Adamas Pharmaceuticals, Inc.

Integrated Summary of Safety for ADS-5102

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Final Statistical Analysis Plan

Version 1.0

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Upon Review of this document, including table, listing, and figure shells, the undersigned approves the statistical analysis plan. The analysis methods and data presentation are acceptable, and the table, listing and figure production can begin.

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List of Abbreviations and Definitions of Terms

Abbreviation	Definition
AE	Adverse Event
ALT	Alanine aminotransferase
ANCOVA	Analysis of Covariance
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
CGI-C	Clinician's Global Impression of Change
CI	Confidence Interval
CNS	Central Nervous System
CSR	Clinical Study Report
DBS	Deep Brain Stimulation
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
eGFR	Estimated Glomerular Filtration Rate
EOS	End–of–study
ET	Early Termination
HEENT	Head, eyes, ears, nose, and throat
ICH	International Conference on Harmonisation
LS	Least Square
LID	Levodopa–Induced Dyskinesia
LOCF	Last Observation Carried Forward
IR	Immediate Release
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Corpuscular Volume
MDS-UPDRS	Movement Disorder Society–Unified Parkinson's Disease Rating Scale
MedDRA	Medical Dictionary for Regulatory Activities
MITT	Modified Intent–To–Treat
MMSE	Mini-Mental Status Examination
PD	Parkinson's Disease
PP	Per Protocol
PT	Preferred Term
RBC	Red Blood Cell(s)
SAE	Serious Adverse Event
SD	Standard Deviation
SE	Standard Error
SOC	System Organ Class
UDysRS	Unified Dyskinesia Rating Scale
WBC	White Blood Cell(s); leukocyte(s)
WHO	World Health Organization

1 Introduction

This analysis plan describes the integrated summary of safety to support the regulatory submission of ADS-5102, an extended release formulation of amantadine HCl. The proposed nightly dose of ADS-5102 is 170 mg during the first week of dosing, and 340 mg thereafter, each dose to be taken once nightly at bedtime. Three studies (ADS-PAR-AM201, ADS-AMT-PD301, and ADS-AMT-PD302) will be included.

2 Submission Objectives

2.1 Safety Summary

Safety and demographic data from:

- ADS-PAR-AM201
- ADS-AMT-PD301
- ADS-AMT-PD302

will be integrated for purposes of further characterizing the safety of ADS-5102. See Section 5.1 for a detailed description of the Safety population.

3 Studies to be included

The following studies will form the basis of the submission:

- ADS-PAR-AM201, a phase II/III, multi-center, randomized, double-blind, placebo-controlled, 4-arm parallel group study of ADS-5102 in subjects with PD who have LID. 83 subjects were randomized in a 1:1:1:1 ratio to one of four treatments (Placebo, 260 mg ADS–5102, 340 mg ADS–5102, or 420 mg ADS–5102). Subjects who were assigned to Placebo or 260 mg ADS–5102 received the same nightly dose throughout the entire 8–week dosing period. Subjects who were assigned 340 mg ADS–5102 or 420 mg ADS–5102 received, in double-blind fashion, escalating doses of ADS-5102 as indicated in Table 1:

Table 1: ADS-PAR-AM201 Dose Escalation

Treatment	Dosing Days 1–7 (Week 1)	Dosing Days 8–14 (Week 2)	Dosing Days 15–56 (Weeks 3–8)
Placebo	Placebo	Placebo	Placebo
260 mg ADS–5102	260 mg ADS–5102	260 mg ADS–5102	260 mg ADS–5102
340 mg ADS–5102	**260 mg ADS–5102**	**340 mg ADS–5102**	**340 mg ADS–5102**
420 mg ADS–5102	260 mg ADS–5102	340 mg ADS–5102	420 mg ADS–5102

The primary objective of the study was to evaluate the efficacy of each of three dose levels of ADS–5102 oral capsules dosed once nightly for the treatment of LID in subjects with PD. The secondary objectives of the study was to evaluate the potential efficacy of each of three dose levels of ADS–5102 for the treatment of PD–related fatigue, to evaluate the safety and tolerability of each of three dose levels of ADS–5102 in this study population, to select an appropriate dose level of ADS–5102 dosed once nightly for future trials, and to measure steady–state amantadine concentrations at each of three dose levels of ADS–5102 dosed once nightly.

- ADS-AMT-PD301, a phase III, multi-center, randomized, double-blind, placebo-controlled, 2-arm, parallel group study of ADS-5102 in subjects with PD who have LID. 126 subjects were randomized in a 1:1 ratio to placebo or active (340 mg ADS-5102). Study medications were administered as 2 capsules once nightly at bedtime (if possible, no earlier than 9 pm) for 25 weeks. The primary objective of the study was to evaluate the efficacy of ADS-5102 oral capsules, an extended release formulation of amantadine, at a dose level of 340 mg, dosed once nightly at bedtime, for the treatment of levodopa induced dyskinesia (LID) in subjects with Parkinson's disease (PD). The secondary objective was to evaluate the safety and tolerability of ADS-5102 in this study population.
- ADS-AMT-PD302, a phase III, multi-center, open-label study of ADS-5102. Up to 250 subjects will be enrolled with each belonging to one of the following three groups:
    1. Group 1 (current Adamas LID study subjects): Subjects who are participating in Adamas efficacy studies evaluating ADS-5102 in LID and choose to immediately transition into ADS-AMT-PD302 without a time gap
    2. Group 2 (previous Adamas LID study subjects): Subjects who have previously participated in Adamas efficacy studies evaluating ADS-5102 in LID and will enter ADS-AMT-PD302 after a time gap
    3. Group 3 (non Adamas LID study subjects with prior DBS): Subjects who would have been deemed ineligible for participation in previous or current Adamas efficacy studies due to having undergone deep brain stimulation

The primary objective of the study is to evaluate the safety and tolerability of ADS-5102 oral capsules, an extended release formulation of amantadine, administered at a dose of 340 mg once nightly at bedtime for the treatment of levodopa induced dyskinesia (LID) in subjects with Parkinson's disease (PD). The secondary objectives of the study are to evaluate duration of ADS-5102 effect on dyskinesia as assessed by the Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Part IV and to evaluate clinical progression of Parkinson's disease as assessed by MDS-UPDRS, Combined Score, Parts I, II, and III.

4 Planned Analyses

Analyses will be performed after database locks for ADS-PAR-AM201 and ADS-AMT-PD301, and database freeze for ADS-AMT-PD302.

5 Analysis Sets

5.1 Safety

The Safety population will include all subjects who received at least one dose of study drug. It will be used for all safety analyses.

6 General Considerations for Statistical Analyses

Analysis Dataset Model (ADaM) datasets will be in accordance with the Clinical Data Interchange Standards Consortium (CDISC) standards and will be derived from the individual study data tabulation model (SDTM) and ADaM datasets for each study.

All tables, listings, figures and any other supportive SAS output will include in the footer explanatory notes that will indicate, at a minimum, the programming source (i.e., name, file path of the SAS program that generates the output), and run date.

Continuous data will be described using descriptive statistics as follows: number of observations (n), mean, median, standard deviation, minimum, and maximum, unless otherwise specified. All minimum and maximum values will be displayed with the same number of decimal places relative to the raw data, the mean and median will be displayed with one additional decimal place, and the standard deviation will be displayed with two additional decimal places.

Categorical data will be summarized by the number and percentage of subjects in each category. The denominator of all percentages will be the number of subjects in the population of interest, unless otherwise stated. When count data are presented, the percent will be suppressed when the count is zero in order to draw attention to the non-zero counts. A row denoted “Missing” will be included in count tabulations where necessary to account for dropouts and missing values. Non-zero percentages will be rounded to one decimal place, except 100% will be displayed without any decimal places.

In summary tables for categorical data, all categories will be presented if they are specified on the Case Report Form (CRF), or if categories are ordered intervals (e.g., age groups), regardless of whether data were present in each category, unless otherwise specified. For other categorical data (e.g., AEs and medications), only categories with non-zero frequencies will be presented.

Data will be displayed in all listings sorted by subject, study ID, and treatment. All summaries will be presented by treatment/analysis group, unless otherwise specified.

When no data are available for a table or appendix, an empty page with the title will be produced with suitable text (e.g., “There are no observations for this table/appendix.”).

7 Data Handling Conventions

7.1 Derived and Transformed Data

Details on derivations and transformations for each individual study are specified in the study SAPs. The study teams have worked closely to ensure consistent algorithms were implemented across studies. Modifications to study algorithms are not planned for data integration. In the rare instance where modifications to specific algorithms are necessary to facilitate programming, documentation will be provided in the data definition tables and reviewer's guide.

7.2 Treatment Assignments and Analysis Groups

Treatment will be assigned using the treatment assignments from the individual studies.

Integrated listings will display the treatment received at the time the data was collected.

The following treatment/analysis groups will be included in summary tables, in the order shown:

- Placebo
- 340 mg ADS-5102
- ≥ 340 mg ADS-5102
- ADS-5102

Individual summaries for 260 mg ADS-5102 and 420 mg ADS-5102 will not be included, but are available in the study results for ADS-PAR-AM201.

Since subjects may have received more than one treatment or ADS-5102 dose-level, they may be counted multiple times in summary tables, but will appear at most once in each treatment/analysis group and at most once in the overall column (where displayed).

7.3 Subject Identification

The Unique Subject Identifier (USUBJID) is unique for all subjects for every study in which they participated and is used to identify subjects in the analysis database. A truncated version of this identifier will be displayed in data listings. Since this identifier was not displayed in the individual study results, a listing will be provided displaying this value along with the subject identifier displayed in the individual study results.

7.4 Coding Dictionaries

Integrated concomitant medication data will be recoded using World Health Organization (WHO) Drug Dictionary dated March, 2014.

Integrated adverse event data will be recoded using Medical Dictionary for Regulatory Activities (MedDRA®) version 17.0.

7.5 Subgroup Definitions

The following subgroups will be explored for key safety analyses:

- Gender
- Age (<65, ≥65, ≥65 to <75, ≥75)
- Race (white, non-white)
- Baseline renal function (estimated GRF <60 or estimated GFR ≥60)
- Weight (< or ≥ median)
- Baseline MAO-B inhibitor medications (Yes, No)
- Baseline Dopamine Agonist medications (Yes, No)
- Baseline levodopa dose (< or ≥ median)
- Time since PD diagnosis in years (< or ≥ median)
- Age at PD diagnosis (< or ≥ median)
- Prior Deep Brain Stimulation (Yes, No)
- Geographic Region (European Union vs North American)

For subgroups categorizations based on median values, a value for each treatment/analysis group will be calculated and subjects will be categorized separately for each treatment/analysis group in which they are included.

7.6 Definitions of Baseline, Analysis Day 1, and Study Day 1

The baseline assessment will be the last available assessment prior to the first dose of study medication for a particular treatment. For subjects receiving multiple treatments, baseline assessments will be defined for each treatment assignment. For subjects receiving 340 mg ADS-5102 in more than one study, the following logic will be applied to assign the baseline value:

- For subjects continuing into ADS-AMT-PD302 with no gap in treatment prior to enrollment, the baseline assessment will be the last available assessment prior to the first dose of 340 mg ADS-5102 in any study.
- For subjects continuing in ADS-AMT-PD302 with a gap in treatment prior to enrollment, the baseline assessment will be the last available assessment prior to the first dose of 340 mg ADS-5102 in ADS-AMT-PD302. Assessments from the first study in which the subject enrolled will not be considered for assignment as baseline.

An overall baseline value will be determined and used in summaries were overall values are calculated and displayed. This value will be assigned following the same logic outlined previously, but study treatment will not be considered in the selection of this value.

Analysis Day 1 is defined as the date of the baseline visit. Subjects should be dispensed the study drug at the baseline visit and presumably take the first dose at bedtime on the same day. No Day 0 is defined. Negative study days indicate observations were obtained prior to treatment.

