STATISTICAL ANALYSIS PLAN

Appendix 5: Mock-up Tables, Listings, and Graphs

Trial Sponsor:	AriBio Co., Ltd.
Protocol Number:	AR1001-ADP2-US01
IND Number:	133281
EUDRACT Number:	Not applicable
Investigational Drug:	AR1001
Indication:	Alzheimer's Disease
Dosage Form/Strength:	Oral 10 or 30 mg or Placebo

Protocol Title: A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Efficacy and Safety of 26-Week Treatment of AR1001 in Patients with Mild to Moderate Alzheimer's Disease

First Sign-off Date:	
Last Revision Date:	18 January 2021
Final Sign-off Date:	
Archive Date:	

For the analysis of the treatment phase of the study, summary tables will not include visits or any data from the Extension phase. No figures with individual data and no listings will be presented. In the final analysis summary tables will include all study visits and data, and all figures and listings will be presented.

General Instructions for End-of-Text TLGs:

Header

The following header should appear at the very top of each page of a table, a listing, or a graph (TLG):

```
Protocol: AR1001-ADP2-US01                                                    AR1001
```

Footer

The following footer should appear at the bottom of each page of a TLG generated in SAS:

```
Source: SRCNAME

Program:/sasdir/PGNAME.sas  Version yyyy-mm-dd hh:mm                    (Page x of y)
```

where: SRC NAME = name(s) of source tables or listings and PGNAME = SAS program name. Version will be replaced by "Draft", "Final", or a descriptive analysis name that indicates draft or final status. Page number should be right justified.

Title

At least two (2) lines should be reserved for the whole title. The first line is for the TLG number (i.e., title index #) and the actual title (title); and the second line is reserved for the analysis population descriptor (Population. All titles should be centered, as shown in the following example:

```
                    Table 1.4.1 Demographics
                (Analysis Set: Safety Population)
```

Footnotes

- In general, a footnote serves as a brief explanation/clarification/definition/concept of a flag symbol or a character, an abbreviation, a terminology, etc., that appears in or related directly to the displayed content of a TFL. Detailed/technical elaboration of, for example, a mathematical/statistical formula, a statistical term/test, or an algorithm for deriving a parameter value, should be addressed in the text of the statistical analysis plan (SAP).
- All footnotes should follow immediately after a horizontal solid line. There should be one and only one space between the last footnote and the footer.
- When a non-standard abbreviation appears the first time in the whole set of TLGs for a study, a footnote should be provided at least once; and it is up to the Study Biostatistician and Study Programmer to decide whether there is a need to repeat the same footnote for the rest of TLGs (if applicable).
- Each line of a complete footnote should end with a period. When a footnote needs more than 1 line, one (1) period is needed.

Page Layout

- All output should be in landscape orientation. A margin of 1.5, 1, 1, and 1 inch should be on the top, right, left, and bottom, respectively.
- All efforts should be made to present all Treatment groups in one page.
- The Study Biostatistician will pre-determine the order for the display of the Treatment groups.

Page Format

- There should be a solid line at the top of the tables and listings just below the title.
- There should be a solid line just below the column headings that runs completely across the width of the tables and listings.
- There should be a solid line at the bottom of the tables and listings just above the footnote(s) on every page.

Font

- The default font to be used in the actual study tables/listings should be Courier New 8 point which is approximately equivalent to the acceptable font size of Times New Roman 9-10 in accordance with the FDA's guidance on Electronic Common Technical Document Specification.
- The use of Courier New 7 point is optional for some tables/listings and will be determined at the study level by the Study Biostatistician and Study Programmer. However, it is recommended that this option be used primarily for data listings.

Descriptive Statistics

By default, descriptive statistics in this template covers: n, Mean, Median, Standard Deviation (SD), Minimum (Min), and Maximum (Max). The mean, standard deviation, standard error of the mean, and median should be displayed to one more decimal place than the original data, while also ensuring that at least 2 significant digits are retained. Exceptions will be determined at the study level by the Study Biostatistician and Study Programmer, and will be explicitly noted in a programmer note for the corresponding table – decimal places in the mocks are not guaranteed to represent intended output.

Rounding for Percentage

Unless specified in the actual table shells for a study, all percentages will be rounded to 1 decimal place in all TFLs.

Unless specified in the actual table shells for a study, p-values will be presented with 4 decimal places.

Alignment of Decimals

- It is recommended that all the decimal places be aligned in summary tables, as shown in the following example:

```
                    Decimal Align

n                   xxx
Mean                 xx.xx
SD                   xx.xxxx
Median               xx.xx

Min, Max             xx.x, xx.x
```

- When numbers with decimal points are included in brackets (e.g., percentages), have the brackets aligned to the right and then padded to allow for all possible percentages and then the left brackets will also be aligned. For example:

```
          Brackets Align

    (99.9%)          (xx.x%)
    ( 9.9%)          ( x.x%)
```

- It is recommended that all column entries in a summary tables and listings are aligned to the center.
- Columns for text fields are all left justified. Columns with whole numbers are all right justified.
- For graphs, the lines are distinguishable and that the symbols for each line are appropriate. Legend is consistent across output for Treatment names and abbreviations.

