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Statistical Analysis Plan

Protocol Title:	A Multicenter, 6-Week, Double-blind, Randomized, Placebo-controlled, Parallel-design Study to Assess the Efficacy and Safety of NFC-1 in Adolescents (Ages 12-17 Years) with Genetic Disorders Impacting Metabotropic Glutamate Receptors and Attention Deficit Hyperactivity Disorder
Protocol Number:	MGDN-NFC1-ADHD-201 (27-OCT-2016)
Compound:	NFC-1
Phase:	II
Sponsor:	Medgenics, Inc. 435 Devon Park Drive Bldg. 700 Wayne, PA 19087
SAP Author:	[redacted]
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1.0	18-JUL-2016	[redacted]	Updated Version numbering, included signature page at end of document
2.0	30-NOV-2016	[redacted]	Updated to include response and remission criteria. Removed PCI analysis for labs. Removed Temperature from PCI vitals, as this is not collected

SIGNATURE PAGE AND APPROVALS

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Date

[redacted]

30 Nov 2016
Date

[redacted]

30 Nov 2016
Date

[redacted]
Vice President and Head Statistical Sciences and Data Management
Medgenics, Inc.
435 Devon Park Drive
Bldg. 700
Wayne, PA 19087
USA

[redacted]

30-Nov 2016
Date

[redacted]
Vice President, Neuroscience
Medgenics, Inc.
435 Devon Park Drive
Bldg. 700
Wayne, PA 19087
USA

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ABBREVIATIONS

ABBREVIATION	DEFINITION OR DESCRIPTION
ADHD	Attention Deficit Hyperactivity Disorder
ADHD-RS-5	Attention Deficit Hyperactivity Disorder Rating Scale Version 5
ANCOVA	Analysis of covariance
ASHS	Adolescent Sleep Hygiene Scale
CGI-I	Clinical Global Impression of Improvement
CGI-S	Clinical Global Impression of Severity
CI	Confidence Interval
CNV	Copy Number Variant
C-SSRS	Columbia Suicide Severity Rating Scale
CSR	Clinical Study Report
CV	Coefficient of Variation
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
ECG	Electrocardiogram
ET	Early Termination
eCRFs	Electronic Case Report Forms
EMA	European Medicines Agency
FAS	Full Analysis Set Population
FDA	Food and Drug Administration
GRM	Glutamate Receptors, Metabotropic
ICH	International Conference on Harmonisation
IP	Investigational Product
IQ	Intelligence Quotient
IWRS	Interactive Web Response System
K-SADS-PL	Kiddie Schedule for Affective Disorders and Schizophrenia - Present and Lifetime Version
LLOQ	Lower Limit of Quantitation
LOCF	Last Observation Carried Forward
LOD	Limit of Detection
MAR	Missing-At-Random
mGluR	Metabotropic Glutamate Receptors
MMRM	Mixed-Effect Model Repeated Measure
PCI	Potentially Clinically Important
SAP	Statistical Analysis Plan
SCARED	Screen for Childhood Anxiety-related Emotional Disorders
SD	Standard Deviation
ULOQ	Upper Limit of Quantitation
WASI-II	Wechsler Abbreviated Scale of Intelligence, 2nd edition

1 OVERVIEW

This Statistical Analysis Plan (SAP) describes the planned analysis and reporting for Medgenics, Inc. Protocol MDGN-NFC1-ADHD-201(A Multicenter, 6-Week, Double-blind, Randomized, Placebo-controlled, Parallel-design Study to Assess the Efficacy and Safety of NFC-1 in Adolescents (Ages 12-17 Years) with Genetic Disorders Impacting Metabotropic Glutamate Receptors and Attention Deficit Hyperactivity Disorder), Final Version 4.0 dated 27-OCT-2016.

The structure and content of this SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on Statistical Principles in Clinical Trials [1]. All work planned and reported for this SAP will follow internationally accepted guidelines, published by the American Statistical Association [2] and the Royal Statistical Society [3], for statistical practice.

The planned analysis identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post-hoc exploratory analysis not necessarily identified in this SAP may be performed to further examine study data. Any post-hoc, or unplanned, exploratory analysis performed will be clearly identified as such in the final CSR.

In addition to the study protocol, the following documents were reviewed in preparation of this SAP:

- The electronic case report forms (eCRFs) for this Protocol.
- ICH Guidance on Statistical Principles for Clinical Trials (E9).

The reader of this SAP is encouraged to also read the clinical protocol, and other identified documents, for details on the planned conduct of this study. Operational aspects related to collection and timing of planned clinical assessments are not repeated in this SAP unless relevant to the planned analysis.

2 STUDY OBJECTIVES AND ENDPOINTS

2.1 Study Objectives

2.1.1 Primary Objective

The primary objectives of this study are:

- To assess the efficacy of NFC-1 relative to placebo in reducing the severity of symptoms associated with Attention Deficit Hyperactivity Disorder (ADHD) in adolescents with genetic disorders impacting mGluRs.
- To obtain additional safety data following exposure to NFC-1 in this population.

2.1.2 Study Endpoints

The primary endpoint for the assessment of efficacy will be the Attention Deficit Hyperactivity Disorder Rating Scale Version 5 (ADHD-RS-5) score. The analysis will be based on the changes from the baseline value and will test the hypothesis that there is no difference between the treatments (i.e., that the difference is 0) against a 2-tailed alternative.

Additionally, secondary endpoints of efficacy will include the CGI-I, CGI-S, ASHS, SCARED scales, and Response and Remission criteria using the ADHD-RS-5 and CGI-I [4]. Further analyses will examine effect of gender and dose level. All quantitative endpoints will be described with traditional summary statistics and tabulated by treatment group and visit.

3 OVERALL STUDY DESIGN AND PLAN

This is a randomized, double-blind, placebo-controlled, parallel-group phase 2 study of adolescents to compare the safety and efficacy of NFC-1 with that of placebo. Approximately 90 male and female subjects will receive randomized treatment with NFC-1 or placebo to obtain 80 subjects that complete the study as planned. Subjects must be ≥ 12 to ≤ 17 years of age and have ADHD as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) and an ADHD-RS-5 > 28 at Baseline. The study will take place in approximately 25 sites in the United States.

The overall maximum study duration for an individual subject is expected to be 70 days with maximum treatment duration of 42 days. As per the schedule of events below (Table 1), subjects will be randomly assigned in a 1:1 ratio to receive either NFC-1 or placebo on Day -1 and will start taking investigational product (IP) at a dose of 100 mg twice daily on Day 1. Dosing will be optimized to 100 mg, 200 mg, or 400 mg twice daily as appropriate, over the 4 weeks of treatment (dose optimization phase), based on clinical response and tolerability. If the subject tolerates their final optimized dose well, the dose will be maintained for an additional 2 weeks (dose maintenance phase) when the primary assessments of efficacy and tolerability will be performed. A follow-up telephone call will be performed 7 days after the last visit.

Table 1. Schedule of Events

	Screening	Wash-out Call	Baseline	Treatment Period						7-day Follow-up Call[a]
				Dose Optimization				Dose Maintenance		
Visit	**1**	**No Visit**	**2**	**3**	**4**	**5**	**6**	**7**	**8/ET**	**No Visit**
Assessment Day	**-21**	**-14**	**-1**	**7**	**14**	**21**	**28**	**35**	**42**	**49**
Visit Window	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**+ 5 days**
Informed consent/ assent[b]	✓									
Psychiatric evaluation (K-SADS-PL)	✓									
WASI-II (brief IQ test)	✓									
Inclusion/exclusion criteria	✓	✓ (review)	✓ (review)							
Demographics	✓									
Randomization			✓							
Medical and medication history[c]	✓									
Physical examination	✓								✓	
Vital signs (resting blood pressure, heart rate, and respiratory rate)	✓		✓	✓	✓	✓	✓	✓	✓	
Height (calibrated stadiometer)	✓								✓	
Weight (calibrated scale)	✓		✓	✓	✓	✓	✓	✓	✓	
Clinical laboratory test	✓		✓	✓	✓	✓	✓	✓	✓	
12-lead ECG	✓		✓	✓	✓	✓	✓	✓	✓	
Serum pregnancy test (females of childbearing potential)	✓									
Urine pregnancy test (females of childbearing potential)			✓	✓	✓	✓	✓	✓	✓	
Urine drug test	✓									
Investigator dose assessment				✓	✓	✓	✓			

	Screening	Wash-out Call	Baseline	Treatment Period						7-day Follow-up Call[a]
				Dose Optimization				Dose Maintenance		
Visit	**1**	**No Visit**	**2**	**3**	**4**	**5**	**6**	**7**	**8/ET**	**No Visit**
Assessment Day	**-21**	**-14**	**-1**	**7**	**14**	**21**	**28**	**35**	**42**	**49**
Visit Window	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**± 2 days**	**+ 5 days**
ADHD-RS-5	✓		✓	✓	✓	✓	✓	✓	✓	
CGI-S[d]	✓		✓						✓	
CGI-I[e]				✓	✓	✓	✓	✓	✓	
ASHS			✓						✓	
SCARED			✓						✓	
C-SSRS	✓		✓	✓	✓	✓	✓	✓	✓	
Access IWRS[f]	✓		✓	✓	✓	✓	✓	✓		
Study drug dispensed			✓	✓	✓	✓	✓	✓		
Study drug returned				✓	✓	✓	✓	✓	✓	
Compliance				✓	✓	✓	✓	✓	✓	
Concomitant medications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Adverse events	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Abbreviations: ADHD-RS-5 = Attention Deficit Hyperactivity Disorder Rating Scale Version 5, ASHS = Adolescent Sleep Hygiene Scale, CGI-I = Clinical Global Impression of Improvement, CGI-S = Clinical Global Impression of Severity, C-SSRS = Columbia Suicide Severity Rating Scale, ECG = electrocardiogram, ET = early termination, IQ = intelligence quotient, IWRS = interactive web response system, K-SADS-PL = Kiddie Schedule for Affective Disorders and Schizophrenia - Present and Lifetime Version, SCARED = Screen for Childhood Anxiety-related Emotional Disorders, WASI-II = Wechsler Abbreviated Scale of Intelligence, second edition

a Caregivers will receive a follow-up telephone call from a study staff member 7 days after the last visit to collect information about any ongoing AEs and concomitant medication.

b Informed consent to be completed by a duly authorized subject representative. Assent is to be provided by subject where required.

c Medical and medication history including confirmation from the sponsor that each subject has been determined to have disruptive mutations in genes within the GRM-network as determined by the presence of CNVs (GRM biomarker-positive subjects).

d The CGI–S rates illness severity on the following 7-point scale: 1 = normal, not at all ill, 2 = borderline mentally ill, 3 = mildly ill, 4 = moderately ill, 5 = markedly ill, 6 = severely ill, and 7 = among the most extremely ill subjects.

e The CGI-I requires the investigator to assess how much the subject's illness has improved or worsened: 1 = very much improved, 2 = much improved, 3 = minimally improved, 4 = no change, 5 = minimally worse, 6 = much worse, and 7 = very much worse.

f IWRS will assign treatment numbers and will also manage all logistical aspects of treatments (eg, drug resupply and expiry dates).

4 ANALYSIS AND REPORTING

4.1 Interim Analysis

No interim analysis is planned for this study.

4.2 Final Analysis

All final, planned analysis identified in the protocol and in this SAP will be performed after the study database has been locked and treatment code has been unblinded.

Any post-hoc, exploratory analysis completed to support planned study analysis, which were not identified in this SAP, will be documented and reported in appendices to the CSR. Any results from these unplanned analyses (post-hoc) will also be clearly identified in the text of the CSR.

5 ANALYSIS POPULATIONS

The following analysis populations are planned for this study:

- **Safety Population (SAFETY):** The Safety Population includes all subjects who are randomized into the study and receive any amount of Investigational Product (IP).
- **Intent-To-Treat Population (ITT):** The ITT Population includes all subjects who are randomized into the study.
- **Per-Protocol Population (PP):** The PP Population includes all randomized subjects who do not have any significant protocol deviations defined as a major protocol dev**i**ation. Major protocol deviations are listed in section 7 (below). Membership in the PP population will be determined by a blinded review of patient data prior to database lock**.**

5.1 Sample Size

Enrollment of 90 subjects is expected to yield 80 subjects who complete the study as planned. Assuming an effect size of 0.7, this number will provide approximately 90% power to detect a significant difference between the treatments based on a 2-tailed $\alpha = 0.05$ comparison of mean change from baseline.

6 GENERAL ISSUES FOR STATISTICAL ANALYSIS

6.1 General Statistical Methodology

Data processing, tabulation of descriptive statistics, calculation of inferential statistics, and graphical representations will be performed using SAS® Software (release 9.3 or higher) for Windows, unless otherwise specified.

Continuous (quantitative) variables will be summarized using descriptive statistics including number of non-missing values, mean, standard deviation (SD), median, minimum, and maximum. Where appropriate, estimates will be presented with 95% confidence intervals (CIs).