Study Day 1 is defined as the date of the first dose of study drug for the individual study in which the subject participated.

7.7 Calculations Using Dates

The following conventions will be used to calculate analysis day for reporting purposes:

- Analysis Day = date of measurement – analysis day 1 +1, if date of measurement is on or after analysis day 1.
- Analysis Day = date of measurement – analysis day 1, if date of measurement is prior to analysis day 1.

Study day will be presented in applicable listings where the calculated analysis day of the measurement is negative due to the definition of baseline for rollover subjects with treatment gaps prior to enrollment in the open-label extension. The following conventions will be used to calculate study day for reporting purposes:

- Study Day = date of measurement – study day 1 +1, if date of measurement is on or after study day 1.
- Study Day = date of measurement – study day 1, if date of measurement is prior to study day 1.

8 Summary Population

8.1 Disposition of Subjects

Disposition data from each study will be integrated, listed, and summarized for the Safety population.

A frequency table by treatment/analysis group and overall will include the number and percentage of subjects along with last available completion status.

A separate table will show the number (%) of subjects who withdrew and the primary reason for withdrawal, by treatment/analysis group and overall. The primary reasons of withdrawal reported by subjects will be presented in this table. The number (%) of subjects who discontinued study drug and the reason for early discontinuation will be summarized in a

separate table. Subjects may contribute more than one event to the summary table since it is possible for a subject to discontinue from more than one study. A footnote indicating the number of subjects with multiple study discontinuations will be included in the summary table.

The time to discontinuation of study drug will be analyzed. The time to discontinuation is defined as the number of days from the Analysis Day 1 date to the last dose of study drug for a particular treatment. Subjects will be censored if no early study drug discontinuation occurred. The median duration and the associated 95% confidence interval for each treatment group will be estimated using the Kaplan-Meier method (log-log transformation). Kaplan-Meier estimates of the survival function will be calculated and displayed graphically.

8.2 Protocol Deviations

Protocol deviations data will not be integrated. Summaries are available in the individual study results.

8.3 Demographic and Baseline Characteristics

Demographic and baseline characteristic data will be integrated, listed, and summarized for the Safety population.

The following demographic information will be summarized by treatment/analysis group and overall.

- Age (years), calculated as (informed consent date – birthdate +1)/365.25
- Age Categories (<65, >=65)
- Sex (male/female)
- Race (White, Black, American Indian/Alaska Native, Native Hawaiian or Other Pacific Islander, Asian, Other)
- Ethnicity (Hispanic or Latino, Non-Hispanic/Non-Latino)
- Height (cm)
- Body Weight (kg)
- Body mass index (BMI)
- eGFR provided by the central lab using subject data and MDRD-NKDEP equation

8.4 Medical History

General medical history data will not be integrated. Summaries are provided in the individual study results.

Parkinson's disease history data including the following will be integrated, listed, and summarized for the Safety population by treatment/analysis group and overall.

- Age (years) at PD diagnosis
- Time since PD diagnosis in years
- Age (years) at start of levodopa treatment
- Duration of levodopa treatment in years
- Duration of levodopa-induced dyskinesia in years
- Baseline Levodopa dose

For the duration of Parkinson's disease, if only the month and year of diagnosis is available, the 15th day of the indicated month is assumed, and when only the year of diagnosis is available, July 1 of the indicated year is assumed. A similar algorithm is used for age at PD diagnosis, age at start of levodopa treatment, duration of levodopa treatment, and duration of levodopa–induced dyskinesia. Fractional years of duration will be used for the analyses.

8.5 Prior and Concomitant Medications

Prior medications are defined as medications with a stop date occurring before the first dose date. Concomitant medications are defined as medications with a stop date occurring on or after the first dose date, or listed as ongoing. Medications with start and stop dates (or ongoing) which bracket the first dose date will be summarized as both prior and concomitant medications.

All non-study drugs (including prescribed and over the counter medications) taken are collected on the CRFs for the individual studies.

Prior and concomitant medication data will be integrated, listed, and summarized by Anatomical Therapeutic Chemical (ATC) Level and preferred term (PT) by treatment/analysis group for the Safety population. At each level of summarization, a subject is counted once if he/she reported one or more medications at that level. The PD prior and concomitant medications will be presented separately.

For the purpose of classifying medications as prior and/or concomitant in summaries, incomplete medication start and stop dates will be imputed as detailed below:

- If year and month are present and day is missing then set start day to last day of month, and set end day to the later of (first day of month, start day)
- If year and day are present and month is missing then set start month to December, and set end month to the later of (January, start month)
- If year is present and month and day are missing then set start month and day to December 31st, and set end month and day to the later of (January 1st, start month and day)
- Completely missing dates will not be imputed

If start date is completely missing and end date is after the first dose, then the medication will be classified as both prior and concomitant. If the end date is missing, then the medication will be classified as ongoing. Medications for which the start and end dates are missing will be classified as prior and concomitant.

8.6 Parkinson's Disease-Related Baseline Characteristics

Parkinson disease related baseline characteristic data will be integrated, listed, and summarized for the Safety population.

- MDS-UPDRS: Part I, Part II, Part III, Combined (Parts I, II, and III), Part IV, Part IV item 4.1, Part IV, item 4.2
- MMSE score
- Hoehn and Yahr Stage

8.7 Physical Examination

Physical examination data will not be integrated. Summaries are available in the individual study results.

8.8 Treatment Compliance

Treatment compliance data will not be integrated. Summaries are provided in the individual study results.

9 Safety Analysis

Safety endpoints will be summarized using integrated data by treatment/analysis group from the time of first dose and include all available safety data. No formal statistical testing is planned.

9.1 Study Drug Exposure

Study drug exposure data will be integrated, listed, and summarized for the Safety population.

Duration of exposure will be summarized by treatment/analysis group and is defined as:

Duration of exposure (Days) = (Date of Last Dose – Analysis Day 1) + 1.

9.2 Adverse Events

An adverse event (AE) is any untoward medical occurrence that occurs in conjunction with the use of a medicinal product in humans, whether or not considered to have a causal relationship to the medicinal product. An AE can, therefore, be any unfavorable or unintended sign (including a clinically significant abnormal laboratory finding), symptom, or disease

temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Adverse event data will be integrated, listed, and summarized for the Safety population. Events will be presented according to MedDRA® system organ class (SOC) and preferred term (PT). Summaries will be ordered alphabetically by SOC and PT, and by decreasing frequency of preferred term among all treatment/analysis groups regardless of whether a "total" column is presented.

Partial (Incomplete) AE onset and end dates will be listed as such. All AEs collected on the AE eCRF page will be considered treatment–emergent.

Most commonly reported (at least 2% of either active or placebo treatments) AEs will be presented by preferred term, and summarized by treatment/analysis group.

For each summary, at each of the SOC and PT levels, a subject will be counted once if he/she reported one or more AEs. Percentages will be calculated out of the number of subjects in the Safety population.

9.2.1 Incidence of Adverse Events

Adverse events will be summarized by treatment/analysis group, SOC and PT.

9.2.2 Causality of Adverse Events due to Study Drug

The investigator will use clinical judgment to assess the causality of each AE/Serious Adverse Event (SAE) due to study drug based on pre-defined criteria. Adverse events will be summarized by this causality.

In the statistical analyses, if a subject experiences multiple occurrences of the same SOC or PT, only the related occurrence (if any exists) will be summarized. If the causality due to the study drug is missing, it will be considered "related". The imputed values for causality due to study drug will be used for the incidence summary while actual values will be listed.

9.2.3 Intensity of Adverse Events

Adverse events will be summarized by treatment/analysis group and intensity. In this summary, if a subject reported multiple occurrences of the same AE, only the most intense AE will be presented. AEs with missing intensity will not be included in the summary table, but will be presented in the data listing with a missing intensity.

9.2.4 Serious Adverse Events

The seriousness of an AE should be assessed by the investigator independently from the intensity of the AE. A SAE is any AE occurring at any dose that:

- results in death;
- is life-threatening (subject is at immediate risk of death at the time of the event);
- requires inpatient hospitalization or results in prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect in the offspring of a subject who received study drug; or
- is a significant or important medical event, i.e., an event that, based upon appropriate medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent one of the above mentioned criteria.

SAEs will be summarized by treatment/analysis group and listed.

9.2.5 Adverse Events Leading to Treatment Discontinuation

Any AEs collected with an investigational product action taken of "Study drug discontinued" will be summarized by treatment/analysis group.

9.2.6 Adverse Events Leading to Study Drug Dose Reduction

Adverse events leading to a study drug dose reduction will be summarized by treatment/analysis group. Events leading to study drug dose reductions will be identified as events having an investigational product action taken response of "Other" with a "Specify" value indicating a study drug dose reduction.

9.2.7 Adverse Events Leading to Death

Any AEs leading to death will be listed.

9.2.8 Adverse Events of Special Interest

Adverse events of special interest are grouped into three event categories: Neuropsychiatric (CNS), Falls, and Hallucinations. The CNS category combines the following SOCs: Nervous system disorder and Psychiatric disorder. The Falls category combines all PTs that contain the term "Fall" or "Falls". The Hallucinations category combines all PTs that contain the term "Hallucination".

Event incidence will be summarized treatment/analysis group.

Time to onset will be analyzed and is defined as the number of days from the first dose of study drug to the onset of the first AE in the category. Subjects will be censored at the latest date known not to have had such AE. The median time to event and the associated 95% confidence interval for the Placebo and 340 mg ADS-5102 treatment groups will be estimated using the Kaplan-Meier method. Kaplan-Meier estimates of the survival function will be calculated and displayed graphically.

9.3 Clinical Laboratory Evaluations

Clinical laboratory data for liver and renal function parameters will be integrated, listed, and summarized for the Safety population. Summaries for all other parameters are available in the individual study reports.

Laboratory assessments for these parameters were performed by a central laboratory. All summaries will be based on the SI units provided by the central lab.

Maximum on-treatment values will be summarized for the liver function parameters and minimum on-treatment values will be summarized for the renal function parameters. For both groups, the change from baseline to the maximum/minimum value will be presented.

All clinical laboratory measures will be classified as Low, Normal, or High, or Normal/Abnormal according to the normal ranges. These categorical data will be summarized in shift tables comparing the results at the baseline visit with the most abnormal results over the treatment period.

Liver function parameters include:

- Bilirubin
- Alkaline phosphatase
- γ-glutamyltransferase
- Alanine aminotransferase
- Aspartate aminotransferase

Renal function parameters include:

- Blood urea nitrogen
- Creatinine
- Estimated GFR – MDRD-NKDEP
- Estimated GFR – Cockcroft-Gault

Estimated GRF – Cockcroft-Gault values are not reported in the individual study databases and will be calculated as follows:

eCreatinine Clearance (ml/min/1.73 m^2) =

[1.73 x (140 – age) x wt (kg) x (0.85 if female) / Serum creatinine (mg/dL) x 72 x Body Surface Area;

Creatinine in mg/dL is rounded to 1 decimal place prior to applying the Cockcroft-Gault equation.

The equation to calculate Body surface area is described as following:

Body Surface Area(m^2) = $[weight\ (kg) \times height\ (cm)/3600]^{1/2}$

9.4 Vital Sign Measurements

Vital sign measures for systolic blood pressure, diastolic blood pressure, and heart rate will be integrated and listed for the Safety population. All other measurements will not be integrated. Summary tables are available in the individual study results.

Minimum and maximum on-study values and change from baseline will be presented by treatment/analysis group for sitting systolic blood pressure, sitting diastolic blood pressure, and heart rate.