Use of N Versus n

- N = total number of subjects in the defined analysis set.
- n = total number of subjects in the specific category.
- If N is specified in the column heading then any reference to the number of subjects in the body should be small n, as shown in the following example:

Demographic Parameter	Treatment Group A (N = XXX)	Treatment Group B (N = XXX)	Total (N = XXX)
Age (years)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Presenting absolute and change from baseline

- Absolute values should be followed by change from baseline when requested in a table, formatted as follows:

Parameter	Treatment Group A (N = XXX)	Treatment Group B (N = XXX)	Total (N = XXX)
Parameter 1 (units)			
n	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline (units)			
n			
Mean (SD)			
Median			
Min, Max			

- If there are additional levels, Change from Baseline (units) should always be indented two spaces beyond the last level.

A Note for Subject Data Listings

- Observed Dates/AE Severity/Relationship to investigational product are used in subject data listings.
- Observed values or raw assessment scores are used in data listings along with their derived values used in analyses, e.g., raw assessment scores and derived total scores.

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1. TABLES AND GRAPHS

1.1 Summary of Subject Disposition, Demographics, and Baseline Characteristics

Protocol: AR1001-ADP2-US01 AR1001

Table 1.1.1 Subject Disposition
(Analysis Set: All Randomized Subjects)

	Placebo n/N (%)	AR1001 10 mg n/N (%)	AR1001 30 mg n/N (%)	Total n/N (%)
Randomized	xx	xx	xx	xx
Treated	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Completed Treatment [a]	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Discontinued Treatment	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Completed the Study [b]	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Early Discontinuation from the study	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Reason for Early Discontinuation from the study:				
Occurrence of Adverse Event/Serious Adverse Event	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Participant withdrew consent	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Participant lost to follow-up	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Participant became pregnant	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Administrative or other reasons according to Sponsor decision	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Study is terminated	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Participant met exclusion criteria	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Participant missed 30% or more out of total doses	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Participant unable to attend major assessment visits	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)

[a] Subjects who completed treatment were treated and either indicated they completed the study on the End of Study CRF or discontinued the study after the Week 26 visit.
[b] Subjects who completed the study indicated they completed the study on the End of Study CRF. This includes subjects who completed Part I or Part II.

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Programmer note: Denominator (N) = [# Randomized] for Treated, Study completion, and Early termination rows. Denominator (N) = [# treated] for Completed Treatment and Discontinued Treatment. % is calculated as 100*n/N. Display only reasons with at least one subject.

Table 1.1.2 Subject Disposition
(Analysis Set: All Randomized Subjects Enrolled in Extension Phase)

Programmer note: Repeat Table 1.1.1 for Subjects Enrolled in Extension Phase. Modify the footnotes as:
[a] Subjects who completed treatment were treated in the Extension Phase and indicated they completed the study on the End of Study CRF.
[b] Subjects who completed the study enrolled in the Extension Phase and indicated they completed the study on the End of Study CRF.

Protocol: AR1001-ADP2-US01 AR1001

Table 1.2 Analysis Populations by Treatment
(Analysis Set: All Randomized Subjects)

Analysis Population	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Intent-to-Treat (ITT) Population [a]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Per-Protocol (PP) Population [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] ITT population includes all subjects who have taken at least one dose and have post-dose efficacy measurements.
[b] PP population includes all subjects valid for ITT who complete Visit 5 (Week 26). [Additional criteria may be added prior to unblinding the study database.]
[c] Safety population includes all subjects who received at least one dose.

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Protocol: AR1001-ADP2-US01 AR1001

Table 1.3.1 Summary of Demographics by Treatment
(Analysis Set: Safety Population)

Parameter	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Age (years)	xx	xx	xx	xx
n	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Mean (SD)	xx.x	xx.x	xx.x	xx.x
Median	xx; xx	xx; xx	xx; xx	xx; xx
Min; Max				
Gender, n(%)				
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race, n(%)	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)
Asian	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)
Native Hawaiian or other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Multiple Races Reported	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)
Unknown				
Ethnicity, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hispanic or Latino	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)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown				

SD = Standard Deviation.

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Table 1.3.2 Summary of Demographics by Treatment
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 1.3.1 for Subjects Enrolled in Extension Phase.

Protocol: AR1001-ADP2-US01 AR1001

Table 1.4.1 Summary of Baseline Characteristics by Treatment
(Analysis Set: Safety Population)

Parameter	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Weight (kg)	xx	xx	xx	xx
n	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Mean (SD)	xx.x	xx.x	xx.x	xx.x
Median	xx; xx	xx; xx	xx; xx	xx; xx
Min; Max				
Height (cm)				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min; Max	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x
BMI (kg/m²)				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min; Max	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x
Age at AD Diagnosis (years)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx

AD = Alzheimer's Disease; BMI = Body Mass Index; SD = Standard Deviation.

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Protocol: AR1001-ADP2-US01 AR1001

Table 1.4.1 Summary of Baseline Characteristics by Treatment (Continued)
(Analysis Set: Safety Population)

Parameter	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Time Since AD Diagnosis (years)	xx	xx	xx	xx
n	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Mean (SD)	xx.x	xx.x	xx.x	xx.x
Median	xx; xx	xx; xx	xx; xx	xx; xx
Min; Max				
GDSAPDD				
n	xx	xx	xx	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline ADAS-Cog 13 Score				
n	xx	xx	xx	xx
Mean (SD)	xx.xxx (xx.xxx)	xx.xxx (xx.xxx)	xx.xxx (xx.xxx)	xx.xxx (xx.xxx)
Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Min; Max	xx.xx; xx.xx	xx.xx; xx.xx	xx.xx; xx.xx	xx.xx; xx.xx

AD = Alzheimer's Disease; GDSAPDD = Global Deterioration Scale for Assessment of Primary Degenerative Dementia scale; ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive Subscale; SD = Standard Deviation.