Categorical (qualitative) variables will be summarized using the number and proportion of each possible value. In general, the denominator for the percentage calculation will be based upon the total number of subjects in the study population for the treatment group. 95% CIs of proportions may also be presented for selected endpoints where applicable. Zero-count levels of variables will not display a percentage.

The minimum and maximum will be reported with the same degree of precision (i.e., the same number of decimal places) as the raw data. Measures of location (mean and median) will be

reported to 1 degree of precision more than the raw data and measures of spread (standard deviation) will be reported to 2 degrees of precision more than the raw data.

All statistical tests will be conducted at the 0.05 significance level using 2-tailed tests, and P-values will be reported. Assessments done on unscheduled visits will not be summarized but will be listed.

In general, baseline and safety tables will be completed for the Safety Population unless otherwise specified. Efficacy tables for primary and secondary endpoints will be presented for the ITT Population. However, analyses of the PP Population may be performed if warranted by the data. These potential PP tables are not present in the table index.

All final, planned analyses identified in the protocol and in this SAP will be performed after all relevant study data have been processed and integrated into the analysis database, analysis populations have been finalized, and the database has been locked. Any post-hoc, exploratory analysis completed to support planned study analyses, which were not identified in this SAP, will be documented and reported in Section 9.8 of the Clinical Study Report (CSR). Any results from these unplanned analyses (post-hoc) will also be clearly identified as such in the text of the CSR.

6.2 Data Adjustments, Handling, Conventions

All collected data will be presented in listings. Data not subject to analyses according to this plan will not appear in any tables or graphs but will be included only in the data listings.

Adverse events will be coded using the MedDRA (version 19.0). Concomitant and Prior medications will be coded using WHO-DD (version March 1, 2016).

If partial dates occur, the convention for replacing missing dates for the purpose of calculating derived variables is as follows:

For partial start dates:

- If the year is unknown, then do not impute the date but assign a missing value.
- If the month is unknown, then:
    - If the year matches the year of the randomization date, then impute the month and day of the randomization date.
    - Otherwise, assign 01 January
- If the day is unknown, then:
    - If the month and year match the month and year of the randomization date, then impute the day of the first dose date.
    - Otherwise, assign 01.

For partial end dates:

- If the year is unknown, then do not impute the date but assign a missing value.
- If the month is unknown, then assign the last day of the year 31 December.
- If the day is unknown, then assign the last day of the month.

If an AE has a missing severity, it will be imputed as 'Severe'; any missing relationship to study drug of an AE will be imputed as 'Related'.

For the primary endpoint, ADHD-RS-5, missing observations will be imputed by the LOCF method (as described in section 8, below). Other ADHD-RS-5 subscales will impute the value of a missing result if enough data is present (as described in section 6.3).

No other missing data will be imputed.

In general, for quantitative laboratory values reported as '<' or '≤', the lower limit of quantitation (LLOQ) or limit of detection (LOD), one-half of the reported value (i.e., LLOQ, LOD) will be used for analysis.

For quantitative laboratory values reported as '>' or '≥', the upper limit of quantitation (ULOQ), the reported value (i.e., ULOQ) will be used for analysis.

For analysis purposes, repeat laboratory test results will not be used unless the original laboratory value is missing or indicated as invalid, in which case the first non-missing repeat laboratory value will be used for data analysis.

6.3 Derived and Computed Variables

- Baseline = the last non-missing measurement/assessment before the date of first dose will be flagged. Typically, this will be the value recorded on Day -1.
- Study Day = Assessment Date - Date of Randomization + 1
- Change from Baseline = Value at Post-Baseline - Value at Baseline
- % Change from Baseline = 100 * Change from Baseline / Value at Baseline
- "Screen Failure" is a patient who has not met eligibility criteria, or otherwise chose not to participate in the study prior to randomization
- ADHD-RS-5 subscales – if at least 80% of the questions needed to calculate a scale or subscale score have valid responses, then that score will be computed as the sum of all non-missing items divided by the percentage of items in that scale or subscale present. If fewer than 80% of items have valid responses, then that score will be assigned as missing.
- ADHD-RS-5 Inattention subscale is computed by summing the first 9 item scores for Question 4 – Question 12.
- ADHD-RS-5 Hyperactivity-Impulsivity subscale is computed by summing the second 9 item scores for Question 19 – Question 27.
- ADHD-RS-5 Total Score is based on 18 items designed to reflect the symptomatology of ADHD based on the DSM-5 criteria. Each item is scored on a 0 (reflecting no symptoms) to 3 (reflecting severe symptoms) and then added for a total score ranging from 0-54.
- ASHS Physiological factor is the mean of Questions 6, 13, 15, 21, and 22.
- ASHS Behavioral Arousal Factor is the mean of Questions 14, 16, and 31.
- ASHS Cognitive/Emotional Factor is the mean of Questions 12, 17, 18, 19, 20, and 32.
- ASHS Sleep Environment Factor is the mean of Questions 23, 24, 25, 26, and 27.
- ASHS Sleep Stability Factor is the mean of Questions 33, 37, and 39.
- ASHS Daytime Sleep Factor is the mean of Questions 4, and 7.
- ASHS Substances Factor is the mean of Questions 9, and 10.
- ASHS Bedtime Routine Factor is the value for Question 30.
- ASHS Total Score is the mean of all 8 subscales, with a higher score indicating better success on each of the dimensions of sleep hygiene.

- SCARED Panic Disorder is the summation of Questions 1, 6, 9, 12, 15, 18, 19, 22, 24, 27, 30, 34, and 38.
- SCARED Generalized Anxiety is the summation of Questions 5, 7, 14, 21, 23, 28, 33, 35, and 37.
- SCARED Separation Anxiety is the summation of Questions 4, 8, 13, 16, 20, 25, 29, and 31.
- SCARED Social Anxiety is the summation of Questions 3, 10, 26, 32, 39, 40 and 41.
- SCARED Significant School Avoidance is the summation of questions 2, 11, 17, and 36.
- SCARED Total Score is the summation of all 41 questions, each scored from 0 to 2 scale.
- C-SSRS Suicidal Ideation is an indicator of any subject who experience any one of the five suicidal ideation events at least once (Questions 4, 6, 8, 10, and 12)
- C-SSRS Suicidal Behavior is an indicator of any subject who experience any one of the suicidal behavior events at least once (Questions 22, 26, 29, 32, and 35)
- C-SSRS composite endpoint of Suicidal Ideation or Behavior is an indicator of any subject who experiences any one of the ten suicidal ideation or behavior events at least once.
- TEAE - An AE is defined as treatment emergent if the first onset or worsening is after the first administration of IP (NFC-1 or placebo) and not more than 7 days after the last administration of IP
- For the tabulation of TEAE's that are related to study drug, these are defined as any TEAE which is determined by the investigator as 'possibly related' or 'related'.
- Post-Treatment AE is an AE that has started more than 7 days after last administration of IP.
- Prior medications are defined as medications or therapies initiated prior to date of first dose of IP and terminating prior to date of first dose of IP. Medications that are started prior to the date of first dose of IP and are continuing after the first dose of IP are considered to be both prior and concomitant medications
- Concomitant medication is defined as any medication a subject received concurrently with study treatment.
- Post-treatment medication is defined as any medication that has started more than 7 days after the last administration of IP.
- Compliance (Overall) = (∑ (Individual Week Compliance) * (Time-Weight)) * 100. A subject is non-compliant if they take < 80% or > 120% of IP.

  - Individual Week Compliance is defined as the number of capsules taken at a particular week divided by the expected number of capsules taken at a particular week. Given that a subject will be dose optimized, the number of expected capsules will vary according to which dose the subject is currently on for each day.

  - Time-Weight is the fraction of **x**/**y** where **x** is the number of days in the week the subject is expected to be on dose and **y** is the whole treatment duration defined as first dose – last dose + 1.

6.4 Adjustment for multiple comparisons

There will be no adjustments for multiple comparisons in the analysis.

7 STUDY PATIENTS/SUBJECTS AND DEMOGRAPHICS

7.1 Disposition of Subjects and Withdrawals

All subjects who provide informed consent will be accounted for in this study. The number of subjects screened, randomized, completing, and withdrawing from the study, as well as reason for withdrawal, will be summarized by treatment group, dose, and overall. Additionally, the number of subjects in each population will be displayed. All disposition information will be included in a listing.

7.2 Protocol Deviations

Protocol deviations will be collected by the clinical team and provided to [redacted] biostatistics prior to database lock. Protocol deviations will be reviewed and on a case-by-case basis to be classified and minor or major by the project team prior to database lock.

The categories of protocol deviations which will be reviewed and classified as major/minor include:

- Informed Consent/Assent
- Inclusion/Exclusion Criteria
- Concomitant Medication
- Use of prohibited medication
- Laboratory Assessment
- Study Assessments/Procedures
- Investigational Product
- Overdose/Misuse
- Visit Window
- Non-compliance
- Other

7.3 Demographics and Other Baseline Characteristics

Descriptive summaries of the demographic and other baseline characteristics will be completed for all patients in the Safety population by treatment group, dose, and overall. These tabulations will include the following variables:

- Demographics (age, gender, race, ethnicity, height, weight, and BMI)
- IQ test (WASI-II)
- K-SADS-PL

Prior medication: The frequency and percentage of all prior medications will be summarized by Anatomical Therapeutic Chemical (ATC) classification level 3 and preferred term for all patients in the Safety population by treatment group and overall.

Medical History: Incidences of medical history will be listed by reported term for all patients in the Safety population.

All demographic and other baseline characteristics will be presented in subject listings.

7.4 Baseline Disease Characteristics

Descriptive summaries of baseline disease characteristics will be provided for all patients in the ITT population by treatment group and overall. These tabulations will include the following variables:

- ADHD Subtype
- Age at Diagnosis
- Time Since ADHD Diagnosis
- ADHD-RS-5 Baseline Score (Overall and sub-scales)
- CGI-S Score at baseline

8 EFFICACY ANALYSIS

8.1 Primary Analysis

The primary efficacy endpoint will be the change in ADHD-RS-5 total score from Baseline to the end of treatment (e.g., Visit 8). For any subjects who discontinue the study prior to Visit 8, their last treated value of the ADHD-RS-5 will be used. That is, the LOCF method of imputation will be employed. The analysis will be performed on the ITT population using an analysis of covariance (ANCOVA) model. The model will use a residual (restricted) maximum likelihood (REML) estimation method and a standard variance components (VC) covariance structure, with treatment group (NFC-1 or placebo) as a fixed factor and baseline ADHD-RS-5 total score as a covariate. The null hypothesis is that there are no differences between the means of the two treatment groups. The hypothesis will be tested at a two-tailed alpha of 0.05. This analysis will be repeated for each of the scheduled visits for ADHD-RS-5 and summarized within the table. Descriptive summaries for actual and change from baseline values will be displayed along with the LS means, LS mean treatment difference, and 95% CIs of the treatment difference, and p-values by visit.

8.2 Secondary Analysis

Secondary analysis endpoints will include the following measurements (ASHS and SCARED treated as continuous measures):

- Improvement in CGI-I/CGI-S
- Change from baseline in ASHS total score
- Change from baseline in SCARED total score

When appropriate, the analysis for these endpoints will employ the same model and approach as in the primary analysis using an ANCOVA as specified above. Additionally, any subscales for the above primary/secondary endpoints will be included on their corresponding table for the total score (i.e. ADHD-RS-5 Inattention subscale, SCARED Generalized Anxiety, etc.). Please see Section 6.3 for a complete list of derived subscales and composite scores.

Results of the CGI-I assessment will be dichotomized and presented by count and frequency for each week of treatment. CGI-I scores of 1 (very much improved) or 2 (much improved)will be combined into a single category labeled 'Improved', and all other scores (3 [minimally improved] to 7 [very much worse]) will be combined into a single category labeled 'Not Improved'. The

observed frequencies of 'Improved' subjects will be compared using a chi-square analysis to test the hypothesis of no association between Improvement and Treatment at type I error rate of 5%.

The CGI-S assessment will be presented similarly. CGI-S scores of 1 (Normal, not at all ill) or 2 (Borderline mentally ill) will be combined into a single category labeled 'Normal or Borderline mentally ill', and all other scores (3 [Mildly Ill] to 7 [Among the most extremely ill patients]) will be combined into a single category labeled 'Mentally ill'.

As to measure treatment response and remission of subjects, three criteria will be defined for each [4]. For response, the criteria are (A) a change in ADHD-RS-5 total score from baseline of 30% or more, (B) a CGI-I score of 1 (very much improved) or 2 (much improved) relative to baseline, and (C) a composite requiring both (A) and (B) to be met. For remission, the criteria are (A) ADHD-RS-5 total score of 18 or less at post-baseline visits, (B) a CGI-I score of 1, and (C) a composite of (A) and (B) to be met. The observed frequency and percentage of subjects in each category will be presented and will be compared using a chi-square analysis to test the hypothesis of no association between response/remission and treatment for each category.