10 References

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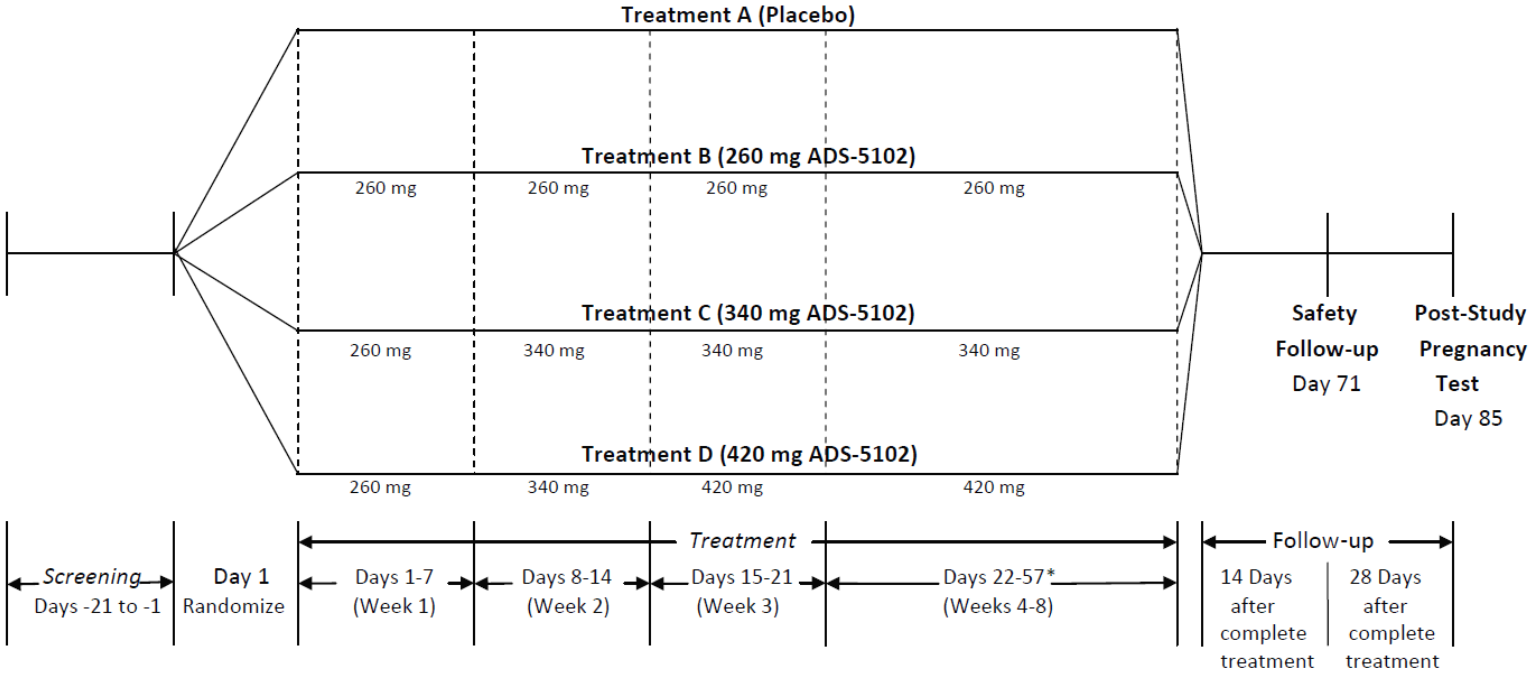
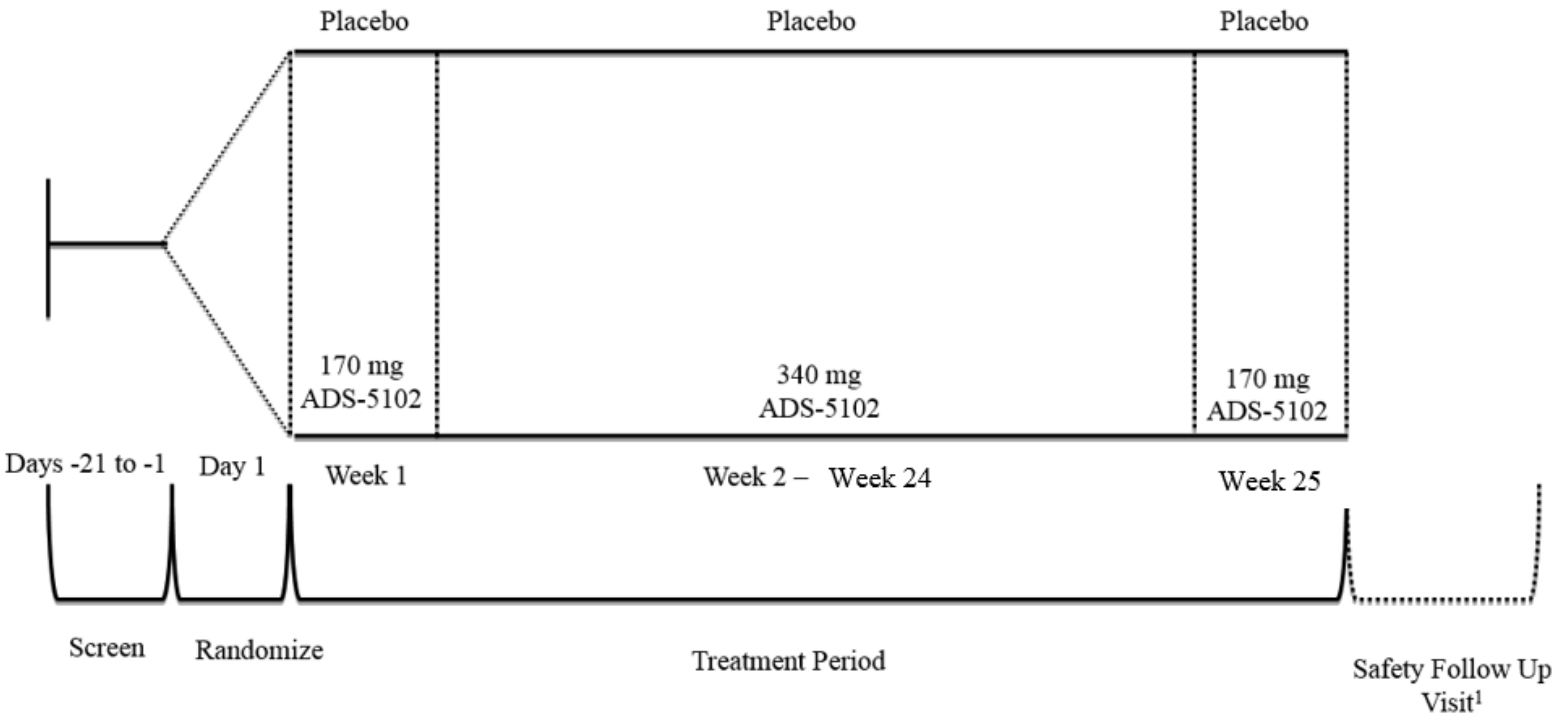
11 Appendices

11.1 Study Design Schematic for ADS-PAR-AM201



*The last dose of study medication is taken in the evening of Day 56; The final efficacy assessment is performed on Day 57.

11.2 Study Design Schematic for ADS-AMT-PD301



[1] Applicable only for subjects who complete 25 weeks of treatment and decline participation in the open-label extension

11.3 Study Design Schematic for ADS-AMT-PD302

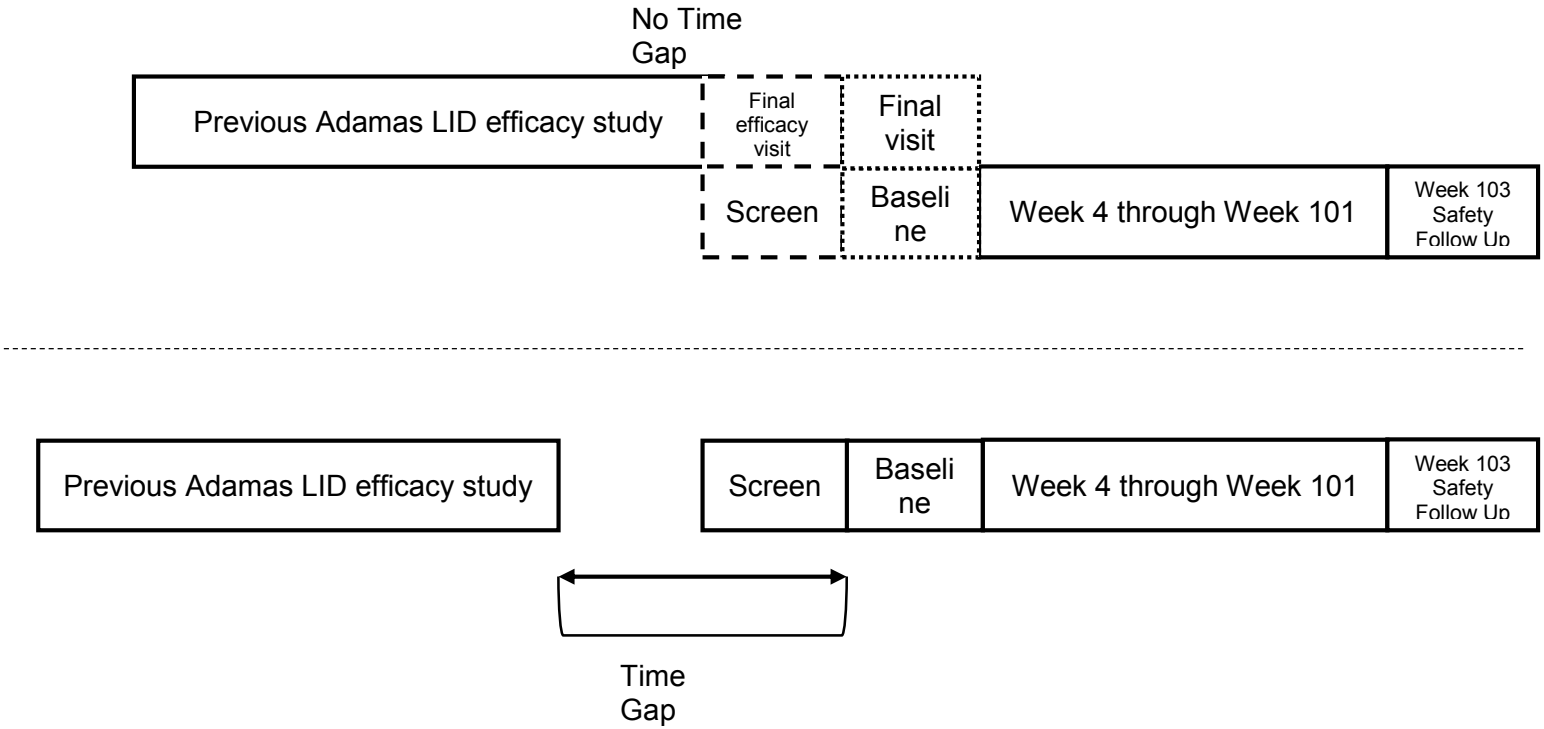


Table 1.1.1
Study Withdrawal and Reason for Withdrawal
Safety Population

	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)	All (N=xx) n (%)
Subjects who withdrew from any study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADS-PAR-AM201	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADS-AMT-PD301	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADS-AMT-PD302	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary reason for withdrawal					
Subject discontinued study drug and wished to withdraw[1]					
Subject unwilling to proceed	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject consent was withdrawn	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject lost to follow up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor's decision	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)

Note: Percentages are based on the number of subjects in the Safety Population in each treatment/analysis group. If a subject withdrew from more than one study, both events will be counted.
[1]Subjects who discontinued study drug were encouraged to complete all study assessments.
Source Data: Listing 2.1.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.1.2
Study Drug Discontinuation and Reason for Discontinuation
Safety Population

	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)	All (N=xx) n (%)
Subjects who discontinued study drug from any study[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADS-PAR-AM201	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADS-AMT-PD301	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADS-AMT-PD302	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary reason for study drug discontinuation					
Estimated glomerular filtration rate (eGFR) decreased to less than 50 mL/min/1.73m^2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Estimated glomerular filtration rate decreased to less than 30 mL/min/1.73m^2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive pregnancy test	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject unwilling to proceed	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject consent was withdrawn	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject lost to follow up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sponsor's decision	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)