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Protocol: AR1001-ADP2-US01 AR1001

Table 1.4.1 Summary of Baseline Characteristics by Treatment (Continued)
(Analysis Set: Safety Population)

Parameter	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Baseline MMSE-2: BV				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx
Baseline MMSE-2: SV				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx
Baseline NPI				
n	xx	xx	xx	xx
Mean (SD)	xxx.x (xxx.x)	xxx.x (xxx.x)	xxx.x (xxx.x)	xxx.x (xxx.x)
Median	xxx.x	xxx.x	xxx.x	xxx.x
Min; Max	xxx; xxx	xxx; xxx	xxx; xxx	xxx; xxx
Baseline GDS				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx

MMSE-2: BV = Mini-mental status examination, 2nd Edition: Brief Version; MMSE-2: SV = Mini-mental status examination, 2nd Edition: Standard Version; NPI = Neuropsychiatric Inventory; GDS = Geriatric Depression Scale; SD = Standard Deviation.

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Protocol: AR1001-ADP2-US01 AR1001

Table 1.4.1 Summary of Baseline Characteristics by Treatment (Continued)
(Analysis Set: Safety Population)

Parameter	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Baseline QOL-AD- Family Version				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx
Baseline QOL-AD- Participant Version				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx

QOL-AD = Quality of Life in Alzheimer's Disease; SD = Standard Deviation.

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Programmer note: Include only categories (race, ethnicity, GDSAPDD) that are present in the data.

Table 1.4.2 Summary of Baseline Characteristics by Treatment
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 1.4.1 for Subjects Enrolled in Extension Phase.

Protocol: AR1001-ADP2-US01 AR1001

Table 1.5.1 Medical and Surgical History by System Organ Class and Preferred Term
(Analysis Set: Safety Population)

System Organ Class Preferred Term	Placebo (N = x)	AR1001 10 mg (N = x)	AR1001 30 mg (N = x)	Total (N = x)
SOC #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Programmer note: Sort by descending overall frequency in SOC then PT.

Table 1.5.2 Medical and Surgical History by System Organ Class and Preferred Term
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 1.5.1 for Subjects Enrolled in Extension Phase.

1.2 Efficacy Analyses

Protocol: AR1001-ADP2-US01 AR1001

Table 2.1.1 ADAS-Cog 13 Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Timepoint Treatment	Baseline	Change from Baseline	Overall Treatment Effect	Pairwise Difference versus Placebo
Week 4				
AR1001 10 mg (N=xx)				
n	xx	xx		
Mean	x.x	x.x		
SD	x.xx	x.xx		
Median	x.x	x.x		
Min; Max	xx; xx	xx; xx		
LS Mean (SE)		x.x (x.xx)		x.x (x.xx)
95% CI		(x.x, x.x)		(x.x, x.x)
P-value			x.xxxx	x.xxxx
AR1001 30 mg (N=xx)				
n	xx	xx		
Mean	x.x	x.x		
SD	x.xx	x.xx		
Median	x.x	x.x		
Min; Max	xx; xx	xx; xx		
LS Mean (SE)		x.x (x.xx)		x.x (x.xx)
95% CI		(x.x, x.x)		(x.x, x.x)
P-value				x.xxxx
Placebo (N=xx)				
n	xx	xx		
Mean	x.x	x.x		
SD	x.xx	x.xx		
Median	x.x	x.x		
Min; Max	xx; xx	xx; xx		
LS Mean (SE)		x.x (x.xx)		
95% CI		(x.x, x.x)		

ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive subscale; SD = Standard Deviation; LS Mean = Least Squares Mean from the ANCOVA model which includes treatment as a categorical covariate and the baseline value as a continuous covariate. P-value for Overall Treatment Effect at Week 26 is for the test of the primary efficacy endpoint. P-values for Overall Treatment Effect at other timepoints and p-values for all pairwise treatment comparisons are for tests of exploratory endpoints.

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Programmer note: Repeat for Week 13, and Week 26. Decimal places in the mock are placeholders. Please refer to general instructions for decimal rules.

Protocol: AR1001-ADP2-US01 AR1001

Table 2.1.2 ADAS-Cog 13 Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

	Randomized Treatment Group:				
	Treatment Phase:	AR1001 10 mg	AR1001 30 mg	Placebo	
Study Phase	Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg
Timepoint		(N=xx)	(N=xx)	(N=xx)	(N=xx)
Treatment Phase					
Week 4					
n		xx	xx	xx	xx
Mean (SE)		x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
SD		x.xx	x.xx	x.xx	x.xx
Median		x.x	x.x	x.x	x.x
Min; Max		xx; xx	xx; xx	xx; xx	xx; xx
…					
Extension Phase					
Week 30					
n		xx	xx	xx	xx
Mean (SE)		x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
SD		x.xx	x.xx	x.xx	x.xx
Median		x.x	x.x	x.x	x.x
Min; Max		xx; xx	xx; xx	xx; xx	xx; xx
…					

ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive subscale; SD = Standard Deviation.

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Programmer note: Repeat for Treatment phase – Week 13 and Week 26, Extension Phase –Week 39 and Week 52. Decimal places in the mock are placeholders. Please refer to general instructions for decimal rules.