9 SAFETY AND TOLERABILITY ANALYSIS

The analysis of safety assessments in this study will include summaries of the following categories of safety and tolerability data collected for each subject:

- Adverse Events
  - Summary of all Adverse Events
  - treatment-emergent adverse events (TEAEs), and serious adverse events (SAEs)
  - TEAEs leading to early termination
  - TEAEs by severity
  - TEAEs deemed related to the IP
  - TEAEs occurring in more than 5% of subjects
  - Post-treatment AEs
  - Any deaths
- Clinical Laboratory Investigations(chemistry, Hematology, Urinalysis)
- Vital Signs (systolic and diastolic blood pressure, pulse, respiratory rate, height, weight, and BMI)
- Electrocardiograms (ECG)
- C-SSRS Score
- Concomitant Medications
- Post-treatment Medications
- Study Drug Exposure and Treatment Compliance

All tabulations and summaries for these categories will be performed on the Safety population unless otherwise noted.

9.1 Adverse Events

The causal relationship of the AE to the study drug is determined by the investigator as 'not related', 'unlikely/remotely related', 'possibly related', or 'related'. Any AE determined as

'possibly related' or 'related' will be considered 'potentially related' to study drug for purposes of analysis of these events.

Missing and partially missing AE start and/or stop dates will be imputed for the purpose of statistical analysis, according to the specifications described in Section 6.2.

Summaries of incidence rates (frequencies and percentages) of individual TEAEs by MedDRA SOC and preferred term will be prepared. Such summaries will be displayed for TEAEs, SAEs, TEAEs leading to early termination, TEAEs by relationship to study drug, TEAEs by severity, TEAEs occurring in more than 5% of subjects, and Post-treatment AEs.

Each patient/subject will be counted only once within each preferred term If a subject experiences more than one TEAE within a preferred term only the TEAE with the strongest relationship or the maximum intensity, as appropriate, will be included in the summaries of relationship and intensity.

Subject listings of all AEs and SAEs, will be presented.

9.1.1 Adverse Events Leading to Early Termination

A summary of incidence rates (frequencies and percentages) of TEAEs leading to early termination of study drug, by treatment group and overall, SOC, and preferred term, will be prepared for the Safety Population.

A listing of TEAEs leading to early termination will also be provided, displaying details of the event(s) captured on the CRF.

9.1.2 Deaths

A summary and data listing of deaths that occurred will be provided, displaying details of the event(s) captured on the CRF.

9.2 Clinical Laboratory Evaluations

Descriptive summaries of actual (absolute) values and changes from baseline will be presented for Chemistry, Hematology, and Urinalysis analytes. These tables will be grouped by treatment group, and by visit. Summaries will be displayed in conventional units.

The number and proportion of subjects with clinical laboratory values below, within, or above normal ranges, at each study visit will be tabulated (shift tables) for each clinical laboratory analyte by treatment group. Normal ranges for lab results will be provided by the Central laboratory used in this study (i.e., Eurofins).

Laboratory values will be displayed in the data listings and those that are outside the normal range will be flagged, along with corresponding normal ranges.

9.3 Vital Signs

Descriptive summaries of actual (absolute) values and changes from baseline will be presented for systolic and diastolic blood pressure, pulse, respiratory rate, and BMI. These tables will be grouped by treatment group, and by visit.

Additionally, the frequency and percentage of subjects with values of Potential Clinical Importance (PCI) will be summarized in shift tables, by treatment group and overall for each study visit. Criteria for assigning PCI to vital signs are as follows:

Criteria for PCI Vital Signs and Change in Body Weight		
Measurement	Lower Criterion	Upper Criterion
Systolic BP	< 90 mmHg	>120 mmHg
Diastolic BP	< 50 mmHg	>80 mmHg
Pulse Rate	≤ 50 bpm	≥ 130 bpm
Respiration Rate	< 10 breaths/minute	>20 breaths/minute
Body Weight Change	≥ 7% decrease	≥ 7% increase

Vital signs and weight/height measurements will also be presented in a subject listing.

9.4 Electrocardiograms

ECG results will be summarized in three ways, as follows:

1. A summary of Central ECG results that presents the number and percent of results that are deemed normal, abnormal, and missing.
2. A summary providing N and % of evaluations that are interpreted by each investigative site as Normal, Abnormal NCS, Abnormal CS, and missing.
3. Tabulation of ECG results that are of potential clinical importance. Criteria for assigning PCI to ECG results are as follows:

Criteria for PCI categories to ECG Results		
ECG Parameter	Lower Criterion	Upper Criterion
Heart Rate	≤ 50 bpm	≥ 130 bpm
PR Interval	None	≥ 180 msec
QRS Interval	None	≥ 100 msec
QT Interval	None	≥ 450 msec
QTcB	None	≥ 450 msec
QTcF	None	≥ 450 msec
Change in Heart Rate	≤ 50 bpm with decrease > 5 bpm	None
Change in QTcB	None	≥ 30 msec
Change in QTcF	None	≥ 30 msec

Depending on the incidence of abnormal ECG results, some of these displays might not be needed.

ECG results will also be displayed in a separate subject listing.

9.5 Columbia Suicide Severity Rating Scale (C-SSRS)

The C-SSRS score will be summarized by treatment group and overall for each study visit it is measured. These C-SSRS evaluations will be presented in a subject listing.

9.6 Physical Examination Findings

Abnormal physical examination findings at screening and indications of clinically significant abnormal findings that were newly diagnosed or worsened since the screening visit will be provided in a subject listing.

9.7 Concomitant Medication

Concomitant medications will be analyzed the same way as prior medications as noted in Section 7.3. The frequency and percentage of all concomitant medications will be summarized by ATC classification level 3 and preferred term for all patients in the Safety population by treatment group and overall. Similarly to previous, post-treatment medications will be analyzed the same way as prior medications as noted in Section 7.3.

A subject listing of all medications will be provided.

9.8 Exposure and Compliance

For each subject, treatment compliance will be calculated at each visit and summarized for the entire study. Overall compliance will be summarized by treatment group. Compliance is defined in Section 6.3. Drug Accountability/Exposure and Treatment compliance will also be provided in a subject listing.

10 CHANGES FROM PLANNED ANALYSIS

Below are the major changes and/or updates from the protocol planned analysis:

- The SAP has ANCOVA with LOCF as the primary endpoint but this was noted as ANOVA in the protocol
- CGI-I and CGI-S were originally going to be analyzed by ANOVA, but will be analyzed by a Chi-Square test
- PCI analyses has been added for ECG, Vitals
- Post-treatment AEs and Post-treatment medications have been added
- Several tables now include dose group summaries instead of NFC-1 vs. Placebo

11 REFERENCES

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APPENDIX A – TABLES, LISTINGS, AND FIGURE SHELLS

This section presents the shells for the planned Tables, Listings and Graphs to be programmed in support of the planned analyses identified in the SAP. This section is intended to support the SAP and provides guidance on the programming specifications (shells) for the planned outputs and may be updated, independent of the SAP, with any updates appropriately documented, reviewed, and approved.

The following reporting conventions will be adopted for the presentation of study data. These conventions will enhance the review process and help to standardize the presentation with common notations.

General Reporting Conventions

- All tables and data listings will be developed in landscape orientation.
- Specialized text styles, such as bolding, italics, borders, shading, superscripted and subscripted text will not be used in tables and data listings unless they add significant value to the table, figure, or data listing.
- Only standard keyboard characters should be used in tables and data listings. Special characters, such as nonprintable control characters, printer-specific characters, or font specific characters, will not be used on a table, figure, or data listing. Hexadecimal character representations are allowed (e.g., μ, α, β).
- All titles will be centered on a page. The ICH numbering convention is to be used for all outputs.
- All footnotes will be left justified and at the bottom of a page.
- Missing values for both numeric and character variables will be presented as blanks in a table or data listing. A value of zero may be used if appropriate to identify when the frequency of a variable is not observed.
- All date values will be presented as ddmmmyyyy (e.g., 29AUG2011) format. A 4-digit year is preferred for all dates.
- If applicable, all observed time values will be presented by using a 24-hour clock HH:MM:SS format (e.g., 01:35:45 or 11:26). Seconds should only be reported if they were measured as part of the study.
- All tables and data listings will have the name of the program, the location, and a date stamp on the bottom of each output.

Population Summary Conventions

- Population sizes may be presented for each classification factor as totals in the column header as (N=xxxx), where appropriate.
- Population sizes shown with summary statistics are the samples sizes (n) of subjects with non-missing values.
- All population summaries for categorical variables will include all categories that were planned and for which the subjects may have had a response. Percentages corresponding to null categories (cells) will be suppressed, however counts and percentages of missing values may be needed.

- All population summaries for continuous variables will include: N, mean, SD, minimum, and maximum. Other summaries (e.g., number missing, geometric mean, median, quartiles, 95% CIs, and coefficient of variation (CV) or % CV) may be used as appropriate.
- All percentages are rounded and reported to a single decimal point (xx.x %). A percentage of 100% will be reported as 100%. No value of 0% will be reported. Any computation of percent that results in 0% is to be presented as a blank.
- Population summaries that include P-values will report the P-value to 4 decimal places with a leading zero (0.0001). All P-values reported on default output from statistical software (i.e., SAS® Software) may be reported at the default level of precision. P-values <0.0001 should be reported as <0.0001 not 0.0000.

11.1 Standard Layout for all Tables, Listings, and Listing

The following standard layout will be applied to all Tables, Listings, and Listings in support of this study. Note that programming notes may be added if appropriate after each TLF shell. These notes are noted within brackets and will not appear on the output "{}".

Medgenics, Inc. Page 1 of x
Protocol: MDGN-NFC1-ADHD-201 <version>

<Table, Listing, Figure> xx.x.x
<Title of Table Listing or Figure>
<Study Population and if applicable subgroup Description>

Body of Table, Listing or Figure

Note: *<Note: If directly Applicable>*
(Running Footnote for all tables, place after last 'Note:' present) Note: All treatments were administered BID.
[1] Footnote 1 *<if applicable>*
[2] Footnote 2 *<if applicable>*
[n] Footnote n *<if applicable>*
T:\Medgenics\NFC-1\ADHD-201\...\xxxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYY

11.2 Planned Table Shells

Table	Table Title	Topline
14.1.1	Disposition of Study Population by Optimized Dose and Randomized Treatment (ITT Population)	x
14.1.2	Major Protocol Deviations (ITT Population)	
14.1.3	Demographics and Baseline Characteristics by Optimized Dose and Randomized Treatment (Safety Population)	x
14.1.4	Disease Characteristics at Baseline by Optimized Dose and Randomized Treatment (Safety Population)	x
14.1.5	Summary of Prior Medications by Randomized Treatment (Safety Population)	
14.2.1.1	Analysis of Change from Baseline in ADHD-RS-5: Total Score and Subscales, by Study Visit (ITT Population)	x
14.2.1.2	Summary of Change from Baseline in ADHD-RS-5 Score and Subscales by Actual Dose and Randomized Treatment, by Study Visit (ITT Population)	
14.2.2.1	Chi-Square Analysis of CGI-I Improvement, by Study Visit (ITT Population)	x
14.2.2.2	Summary of Categorical and Continuous CGI-I Scores by Randomized Treatment Group and Study Visit (ITT Population)	x
14.2.2.3	Summary of CGI-I Improvement by Optimized Dose and Randomized Treatment, by Study Visit (ITT Population)	
14.2.3.1	Chi-Square Analysis of CGI-S Improvement, by Study Visit (ITT Population)	
14.2.3.2	Summary of Categorical and Continuous CGI-S Scores by Randomized Treatment Group and Study Visit (ITT Population)	
14.2.3.3	Summary of CGI-S Improvement by Optimized Dose and Randomized Treatment, by Study Visit (ITT Population)	
14.2.4.1	Analysis of Change from Baseline in ASHS Total Score and Factors, by Study Visit (ITT Population)	
14.2.4.2	Summary of Change from Baseline in ASHS Total Score and Factors by Randomized Treatment, by Study Visit (ITT Population)	
14.2.5.1	Analysis of Change from Baseline in SCARED Score and Factors, by Study Visit (ITT Population)	
14.2.5.2	Summary of Change from Baseline in SCARED Score and Factors by Randomized Treatment, by Study Visit (ITT Population)	
14.2.6.1	Chi-Square Analysis of Response and Remission Criteria, at End of Study (ITT Population)	x
14.3.1.1	Summary of TEAEs by Dose at Onset (Safety Population)	
14.3.1.2	Incidence of TEAEs by Dose at Onset and Randomized Treatment (Safety Population)	x
14.3.1.3	Incidence of TEAEs occurring in more than 5% of subjects by Randomized Treatment (Safety Population)	