Note: Percentages are based on the number of subjects in the Safety Population in each treatment group. If a subject withdrew from more than one study, both events will be counted.
[1]Subjects who discontinued study drug early were encouraged to complete all study assessments.
Source Data: Listing 2.1.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.1.3
Kaplan-Meier Analysis of Time to Study Drug Discontinuation
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Time to study drug discontinuation (Days)					
Event n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
10th percentile (days)	xx.x	xx.x	xx.x	xx.x	xx.x
25th percentile (days)	xx.x	xx.x	xx.x	xx.x	xx.x
50th percentile (days)	xx.x	xx.x	xx.x	xx.x	xx.x
75th percentile (days)	xx.x	xx.x	xx.x	xx.x	xx.x
90th percentile (days)	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
Median (days)					
Estimate	xx.x	xx.x	xx.x	xx.x	xx.x
95% CI	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx

Note: Percentages are calculated out of the number of subjects in each treatment/analysis group. "+" in MIN – MAX means censored value. The time to discontinuation is defined as the number of days from Analysis Day 1 to the last dose of study drug. Subjects will be censored if no study drug early discontinuation occurred. NE = Non-estimable.
Source Data: Listing 2.1.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Some percentiles will be non-estimable. When this occurs, use "NE[1]"

Table 1.2
Demographics and Baseline Characteristics
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Age (yrs)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Age categories (yrs) n (%)					
<65	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥65					
≥65 to <75	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥75	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex n (%)					
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race n (%)					
White	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-White	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)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	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)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentages are based on the number of subjects in the Safety Population in each treatment group.
Source Data: Listing 2.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.2
Demographics and Baseline Characteristics
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Ethnicity n (%)					
Hispanic or Latino	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)
Height (cm)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
< median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Body Mass Index (kg/m^2)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Percentages are based on the number of subjects in the Safety Population in each treatment group.
Source Data: Listing 2.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.2
Demographics and Baseline Characteristics
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Estimated GFR – MDRD (mL/min/1.73m^2)	xx	xx	xx	xx	xx
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
<60 n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥60 n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline MAO-B inhibitor medications n (%)					
Yes	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)
Baseline Dopamine Agonist medications n (%)					
Yes	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)
Prior deep brain stimulation n (%)					
Yes	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)
Geographic Region n (%)					
Eurpean Union	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
North America	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentages are based on the number of subjects in the Safety Population in each treatment group.
Source Data: Listing 2.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.3.1
Parkinson's Disease History
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Time since PD diagnosis (yrs)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
< median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Age at PD diagnosis (yrs)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
< median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Age at start of levodopa treatment (yrs)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note: Durations calculated using diagnosis/start/onset dates.
Source Data: Listing 2.3.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.3.1
Parkinson's Disease History
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Duration of levodopa treatment (yrs)					
N	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Duration of levodopa-induced dyskinesia					
N	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Baseline levodopa (any preparation) dose (mg)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
< median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ median n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Durations calculated using diagnosis/start/onset dates.
Source Data: Listing 2.3.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.3.2
Parkinson's Disease Related Baseline Characteristics
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
MDS-UPDRS: Part I					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
MDS-UPDRS: Part II					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
MDS-UPDRS: Part III					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
MDS-UPDRS: Combined (Part I, II, and III)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Source Data: Listings 2.3.2, 2.3.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.3.2
Parkinson's Disease Related Baseline Characteristics
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
MDS-UPDRS: Part IV					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
MDS-UPDRS: Part IV, Item 4.1					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
MDS-UPDRS: Part IV, Item 4.2					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
MMSE					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Source Data: Listings 2.3.2, 2.3.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.3.2
Parkinson's Disease Related Baseline Characteristics
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)	All (N=xx)
Hoehn and Yahr Stage					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Source Data: Listings 2.3.2, 2.3.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.4.1
Prior PD Medications
Safety Population

ATC LEVEL 1 ATC LEVEL 2 PD Medication Class Preferred Term Combined PREFERRED TERM	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)	All (N=xx) n (%)
Number (%) of subjects with any prior PD medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PD Medication Class	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term Combined 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term Combined 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Note: Subjects may have more than one medication per ATC level category and preferred term. At each level of subject summarization, a subject is counted once if the subject reported one or more medications. Prior medications were coded with the WHO Drug dictionary dated March, 2014. PD medications are medications indicated by the investigator as prescribed for PD and are classified as Anti-Parkinson Drugs.
Source Data: Listing 2.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Medications will be sorted in descending order by ATC level 1 category based on the total of all treatment groups. Within each ATC level category, preferred terms will be sorted in alphabetical order.

Table 1.4.2
Prior Non-PD Medications
Safety Population

ATC LEVEL 1 ATC LEVEL 2 PREFERRED TERM	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)	All (N=xx) n (%)
Number (%) of subjects with any Non-PD prior medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 1 #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 2 #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Note: Subjects may have more than one medication per ATC level category and preferred term. At each level of subject summarization, a subject is counted once if the subject reported one or more medications. Prior medications were coded with the WHO Drug dictionary dated March, 2014. Non-PD medications are medications indicated by the investigator as prescribed for non-PD related treatment. Anti-Parkinson Drugs may be listed if taken for a non-PD indication.
Source Data: Listing 2.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.4.3
Concomitant PD Medications
Safety Population

ATC LEVEL 1 ATC LEVEL 2 PD Medication Class Preferred Term Combined PREFERRED TERM	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)	All (N=xx) n (%)
Number (%) of subjects with any concomitant PD medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PD Medication Class	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term Combined 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term Combined 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Note: Subjects may have more than one medication per ATC level category and preferred term. At each level of subject summarization, a subject is counted once if the subject reported one or more medications. Concomitant medications were coded with the WHO Drug dictionary dated March, 2014. PD medications are medications indicated by the investigator as prescribed for PD and are classified as Anti-Parkinson Drugs.
Source Data: Listing 2.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.4.4
Concomitant Non-PD Medications
Safety Population

ATC LEVEL 1 ATC LEVEL 2 PREFERRED TERM	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)	All (N=xx) n (%)
Number (%) of subjects with any Non-PD concomitant medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 1 #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC LEVEL 2 #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PREFERRED TERM #4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Note: Subjects may have more than one medication per ATC level category and preferred term. At each level of subject summarization, a subject is counted once if the subject reported one or more medications. Concomitant medications were coded with the WHO Drug dictionary dated March, 2014. Non-PD medications are medications indicated by the investigator as prescribed for non-PD related treatment. Anti-Parkinson Drugs may be listed if taken for a non-PD indication.
Source Data: Listing 2.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.5
Study Drug Duration of Exposure
Safety Population

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)
Study drug duration of exposure (days)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Note: Treatment duration is defined as (Last dose date – First dose date) + 1. For subjects with a gap in treatment prior to enrolling in ADS-AMT-PD302, only data from ADS-AMT-PD302 is used.
Source Data: Listing 2.1.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.1
Overview of Adverse Events
Safety Population

	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)
Number (%) of subjects with any:				
AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study drug related serious AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number (%) of subjects who permanently discontinued study drug due to any:				
AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any AEs by highest intensity				
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any study drug related AEs by highest intensity				
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each treatment group.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.2
Overview of Adverse Events by Gender
Safety Population

Treatment: Placebo

	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Serious AEs	xx (xx.x)	xx (xx.x)
Study drug related serious AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects who permanently discontinued study drug due to any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any study drug related AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each treatment group.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.2
Overview of Adverse Events by Gender
Safety Population

Treatment: 340 mg ADS-5102

	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Serious AEs	xx (xx.x)	xx (xx.x)
Study drug related serious AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects who permanently discontinued study drug due to any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any study drug related AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each treatment group.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.2
Overview of Adverse Events by Gender
Safety Population

Treatment: ≥340mg ADS-5102

	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Serious AEs	xx (xx.x)	xx (xx.x)
Study drug related serious AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects who permanently discontinued study drug due to any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any study drug related AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each treatment group.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.2
Overview of Adverse Events by Gender
Safety Population

Treatment: ADS-5102

	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Serious AEs	xx (xx.x)	xx (xx.x)
Study drug related serious AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects who permanently discontinued study drug due to any		
AEs	xx (xx.x)	xx (xx.x)
Study drug related AEs	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Number (%) of subjects with any study drug related AEs by highest intensity		
Mild	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.3
Overview of Adverse Events by Age
Safety Population

Repeat of 1.6.1.2

Columns:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.4
Overview of Adverse Events by Race
Safety Population

Repeat of 1.6.1.2

Columns:
1. White
2. Non-White

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.5
Overview of Adverse Events by Baseline Renal Function
Safety Population

Repeat of 1.6.1.2

Columns:
1. Estimated GFR <60
2. Estimated GFR ≥60

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.6
Overview of Adverse Events by Weight
Safety Population

Repeat of 1.6.1.2
Columns:
1. < median
2. ≥ median

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.7
Overview of Adverse Events by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 1.6.1.2

Columns:
1. Yes
2. No

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.8
Overview of Adverse Events by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 1.6.1.2

Columns:
1. < median
2. ≥ median

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.9
Overview of Adverse Events by Baseline Baseline Levodopa Dose
Safety Population

Repeat of 1.6.1.2

Columns:
3. < median
4. ≥ median

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.10
Overview of Adverse Events by Time Since PD Diagnosis in Years
Safety Population

Repeat of 1.6.1.2

Columns:
1. < median
2. ≥ median

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.11
Overview of Adverse Events by Age at PD Diagnosis
Safety Population

Repeat of 1.6.1.2

Columns:
1. < median
2. ≥ median

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.12
Overview of Adverse Events by Prior Deep Brain Stimulation
Safety Population

Repeat of 1.6.1.2

Columns:
1. Yes
2. No

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.1.13
Overview of Adverse Events by Geographic Region
Safety Population

Repeat of 1.6.1.2

Columns:
1. European Union
2. North America

Note: A subject is counted once for each type of event. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.1
Adverse Events, by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.2
Adverse Events, by System Organ Class, Preferred Term by Gender
Safety Population

Treatment: Placebo

System Organ Class Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
System Organ Class 2	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)

…

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Sort by descending total frequency for the treatment/analysis group displayed.

Table 1.6.2.2
Adverse Events, by System Organ Class, Preferred Term by Gender
Safety Population

Treatment: 340mg ADS-5102

System Organ Class Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
System Organ Class 2	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
…		

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Sort by descending total frequency for the treatment/analysis group displayed.

Table 1.6.2.2
Adverse Events, by System Organ Class, Preferred Term by Gender
Safety Population

Treatment: ≥340mg ADS-5102

System Organ Class Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
System Organ Class 2	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
…		

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Sort by descending total frequency for the treatment/analysis group displayed.

Table 1.6.2.2
Adverse Events, by System Organ Class, Preferred Term by Gender
Safety Population

Treatment: ADS-5102

System Organ Class Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
System Organ Class 2	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)

…

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Sort by descending total frequency for the treatment/analysis group displayed.