Protocol: AR1001-ADP2-US01 AR1001

Table 2.1.3 ADAS-Cog 13 Least Squares Mean Difference in Change from Baseline Between Treatment Groups, Using Multiple Imputation: Treatment Phase
(Analysis Set: ITT Population)

Timepoint / Treatment	Baseline	Change from Baseline	Overall Treatment Effect	Pairwise Difference versus Placebo
Week 26				
AR1001 10 mg (N=xx)				
n-obs	xx	xx		
n-obs + n-imp	xx	xx		
Mean [a]	x.x	x.x		
Mean (SE) [b]		x.x (x.xx)		x.x (x.xx)
95% CI [b]		(x.x, x.x)		(x.x, x.x)
P-value			x.xxxx	x.xxxx
AR1001 30 mg (N=xx)				
n-obs	xx	xx		
n-obs + n-imp	xx	xx		
Mean [a]	x.x	x.x		
Mean (SE) [b]		x.x (x.xx)		x.x (x.xx)
95% CI [b]		(x.x, x.x)		(x.x, x.x)
P-value				x.xxxx
Placebo (N=xx)				
n-obs	xx	xx		
n-obs + n-imp	xx	xx		
Mean [a]	x.x	x.x		
Mean (SE) [b]		x.x (x.xx)		
95% CI [b]		(x.x, x.x)		

ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive subscale; SD = Standard Deviation; LS Mean = Least Squares Mean from the ANCOVA model which includes treatment as a categorical covariate and the baseline value as a continuous covariate.
[a] Mean of the 100 means after imputation.
[b] Mean (SE) and 95% CI for the mean are those reported by PROC MIANALYZE.

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Programmer note: Decimal places in the mock are placeholders. Please refer to general instructions for decimal rules.

Table 2.1.4 ADAS-Cog 13 Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.2.1 ADAS-Cog 13 Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with PP Population. Remove footnotes for p-values.

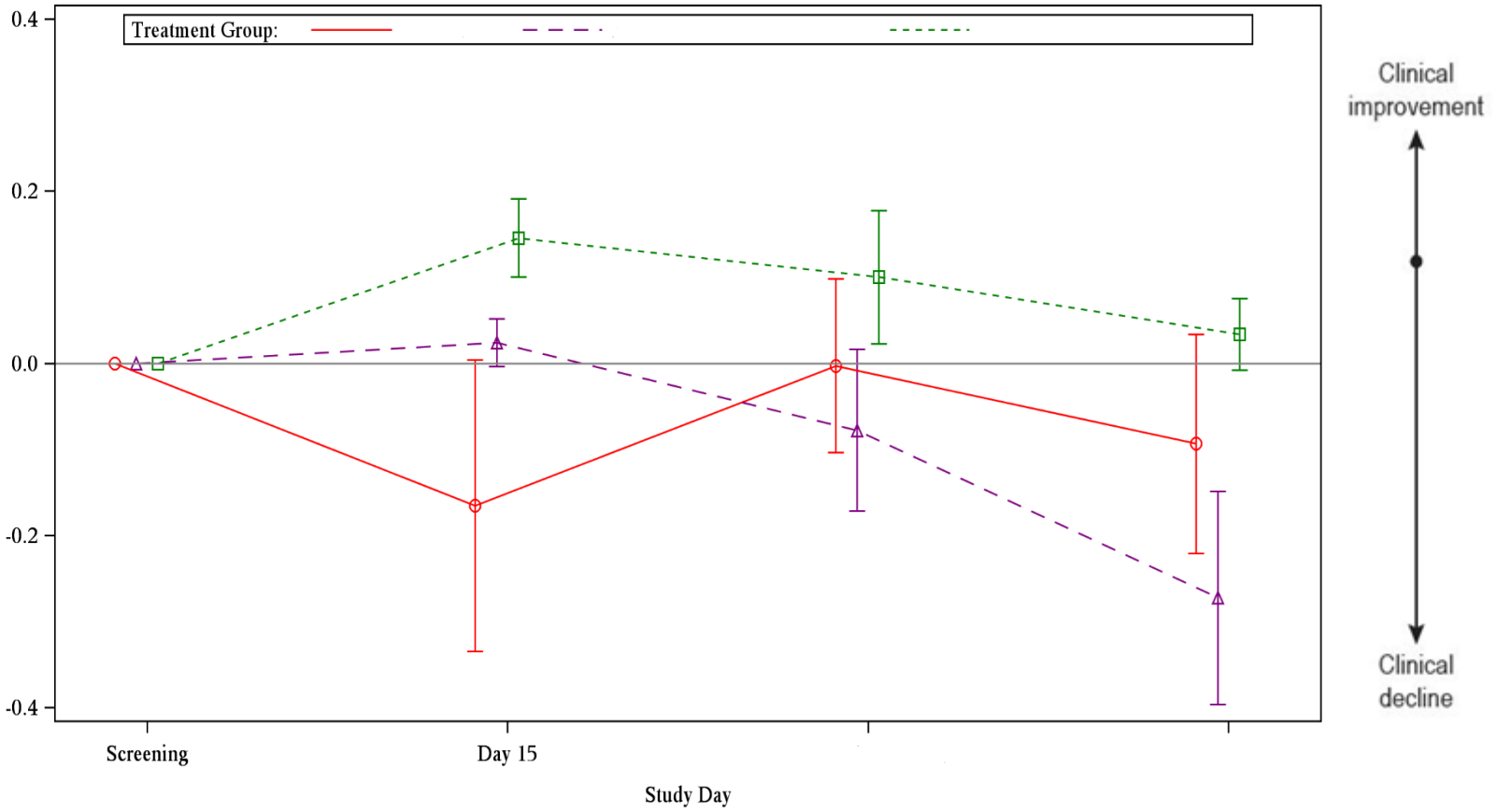
Table 2.2.2 ADAS-Cog 13 Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with PP Population.