14.3.1.4	Incidence of Post-Treatment AE's by Randomized Treatment (Safety Population)	
14.3.1.5	Incidence of SAE's by Randomized Treatment (Safety Population)	
14.3.1.6	Incidence of TEAEs Leading to Early Termination by Randomized Treatment (Safety Population)	
14.3.1.7	Incidence of Deaths by Randomized Treatment (Safety Population)	
14.3.1.8	Incidence of TEAEs by Relationship to Study Drug by Randomized Treatment (Safety Population)	
14.3.1.9	Incidence of TEAEs by Maximum Severity by Randomized Treatment (Safety Population)	
14.3.2	Summary of Exposure to Study Drug and Compliance by Actual Dose and Randomized Treatment (Safety Population)	
14.3.3.1	Summary of Clinical Laboratory Data: Clinical Chemistry by Randomized Treatment by Study Visit (Safety Population)	
14.3.3.2	Summary of Clinical Laboratory Data: Hematology by Randomized Treatment by Study Visit (Safety Population)	
14.3.3.3	Summary of Clinical Laboratory Data: Urinalysis by Randomized Treatment by Study Visit (Safety Population)	
14.3.3.4	Shifts from Baseline of Clinical Laboratory Data: Clinical Chemistry by Randomized Treatment (Safety Population)	
14.3.3.5	Shifts from Baseline of Clinical Laboratory Data: Hematology by Randomized Treatment (Safety Population)	
14.3.3.6	Shifts from Baseline of Clinical Laboratory Data: Urinalysis by Randomized Treatment (Safety Population)	
14.3.4.1	Summary of Vital Signs by Randomized Treatment by Study Visit (Safety Population)	
14.3.4.2	Potentially Clinically Important Vital Signs by Randomized Treatment (Safety Population)	
14.3.5.1	Incidence of Abnormal ECG Findings: based on Site Interpretations by Randomized Treatment by Study Visit (Safety Population)	
14.3.5.2	Incidence of Abnormal ECG Findings: based on Central Reading by Randomized Treatment by Study Visit (Safety Population)	
14.3.5.3	Potentially Clinically Important ECG Results by Randomized Treatment (Safety Population)	
14.3.6	Summary of C-SSRS Assessments by Randomized Treatment (Safety Population)	
14.3.7	Summary of Concomitant Medications by Randomized Treatment (Safety Population)	
14.3.8	Summary of Post-Treatment Medications by Randomized Treatment (Safety Population)	

11.3 Planned Listing Shells

Listing	Listing Title
16.2.1.1	Analysis Populations and Treatment (All Subjects)
16.2.1.2	Subject Disposition (Safety Population)
16.2.1.3	Inclusion/Exclusion Criteria (All Subjects)
16.2.2	Major and Minor Protocol Deviations (Safety Population)
16.2.3.1	Demographics and Other Baseline Characteristics (Safety Population)
16.2.3.2	Prior, Concomitant, and Post-treatment Medications (Safety Population)
16.2.3.3	Behavioral Therapies (Safety Population)
16.2.3.4	Medical History (Safety Population)
16.2.4.1	Study Drug Exposure (Safety Population)
16.2.4.2	Study Drug Accountability and Compliance (Safety Population)
16.2.4.3	Investigator Dose Assessment (Safety Population)
16.2.5.1.1	Attention Deficit Hyperactivity Disorder Rating Scale Version 5 (ADHD-RS-5), part 1 (ITT Population)
16.2.5.1.2	Attention Deficit Hyperactivity Disorder Rating Scale Version 5 (ADHD-RS-5), part 2 (ITT Population)
16.2.5.2	Clinical Global Impression of Improvement (CGI-I) and Clinical Global Impression of Severity (CGI-S) (ITT Population)
16.2.5.3.1	Adolescent Sleep Hygiene Scale (ASHS), part 1 (ITT Population)
16.2.5.3.2	Adolescent Sleep Hygiene Scale (ASHS), part 2 (ITT Population)
16.2.5.3.3	Adolescent Sleep Hygiene Scale (ASHS), part 3 (ITT Population)
16.2.5.3.4	Adolescent Sleep Hygiene Scale (ASHS), part 4 (ITT Population)
16.2.5.4.1	Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 1 (ITT Population)
16.2.5.4.2	Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 2 (ITT Population)
16.2.5.4.3	Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 3 (ITT Population)
16.2.5.4.4	Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 4 (ITT Population)
16.2.5.5	WASI-II (brief IQ test) (ITT Population)
16.2.5.6.1	Kiddie Schedule for Affective Disorders (K-SADS-PL), part 1 (ITT Population)
16.2.5.6.2	Kiddie Schedule for Affective Disorders (K-SADS-PL), part 2 (ITT Population)
16.2.5.6.3	Kiddie Schedule for Affective Disorders (K-SADS-PL), part 3 (ITT Population)
16.2.5.6.4	Kiddie Schedule for Affective Disorders (K-SADS-PL), part 4 (ITT Population)
16.2.6.1	Adverse Events (Safety Population)
16.2.6.2	Serious Adverse Events (Safety Population)
16.2.6.3	Adverse Events leading to Early Termination (Safety Population)
16.2.6.4	Listing of Deaths (All Subjects)
16.2.7.1	Clinical Laboratory Data: Chemistry (Safety Population)

16.2.7.2	Clinical Laboratory Data: Hematology (Safety Population)
16.2.7.3	Clinical Laboratory Data: Urinalysis (Safety Population)
16.2.7.4	Pregnancy Tests (Safety Population)
16.2.7.5	Urine Drug Screen (Safety Population)
16.2.8	Vital Signs (Safety Population)
16.2.9	Electrocardiograms (ECGs), Site Interpretation (Safety Population)
16.2.10	Electrocardiograms (ECGs), Central Reading (Safety Population)
16.2.11	Physical Examinations (Safety Population)
16.2.12	Columbia Suicide Severity Rating Scale (C-SSRS) (Safety Population)

Table 14.1.1
Disposition of Study Population by Optimized Dose and Randomized Treatment
Intent-To-Treat Population

Disposition	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Screened for Eligibility	xx	xx	xx	xx	xx	xx
Screen Failure [1]	xx	xx	xx	xx	xx	xx
Randomized	xx	xx	xx	xx	xx	xx
Intent-To-Treat Population [2]	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)
Safety Population [3]	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)
Per-Protocol Population [4]	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)
Completed Study	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)	xx (xx x %)	xx (xx.x %)
Completed Follow-Up Phone Call	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)	xx (xx x %)	xx (xx.x %)
Discontinued Early	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)
Adverse Event	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)
Lack of Efficacy	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)	xx (xx x %)	xx (xx.x %)
Non-compliance/Protocol Violation	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)
Subject Withdrawal of Consent	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)
Lost to Follow up	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)
Other	xx (xx.x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx x %)	xx (xx.x %)

Note: Percentages are 100*n/N.
[1] Subjects who have not met eligibility criteria, or otherwise chose not to participate in the study.
[2] The ITT Population includes all subjects who are randomized into the study.
[3] The Safety Population includes all subjects who are randomized into the study and receive any amount of IP.
[4] The Per-Protocol Population includes all subjects who do not have any significant protocol deviations.
Source: Listing 16.2.1.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.2
Major Protocol Deviations
Intent-To-Treat Population

Major Protocol Deviation Category	NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Subjects with any Major Deviation	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Deviation 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Deviation 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Deviation 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
...			
{Continue for all major deviations}			

Note: Percentages are 100*n/N. Subjects may be counted under multiple major deviation categories.
Source: Listing 16.2.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.3
Demographics and Baseline Characteristics by Optimized Dose and Randomized Treatment
Safety Population

Parameter Category	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Age (years)						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx xx	xx.xx	xx xx	xx xx
Standard Deviation	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx xx	xx.xx	xx xx	xx xx
Minimum, Maximum	(x.x, x x)	(x x, x x)	(x x, x x)	(x x, x.x)	(x.x, x x)	(x x, x x)
Gender						
Male	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Female	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Ethnicity						
Hispanic or Latino	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Not Reported	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Unknown	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Race						
American Indian or Alaska Native	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
Asian	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Black or African American	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
Native Hawaiian or Other Pacific Islander	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
White	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Other	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)

Note: Percentages are 100*n/N. K-SADS-PL = Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version. WASI-II = Wechsler Abbreviated Scale of Intelligence, 2nd edition.
Source: Listing 16.2.3.1, 16.2.5.5, 16.2.5.6.1, 16.2.5.6.2, 16.2.5.6.3, 16.2.5.6.4
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.3
Demographics and Baseline Characteristics by Optimized Dose and Randomized Treatment
Safety Population

Parameter Category	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Height (cm)						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x x, x.x)
Weight (kg)						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x x, x.x)
BMI (kg/m^2)						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x x, x.x)

Note: Percentages are 100*n/N. K-SADS-PL = Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version. WASI-II = Wechsler Abbreviated Scale of Intelligence, 2nd edition.
Source: Listing 16.2.3.1, 16.2.5.5, 16.2.5.6.1, 16.2.5.6.2, 16.2.5.6.3, 16.2.5.6.4
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.3
Demographics and Baseline Characteristics by Optimized Dose and Randomized Treatment
Safety Population

Parameter Category	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
WASI-II						
FSIQ-4 Composite Score						
n	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx xx	xx.xx	xx xx	xx xx	xx xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx.xxx
Median	xx.xx	xx xx	xx.xx	xx xx	xx xx	xx xx
Minimum, Maximum	(x x, x.x)	(x x, x x)	(x.x, x x)	(x x, x x)	(x.x, x x)	(x x, x.x)
Verbal Comprehension						
n	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx xx	xx.xx	xx xx	xx xx	xx xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx xxx	xx xxx	xx.xxx
Median	xx.xx	xx xx	xx.xx	xx xx	xx xx	xx xx
Minimum, Maximum	(x x, x.x)	(x x, x x)	(x.x, x x)	(x x, x x)	(x.x, x x)	(x x, x x)
Perceptual Reasoning Comprehension						
n	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx xx	xx.xx	xx xx	xx xx	xx xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx xxx	xx xxx	xx.xxx
Median	xx.xx	xx xx	xx.xx	xx xx	xx xx	xx xx
Minimum, Maximum	(x x, x.x)	(x x, x x)	(x.x, x x)	(x x, x x)	(x.x, x x)	(x x, x x)

Note: Percentages are 100*n/N. K-SADS-PL = Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version. WASI-II = Wechsler Abbreviated Scale of Intelligence, 2nd edition.
Source: Listing 16.2.3.1, 16.2.5.5, 16.2.5.6.1, 16.2.5.6.2, 16.2.5.6.3, 16.2.5.6.4
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.3
Demographics and Baseline Characteristics by Optimized Dose and Randomized Treatment
Safety Population

Parameter Category	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
K-SADS-PL						
Probable Diagnosis						
Major Depressive Episode						
Yes	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
No	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Dysthymia						
Yes	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
No	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
Unspecified Depressive Disorder						
Yes	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)
No	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)

{Continue for all K-SADS-PL parameters}

Note: Percentages are 100*n/N. K-SADS-PL = Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version. WASI-II = Wechsler Abbreviated Scale of Intelligence, 2nd edition.
Source: Listing 16.2.3.1, 16.2.5.5, 16.2.5.6.1, 16.2.5.6.2, 16.2.5.6.3, 16.2.5.6.4
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.4
Disease Characteristics at Baseline by Optimized Dose and Randomized Treatment
Safety Population

Parameter Category	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
ADHD Subtype						
Combined	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
Inattentive	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
Impulsive/Hyperactive	xx (xx x%)	xx (xx.x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
Age at Diagnosis (years)						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x x, x.x)
Time Since ADHD Diagnosis (years)						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x x, x x)
CGI-S at Baseline						
1 = Normal, not at all ill	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
2 = Borderline mentally ill	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
3 = Mildly ill	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
4 = Moderately ill	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
5 = Markedly ill	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
6 = Severely ill	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
7 = Among the most extremely ill patients	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)

Note: Percentages are 100*n/N.
Source: Listing 16.2.3.1
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.4
Disease Characteristics at Baseline by Optimized Dose and Randomized Treatment
Safety Population

Parameter Category	100mg NFC-1 (N=xx)	200mg NFC-1 (N=xx)	400mg NFC-1 (N=xx)	All Doses NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
ADHD-RS-5 Total Score at Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x x, x.x)
ADHD RS-5 Inattention subscale at Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x.x, x x)
ADHD RS-5 Hyperactivity-Impulsivity subscale at Baseline						
n	xx	xx	xx	xx	xx	xx
Mean	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx
Median	xx xx	xx xx	xx.xx	xx xx	xx xx	xx.xx
Minimum, Maximum	(x x, x x)	(x.x, x x)	(x x, x.x)	(x x, x x)	(x x, x x)	(x.x, x x)

Note: Percentages are 100*n/N.
Source: Listing 16.2.3.1
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.1.5
Summary of Prior Medications by Randomized Treatment
Safety Population

ATC Preferred Term [1]	NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Number of Subjects with at least one prior medication	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<ATC 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<ATC 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<ATC 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)