Table 1.6.2.3
Adverse Events, by System Organ Class, Preferred Term by Age
Safety Population

Repeat of 1.6.2.2

Columns:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.4
Adverse Events, by System Organ Class, Preferred Term by Race
Safety Population

Repeat of 1.6.2.2

Columns:
1. White
2. Non-White

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.5
Adverse Events, by System Organ Class, Preferred Term by Baseline Renal Function
Safety Population

Repeat of 1.6.2.2

Columns:
1. Estimated GFR <60
2. Estimated GFR ≥60

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.6
Adverse Events, by System Organ Class, Preferred Term by Weight
Safety Population

Repeat of 1.6.2.2

Columns:
1. < median
2. ≥ median

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.7
Adverse Events, by System Organ Class, Preferred Term by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 1.6.2.2

Columns:
1. Yes
2. No

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.8
Adverse Events, by System Organ Class, Preferred Term by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 1.6.2.2

Columns:
1. Yes
2. No

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.9
Adverse Events, by System Organ Class, Preferred Term by Baseline Levodopa Dose
Safety Population

Repeat of 1.6.2.2

Columns:
1. < median
2. ≥ median

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.10
Adverse Events, by System Organ Class, Preferred Term by Time since PD Diagnosis in Years
Safety Population

Repeat of 1.6.2.2

Columns:
3. < median
4. ≥ median

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.11
Adverse Events, by System Organ Class, Preferred Term by Age at PD Diagnosis
Safety Population

Repeat of 1.6.2.2

Columns:
1. < median
2. ≥ median

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.12
Adverse Events, by System Organ Class, Preferred Term by Prior Deep Brain Stimulation
Safety Population

Repeat of 1.6.2.2

Columns:
1. Yes
2. No

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.2.13
Adverse Events, by System Organ Class, Preferred Term by Geographic Region
Safety Population

Repeat of 1.6.2.2

Columns:
1. European Union
2. North America

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each subgroup category for the given treatment/analysis group.
AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.3
Most Common Adverse Events (at least 2% of subjects)
Safety Population

Preferred Term	Placebo (N=xx) n (%)	340mg ADS-5102 (N=xx) n (%)	≥340mg ADS-5102 (N=xx) n (%)	ADS-5102 (N=xx) n (%)
Number (%) of subjects with any AEs experienced by ≥2% of subjects	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 6	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

Note: A subject is counted once within each preferred term. Percentages are calculated out of the number of subjects in the active treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Sort by descending frequency in ADS-5102 treatment group

Table 1.6.4
Study-Drug Related Adverse Events, by System Organ Class and Preferred Term
Safety Population

Same display as 1.6.2.1

Note: A subject is counted once within each preferred term. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.5
Adverse Events by Highest Intensity, System Organ Class and Preferred Term
Safety Population

Treatment: Placebo

System Organ Class Preferred Term	(N=xx) n (%) Mild	Moderate	Severe	Total
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.5
Adverse Events by Highest Intensity, System Organ Class and Preferred Term
Safety Population

Treatment: 340mg ADS-5102

System Organ Class Preferred Term	(N=xx) n (%) Mild	Moderate	Severe	Total
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.5
Adverse Events by Highest Intensity, System Organ Class and Preferred Term
Safety Population

Treatment: ≥340mg ADS-5102

System Organ Class Preferred Term	(N=xx) n (%) Mild	Moderate	Severe	Total
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.5
Adverse Events by Highest Intensity, System Organ Class and Preferred Term
Safety Population

Treatment: ADS-5102

System Organ Class Preferred Term	(N=xx) n (%) Mild	Moderate	Severe	Total
Number (%) of subjects with any AEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.6
Listing of Serious Adverse Events
Safety Population

Subject Identifier	Study Identifier	Treatment	System Organ Class/ Preferred Term/ VERBATIM TERM	Start Date (Day)/ Stop Date (Day)/ Duration (Days)[1]	Intensity/ Causality/ Outcome/ Action Taken
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Mild/ Not Related/ Recovered/Resolved/ Dose not changed
XXXXX-XX-XXX	XXXXX	340mg ADS-5102	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Moderate/ Related/ Recovered/Resolved with sequelae/ Drug Interrupted
XXXXX-XX-XXX	XXXXX	340mg ADS-5102	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Severe/ Not Related/ Unknown/ Drug Withdrawn
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Mild/ Related/ Not Recovered/Not resolved/ Other
XXXXX-XX-XXX	XXXXX	340mg ADS-5102	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Severe/ Not Related/ Fatal/ Dose not changed

[1]Duration (Days) = Stop date – Start date + 1.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.7
Adverse Events Leading to Study Drug Discontinuation, by System Organ Class and Preferred Term
Safety Population

Same display as 1.6.2.1

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.8
Adverse Events Leading to Study Drug Dose Reduction, by System Organ Class and Preferred Term
Safety Population

Same display as 1.6.2.1

Note: A subject is counted once within each preferred term and system organ class. Percentages are calculated out of the number of subjects in each treatment/analysis group. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.9
Listing of Adverse Events Leading to Death
Safety Population

Same display as 1.6.6, with outcome “Death”.

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[1]Dur = Duration (Days = Stop date – Start date + 1).
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.1
Incidence of AE (Neuropsychiatric)
Safety Population

System Organ Class Preferred Term	Placebo	340mg ADS-5102	≥340mg ADS-5102	ADS-5102
Number of AE (Neuropsychiatric) events	xx	xx	xx	xx
System Organ Class 1	xx	xx	xx	xx
Preferred Term 1	xx	xx	xx	xx
Preferred Term 2	xx	xx	xx	xx
Preferred Term 3	xx	xx	xx	xx
…	xx	xx	xx	xx
	xx	xx	xx	xx
System Organ Class 2	xx	xx	xx	xx
Preferred Term 1	xx	xx	xx	xx
Preferred Term 2	xx	xx	xx	xx
Preferred Term 3	xx	xx	xx	xx

Note: The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. AEs are coded using MedDRA Version 17.0.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.2
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric)
Safety Population

	Placebo (N=xx)	340 mg ADS-5102 (N=xx)
Days to onset of first AE: Neuropsychiatric		
Event n(%)	xx (xx.x)	xx (xx.x)
10th percentile (days)	xx.x	xx.x
25th percentile (days)	xx.x	xx.x
50th percentile (days)	xx.x	xx.x
75th percentile (days)	xx.x	xx.x
90th percentile (days)	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x
Median (days)		
Estimate	xx.x	xx.x
95% CI	x.xx, x.xx	x.xx, x.xx

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Some percentiles will be non-estimable. When this occurs, use "NE[1]"

Table 1.6.10.3
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Gender
Safety Population

Gender: Female

	Placebo (N=xx)	340 mg ADS-5102 (N=xx)
Days to onset of first AE: Neuropsychiatric		
Event n(%)	xx (xx.x)	xx (xx.x)
10th percentile (days)	xx.x	xx.x
25th percentile (days)	xx.x	xx.x
50th percentile (days)	xx.x	xx.x
75th percentile (days)	xx.x	xx.x
90th percentile (days)	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x
Median (days)		
Estimate	xx.x	xx.x
95% CI	x.xx, x.xx	x.xx, x.xx

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Some percentiles will be non-estimable. When this occurs, use "NE[1]"

Table 1.6.10.3
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Gender
Safety Population

Gender: Male

	Placebo (N=xx)	340 mg ADS-5102 (N=xx)
Days to onset of first AE: Neuropsychiatric		
Event n(%)	xx (xx.x)	xx (xx.x)
10th percentile (days)	xx.x	xx.x
25th percentile (days)	xx.x	xx.x
50th percentile (days)	xx.x	xx.x
75th percentile (days)	xx.x	xx.x
90th percentile (days)	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x
Median (days)		
Estimate	xx.x	xx.x
95% CI	x.xx, x.xx	x.xx, x.xx

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Some percentiles will be non-estimable. When this occurs, use "NE[1]"

Table 1.6.10.4
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Age
Safety Population

Repeat of 1.6.10.3

Age:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.5
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Race
Safety Population

Repeat of 1.6.10.3

Race:
1. White
2. Non-White

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.6
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline Renal Function
Safety Population

Repeat of 1.6.10.3

Baseline Renal Function:
1. Estimated GFR <60
2. Estimated GFR ≥60

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.7
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Weight
Safety Population

Repeat of 1.6.10.3

Weight:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.8
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 1.6.10.3

Baseline MAO-B Inhibitors:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.9
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 1.6.10.3

Baseline Dopamine Agonist Medications:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.10
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline Levodopa Dose
Safety Population

Repeat of 1.6.10.3

Baseline Levodopa Dose:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.11
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) Time since PD Diagnosis in Years
Safety Population

Repeat of 1.6.10.3

Time since PD Diagnosis in Years:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.12
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Age at PD Diagnosis
Safety Population

Repeat of 1.6.10.3

Age at PD Diagnosis:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.13
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Prior Deep Brain Stimulation
Safety Population

Repeat of 1.6.10.3

Prior Deep Brain Stimulation:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.10.14
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Geographic Region
Safety Population

Repeat of 1.6.10.3

Geographic Region:
1. European Union
2. North America

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Neuropsychiatric category combines the following System of Organs: Nervous system disorder and Psychiatric disorder. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.1
Incidence of AE (Falls)
Safety Population

Repeat of 1.6.10.1

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.2
Kaplan-Meier Analysis of Time to Onset of AE (Falls)
Safety Population

Repeat of 1.6.10.2

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Some percentiles will be non-estimable. When this occurs, use "NE[1]"

Table 1.6.11.3
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Gender
Safety Population

Repeat of 1.6.10.3

Gender:
1. Female
2. Male

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.4
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Age
Safety Population

Repeat of 1.6.10.3
Age:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.5
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Race
Safety Population

Repeat of 1.6.10.3

Race:
1. White
2. Non-White

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.6
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline Renal Function
Safety Population

Repeat of 1.6.10.3

Baseline Renal Function:
1. Estimated GFR <60
2. Estimated GFR ≥60

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.7
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Weight
Safety Population

Repeat of 1.6.10.3

Weight:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.8
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 1.6.10.3

Baseline MAO-B Inhibitors:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.9
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 1.6.10.3

Baseline Dopamine Agonist Medications:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.10
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline Levodopa Dose
Safety Population

Repeat of 1.6.10.3

Baseline Levodopa Dose:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.11
Kaplan-Meier Analysis of Time to Onset of AE (Falls) Time since PD Diagnosis in Years
Safety Population

Repeat of 1.6.10.3

Time since PD Diagnosis in Years:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.12
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Age at PD Diagnosis
Safety Population

Repeat of 1.6.10.3

Age at PD Diagnosis:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.]
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.13
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Prior Deep Brain Stimulation
Safety Population

Repeat of 1.6.10.3

Prior Deep Brain Stimulation:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.11.14
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Geographic Region
Safety Population

Repeat of 1.6.10.3

Geographic Region:
1. European Union
2. North America

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Falls category combines all Preferred Terms that contain the terms "Fall" or "Falls". Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.6.12.1
Incidence of AE (Hallucinations)
Safety Population

Repeat of 1.6.10.1

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.2
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations)
Safety Population

Repeat of 1.6.10.2

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Programming Note: Some percentiles will be non-estimable. When this occurs, use "NE[1]"

1.6.12.3
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Gender
Safety Population

Repeat of 1.6.10.3

Gender:
1. Female
2. Male

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.4
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Age
Safety Population

Repeat of 1.6.10.3

Age:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.5
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Race
Safety Population

Repeat of 1.6.10.3

Race:
1. White
2. Non-White

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.6
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline Renal Function
Safety Population

Repeat of 1.6.10.3

Baseline Renal Function:
1. Estimated GFR <60
2. Estimated GFR ≥60

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.7
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Weight
Safety Population

Repeat of 1.6.10.3

Weight:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.8
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 1.6.10.3

Baseline MAO-B Inhibitors:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.9
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 1.6.10.3

Baseline Dopamine Agonist Medications:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.10
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline Levodopa Dose
Safety Population

Repeat of 1.6.10.3

Baseline Levodopa Dose:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.11
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) Time since PD Diagnosis in Years
Safety Population

Repeat of 1.6.10.3

Time since PD Diagnosis in Years:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.12
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Age at PD Diagnosis
Safety Population

Repeat of 1.6.10.3

Age at PD Diagnosis:
1. < median
2. ≥ median

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.13
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Prior Deep Brain Stimulation
Safety Population

Repeat of 1.6.10.3

Prior Deep Brain Stimulation:
1. Yes
2. No

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

1.6.12.14
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Geographic Region
Safety Population

Repeat of 1.6.10.3

Geographic Region:
1. European Union
2. North America

Note: Percentages are calculated out of the number of subjects in each treatment group. "+" in MIN – MAX means censored value. AEs are coded using MedDRA Version 17.0. NE = Non-estimable.
Note: The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.7.1.1
Liver Function Tests
Safety Population