Table 2.2.3 ADAS-Cog 13 Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.2.2 but with Change from Week 26. Only include Extension Phase visits.

Figure 2.1.1 LS Mean Change in ADAS-Cog 13 from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)



Programmer Note: Create a series plot of the LS mean (+/- SE with error bars) of the parameter by week of nominal visit for each treatment group. Assign Baseline=time point 0. Label the x-axis "Study Week" and the y-axis with the parameter name. Include timepoints Baseline, Week 4, Week 13, and Week 26. Ensure y-axis is sufficient to present all values (including errors). Reverse order of y-axis (negative values at the top, positive values at the bottom). Add footnote, "Negative values indicate improvement. Positive values indicate worsening.". For arrow to the right of the figure, line up dot on arrow with 0 on y-axis.

Figure 2.1.2 Mean Change in ADAS-Cog 13 from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Create a series plot of the mean (+/- SE with error bars) of the parameter by week of nominal visit for each of the 4 treatment groups from Table 2.1.2 (Present as “AR1001 10 mg/AR1001 10 mg”, “AR1001 30 mg/AR1001 30 mg”, “Placebo/AR1001 10 mg”, “Placebo/AR1001 30 mg”,. Assign Baseline=time point 0. Label the x-axis “Study Week” and the y-axis with the parameter name. Include timepoints Baseline, Week 4, Week 13, Week 26, Week 30, Week 39, and Week 52. Ensure y-axis is sufficient to present all values (including errors). Reverse order of y-axis (negative values at the top, positive values at the bottom). Add footnote, “Negative values indicate improvement. Positive values indicate worsening.”

Figure 2.2.1 LS Mean Change in ADAS-Cog 13 from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.1.1 with PP Population.

Figure 2.2.2 Mean Change in ADAS-Cog 13 from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with PP Population.

Table 2.3.1 ADCS-CGIC Least Squares Mean Difference Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with ADCS-CGIC. Replace parameter footnote with "ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change". Remove Baseline column. Replace LS Mean definition footnote with "LS Mean = Least Squares Mean from the ANCOVA model which includes treatment as a categorical covariate."

Table 2.3.2 ADCS-CGIC Mean Difference Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with ADCS-CGIC. Replace parameter footnote with "ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change".

Table 2.4.1 ADCS-CGIC Least Squares Mean Difference Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.2.1 with ADCS-CGIC in the PP Population. Replace parameter footnote with "ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change". Remove footnotes for p-values. Remove Baseline column. Replace LS Mean definition footnote with "LS Mean = Least Squares Mean from the ANCOVA model which includes treatment as a categorical covariate."

Table 2.4.2 ADCS-CGIC Mean Difference Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.2.2 with ADCS-CGIC in the PP Population. Replace parameter footnote with "ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change".

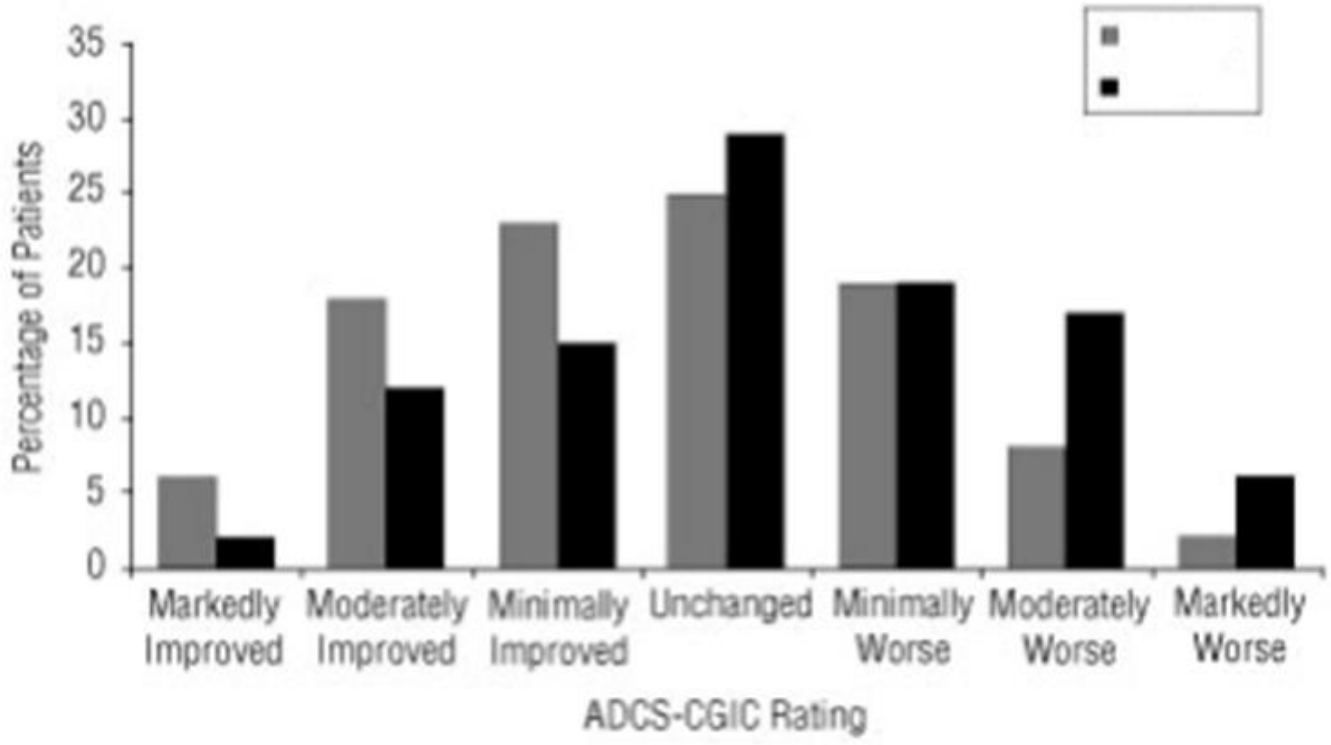
Figure 2.3.1 LS Mean ADCS-CGIC (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with ADCS-CGIC. Y-axis range: 1 to 7 (put 1 at the top and 7 at the bottom). Include timepoints Week 4, Week 13, and Week 26. Add footnote, "Lower values indicate improvement. Higher values indicate worsening."