Note: Percentages are 100*n/N. Subjects were counted only once for each Anatomical Therapeutic Chemical (ATC) or Preferred Term. Prior medications are defined as medications or therapies initiated prior to date of first dose and terminating prior to date of first dose. Mediations that are started prior to the date of first dose of IP and are continuing after the first dose of IP are considered to be both prior and concomitant medications.
[1] Medications were coded using WHO-DD (Enhanced version xxxx) and summarized at ATC Level 3.
Source: Listing 16.2.3.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.2.1.1
Analysis of Change from Baseline in ADHD-RS-5:
Total Score and Subscales, by Study Visit
Intent-To-Treat Population

Variable Visit Statistic [1]	NFC-1 (N=xx)	Placebo (N=xx)
ADHD-RS-5		
Visit 3		
LS Mean (SE)	x xx (x xxx)	x.xx (x.xxx)
(95% CI for LS Mean)	(x xx, x xx)	(x xx, x xx)
LS Mean Difference from Placebo (SE)	x xx (x xxx)	
(95% CI for Mean Difference from Placebo)	(x xx, x xx)	
p-value vs. Placebo [2]	0 xxxx	
{Continue for all scheduled post-baseline visits and subscales}		

Note: ADHD-RS-5 = Attention Deficit Hyperactivity Disorder Rating Scale Version 5; CI = Confidence Interval; LS = Lease-squares; SE = Standard error.
[1] Estimates are from an analysis of covariance (ANCOVA) model. The model uses a residual (restricted) maximum likelihood (REML) estimation method and a standard variance components (VC) covariance structure, with treatment group (NFC-1 or placebo) as a fixed factor and baseline ADHD-RS-5 total score (or appropriate subscale) as a covariate.
[2] P-value for testing if the mean change from baseline for NFC-1 versus Placebo at the specified timepoint is zero.
Source: Listing 16.2.5.1.1, 16.2.5.1.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.2.1.2
Summary of Change from Baseline in
ADHD-RS-5 Score and Subscales by Actual Dose and Randomized Treatment, by Study Visit
Intent-To-Treat Population

	NFC1 100mg (N=xx)		NFC1 200mg (N=xx)		NFC1 400mg (N=xx)		All NFC1 Doses (N=xx)		Placebo (N=xx)	
Variable Visit Statistic [1]	Value	Change From Baseline	Value	Change From Baseline	Value	Change From Baseline	Value	Change From Baseline	Value	Change From Baseline
ADHD-RS-5										
Baseline										
n	xx	--	xx	--	xx	--	xx	--	xx	--
Mean	xx.xx	--	xx xx	--	xx xx	--	xx xx	--	xx xx	--
Standard Deviation	xx xxx	--	xx.xxx	--	xx.xxx	--	xx xxx	--	xx xxx	--
Median	xx.xx	--	xx xx	--	xx xx	--	xx xx	--	xx xx	--
Minimum, Maximum	(x x, x.x)	--	(x x, x.x)	--	(x x, x x)	--	(x x, x x)	--	(x.x, x x)	--
Visit 3										
n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx xx	xx xx	xx xx	xx xx	xx.xx	xx xx	xx xx	xx xx	xx xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx.xxx
Median	xx.xx	xx xx	xx xx	xx xx	xx xx	xx.xx	xx xx	xx xx	xx xx	xx xx
Minimum, Maximum	(x x, x.x)	(x x, x x)	(x x, x.x)	(x.x, x x)	(x x, x x)	(x x, x.x)	(x x, x x)	(x x, x.x)	(x.x, x x)	(x x, x x)
Visit 4										
n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx xx	xx xx	xx xx	xx xx	xx.xx	xx xx	xx xx	xx xx	xx xx
Standard Deviation	xx xxx	xx xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx xxx	xx.xxx	xx xxx	xx.xxx
Median	xx.xx	xx xx	xx xx	xx xx	xx xx	xx.xx	xx xx	xx xx	xx xx	xx xx
Minimum, Maximum	(x x, x.x)	(x x, x x)	(x x, x.x)	(x.x, x x)	(x x, x x)	(x x, x.x)	(x x, x x)	(x x, x.x)	(x.x, x x)	(x x, x x)
{Continue for all scheduled post-baseline visits and subscales}										

Source: Listing 16.2.5.1.1, 16.2.5.1.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.2.2.1
Chi-Square Analysis of CGI-I Improvement, by Study Visit
Intent-To-Treat Population

Variable Visit Statistic	NFC-1 (N=xx)	Placebo (N=xx)
CGI-I Improvement [1]		
Visit 3		
n	xx	xx
Improved	xx (xx x%)	xx (xx.x%)
95% CI	xx x%, xx x%	xx x%, xx.x%
p-value [2]	0 xxxx	
Visit 4		
n	xx	xx
Improved	xx (xx x%)	xx (xx.x%)
95% CI	xx x%, xx x%	xx x%, xx.x%
p-value [2]	0 xxxx	
Visit 5		
n	xx	xx
Improved	xx (xx x%)	xx (xx.x%)
95% CI	xx x%, xx x%	xx x%, xx.x%
p-value [2]	0 xxxx	
{Continue for all scheduled post-baseline visits}		

Note: CGI-I = Clinical Global Impression of Improvement.
[1] Improvement defined as achieving a CGI-I score of 1 or 2, scores of 3 to 7 or missing are defined as Not Improved.
[2] P-value for comparison of the frequency of 'Improved' versus 'No Improvement' between the NFC-1 and Placebo treatment. The analysis is from a Chi-Square test of association at alpha = 0.05.
Source: Listing 16.2.5.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.2.2.2
Summary of Categorical and Continuous CGI-I Scores by Randomized Treatment Group and Study Visit
Intent-To-Treat Population

Variable Visit Score	NFC-1 (N=xx)	Placebo (N=xx)
CGI-I score		
Visit 3		
1) Very Much Improved, n (%)	xx (xx x%)	xx (xx.x%)
2) Much Improved, n (%)	xx (xx x%)	xx (xx.x%)
3) Minimally Improved, n (%)	xx (xx x%)	xx (xx.x%)
4) No Change, n (%)	xx (xx x%)	xx (xx.x%)
5) Minimally Worse, n (%)	xx (xx x%)	xx (xx.x%)
6) Much Worse, n (%)	xx (xx x%)	xx (xx.x%)
7) Very Much Worse, n (%)	xx (xx x%)	xx (xx.x%)
8) Missing	xx (xx x%)	xx (xx.x%)
n	xx	xx
Mean	xx.xx	xx xx
Standard Deviation	xx xxx	xx xxx
Median	xx.xx	xx xx
Minimum, Maximum	(x x, x.x)	(x.x, x x)

{Continue for all scheduled post-baseline visits}

Note: CGI-I = Clinical Global Impression of Improvement.
Source: Listing 16.2.5.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.2.2.3
Summary of CGI-I Improvement by Optimized Dose and Randomized Treatment, by Study Visit
Intent-To-Treat Population

Variable Visit Statistic	NFC-1 100mg (N=xx)	NFC-1 200mg (N=xx)	NFC-1 400mg (N=xx)	All NFC-1 (N=xx)	Placebo (N=xx)
CGI-I Response [1]					
Visit 3					
n	xx	xx	xx	xx	xx
Improved	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Not Improved	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Missing	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Visit 4					
n	xx	xx	xx	xx	xx
Improved	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Not Improved	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Missing	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Visit 5					
n	xx	xx	xx	xx	xx
Improved	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Not Improved	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Missing	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
{Continue for all scheduled post-baseline visits}					

Note: CGI-I = Clinical Global Impression of Improvement.
[1] Improved is defined as a CGI-I scores of 1 or 2. Scores of 3 to 7 are defined as Not Improved.
Source: Listing 16.2.5.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.2.3.1
Chi-Square Analysis of CGI-S Improvement, by Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.2.1; Source: Listing 16.2.5.2}
{Update footnote to replace CGI-I with CGI-S acronym}
{Update footnote for categorization: CGI-S scores of 1 (Normal, not at all ill) or 2 (Borderline mentally ill) are combined into a single category labeled 'Normal or Borderline mentally ill', and all other scores (3 [Mildly Ill] to 7 [Among the most extremely ill patients]) are combined into a single category labeled 'Mentally ill'.

Table 14.2.3.2
Summary of Categorical and Continuous CGI-S Scores by Randomized Treatment Group and Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.2.2; Source: Listing 16.2.5.2}
{Update footnote to replace CGI-I with CGI-S acronym}
{Update row labels to corresponding CGI-S levels}

Table 14.2.3.3
Summary of CGI-S Improvement by Optimized Dose and Randomized Treatment, by Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.2.3; Source: Listing 16.2.5.2}
{Update footnote to replace CGI-I with CGI-S acronym}
{Update footnote for categorization: CGI-S scores of 1 (Normal, not at all ill) or 2 (Borderline mentally ill) are combined into a single category labeled 'Normal or Borderline mentally ill', and all other scores (3 [Mildly Ill] to 7 [Among the most extremely ill patients]) are combined into a single category labeled 'Mentally ill'.

Table 14.2.4.1
Analysis of Change from Baseline in
ASHS Total Score and Factors, by Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.1.1; Source: Listing 16.2.5.3.1, 16.2.5.3.2, 16.2.5.3.3, 16.2.5.3.4}
{Update footnote to replace ADHD-RS-5 with ASHS acronym}

Table 14.2.4.2
Summary of Change from Baseline in
ASHS Total Score and Factors by Randomized Treatment, by Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.1.2; Source: Listing 16.2.5.3.1, 16.2.5.3.2, 16.2.5.3.3, 16.2.5.3.4}
{Update footnote to replace ADHD-RS-5 with ASHS acronym}

Table 14.2.5.1
Analysis of Change from Baseline in
SCARED Score and Factors, by Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.1.1; Source: Listing 16.2.5.4.1, 16.2.5.4.2, 16.2.5.4.3, 16.2.5.4.4}
{Update footnote to replace ADHD-RS-5 with SCARED acronym}

Table 14.2.5.2
Summary of Change from Baseline in
SCARED Score and Factors by Randomized Treatment, by Study Visit
Intent-To-Treat Population

{Similar shell as Table 14.2.1.2; Source: Listing 16.2.5.4.1, 16.2.5.4.2, 16.2.5.4.3, 16.2.5.4.4}
{Update footnote to replace ADHD-RS-5 with SCARED acronym}

Table 14.2.6.1
Chi-Square Analysis of Response and Remission Criteria, at End of Study
Intent-To-Treat Population

Endpoint Definition Statistic	NFC-1 (N=xx)		Placebo (N=xx)
Response[1]			
Definition A			
n	xx		xx
Response	xx (xx x%)		xx (xx.x%)
95% CI	xx x% - xx x%		xx x% -xx x%
p-value [3]		0 xxxx	
Definition B			
n	xx		xx
Response	xx (xx x%)		xx (xx.x%)
95% CI	xx x% - xx x%		xx x% -xx x%
p-value [3]		0 xxxx	
Definition C			
n	xx		xx
Response	xx (xx x%)		xx (xx.x%)
95% CI	xx x% - xx x%		xx x% -xx x%
p-value [3]		0 xxxx	
{Repeat for Remission definitions A, B, and C}			

Note: ADHD-RS-5 = Attention Deficit Hyperactivity Disorder Rating Scale Version 5, CGI-I = Clinical Global Impression of Improvement. Percentages are 100*n/N, where N is the number of non-missing values for corresponding treatment.
[1] Response is defined as: (A) a change in ADHD-RS-5 total score from baseline of 30% or more, (B) a CGI-I score of 1 (very much improved) or 2 (much improved) relative to baseline, and (C) a composite requiring both (A) and (B) to be met.
[2] Remission is defined as: (A) ADHD-RS-5 total score of 18 or less at post-baseline visits, (B) a CGI-I score of 1, and (C) a composite of (A) and (B) to be met
[3] P-value for comparison of the frequency of Response versus No Response between the NFC-1 and Placebo treatment. The analysis is from a Chi-Square test of association at alpha = 0.05.
Source: Listing 16.2.5.1.1, 16.2.5.1.2, 16.2.5.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.1.1
Summary of TEAEs by Dose at Onset
Safety Population

Category	NFC-1 100mg (N=xx)	NFC-1 200mg (N=xx)	NFC-1 400mg (N=xx)	All NFC-1 (N=xx)	Placebo (N=xx)
Subjects with at least one:					
Treatment-Emergent Adverse Event	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx.x%)
TEAE Related to Study Drug [1]	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx.x%)
Serious Adverse Event	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx.x%)
TEAE Leading to Study Drug Discontinuation	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx.x%)
Adverse Event Leading to Death	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx.x%)

Note: Percentages are 100*n/N. TEAE = Treatment-Emergent Adverse Event
[1] Any AE determined by the investigator as 'possibly related' or 'related' is considered related for purposes of analysis.
Source: Listing 16.2.6.1, 16.2.6.2, 16.2.6.3, 16.2.6.4
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.1.2
Incidence of TEAEs by Dose at Onset and Randomized Treatment
Safety Population