Parameter: XXXXX (units)

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)
Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Maximum				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Change From Baseline[1]				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Note: Baseline is defined as last available value prior to ther first dose of study medication for a particular treatment.
[1]Change from baseline: post-baseline value – baseline value. For the change from baseline, only subjects with a value at both the baseline visit and the specific post-baseline visit are included.
Source Data: Listing 2.7.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Parameters: Bilirubin, Alkaline phosphatase, γ-glutamyltransferase, Alanine aminotransferase, Aspartate aminotransferase

Table 1.7.1.2
Liver Function Tests - Shifts from Baseline to Worst On-Study Value
Safety Population

Parameter: XXXXXXXXXXXX (unit)

	Baseline			
	Low n (%)	Normal n (%)	High n (%)	Missing n (%)
Placebo (N = XXX)				
Low	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)
High	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)
340mg ADS-5102 (N = XXX)				
Low	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)
High	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)
≥340mg ADS-5102 (N = XXX)				
Low	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)
High	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)
ADS-5102 (N = XXX)				
Low	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)
High	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)

Note: Baseline is defined as last available value prior to ther first dose of study medication for a particular treatment. The worst value is defined as the maximum on-study value. High = Higher than the upper limit of the normal range, Low = Lower than the lower limit of the normal range, Normal = within the lower and upper limits of the normal range. Percentages are based on the number of subjects in each treatment/analysis group.
Source Data: Listing 2.7.1

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.7.2.1
Renal Function Tests
Safety Population

Repeat of 1.7.1.1

Note: Baseline is defined as last available value prior to ther first dose of study medication for a particular treatment.
[1]Change from baseline: post-baseline value – baseline value. For the change from baseline, only subjects with a value at both the baseline visit and the specific post-baseline visit are included.
Source Data: Listing 2.7.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Parameters: Blood Urea Nitrogen, Creatinine, Estimated GFR – MDRD, Estimated GFR – Cockcroft-Gault

Table 1.7.2.2
Renal Function Tests - Shifts from Baseline to Worst On-Study Value
Safety Population

Repeat of 1.7.1.2

Note: Baseline is defined as last available value prior to ther first dose of study medication for a particular treatment. The worst value is defined as the minimum on-study value. High = Higher than the upper limit of the normal range, Low = Lower than the lower limit of the normal range, Normal = within the lower and upper limits of the normal range. Percentages are based on the number of subjects in each treatment/analysis group.
Source Data: Listing 2.7.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Table 1.8
Vital Signs
Safety Population

Parameter: XXXXX (units)

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)
Baseline				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Minimum				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Maximum				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Note: Baseline is defined as last available value prior to ther first dose of study medication for a particular treatment. For the change from baseline, only subjects with a value at both the baseline visit and the specific post-baseline visit are included.
Source Data: Listing 2.8

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Parameters: Sitting Systolic BP, Sitting Diastolic DP, Heart Rate

Table 1.8
Vital Signs
Safety Population

Parameter: XXXXX (units)

	Placebo (N=xx)	340mg ADS-5102 (N=xx)	≥340mg ADS-5102 (N=xx)	ADS-5102 (N=xx)
Change from Baseline (Minimum)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Change from Baseline (Maximum)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Note: Baseline is defined as last available value prior to ther first dose of study medication for a particular treatment. For the change from baseline, only subjects with a value at both the baseline visit and the specific post-baseline visit are included.
Source Data: Listing 2.8

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Parameters: Sitting Systolic BP, Sitting Diastolic DP, Heart Rate

Listing 2.1.1 Subject Identification Lookup Table Safety Population
Listing 2.1.2 Study Withdrawal and Reason for Withdrawal Safety Population
Listing 2.1.3 Study Drug Discontinuation and Reason for Discontinuation Safety Population
Listing 2.2 Demographics and Other Baseline Characteristics Safety Population
Listing 2.3.1 Parkinson's Disease History Safety Population
Listing 2.3.2 Parkinson's Disease-Related Baseline Characteristics (Part I) Safety Population
Listing 2.3.3 Parkinson's Disease-Related Baseline Characteristics (Part II) Safety Population
Listing 2.4 Prior and Concomitant Medications Safety Population
Listing 2.6.1 Adverse Events Safety Population
Listing 2.6.2 Adverse Events Leading to Study Drug Dose Reduction Safety Population
Listing 2.6.3 Adverse Events Leading to Study Drug Discontinuation Safety Population
Listing 2.7.1 Laboratory Results – Liver Function Tests Safety Population
Listing 2.7.2 Laboratory Results – Renal Function Tests Safety Population
Listing 2.8 Vital Sign Results Safety Population

Listing 2.1.1
Subject Identification Lookup Table
Safety Population

Subject Identifier	Unique Subject Identifier	Study Identifier	Study Subject Identifier
XXXXX-XX-XXX	ADS-XXX-XXXXX-XX-XXX	AM201	XXX
	ADS-XXX-XXXXX-XX-XXX	PD302	XX-X-XXX
XXXXX-XX-XXX	ADSXXXXXXXX-XX-X-XXX	PD301	XX-X-XXX
XXXXX-XX-XXX	ADSXXXXXXXX-XX-X-XXX	PD302	XX-X-XXX

Listing 2.1.2
Study Withdrawal and Reason for Withdrawal
Safety Population

Subject Identifier	Study Identifier	Treatment	First Dose Date/ Last Dose Date/	Subject Completed Study	Reason for Not Completing Study
XXXXX-XX-XXX	XXXXX	Placebo	DDMMMYYYY/ DDMMMYYYY	Y	
	XXXXX	340mg ADS-5102	DDMMMYYYY/ DDMMMYYYY	N	INTOLERABLE OR UNACCEPTABLE AES
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	DDMMMYYYY/ DDMMMYYYY	Y	
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	DDMMMYYYY/ DDMMMYYYY	N	NON-COMPLIANCE WITH STUDY DRUG

Listing 2.1.3
Study Drug Discontinuation and Reason for Discontinuation
Safety Population

Subject Identifier	Study Identifier	Treatment	First Dose Date/ Last Dose Date/ Treatment Duration (Days)[1]	Subject Completed Treatment	Reason for Not Completing Treatment
XXXXX-XX-XXX	XXXXX	Placebo	DDMMMYYYY/ DDMMMYYYY/ XX	Y	
	XXXXX	340mg ADS-5102	DDMMMYYYY/ DDMMMYYYY/ XX	N	INTOLERABLE OR UNACCEPTABLE AES
XXXXX-XX-X-XXX	XXXXX	260mg ADS-5102	DDMMMYYYY/ DDMMMYYYY/ XX	Y	
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	DDMMMYYYY/ DDMMMYYYY/ XX	N	NON-COMPLIANCE WITH STUDY DRUG

[1] Treatment duration is defined as (Last dose date – First dose date) + 1.

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.2
Demographics and Other Baseline Characteristics
Safety Population

Subject Identifier	Study Identifier	Treatment	Age(yrs)/ Sex[1]/ Race[2]/ Ethnicity[3]	Country/ Geographic Region	Height(cm)/ Weight(kg)/ BMI(kg/m^2)	Baseline Estimated GFR (mL/min/1.73m2)	Baseline MAO-B Inhibitor/ Baseline Dopamine Agonist	Prior DBS
XXXXX-XX-X-XXX	XXXXX	Placebo	50/ M/ W/ HL	Canada/ North America	xxx.x/ xxx.x/ xx.x	xx.x	Y/N	Y
	XXXXX	340mg ADS-5102	51/ M/ W/ HL	Canada/ North America	xxx.x/ xxx.x/ xx.x	xx.x	Y/N	Y
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	60/ F/ O/ NHL	Austria/ European Union	xxx.x/ xxx.x/ xx.x	xx.x	Y/Y	N
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	65/ M/ PI/ NHL	United States/ North America	xxx.x/ xxx.x/ xx.x	xx.x	N/N	N

Note: BMI = Body mass index, DBS = Deep Brain Stimulation
[1] F = Female, M = Male
[2] AI = American Indian or Alaska Native, AS = Asian, B = Black or African American, PI = Native Hawaiian or Other Pacific Islander, W = White, O = Other
[3] HL = Hispanic or Latino, NHL = Not Hispanic or Latino

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.3.1
Parkinson's Disease History
Safety Population

Subject Identifier	Study Identifier	Treatment	Age at PD Diagnosis (yrs.)	Time Since PD Diagnosis (yrs.)[1]	Age at Start of Levodopa Treatment (yrs.)	Duration of Levodopa Treatment (yrs.)[1]	Duration of LID (yrs.)[1]	Baseline Levodopa Dose (mg)[2]
XXXXX-XX-X-XXX	XXXXX	Placebo	xx	x	x	x.x	x.x	xx.x
	XXXXX	340mg ADS-5102	xx	x	x	x.x	x.x	xx.x
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	xx	x	x	x.x	x.x	xx.x
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	xx	x	x	x.x	x.x	xx.x

Note: PD = Parkinson's disease, LID = Levodopa-induced dyskinesia, # indicates an imputed date.
[1]Time since Parkinson's disease diagnosis = (Analysis Day 1 – Date of diagnosis of Parkinson's disease)/ 365.25. When only the month and year of diagnosis are available, the 15th day of the indicated month is assumed, and when only the year of diagnosis is available, July 1 of the indicated year is assumed. A similar algorithm is used for duration of levodopa treatment, and duration of levodopa-induced dyskinesia.
[2] Baseline total levodopa dosage is defined as the levodopa medication (any preparation) with last start date prior to first dose of study medication.

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.3.2
Parkinson's Disease-Related Baseline Characteristics (Part I)
Safety Population

Subject Identifier	Study Identifier	Treatment	MDS-UPDRS Part I	MDS-UPDRS Part II	MDS-UPDRS Part III	MDS-UPDRS Combined	MDS-UPDRS Part IV
XXXXX-XX-X-XXX	XXXXX	Placebo	xx	x	x	x.x	x.x
	XXXXX	340mg ADS-5102	xx	x	x	x.x	x.x
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	xx	x	x	x.x	x.x
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	xx	x	x	x.x	x.x

Note: PD = Parkinson’s disease, LID = Levodopa-induced dyskinesia, # indicates an imputed date.
[1]Time since Parkinson’s disease diagnosis = (Analysis Day 1 – Date of diagnosis of Parkinson’s disease)/ 365.25. When only the month and year of diagnosis are available, the 15th day of the indicated month is assumed, and when only the year of diagnosis is available, July 1 of the indicated year is assumed. A similar algorithm is used for duration of levodopa treatment, and duration of levodopa–induced dyskinesia.
[2] Baseline total levodopa dosage is defined as the levodopa medication (any preparation) with last start date prior to first dose of study medication.

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.3.3
Parkinson's Disease-Related Baseline Characteristics (Part II)
Safety Population

Subject Identifier	Study Identifier	Treatment	MDS-UPDRS Part IV Item 4.1	MDS-UPDRS Part IV Item 4.2	MMSE Score	Hoehn and Yahr Stage
XXXXX-XX-X-XXX	XXXXX	Placebo	xx	x	x	x.x
	XXXXX	340mg ADS-5102	xx	x	x	x.x
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	xx	x	x	x.x
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	xx	x	x	x.x

Listing 2.4
Prior and Concomitant Medications
Safety Population

Subject Identifier	Study Identifier	Treatment	ATC TERM/ PREFFERED TERM/ MEDICATION REPORTED	Indication	Start Date/ Stop Date/ Flag[1]	Dose/ Unit/ Route/ Frequency
XXXXX-XX-X-XXX	XXXXX	Placebo	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	XXXXXXXXXX	DDMMMYYYY/ Ongoing/ P	XXXXX/ XXXXXX/ XXXXXX/ XXXXXX
XXXXX-XX-XXX	XXXXX	340mg ADS-5102	XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	XXXXXXXXXX	DDMMMYYYY/ DDMMMYYYY/ P/C	XXXXX/ XXXXXX/ XXXXXX/ XXXXXX

Note: Freq = Frequency
Prior medications are defined as medications taken within the 30 days that started and stopped prior to Analysis Day 1 (first day of study drug administration).
[1]P=Prior medication, C=Concomitant medication
Prior and concomitant medications were coded with the WHO Drug dictionary dated MAR 2014.