Figure 2.3.2 Mean ADCS-CGIC (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with ADCS-CGIC. Y-axis range: 1 to 7 (put 1 at the top and 7 at the bottom). Include timepoints Week 4, Week 13, Week 26, Week 30, Week 39, and Week 52. Add footnote, “Lower values indicate improvement. Higher values indicate worsening.”

Figure 2.3.3 ADCS-CGIC at Week 26
(Analysis Set: ITT Population)



Programmer Note: Update legend with 3 treatment groups. Plot 3 bars at each rating (one for each treatment group).

Figure 2.4.1 LS Mean ADCS-CGIC (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.3.1 with PP Population.

Figure 2.4.2 Mean ADCS-CGIC (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.3.2 with PP Population.

Figure 2.4.3 ADCS-CGIC at Week 26
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.3.3 with PP Population.

Table 2.5.1 MMSE-2: BV Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with MMSE-2: BV. Remove Week 4. Replace parameter footnote with "MMSE-2: BV = Mini-mental status examination, 2nd Edition: Brief Version". Remove footnotes for p-values.

Table 2.5.2 MMSE-2: BV Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with MMSE-2: BV. Replace parameter footnote with "MMSE-2: BV = Mini-mental status examination, 2nd Edition: Brief Version".

Table 2.5.3 MMSE-2: BV Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.5.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.6.1 MMSE-2: BV Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with MMSE-2: BV in the PP Population. Remove Week 4. "MMSE-2: BV = Mini-mental status examination, 2nd Edition: Brief Version". Remove footnotes for p-values.

Table 2.6.2 MMSE-2: BV Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with MMSE-2: BV in the PP Population. "MMSE-2: BV = Mini-mental status examination, 2nd Edition: Brief Version".

Table 2.6.3 MMSE-2: BV Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.6.2 but with Change fromWeek 26. Only include Extension Phase visits.

Table 2.7.1 MMSE-2: SV Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with MMSE-2: SV. Remove Week 4. Replace parameter footnote with "MMSE-2: SV = Mini-mental status examination, 2nd Edition: Standard Version". Remove footnotes for p-values.

Table 2.7.2 MMSE-2: SV Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with MMSE-2: SV. Replace parameter footnote with "MMSE-2: SV = Mini-mental status examination, 2nd Edition: Standard Version".

Table 2.7.3 MMSE-2: SV Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.7.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.8.1 MMSE-2: SV Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with MMSE-2: SV in the PP Population. Remove Week 4. "MMSE-2: SV = Mini-mental status examination, 2nd Edition: Standard Version". Remove footnotes for p-values.

Table 2.8.2 MMSE-2: SV Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with MMSE-2: SV in the PP Population. "MMSE-2: SV = Mini-mental status examination, 2nd Edition: Standard Version".

Table 2.8.3 MMSE-2: SV Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.8.2 but with Change from Week 26. Only include Extension Phase visits.

Figure 2.5.1 LS Mean Change in MMSE-2: BV from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with MMSE-2: BV. Include Treatment Phase timepoints in Table 2.5.1. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.5.2 Mean Change in MMSE-2: BV from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with MMSE-2: BV. Include Treatment and Extension Phase timepoints in Tables 2.5.1 and 2.5.2. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.6.1 LS Mean Change in MMSE-2: BV from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.5.1 with PP Population.

Figure 2.6.2 Mean Change in MMSE-2: BV from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.5.2 with PP Population.

Figure 2.7.1 LS Mean Change in MMSE-2: SV from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with MMSE-2: SV. Include Part I timepoints in Table 2.7.1. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.7.2 Mean Change in MMSE-2: SV from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with MMSE-2: SV. Include Treatment and Extension Phase timepoints in Tables 2.7.1 and 2.7.2. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.8.1 LS Mean Change in MMSE-2: SV from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.7.1 with PP Population.

Figure 2.8.2 Mean Change in MMSE-2: SV from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.7.2 with PP Population.

Table 2.9.1 NPI Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with NPI. Remove Week 4. Replace parameter footnote with "NPI = Neuropsychiatric Inventory". Remove footnotes for p-values.

Table 2.9.2 NPI Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with NPI. Replace parameter footnote with "NPI = Neuropsychiatric Inventory".

Table 2.9.3 NPI Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.9.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.10.1 NPI Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with NPI in the PP Population. Remove Week 4. "NPI = Neuropsychiatric Inventory". Remove footnotes for p-values.

Table 2.10.2 NPI Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with NPI in the PP Population. "NPI = Neuropsychiatric Inventory".

Table 2.10.3 NPI Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.10.2 but with Change from Week 26. Only include Extension Phase visits.

Figure 2.9.1 LS Mean Change in NPI from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with NPI. Include Treatment Phase timepoints in Table 2.9.1. Reverse order of y-axis (negative values at the top, positive values at the bottom). Add footnote, "Negative values indicate improvement. Positive values indicate worsening."