SOC Preferred Term [1]	NFC-1 100mg (N=xx)	NFC-1 200mg (N=xx)	NFC-1 400mg (N=xx)	NFC-1 (N=xx)	Placebo (N=xx)
Number of Subjects with at Least One AE	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<SOC 1>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 1>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 2>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 3>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<SOC 2>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 1>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 2>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 3>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<SOC 3>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 1>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 2>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
<Event 3>	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)

Note: Percentages are 100*n/N. Subjects were counted only once for each System Organ Class (SOC) or Preferred Term. TEAE is defined as AEs occurring or worsening with an onset at the time of or following the start of treatment with study medication. TEAE = Treatment-Emergent Adverse Event.
[1] Adverse Events were coded from MedDRA (version xx x).
Source: Listing 16.2.6.1
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.1.3
Incidence of TEAEs occurring in more than 5% of subjects by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.1.2; Source: Listing 16.2.6.1}
{Update footnote to add definition of TEAE, update first row of table}

Table 14.3.1.4
Incidence of Post-Treatment AEs by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.1.2; Source: Listing 16.2.6.1}
{Update footnote to add definition of TEAE, update first row of table}

Table 14.3.1.5
Incidence of SAEs by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.1.2; Source: Listing 16.2.6.2}
{Update footnote to add definition of SAE, update first row of table}

Table 14.3.1.6
Incidence of TEAEs Leading to Early Termination by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.1.2; Source: Listing 16.2.6.3}
{Update update first row of table}

Table 14.3.1.7
Incidence of Deaths by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.1.2; Source: Listing 16.2.6.1}
{Update update first row of table}

Table 14.3.1.8
Incidence of TEAEs by Relationship to Study Drug by Randomized Treatment
Safety Population

SOC Preferred Term [1] Causality	NFC-1 (N=xx)	Placebo (N=xx)
Number of Subjects with at least one TEAE	xx (xx.x%)	xx (xx.x%)
Potentially Related	xx (xx x%)	xx (xx.x%)
Not Related	xx (xx x%)	xx (xx.x%)
<SOC 1>	xx (xx x%)	xx (xx.x%)
Potentially Related	xx (xx x%)	xx (xx.x%)
Not Related	xx (xx x%)	xx (xx.x%)
<Event 1>	xx (xx x%)	xx (xx.x%)
Potentially Related	xx (xx x%)	xx (xx.x%)
Not Related	xx (xx x%)	xx (xx.x%)
<Event 2>	xx (xx x%)	xx (xx.x%)
Potentially Related	xx (xx x%)	xx (xx.x%)
Not Related	xx (xx x%)	xx (xx.x%)
<Event 3>	xx (xx x%)	xx (xx.x%)
Potentially Related	xx (xx x%)	xx (xx.x%)
Not Related	xx (xx x%)	xx (xx.x%)

Note: Percentages are 100*n/N. Subjects were counted only once for each System Organ Class (SOC) or Preferred Term. If a subject experiences the same event, the event which most related to study drug is used. Any AE determined by the investigator as 'possibly related' or 'related' is considered potentially related for purposes of analysis.
[1] Adverse Events were coded from MedDRA (version xx x).
Source: Listing 16.2.6.1
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.1.9
Incidence of TEAEs by Maximum Severity by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.1.8; Source: Listing 16.2.6.1}
{Update update first row of table, nest Severity within each category.}

14.3.2
Summary of Exposure to Study Drug and Compliance by Actual Dose and Randomized Treatment
Safety Population

Variable Statistic	NFC-1 100mg (N=xx)	NFC-1 200mg (N=xx)	NFC-1 400mg (N=xx)	All NFC-1 (N=xx)	Placebo (N=xx)
Total Drug Exposure (mg)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx x	xx x	xx x	--
Standard Deviation	xx xx	xx.xx	xx.xx	xx xx	--
Median	xx.x	xx x	xx x	xx x	--
Minimum, Maximum	(x, x)	(x, x)	(x, x)	(x, x)	--
Treatment Duration (days) [1]					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx x	xx x	xx x	xx.x
Standard Deviation	xx xx	xx.xx	xx.xx	xx xx	xx xx
Median	xx.x	xx x	xx x	xx x	xx.x
Minimum, Maximum	(x, x)	(x, x)	(x, x)	(x, x)	(x, x)
Compliance [2]					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx x	xx x	xx x	xx.x
Standard Deviation	xx xx	xx.xx	xx.xx	xx xx	xx xx
Median	xx.x	xx x	xx x	xx x	xx.x
Minimum, Maximum	(x, x)	(x, x)	(x, x)	(x, x)	(x, x)

[1] Treatment Duration is defined as Date of Last Dose – Date of First Dose + 1.
[2] A subject is non-compliant if they take < 80% or > 100% of IP. Compliance (Overall) = (sum of (Individual Week Compliance) * (Time-Weight)) * 100. Individual Week Compliance is defined as the number of capsules taken at a particular week divided by the expected number of capsules taken at a particular week. Given that a subject will be dose optimized, the number of expected capsules will vary according to which dose the subject is currently on for each day. Time-Weight is the fraction of x/y where x is the number of days in the week the subject is expected to be on dose and is the whole treatment duration.

Source: Listing 16.2.4.1, 16.2.4.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.3.1
Summary of Clinical Laboratory Data: Clinical Chemistry
by Randomized Treatment by Study Visit
Safety Population

Analyte Visit Statistic	NFC-1 (N=xx)	Placebo (N=xx)
<Analyte (unit)>		
Baseline		
n	xx	xx
Mean	xx xx	xx xx
Standard Deviation	xx.xxx	xx xxx
Median	xx xx	xx xx
Minimum, Maximum	(x x, x x)	(x x, x x)
Visit 3		
n	xx	xx
Mean	xx xx	xx xx
Standard Deviation	xx.xxx	xx xxx
Median	xx xx	xx xx
Minimum, Maximum	(x x, x x)	(x x, x x)

{Continue for all scheduled post-baseline visits and all analytes. Start a new page for every additional analyte}

Source: Listing 16.2.7.1
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.3.2
Summary of Clinical Laboratory Data: Hematology
by Randomized Treatment by Study Visit
Safety Population

{Similar shell as Table 14.3.3.1; Source: Listing 16.2.7.2}

Table 14.3.3.3
Summary of Clinical Laboratory Data: Urinalysis
by Randomized Treatment by Study Visit
Safety Population

{Similar shell as Table 14.3.3.1; Source: Listing 16.2.7.3}

Table 14.3.3.4
Shifts from Baseline of Clinical Laboratory Data: Clinical Chemistry by Randomized Treatment
Safety Population

Analyte Visit [1] Category	NFC-1 (N=xx)				Placebo (N=xx)			
	Missing	Low	Normal	High	Missing	Low	Normal	High
<Analyte (unit)>								
Visit 3								
Missing	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Low	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Normal	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
High	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)
Visit 4								
Missing	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Low	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
Normal	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)
High	xx (xx.x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)	xx (xx x%)	xx (xx x%)	xx (xx.x%)	xx (xx x%)

{Continue for all scheduled post-baseline visits and all analytes. Start a new page for every additional analyte}

Note: Percentages are 100*n/N. A low value is a result less than the lower normal reference range; A high value is a result greater than the normal reference range; A normal value is a result which falls between the low and high normal reference ranges.
[1] Baseline value is on the column, post-baseline value is on the row.
Source: Listing 16.2.7.1
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.3.5
Shifts from Baseline of Clinical Laboratory Data: Hematology by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.3.4; Source: Listing 16.2.7.2}

Table 14.3.3.6
Shifts from Baseline of Clinical Laboratory Data: Urinalysis by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.3.4; Source: Listing 16.2.7.3}

Table 14.3.4.1
Summary of Vital Signs by Randomized Treatment by Study Visit
Safety Population

{Similar shell as Table 14.3.3.1; Source: Listing 16.2.8}

Table 14.3.4.2
Potentially Clinically Important Vital Signs by Randomized Treatment
Safety Population

Parameter Visit Category	NFC-1 (N=xx)	Placebo (N=xx)
Temperature (ºF)		
Baseline		
n	xx	xx
< 96 ºF	xx (xx x%)	xx (xx x%)
≥ 96 ºF and ≤ 102ºF	xx (xx x%)	xx (xx x%)
> 102ºF	xx (xx x%)	xx (xx x%)
Missing	xx (xx x%)	xx (xx x%)
Visit 3		
n	xx	xx
< 96 ºF	xx (xx x%)	xx (xx x%)
≥ 96 ºF and ≤ 102ºF	xx (xx x%)	xx (xx x%)
> 102ºF	xx (xx x%)	xx (xx x%)
Missing	xx (xx x%)	xx (xx x%)
{Continue for all scheduled post-baseline visits and all parameters. Start a new page for every additional parameter, individual parameter ranges are given within the SAP text Section 9.3}		

Source: Listing 16.2.8
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.5.1
Incidence of Abnormal ECG Findings: based on Site Interpretations by Randomized Treatment by Study Visit
Safety Population

Visit Category	NFC-1 (N=xx)	Placebo (N=xx)
Baseline		
n	xx	xx
Normal	xx (xx x%)	xx (xx.x%)
Abnormal – Not Clinically Significant	xx (xx x%)	xx (xx.x%)
Abnormal – Clinically Significant	xx (xx x%)	xx (xx.x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx.x%)
Visit 3		
n	xx	xx
Normal	xx (xx x%)	xx (xx.x%)
Abnormal – Not Clinically Significant	xx (xx x%)	xx (xx.x%)
Abnormal – Clinically Significant	xx (xx x%)	xx (xx.x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx.x%)
Visit 4		
n	xx	xx
Normal	xx (xx x%)	xx (xx.x%)
Abnormal – Not Clinically Significant	xx (xx x%)	xx (xx.x%)
Abnormal – Clinically Significant	xx (xx x%)	xx (xx.x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx.x%)
{Continue for all scheduled post-baseline visits}		

Note: Percentages are 100*n/N. ECG = Electrocardiogram.
Source: Listing 16.2.9
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.5.2
Incidence of Abnormal ECG Findings: based on Central Reading by Randomized Treatment by Study Visit
Safety Population

Visit Category	NFC-1 (N=xx)	Placebo (N=xx)
Baseline		
n	xx	xx
Normal	xx (xx x%)	xx (xx.x%)
Abnormal	xx (xx x%)	xx (xx.x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx.x%)
Visit 3		
n	xx	xx
Normal	xx (xx x%)	xx (xx.x%)
Abnormal	xx (xx x%)	xx (xx.x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx.x%)
Visit 4		
n	xx	xx
Normal	xx (xx x%)	xx (xx.x%)
Abnormal	xx (xx x%)	xx (xx.x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx.x%)
{Continue for all scheduled post-baseline visits}		

Note: Percentages are 100*n/N. ECG = Electrocardiogram.
Source: Listing 16.2.10
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.5.3
Potentially Clinically Important ECG Results by Randomized Treatment
Safety Population

Parameter Visit Category	NFC-1 (N=xx)	Placebo (N=xx)
Heart Rate		
Baseline		
n	xx	xx
≤ 50 bpm	xx (xx x%)	xx (xx x%)
> 50 bpm and < 130 bpm	xx (xx x%)	xx (xx x%)
≥ 130 bpm	xx (xx x%)	xx (xx x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx x%)
Visit 3		
n	xx	xx
≤ 50 bpm	xx (xx x%)	xx (xx x%)
> 50 bpm and < 130 bpm	xx (xx x%)	xx (xx x%)
≥ 130 bpm	xx (xx x%)	xx (xx x%)
Unable To Be Evaluated	xx (xx x%)	xx (xx x%)

{Continue for all scheduled post-baseline visits and all parameters. Start a new page for every additional parameter, individual parameter ranges are given within the SAP text Section 9.4}

Source: Listing 16.2.9
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.6
Summary of C-SSRS Assessments by Randomized Treatment
Safety Population

Category [1]	NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Suicidal Ideation (1-5)	xx (xx x%)	xx (xx x%)	xx (xx x%)
(1) Wish to be dead	xx (xx x%)	xx (xx x%)	xx (xx x%)
(2) Non-specific active suicidal thoughts	xx (xx x%)	xx (xx x%)	xx (xx x%)
(3) Active suicidal ideation with any methods (not plan) with intent to act	xx (xx x%)	xx (xx x%)	xx (xx x%)
(4) Active suicidal ideation with some intent to act, without specific plan	xx (xx x%)	xx (xx x%)	xx (xx x%)
(5) Active suicidal ideation with specific plan and intent	xx (xx x%)	xx (xx x%)	xx (xx x%)
Suicidal Behaviour (6-10)	xx (xx x%)	xx (xx x%)	xx (xx x%)
(6) Preparatory acts or behaviour	xx (xx x%)	xx (xx x%)	xx (xx x%)
(7) Aborted attempt	xx (xx x%)	xx (xx x%)	xx (xx x%)
(8) Interrupted attempt	xx (xx x%)	xx (xx x%)	xx (xx x%)
(9) Non-fatal suicide attempt	xx (xx x%)	xx (xx x%)	xx (xx x%)
(10) Completed suicide	xx (xx x%)	xx (xx x%)	xx (xx x%)
Suicidal Ideation or Behaviour (1-10)	xx (xx x%)	xx (xx x%)	xx (xx x%)

Note: Percentages are 100*n/N. For the composite endpoint of suicidal ideation (1-5), n and (%) refer to the number and percent of patients who experience any one of the five suicidal ideation events at least once. For the composite endpoint of suicidal behavior (6-10), n and (%) refer to the number and percent of patients who experience any one of the five suicidal behavior events at least once. For the composite endpoint of suicidal ideation or behavior (1-10), n and (%) refer to the number and percent of patients who experience any one of the ten suicidal ideation or behavior events at least once.