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.6.1
Adverse Events
Safety Population

Subject Identifier	Study Identifier	Treatment	System Organ Class/ Preferred Term/ VERBATIM TERM	Start Date (Day)/ Stop Date (Day)/ Duration (Days)[1]	Serious/ Intensity/ Causality/ Outcome/ Action Taken
XXXXX-XX-X-XXX	XXXXX	Placebo	XXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Yes/ Mild/ Not Related/ Recovered/Resolved/ Dose not changed
XXXXX-XX-XXX	XXXXX	340mg ADS-5102	XXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	No/ Moderate/ Related/ Recovered/Resolved with sequelae/ Drug Interrupted
XXXXX-XX-XXX	XXXXX	260mg ADS-5102	XXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Yes/ Severe/ Not Related/ Unknown/ Drug Withdrawn
XXXXX-XX-XXX	XXXXX	420mg ADS-5102	XXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	No/ Mild/ Related/ Not Recovered/Not resolved/ Other
XXXXX-XX-XXX	XXXXX	340mg ADS-5102	XXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMMMYYYY (xx)/ DDMMMYYYY (xx)/ XX	Yes/ Severe/ Not Related/ Fatal/ Dose not changed

[1]Duration (Days = Stop date – Start date + 1).
Adverse events are coded using MedDRA Version 17.0.

Listing 2.6.2
Adverse Events Leading to Study Drug Dose Reduction
Safety Population

Same layout as X.X

---

[1]Duration (Days = Stop date — Start date + 1).
Adverse events are coded using MedDRA Version 17.0.

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.6.3
Adverse Events Leading to Study Drug Discontinuation
Safety Population

Same layout as X.X

---

[1]Duration (Days = Stop date — Start date + 1).
Adverse events are coded using MedDRA Version 17.0.

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.7.1
Laboratory Results – Liver Function Tests
Safety Population

Subject Identifier	Study Identifier	Treatment	Sample Date	Laboratory Test	Result	Units	Flag	Normal Range
XXXXX-XX-X-XXX	XXXXX	260mg ADS-5102	DDMMMYYYY	XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X
				XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X
			DDMMMYYYY	XXXXXXXXXXXXXXX	XXX.X	XXXXX	L*	XXX.X-XXX.X
				XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X
	XXXXX	340mg ADS-5102	DDMMMYYYY	XXXXXXXXXXXXXXX	XXX.X	XXXXX	H	XXX.X-XXX.X
				XXXXXXXXXXXXXXX	XXX.X	XXXXX	H	XXX.X-XXX.X
			DDMMMYYYY	XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X
				XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X

Note: H = Above Normal Range, L = Below Normal Range, N = Normal, * indicates minimum value

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Listing 2.7.2
Laboratory Results – Renal Function Tests
Safety Population

Same as X.X

Note: H = Above Normal Range, L = Below Normal Range, N = Normal, * indicates maximum value

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

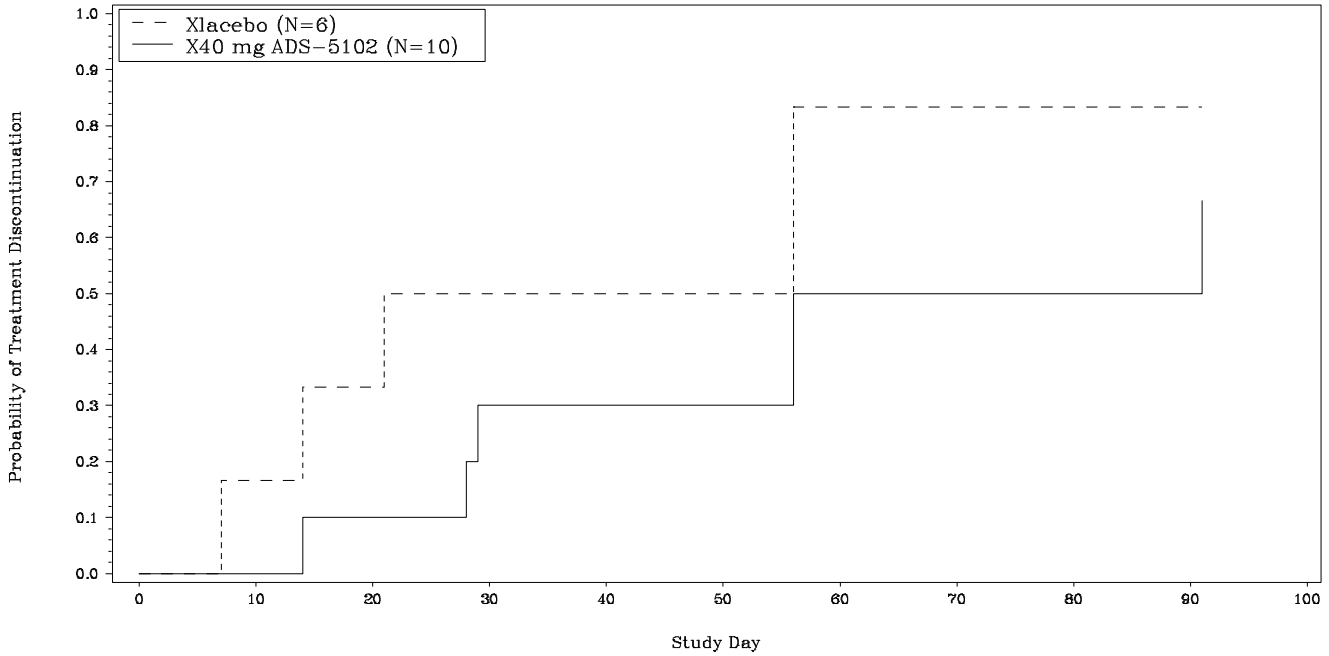
Listing 2.8
Vital Sign Results
Safety Population

Subject Identifier	Study Identifier	Treatment	Test Date	Blood Pressure(mmHg)		Heart Rate (bpm)	Height (cm)	Weight (kg)
				Sitting Systolic/Diastolic	Standing Systolic/Diastolic			
XXXXX-XX-X-XXX	XXXXX	260mg ADS-5102	DDMMMYYYY	xx/xx	xx/xx	xxx	xxx.x	xx.x
			DDMMMYYYY	xx/xx		xxx		
		340mg ADS-5102	DDMMMYYYY	xx/xx	xx/xx	xxx	xxx.x	xx.x

Heart Rate (bpm=beats/minute)

<DIRECTORY PATH>PROGRAM NAME Executed: DDMMMYYYY hh:mm

Figure 3.1
Kaplan-Meier Analysis of Time to Study Drug Discontinuation
Safety Population

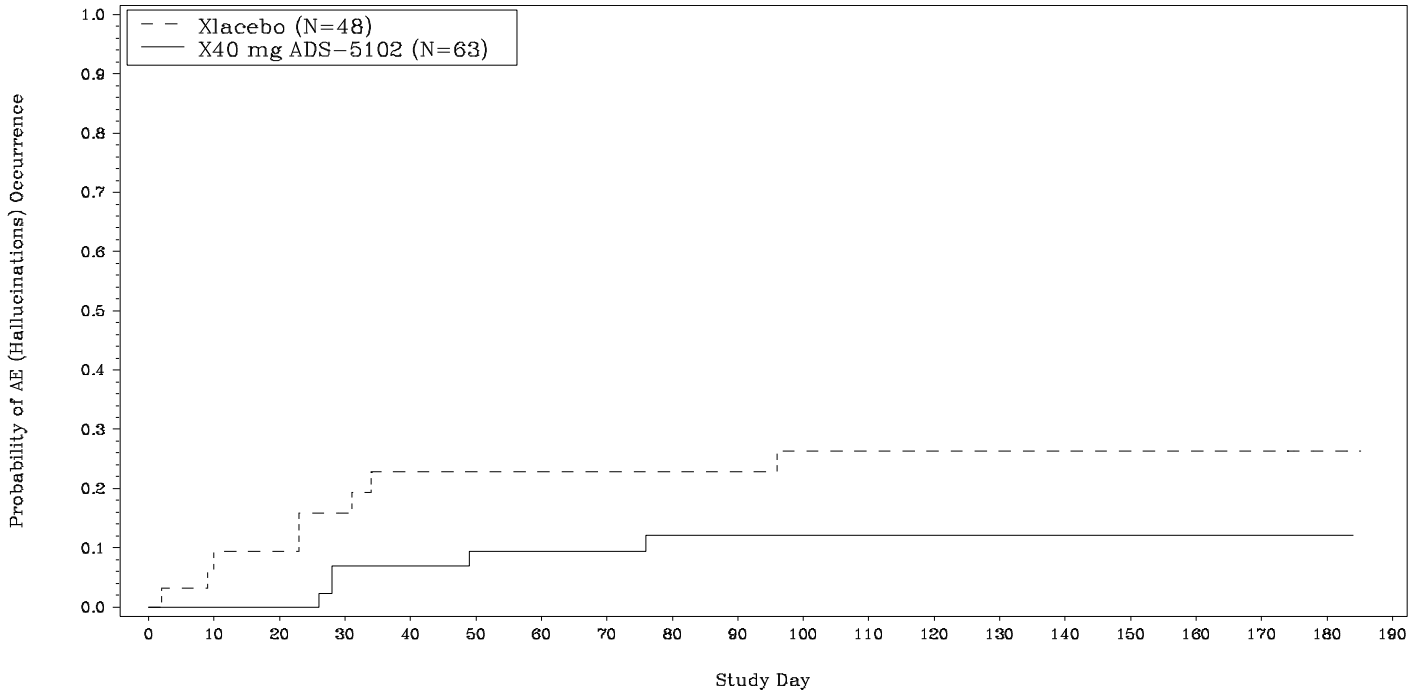


Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored if study drug was not discontinued at or before the last contact.
Source Data: Listing 2.1.3, Table 1.1.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Programming note: All treatment/analysis groups will be presented.