Figure 2.9.2 Mean Change in NPI from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with NPI. Include Treatment and Extension Phase timepoints in Tables 2.9.1 and 2.9.2. Reverse order of y-axis (negative values at the top, positive values at the bottom). Add footnote, "Negative values indicate improvement. Positive values indicate worsening."

Figure 2.10.1 LS Mean Change in NPI from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.9.1 with PP Population.

Figure 2.10.2 Mean Change in NPI from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.9.2 with PP Population.

Table 2.11.1 GDS Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with GDS. Remove Week 4. Replace parameter footnote with "GDS = Geriatric Depression Scale". Remove footnotes for p-values.

Table 2.11.2 GDS Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with GDS. Replace parameter footnote with "GDS = Geriatric Depression Scale".

Table 2.11.3 GDS Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.11.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.12.1 GDS Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with GDS in the PP Population. Remove Week 4. "GDS = Geriatric Depression Scale". Remove footnotes for p-values.

Table 2.12.2 GDS Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with GDS in the PP Population. "GDS = Geriatric Depression Scale".

Table 2.12.3 GDS Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.12.2 but with Change from Week 26. Only include Extension Phase visits.

Figure 2.11.1 LS Mean Change in GDS from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with GDS. Include Treatment Phase timepoints in Table 2.11.1. Reverse order of y-axis (negative values at the top, positive values at the bottom). Add footnote, "Negative values indicate improvement. Positive values indicate worsening."

Figure 2.11.2 Mean Change in GDS from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with GDS. Include Treatment and Extension Phase timepoints in Tables 2.11.1 and 2.11.2. Reverse order of y-axis (negative values at the top, positive values at the bottom). Add footnote, "Negative values indicate improvement. Positive values indicate worsening."

Figure 2.12.1 LS Mean Change in GDS from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.11.1 with PP Population.

Figure 2.12.2 Mean Change in GDS from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.11.2 with PP Population.

Table 2.13.1 QOL-AD- Family Version Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with QOL-AD- Family Version. Remove Weeks 4 and 13. Replace parameter footnote with "QOL-AD- Family Version = Quality of Life in Alzheimer's Disease - Family Version". Remove footnotes for p-values.

Table 2.13.2 QOL-AD- Family Version Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with QOL-AD- Family Version. Replace parameter footnote with "QOL-AD- Family Version = Quality of Life in Alzheimer's Disease - Family Version".

Table 2.13.3 QOL-AD- Family Version Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.13.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.14.1 QOL-AD- Family Version Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with QOL-AD- Family Version in the PP Population. Remove Weeks 4 and 13. "QOL-AD- Family Version = Quality of Life in Alzheimer's Disease - Family Version". Remove footnotes for p-values.

Table 2.14.2 QOL-AD- Family Version Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with QOL-AD- Family Version in the PP Population. "QOL-AD- Family Version = Quality of Life in Alzheimer's Disease - Family Version".

Table 2.14.3 QOL-AD- Family Version Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.14.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.15.1 QOL-AD- Participant Version Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.1.1 with QOL-AD- Participant Version. Remove Weeks 4 and 13. Replace parameter footnote with "QOL-AD- Participant Version = Quality of Life in Alzheimer's Disease - Participant Version". Remove footnotes for p-values.

Table 2.15.2 QOL-AD- Participant Version Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with QOL-AD- Participant Version. Replace parameter footnote with "QOL-AD- Participant Version = Quality of Life in Alzheimer's Disease - Participant Version".

Table 2.15.3 QOL-AD- Participant Version Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.15.2 but with Change from Week 26. Only include Extension Phase visits.

Table 2.16.1 QOL-AD- Participant Version Least Squares Mean Difference in Change from Baseline Between Treatment Groups: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer note: Repeat Table 2.1.1 with QOL-AD- Participant Version in the PP Population. Remove Weeks 4 and 13. "QOL-AD- Participant Version = Quality of Life in Alzheimer's Disease - Participant Version". Remove footnotes for p-values.

Table 2.16.2 QOL-AD- Participant Version Mean Difference in Change from Baseline Between Treatment Groups: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.1.2 with QOL-AD- Participant Version in the PP Population. "QOL-AD- Participant Version = Quality of Life in Alzheimer's Disease - Participant Version".

Table 2.16.3 QOL-AD- Participant Version Mean Difference in Change from Week 26 Between Treatment Groups: Extension Phase
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer note: Repeat Table 2.16.2 but with Change from Week 26. Only include Extension Phase visits.

Figure 2.13.1 LS Mean Change in QOL-AD- Family Version from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with QOL-AD- Family Version. Include Treatment Phase timepoints in Table 2.13.1. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.13.2 Mean Change in QOL-AD- Family Version from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with QOL-AD- Family Version. Include Treatment and Extension Phase timepoints in Tables 2.13.1 and 2.13.2. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.14.1 LS Mean Change in QOL-AD- Family Version from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.13.1 with PP Population.

Figure 2.14.2 Mean Change in QOL-AD- Family Version from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.13.2 with PP Population.

Figure 2.15.1 LS Mean Change in QOL-AD- Participant Version from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: ITT Population)

Programmer Note: Repeat Figure 2.1.1 with QOL-AD- Participant Version. Include Part I timepoints in Table 2.15.1. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.15.2 Mean Change in QOL-AD- Participant Version from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: ITT Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.1.2 with QOL-AD- Participant Version. Include Treatment and Extension Phase timepoints in Tables 2.15.1 and 2.15.2. Y-axis: positive values at the top, negative values at the bottom. Add footnote, "Positive values indicate improvement. Negative values indicate worsening."