[1] Results are calculated at any point during the study for each subject and reflect any positive response to these questions. For example, if a subject answered Yes to (1) and (2) on two separate visits, both of those values would be shown instead of just one or the other.

Source: Listing 16.2.11

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.7
Summary of Concomitant Medications by Randomized Treatment
Safety Population

ATC Preferred Term [1]	NFC-1 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Number of Subjects with at least one concomitant medication	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<ATC 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<ATC 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<ATC 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 1>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 2>	xx (xx x%)	xx (xx x%)	xx (xx.x%)
<Medication 3>	xx (xx x%)	xx (xx x%)	xx (xx.x%)

Note: Percentages are 100*n/N. Subjects were counted only once for each Anatomical Therapeutic Chemical (ATC) or Preferred Term. Concomitant medications are defined as any medication a subject received concurrently with study treatment.
[1] Medications were coded using WHO-DD (Enhanced version xxxx) ATC Level 3.
Source: Listing 16.2.3.2
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Table 14.3.8
Summary of Post-Treatment Medications by Randomized Treatment
Safety Population

{Similar shell as Table 14.3.7; Source: Listing 16.2.3.2}
{Update footnote and first row label accordingly}

Listing 16.2.1.1
Analysis Populations and Treatment
All Subjects

Subject ID	Treatment	Treatment Start Date	Treatment End Date	Randomization Number	Reason Excluded From Population	Analysis Population		
						Safety	ITT	Per-Protocol
xxxxxxxx	NFC-1	DDMMYYYY	DDMMYYYY	XXXXX	xxxxxxxxxxx	Yes	Yes	No
xxxxxxxx	NFC-1	DDMMYYYY	DDMMYYYY	XXXXX		Yes	Yes	Yes
xxxxxxxx	Placebo	DDMMYYYY	DDMMYYYY	XXXXX	xxxxxxxxxxxxx; xxxxxxxx	No	Yes	No
xxxxxxxx	NFC-1	DDMMYYYY	DDMMYYYY	XXXXX	xxxxxx; xxxxxxxxx; xxxxx	No	No	No

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.1.2
Subject Disposition
Safety Population

Subject ID	Treatment	Completed Study?	Follow-up Phone Call?	Date of Discontinuation	Reason for Discontinuation	Date of Last Contact
xxxxxxxx	NFC-1	Yes	Yes			DDMMYYYY
xxxxxxxx	NFC-1	Yes	Yes			DDMMYYYY
xxxxxxxx	Placebo	No	No	DDMMYYYY	xxxxxxxxxxxx	DDMMYYYY
xxxxxxxx	NFC-1	No	No	DDMMYYYY	Other; xxxxxxx xxxxxxx	DDMMYYYY

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

{If subject discontinued due to reason = 'Other', concatenate discontinuation reason field with Other with a ';', as per the example above}

Listing 16.2.1.3
Inclusion/Exclusion Criteria
All Subjects

Treatment: XXXXX

Subject ID	Were all Inclusion Criteria Met?	Category Not Met	Criteria Not Met
xxxxxxxx	No	Inclusion	INCL01; INCL04; INCL10
xxxxxxxx	Yes		
xxxxxxxx	Yes		
xxxxxxxx	No	Inclusion; Exclusion	INCL02; INCL03; EXCL15; EXCL18G

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.2
Major and Minor Protocol Deviations
Safety Population

Treatment: XXXXX

Subject ID	Event Date	Event Report Date	Event Category	Event Type	Description
xxxxxxxx	DDMMYYYY	DDMMYYYY	Major	Informed Consent/Assent	xxxxxxxxxxxxxxxxxxxxxxxx; xxxxxxxxxxxxxx xxxx xxxx
	DDMMYYYY	DDMMYYYY	Major	Concomitant Medication	xxxxxxxxxxxxxxxxxxx
	DDMMYYYY	DDMMYYYY	Minor	Other	xxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxx xxxxxxxxxxxx
xxxxxxxx	DDMMYYYY	DDMMYYYY	Minor	Study Assessments/Procedures	xxxxxxxxxxxx xxxxxxxxxxxxxxxxxxx
	DDMMYYYY	DDMMYYYY	Minor	Inclusion/Exclusion Criteria	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxx	DDMMYYYY	DDMMYYYY	Major	Laboratory Assessment	xxxxxxxxxxxxxxxxxx
	DDMMYYYY	DDMMYYYY	Major	Laboratory Assessment	xxxxxxxx
xxxxxxxx	DDMMYYYY	DDMMYYYY	Major	Other	xxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxx xxxxxxx

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.3.1
Demographics and Other Baseline Characteristics
Safety Population

Treatment: XXXXXX

Subject ID	Previous Subject ID from ADHD-001	Date of Parental Informed Consent	Date of Informed Assent	Date of Birth	Age (yrs)/ Gender	CB	Ethnicity	Race	ADHD Diagnosis Date (Age at Onset) (yrs)
xxxxxxxx	xxxxxxxx	DDMMYYYY	DDMMYYYY	DDMMYYYY	xx/F	No	xxxxxxxxxx	White	DDMMYYYY (13)
xxxxxxxx	xxxxxxxx	DDMMYYYY	DDMMYYYY	DDMMYYYY	xx/M	No	xxxxx	Asian	DDMMYYYY (8)
xxxxxxxx	xxxxxxxx	DDMMYYYY	DDMMYYYY	DDMMYYYY	xx/F	Yes	xxxxxxxxxxx	White	DDMMYYYY (10)
xxxxxxxx	xxxxxxxx	DDMMYYYY	DDMMYYYY	DDMMYYYY	xx/F	Yes	xxxxxxxxxxx	Black or African American	DDMMYYYY (14)

Note: NA = not applicable. yrs = Years. CB = If Female, is She of Childbearing Potential.
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

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Protocol: MDGN-NFC1-ADHD-201

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Listing 16.2.3.2
Prior, Concomitant, and Post-treatment Medications
Safety Population

Treatment: XXXXXX

Subject ID	Any Meds?	Concomitant/ Prior/Both	Anatomic Therapeutic Class/ Preferred Term/ Verbatim Term	Start Date/ End Date	Indication	Dose (unit)/ Route/ Frequency
xxxxxxxx	Yes	P	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxx	DDMMYYYY/ DDMMYYYY	xxxxxxxxxxxxx	xxxx (xxxx)/ xxxxxxxxxx/ xxxxxxxxxxxx
		P	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxx	DDMMYYYY/ ONGOING	xxxxxxxxxxxxx	xxxx (xxxx)/ xxxxxxxxxx/ xxxxxxxxxxxx
		C	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxx	DDMMYYYY/ DDMMYYYY	xxxxxxxxxxxxx	xxxx (xxxx)/ xxxxxxxxxx/ xxxxxxxxxxxx
xxxxxxxx	Yes	B	xxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxx	DDMMYYYY/ DDMMYYYY	xxxxxxxxxxxxx	xxxx (xxxx)/ xxxxxxxxxx/ xxxxxxxxxxxx
		B	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxx/ xxxxxxxxxxxxxxxxxx	DDMMYYYY/ DDMMYYYY	xxxxxxxxxxxxx	xxxx (xxxx)/ xxxxxxxxxx/ xxxxxxxxxxxx

Note: Medications were coded using WHO-DD (Enhanced version xxxxxx), Anatomic Therapeutic Class (ATC), level 4. B = Both, C = Concomitant, P = Prior.
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.3.3
Behavioral Therapies
Safety Population

Treatment: XXXXXX

Subject ID	Any Therapies?	Type of Therapy	Start Date/ End Date	Frequency
xxxxxxxx	Yes	xxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY	xxxxxxxxxxx
		xxxxxxxxxxxxxxxxx	DDMMYYY/ ONGOING	xxxxxxxxxxxxxx
		xxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY	xxxxxxxxxxxxx
xxxxxxxx	Yes	xxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY	xxxxxxxxxxx
		xxxxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY	xxxxxxxxxxxxxxxx

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.3.4
Medical History
Safety Population

Treatment: XXXXXX

Subject ID	Any History?	Verbatim Term	Start Date/ End Date
xxxxxxxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY
		xxxxxxxxxxxxxxxxxxxxxxx	DDMMYYY/ ONGOING
		xxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY
xxxxxxxx	Yes	xxxxxxxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	DDMMYYY/ DDMMYYY

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.4.1
Study Drug Exposure
Safety Population

Treatment: XXXXXX

Subject ID	Dose (mg)	Start Date (Study Day) [1]	End Date (Study Day) [1]	Treatment Duration (days) [2]
xxxxxxxx	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	xx
	xxx	DDMMYYYY	DDMMYYYY	xx
	xxx	DDMMYYYY	DDMMYYYY	xx
xxxxxxxx	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	xx
	xxx	DDMMYYYY	DDMMYYYY	xx
	xxx	DDMMYYYY	DDMMYYYY	xx
xxxxxxxx	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	xx
xxxxxxxx	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	x
	xxx	DDMMYYYY	DDMMYYYY	xx
	xxx	DDMMYYYY	DDMMYYYY	xx
	xxx	DDMMYYYY	DDMMYYYY	xx

[1] Study Day is calculated relative to the date of the first dose of study drug.
[2] Treatment Duration is defined as Date of Last Dose – Date of First Dose + 1 for the specified Dose level.
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.4.2
Study Drug Accountability and Compliance
Safety Population

Treatment: XXXXXX

Subject ID	Visit	Bottles dispensed at this visit	Date Bottle Dispensed	Date Bottle Returned	Capsules Returned	Compliance [1]	
						By Week	Overall
xxxxxxxx	Visit 3	xx	DDMMYYYY			xx x%	
	Visit 4					xx x%	
	Visit 5					xx x%	
	Visit 6			DDMMYYYY	xx	xx x%	xx x%
xxxxxxxx	Visit 3	xx	DDMMYYYY			xx x%	
	Visit 4					xx x%	
	Visit 5					xx x%	
	Visit 6			DDMMYYYY	xx	xx x%	
	Visit 7					xx x%	
	Visit 8/ET			DDMMYYYY	xx	xx x%	xx x%

[1] A subject is non-compliant if they take < 80% or > 100% of IP. Compliance (Overall) = (sum of (Individual Week Compliance) * (Time-Weight)) * 100. Individual Week Compliance is defined as the number of capsules taken at a particular week divided by the expected number of capsules taken at a particular week. Given that a subject will be dose optimized, the number of expected capsules will vary according to which dose the subject is currently on for each day. Time-Weight is the fraction of x/y where x is the number of days in the week the subject is expected to be on dose and is the whole treatment duration.
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.4.3
Investigator Dose Optimization
Safety Population

Treatment: XXXXXX

Subject ID	Dose (mg)	Investigator Assess Efficacy of Current Dose?	Date of Dose Assessment	Response Categorization	Dose Optimization – Action Taken
xxxxxxxx	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	No			
	xxx	Yes	DDMMYYYY	Acceptable	DOSE MAINTAINED
xxxxxxxx	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	No			
	xxx	Yes	DDMMYYYY	Acceptable	DOSE MAINTAINED
xxxxxxxx	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Ineffective	DOSE MAINTAINED
xxxxxxxx	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Acceptable	DOSE INCREASED
	xxx	Yes	DDMMYYYY	Ineffective	DOSE DECREASED
	xxx	Yes	DDMMYYYY	Intolerable	IP DISCONTINUED

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.5.1.1
Attention Deficit Hyperactivity Disorder Rating Scale Version 5 (ADHD-RS-5), part 1
Intent-To-Treat Population

Treatment: XXXXXX

Subject ID	Visit	Performed?	Date Performed	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20
xxxxxxxx	Screening	Yes	DDMMYYYY	Y	Y	Y	Y	N	Y	Y	N	Y	0	0	0	0	0	0	1	2
	Baseline	Yes	DDMMYYYY	Y	Y	Y	Y	N	Y	Y	N	Y	1	0	0	1	0	0	3	1
	Visit 3	Yes	DDMMYYYY	Y	Y	Y	Y	N	Y	Y	N	N	0	0	0	0	0	0	1	2
	Visit 4	Yes	DDMMYYYY	Y	Y	Y	Y	N	Y	Y	N	N	1	0	0	1	0	0	3	1
	Visit 5	No																		
	Visit 6	Yes	DDMMYYYY	Y	Y	Y	Y	Y	Y	Y	N	N	0	0	0	0	0	0	1	2
	Visit 7	Yes	DDMMYYYY	Y	Y	Y	Y	Y	Y	Y	N	Y	1	0	0	1	0	0	3	1
	Visit 8/ET	Yes	DDMMYYYY	Y	Y	Y	Y	N	Y	Y	N	N	1	0	0	1	0	0	3	1

