazepines and by Subject who have Status Epilepticus or seizures as AE that leading to hospitalization.

Kaplan-Meier plot for following subgroups will be presented in figures.

a. KM plot of time to second dosed subject (first vs. second in each seizure cluster) by treatment
b. KM plot of time to dosed subject (first vs. second in each seizure cluster) by age
c. KM plot of time to dosed subject (first vs. second in each seizure cluster) by use pattern (< 1 dose/month, 1-2 doses/month, >2 doses/month), > 5 doses/month)
d. KM plot of time to dosed subject (first vs. second in each seizure cluster) by usage time (6,1 2 and > 12 months)
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Table 14.3.5.2.2.1	Laboratory: Chemistry - Shift Tables by Treatment and Visit (6-11 years old subject) - Safety Population
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Table 14.3.8.2.2	Physical Examination - Shift Tables by Treatment and Visit (>= 12 years old subject) - Safety Population
Table 14.3.8.2.3	Physical Examination - Shift Tables by Treatment and Visit (All subject) - Safety Population

12.1.2. Listings

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Listing 16.2.9.7.3	Columbia-suicidality severity-Children's Baseline/Screening - Safety Population
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Listing 16.2.9.12	Nasal Discharge - Safety Population
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Listing 16.2.9.18	Telephone Contact - Safety Population
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12.1.3. Graphs

Figure No	Title
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Figure 14.2.1.2	Nasal Irritation Assessments Mean and Standard Deviation by Treatment and Visit (>= 12 years old subject) - Safety Population
Figure 14.2.1.3	Nasal Irritation Assessments Mean and Standard Deviation by Treatment and Visit (All subject) - Safety Population
Figure 14.2.2.1	Mucosal Erythema Mean and Standard Deviation by Treatment and Visit (6-11 years old subject) - Safety Population
Figure 14.2.2.2	Mucosal Erythema Mean and Standard Deviation by Treatment and Visit (>= 12 years old subject) - Safety Population
Figure 14.2.2.3	Mucosal Erythema Mean and Standard Deviation by Treatment and Visit (All subject) - Safety Population
Figure 14.2.3.1	Mucosal Edema Mean and Standard Deviation by Treatment and Visit (6-11 years old subject) - Safety Population
Figure 14.2.3.2	Mucosal Edema Mean and Standard Deviation by Treatment and Visit (>= 12 years old subject) - Safety Population
Figure 14.2.3.3	Mucosal Edema Mean and Standard Deviation by Treatment and Visit (All subject) - Safety Population
Figure 14.2.4.1	Nasal Discharge Mean and Standard Deviation by Treatment and Visit (6-11 years old subject) - Safety Population
Figure 14.2.4.2	Nasal Discharge Mean and Standard Deviation by Treatment and Visit (>= 12 years old subject) - Safety Population
Figure 14.2.4.3	Nasal Discharge Mean and Standard Deviation by Treatment and Visit (All subject) - Safety Population
Figure 14.2.5.1	Mucosal Crusting Mean and Standard Deviation by Treatment and Visit (6-11 years old subject) - Safety Population
Figure 14.2.5.2	Mucosal Crusting Mean and Standard Deviation by Treatment and Visit (>= 12 years old subject) - Safety Population
Figure 14.2.5.3	Mucosal Crusting Mean and Standard Deviation by Treatment and Visit (All subject) - Safety Population
Figure 14.2.6.1	Mucosal Epistaxis Mean and Standard Deviation by Treatment and Visit (6-11 years old subject) - Safety Population

Figure 14.2.6.2	Mucosal Epistaxis Mean and Standard Deviation by Treatment and Visit (>= 12 years old subject) - Safety Population
Figure 14.2.6.3	Mucosal Epistaxis Mean and Standard Deviation by Treatment and Visit (All subject) - Safety Population
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Figure 14.2.9.3	KM plot for second dosed subject (first vs. last in each seizure cluster) by use pattern - Safety Population
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Figure 14.2.9.5	KM plot for second dosed subject (first vs. last in each seizure cluster) by gender - Safety Population

13. REFERENCES

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