Figure 3.6.1.1
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric)
Safety Population

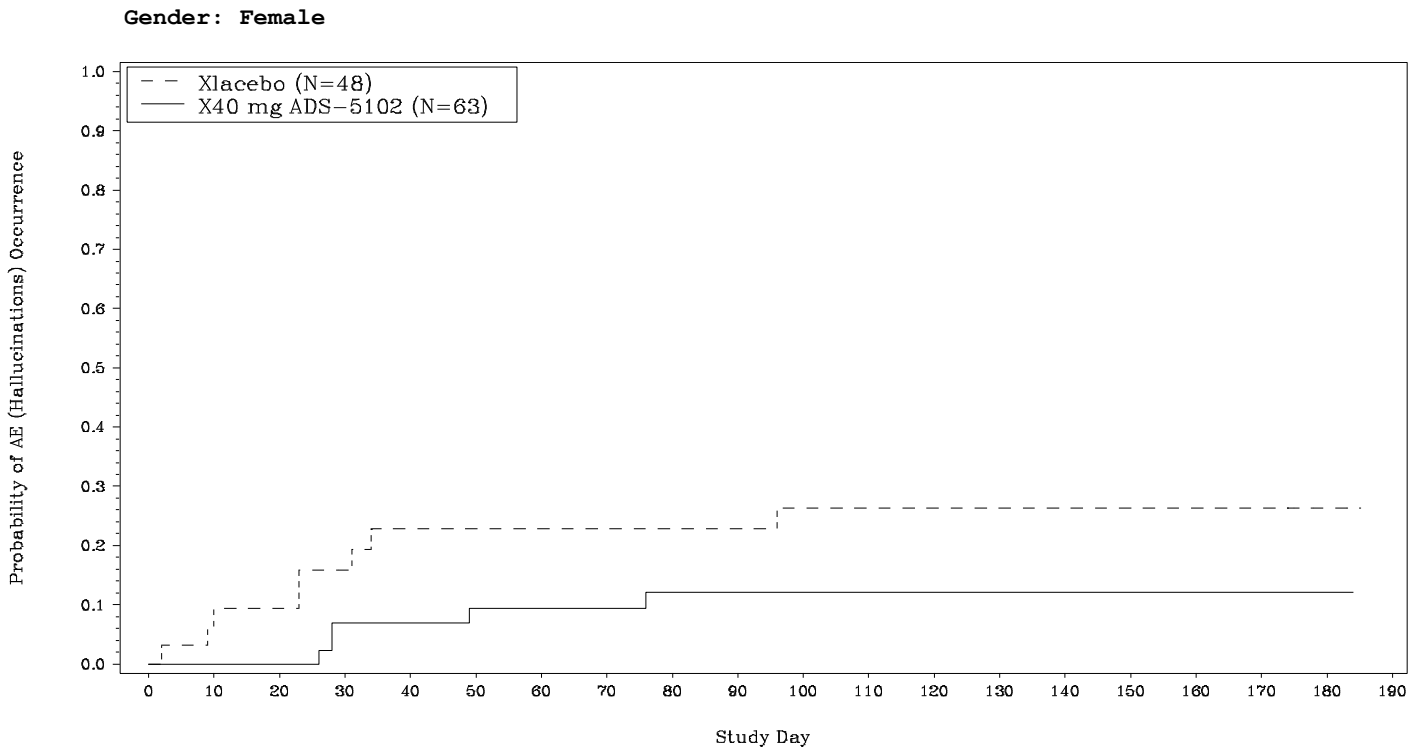


The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Programming note: Only Placebo and 340mg ADS-5102 will be presented.

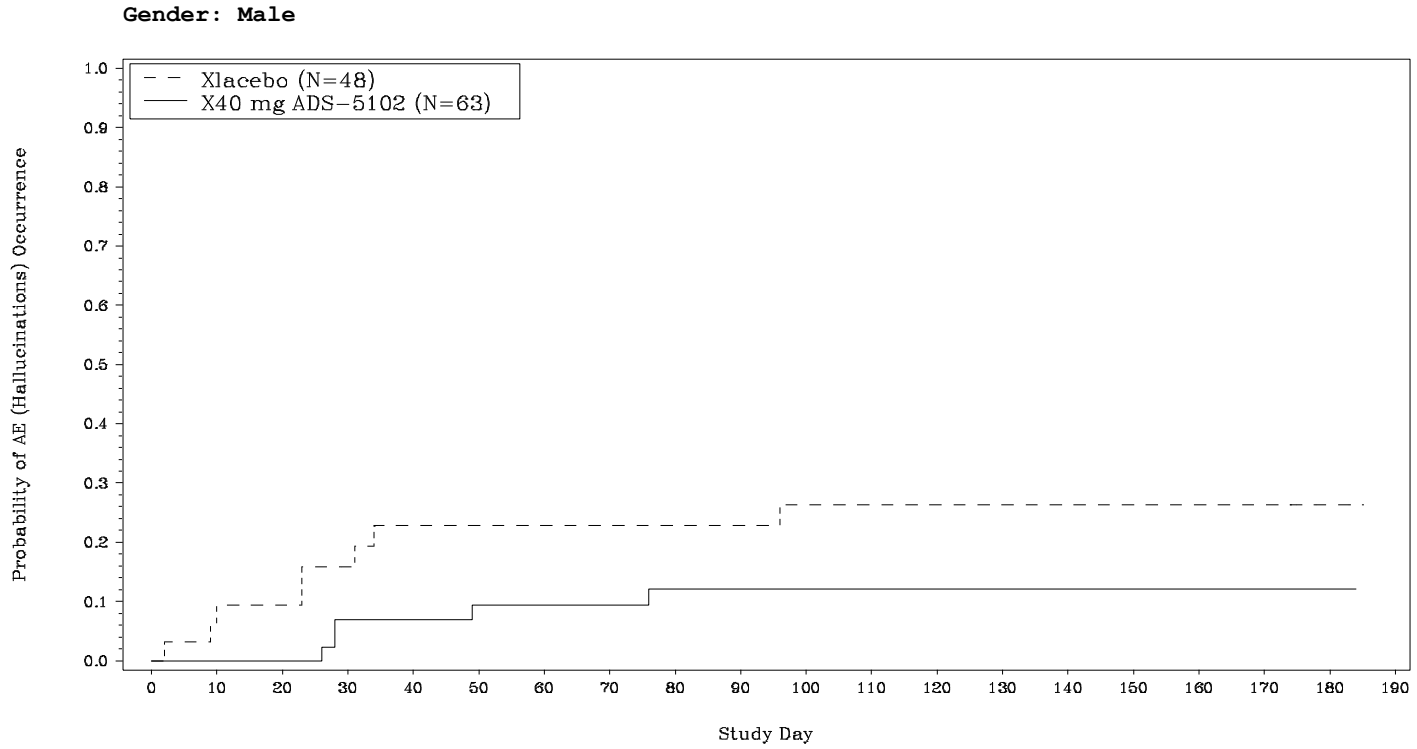
Figure 3.6.1.2
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Gender
Safety Population



The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.1.2
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Gender
Safety Population



The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.3

Figure 3.6.1.3
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Age
Safety Population

Repeat of 3.6.1.2

Age:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.1.4
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Race
Safety Population

Repeat of 3.6.1.2

Race:
1. White
2. Non-White

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.5

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.1.5
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline Renal Function
Safety Population

Repeat of 3.6.1.2

Baseline Renal Function:
1. Estimated GFR <60
2. Estimated GFR ≥60

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.6

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.1.6
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Weight
Safety Population

Repeat of 3.6.1.2

Weight:
1. < median
2. ≥ median

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.7

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.1.7
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 3.6.1.2

Baseline MAO-B Inhibitors:
1. Yes
2. No

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.8

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.1.8
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 3.6.1.2

Baseline Dopamine Agonist Medications:
1. Yes
2. No

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.9

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 13.6.1.9
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Baseline Levodopa Dose
Safety Population

Repeat of 3.6.1.2

Baseline Levodopa Dose:
1. < median
2. ≥ median

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.10

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 13.6.1.10
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Time since PD Diagnosis in Years
Safety Population

Repeat of 3.6.1.2

Time since PD Diagnosis in Years:
1. < median
2. ≥ median

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.11

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 13.6.1.11
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Age at PD Diagnosis
Safety Population

Repeat of 3.6.1.2

Age at PD Diagnosis:
1. < median
2. ≥ median

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.12

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 13.6.1.12
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Prior Deep Brain Stimulation
Safety Population

Repeat of 3.6.1.2

Prior Deep Brain Stimulation:
1. Yes
2. No

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.13

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 13.6.1.13
Kaplan-Meier Analysis of Time to Onset of AE (Neuropsychiatric) by Geographic Region
Safety Population

Repeat of 3.6.1.2

Geographic Region:
1. European Union
2. North America

The Neuropsychiatric category combines the following System Organ Classes: Nervous system disorder and Psychiatric disorder. Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Neuropsychiatric) occurred.
Source Data: Listing 2.6.1, Table 1.6.10.14

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.1
Kaplan-Meier Analysis of Time to Onset of AE (Falls)
Safety Population

Repeat of 3.6.1.1

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.2
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Gender
Safety Population

Repeat of 3.6.1.2

Gender:
1. Female
2. Male

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.3
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Age
Safety Population

Repeat of 3.6.1.2

Age:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.4
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Race
Safety Population

Repeat of 3.6.1.2

Race:
1. White
2. Non-White

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.5

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.5
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline Renal Function
Safety Population

Repeat of 3.6.1.2

Baseline Renal Function:
1. Estimated GFR <60
2. Estimated GFR ≥60

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.6

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.6
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Weight
Safety Population

Repeat of 3.6.1.2

Weight:
1. > median
2. ≥ median

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.7

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.7
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 3.6.1.2

Baseline MAO-B Inhibitors:
1. Yes
2. No

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.8

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.8
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 3.6.1.2

Baseline Dopamine Agonist Medications:
1. Yes
2. No

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.9

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.9
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Baseline Levodopa Dose
Safety Population

Repeat of 3.6.1.2

Baseline Levodopa Dose:
1. < median
2. ≥ median

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.10

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.10
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Time since PD Diagnosis in Years
Safety Population

Repeat of 3.6.1.2

Time since PD Diagnosis in Years:
1. < median
2. ≥ median

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.11

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.11
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Age at PD Diagnosis
Safety Population

Repeat of 3.6.1.2

Age at PD Diagnosis:
1. < median
2. ≥ median

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.12

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.12
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Prior Deep Brain Stimulation
Safety Population

Repeat of 3.6.1.2

Prior Deep Brain Stimulation:
1. Yes
2. No

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.13

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.2.13
Kaplan-Meier Analysis of Time to Onset of AE (Falls) by Geographic Region
Safety Population

Repeat of 3.6.1.2

Geographic Region:
1. European Union
2. North America

The Falls category combines all Preferred Terms that contain the term "Fall" or "Falls". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Falls) occurred.
Source Data: Listing 2.6.1, Table 1.6.11.14

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.3.1
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations)
Safety Population

Repeat of 3.6.1.1

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.2

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.3.2
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Gender
Safety Population

Repeat of 3.6.1.2

Gender:
1. Female
2. Male

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.3

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.3.3
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Age
Safety Population

Repeat of 3.6.1.2

Age:
1. <65
2. ≥65
3. ≥65 to <75
4. ≥75

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.4

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY HH:MM

Figure 3.6.3.4
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Race
Safety Population

Repeat of 3.6.1.2

Race:
1. White
2. Non-White

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.5

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Figure 3.6.3.5
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline Renal Function
Safety Population

Repeat of 3.6.1.2

Baseline Renal Function:
1. Estimated GFR <60
2. Estimated GFR ≥60

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.6

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Figure 3.6.3.6
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Weight
Safety Population

Repeat of 3.6.1.2

Weight:
1. < median
2. ≥ median

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.7

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Figure 3.6.3.7
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline MAO-B Inhibitor Medications
Safety Population

Repeat of 3.6.1.2

Baseline MAO-B Inhibitors:
1. Yes
2. No

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.8

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Figure 3.6.3.8
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline Dopamine Agonist Medications
Safety Population

Repeat of 3.6.1.2

Baseline Dopamine Agonist Medications:
1. Yes
2. No

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.9

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Figure 3.6.3.9
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Baseline Levodopa Dose
Safety Population

Repeat of 3.6.1.2

Baseline Levodopa Dose:
1. < median
2. ≥ median

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.10

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Figure 3.6.3.10
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Time since PD Diagnosis in Years
Safety Population

Repeat of 3.6.1.2

Time since PD Diagnosis in Years:
1. < median
2. ≥ median

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.11

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Figure 3.6.3.11
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Age at PD Diagnosis
Safety Population

Repeat of 3.6.1.2

Age at PD Diagnosis:
1. < median
2. ≥ median

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.12

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Figure 3.6.3.12
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Prior Deep Brain Stimulation
Safety Population

Repeat of 3.6.1.2

Prior Deep Brain Stimulation:
1. Yes
2. No

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.13

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Figure 3.6.3.13
Kaplan-Meier Analysis of Time to Onset of AE (Hallucinations) by Geographic Region
Safety Population

Repeat of 3.6.1.2

Geographic Region:
1. European Union
2. North America

The Hallucinations category combines all Preferred Terms that contain the term "Hallucination". Analysis Day is the number of days since Analysis Day 1 + 1. Subjects will be censored at their last contact date if no AE (Hallucinations) occurred.
Source Data: Listing 2.6.1, Table 1.6.12.14

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