Note: Y = Yes, N = No. For Questions 13 – 18: 0 – Never or Rarely, 1 – Sometimes, 2 – Often, 3 – Very often. For Questions 19-33: 0 – No problem, 1 – Minor problem, 2 –Moderate Problem, 3 – Severe Problem
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.5.1.2
Attention Deficit Hyperactivity Disorder Rating Scale Version 5 (ADHD-RS-5), part 2
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1, using Questions 21 – 33 and Inattention Subscale, Hyperactivity/Impulsivity Subscale, and ADHD RS-5 Total Score}

Listing 16.2.5.2
Clinical Global Impression of Improvement (CGI-I) and Clinical Global Impression of Severity (CGI-S)
Intent-To-Treat Population

Treatment: XXXXXX

Subject ID	Visit	Performed CGI-I/ Performed CGI-S	Date Performed	CGI-I	CGI-S
xxxxxxxx	Screening	NA/Yes	DDMMYYYY		Normal, not at all ill
	Baseline	NA/Yes	DDMMYYYY		Borderline mentally ill
	Visit 3	Yes/NA	DDMMYYYY	No change	
	Visit 4	Yes/NA	DDMMYYYY	Minimally worse	
	Visit 5	Yes/NA	DDMMYYYY	Minimally improved	
	Visit 6	Yes/NA	DDMMYYYY	Much improved	
	Visit 7	Yes/NA	DDMMYYYY	Much improved	
	Visit 8/ET	Yes/Yes	DDMMYYYY	Very much Improved	Normal, not at all ill

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.5.3.1
Adolescent Sleep Hygiene Scale (ASHS), part 1
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include questions 4-15, add footnote regarding decode values, see eCRF}

Listing 16.2.5.3.2
Adolescent Sleep Hygiene Scale (ASHS), part 2
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include questions 16-25, add footnote regarding decode values, see eCRF}

Listing 16.2.5.3.3
Adolescent Sleep Hygiene Scale (ASHS), part 3
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include questions 26-40, add footnote regarding decode values, see eCRF}

Listing 16.2.5.3.4
Adolescent Sleep Hygiene Scale (ASHS), part 4
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include factors for ASHS and total score, add footnote regarding decode values, see eCRF}

Listing 16.2.5.4.1
Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 1
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include questions 1-15, add footnote regarding decode values, see eCRF}

Listing 16.2.5.4.2
Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 2
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include questions 16-25, add footnote regarding decode values, see eCRF}

Listing 16.2.5.4.3
Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 3
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include questions 26-41, add footnote regarding decode values, see eCRF}

Listing 16.2.5.4.4
Screen for Childhood Anxiety-related Emotional Disorders (SCARED), part 4
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}
{Include factors for SCARED and total score, add footnote regarding decode values, see eCRF}

Listing 16.2.5.5
WASI-II (brief IQ test)
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}

Listing 16.2.5.6.1
Kiddie Schedule for Affective Disorders (K-SADS-PL), part 1
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1,
{Include questions 4-20, add footnote regarding decode values, see eCRF}

Listing 16.2.5.6.2
Kiddie Schedule for Affective Disorders (K-SADS-PL), part 2
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1,
{Include questions 21-37, add footnote regarding decode values, see eCRF}

Listing 16.2.5.6.3
Kiddie Schedule for Affective Disorders (K-SADS-PL), part 3
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1,
{Include questions 38-55, add footnote regarding decode values, see eCRF}

Listing 16.2.5.6.4
Kiddie Schedule for Affective Disorders (K-SADS-PL), part 4
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1,
{Include questions 56-60, add footnote regarding decode values, see eCRF}

Listing 16.2.6.1
Adverse Events
Safety Population

Treatment: XXXXXX

Subject ID	Any AEs?	System Organ Class/ Preferred Term/ Verbatim Term	TEAE?	Start Datetime/ End Datetime	Severity/ Relationship to IP	Outcome/ Study Drug Action Taken	SE	IME/CA/SD/ DE/HO/LT/
		xxxxxxxxxxxxxx/						
		xxxxxxxxxxxxxxxxx/		DDMMYYY:HH:MM/	xxxxxxxx/	xxxxxxxx/		No/No/No
xxxxxxxx	Yes	xxxxxxxxxxxxxxxxxxxxx	Yes	DDMMYYY:HH:MM	xxxxxx	xxxxxx xxxxx	No	No/No/No
		xxxxxxxxxxxxxx/						
		xxxxxxxxxxxxxxxxxxxx/		DDMMYYY:HH:MM /	xxxxxxx/	xxxxxxx/		No/No/No
		xxxxxxxx	Yes	ONGOING	xxxx	xxxxxxxxxxx	No	No/No/No
		xxxxxxxxxxxxxx/						
		xxxxxxx/		DDMMYYY:HH:MM/	xxxxxxxx/	xxxxxxxx/		Yes/Yes/No/
		xxxxxxxxxxxxxxxx	No	DDMMYYY:HH:MM	xxxxx	xxxxxxxxxxxx	Yes	Yes/No/No
		xxxxxxxxxxxxxx/						
		xxxxxxxxxxxxxxxx/		DDMMYYY:HH:MM/	xxxxxx/	xxxxxx/		No/No/No/
xxxxxxxx	Yes	xxxxxxxxxxxxxx	Yes	DDMMYYY:HH:MM	xxxx	xxxxxxxx	Yes	Yes/No/No
		xxxxxxxxxxxxxxxxxxxxxxxx/						
		xxxxxxxxxxxxxxxx/		DDMMYYY:HH:MM/	xxxxxxx/	xxxxxxx/		No/No/No
		xxxxxxx	Yes	DDMMYYY:HH:MM	xxxxx	xxxxx	No	No/No/No

Note: Adverse Events were coded using MedDRA version xx x. CA = Congenital Anomaly; DE = Results in Death; HO = Hospitalization; IME = Important Medical Event; IP = Investigational Product; LT = Life Threatening; SD = Results in Persistent or Significant Disability/Incapacity; SE = Serious Event; TEAE = Treatment-Emergent Adverse Event
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.6.2
Serious Adverse Events
Safety Population

{Similar shell as Listing 16.2.6.1, remove Any AEs column}

Listing 16.2.6.3
Adverse Events leading to Early Termination
Safety Population

{Similar shell as Listing 16.2.6.1, remove Any AEs column}

Listing 16.2.6.4
Listing of Deaths
All Subjects

{Similar shell as Listing 16.2.6.1, remove Any AEs column}

Listing 16.2.7.1
Clinical Laboratory Data: Chemistry
Safety Population

Treatment: XXXXXX

Subject ID	Laboratory Test (unit)	Visit	Collection Date	Test Result	Reference Range Low	Reference Range High	Flag [1]
xxxxxxxx	xxxxxxxxxxxxxx	Screening	DDMMMYYYY	xx.xx	xxx	xxx	H
		Baseline	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 3	DDMMMYYYY	xx.xx	xxx	xxx	P; L
		Visit 4	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 5	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 6	DDMMMYYYY	xx.xx	xxx	xxx	L
		Visit 7	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 8/ET	DDMMMYYYY	xx.xx	xxx	xxx	
	xxxxxxxxxxxxxx	Screening	DDMMMYYYY	xx.xx	xxx	xxx	P
		Baseline	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 3	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 4	DDMMMYYYY	xx.xx	xxx	xxx	P; H
		Visit 5	DDMMMYYYY	xx.xx	xxx	xxx	
		Visit 6	DDMMMYYYY	xx.xx	xxx	xxx	H
		Visit 7	DDMMMYYYY	xx.xx	xxx	xxx	H
		Visit 8/ET	DDMMMYYYY	xx.xx	xxx	xxx	

{Repeat for all scheduled analytes}

[1] H = High, L = Low, P = Potential Clinical Importance.
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.7.2
Clinical Laboratory Data: Hematology
Safety Population

{Similar shell as Listing 16.2.7.1}

Listing 16.2.7.3
Clinical Laboratory Data: Urinalysis
Safety Population

{Similar shell as Listing 16.2.7.1}

Listing 16.2.7.4
Pregnancy Tests
Safety Population

{Similar shell as Listing 16.2.7.1, limit to only female subjects, remove flag column}

Listing 16.2.7.5
Urine Drug Screen
Safety Population

{Similar shell as Listing 16.2.7.1, remove reference limit columns and flag column}

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Listing 16.2.8
Vital Signs
Safety Population

Treatment: XXXXXX

Subject ID	Visit	Vital Signs Collected?	Date of Measurement	Height (cm)	Weight (kg)	Heart Rate (beats/min)	Respiratory Rate (breaths/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	BMI (kg/m^2)
xxxxxxxx	Screening	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x
	Baseline	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x
	Visit 3	Yes	DDMMYYYY	xx x	xx x*	xxx	xxx	xx	xx	xx x
	Visit 4	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x
	Visit 5	Yes	DDMMYYYY	xx.x	xx.x	xxx	xxx^	xx	xx	xx x
	Visit 6	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx*	xx x
	Visit 7	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x
	Visit 8/ET	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x^
xxxxxxxx	Screening	Yes	DDMMYYYY	xx x	xx.x	xxx*#	xxx	xx	xx	xx x
	Baseline	Yes	DDMMYYYY	xx x	xx x^#	xxx	xxx	xx	xx	xx x
	Visit 3	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x
	Visit 4	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx*	xx	xx	xx x
	Visit 5	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x
	Visit 6	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x^
	Visit 7	Yes	DDMMYYYY	xx x	xx.x	xxx*	xxx	xx	xx	xx x
	Visit 8/ET	Yes	DDMMYYYY	xx x	xx.x	xxx	xxx	xx	xx	xx x

Note: * = High, ^ = Low, # = Potential Clinical Significance.
T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.9
Electrocardiograms (ECGs), Site Interpretation
Safety Population

Treatment: XXXXXX

Subject ID	Visit	ECG Collected?	Datetime of Measurement	Investigator Interpretation
xxxxxxxx	Screening	Yes	DDMMYYYY:HH:MM	Normal
	Baseline	Yes	DDMMYYYY:HH:MM	Normal
	Visit 3	Yes	DDMMYYYY:HH:MM	Normal
	Visit 4	Yes	DDMMYYYY:HH:MM	Abnormal – Not clinically significant
	Visit 5	Yes	DDMMYYYY:HH:MM	Normal
	Visit 6	Yes	DDMMYYYY:HH:MM	Normal
	Visit 7	Yes	DDMMYYYY:HH:MM	Normal
	Visit 8/ET	Yes	DDMMYYYY:HH:MM	Unable to be evaluated
xxxxxxxx	Screening	Yes	DDMMYYYY:HH:MM	Normal
	Baseline	Yes	DDMMYYYY:HH:MM	Normal
	Visit 3	Yes	DDMMYYYY:HH:MM	Normal
	Visit 4	Yes	DDMMYYYY:HH:MM	Normal
	Visit 5	Yes	DDMMYYYY:HH:MM	Normal
	Visit 6	No		
	Unscheduled	Yes	DDMMYYYY:HH:MM	Normal
	Visit 7	Yes	DDMMYYYY:HH:MM	Normal
	Visit 8/ET	Yes	DDMMYYYY:HH:MM	Abnormal – Clinically significant

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.10
Electrocardiograms (ECGs), Central Reading
Safety Population

{Similar shell as Listing 16.2.9}

Listing 16.2.11
Physical Examination
Safety Population

Treatment: XXXXXX

Subject ID	Visit	Physical Examination Performed	Date of Measurement	Body System	Abnormal Finding
xxxxxxxx	Screening	Yes	DDMMYYYY	System 1	xxxxxxxxxxxx
				System 2	xxxxxxxxxxxxxxxxx
				System 3	xxxxxxxxxxxxxxxxxxxxx
	Visit 8/ET	Yes	DDMMYYYY		
xxxxxxxx	Screening	Yes	DDMMYYYY	System 1	xxxxxxxxxxx
	Visit 8/ET	Yes	DDMMYYYY		
xxxxxxxx	Screening	Yes	DDMMYYYY		
	Visit 8/ET	Yes	DDMMYYYY		

T:\Medgenics\NFC-1\ADHD-201\...\xxx.sas run on DDMMMYYYY at HH:MM on data extracted on DDMMMYYYY

Listing 16.2.12
Columbia Suicide Severity Rating Scale (C-SSRS)
Intent-To-Treat Population

{Similar shell as Listing 16.2.5.1.1}