Figure 2.16.1 LS Mean Change in QOL-AD- Participant Version from Baseline (+/- SE) by Visit: Treatment Phase
(Analysis Set: Per-Protocol Population)

Programmer Note: Repeat Figure 2.15.1 with PP Population.

Figure 2.16.2 Mean Change in QOL-AD- Participant Version from Baseline (+/- SE) by Visit: Both Phases
(Analysis Set: Per-Protocol Population Enrolled in Extension Phase)

Programmer Note: Repeat Figure 2.15.2 with PP Population.

Protocol: AR1001-ADP2-US01 AR1001

Table 2.17.1 ADAS-Cog 13 Mean Difference in Change from Baseline Between Treatment Groups – Subgroup Analysis: Treatment Phase
(Analysis Set: ITT Population)

Subjects who Took Concomitant Alzheimer's Disease Medications

Study Phase Timepoint	AR1001 10 mg (N=xx)	AR1001 30 mg (N=xx)	Placebo (N=xx)
Week 4			
n	xx	xx	xx
Mean	x.x	x.x	x.x
SD	x.xx	x.xx	x.xx
Median	x.x	x.x	x.x
Min; Max	xx; xx	xx; xx	xx; xx
…			

ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive subscale; SD = Standard Deviation.

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Programmer note: Repeat for Week 13 and Week 26. Repeat on a 2nd page for: Subjects who Did Not Take Concomitant Alzheimer's Disease Medications. See SAP Section 7.4.1.3, Table 5, for list of Concomitant AD Medications. Decimal places in the mock are placeholders. Please refer to general instructions for decimal rules.

Table 2.17.2 ADCS-CGIC Mean Difference Between Treatment Groups – Subgroup Analysis: Treatment Phase
(Analysis Set: ITT Population)

Programmer note: Repeat Table 2.17.1 with ADCS-CGIC. Replace parameter footnote with "ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change".

1.3 Safety Data

1.3.1 Extent of Exposure to Study Medication

Protocol: AR1001-ADP2-US01 AR1001

Table 3.1.1 Summary of Exposure: Treatment Phase
(Analysis Set: Safety Population)

	Placebo (N = x)	AR1001 10 mg (N = x)	AR1001 30 mg (N = x)	Total (N = x)
Study Drug Duration (days) [a]				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx	xx; xx

SD = Standard Deviation.
[a] Study Drug Duration (days) = (Date of last dose of study drug – Date of first dose of study drug) + 1

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Table 3.1.2 Summary of Exposure: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer Note: Repeat Table 3.1.1 with Extension Phase exposure, with Placebo column removed.

Table 3.1.3 Summary of Exposure: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

	Randomized Treatment Group:					
	Treatment Phase:	Placebo		AR1001 10 mg	AR1001 30 mg	
	Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
		(N = x)	(N = x)	(N = x)	(N = x)	(N = x)
Study Drug Duration (days) [a]						
n		xx	xx	xx	xx	xx
Mean (SD)		xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median		xx.x	xx.x	xx.x	xx.x	xx.x
Min; Max		xx; xx	xx; xx	xx; xx	xx; xx	xx; xx

SD = Standard Deviation.
[a] Study Drug Duration (days) = (Date of last dose of study drug – Date of first dose of study drug) + 1

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1.3.2 Adverse Events

Protocol: AR1001-ADP2-US01 AR1001

Table 4.1.1 Summary of Adverse Events: Treatment Phase
(Analysis Set: Safety Population)

	Placebo (N = x) # of Subjects n(%) [events]	AR1001 10 mg (N = x) # of Subjects n(%) [events]	AR1001 30 mg (N = x) # of Subjects n(%) [events]	Total (N = x) # of Subjects n(%) [events]
TEAEs	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Severe	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)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs related to study drug	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Severe	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)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AEs leading to early study discontinuation	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
AEs leading to early discontinuation from study drug	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Serious AEs	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Serious AEs related to study drug	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Fatal AEs	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]

AE = Adverse Event; TEAE = Treatment Emergent Adverse Event.
Each subject is counted only once in the highest severity category, and events are not tabulated by severity.
Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related.

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Programmer note: Subjects should be counted at most once in their AE of highest severity category (if they have no AEs, they will not be counted) for the summaries by severity.

Table 4.1.2 Summary of Adverse Events: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer Note: Repeat Table 4.1.1 for Extension Phase, with Placebo column removed.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.1.3 Summary of Adverse Events: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Randomized Treatment Group:					
Treatment Phase:	Placebo		AR1001 10 mg	AR1001 30 mg	
Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
	(N = x)	(N = x)	(N = x)	(N = x)	(N = x)
	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]
TEAEs	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Severe	xx (xx.x)	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)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs related to study drug	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Severe	xx (xx.x)	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)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AEs leading to early study discontinuation	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
AEs leading to early discontinuation from study drug	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Serious AEs	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Serious AEs related to study drug	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
Fatal AEs	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]

AE = Adverse Event; TEAE = Treatment Emergent Adverse Event.
Each subject is counted only once in the highest severity category, and events are not tabulated by severity.
Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related.

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Programmer note: Subjects should be counted at most once in their AE of highest severity category (if they have no AEs, they will not be counted) for the summaries by severity.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.2.1 Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

	Placebo	AR1001 10 mg	AR1001 30 mg	Total
	(N = x)	(N = x)	(N = x)	(N = x)
System Organ Class Preferred Term	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]
Subjects with at least one TEAE	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
SOC #1	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
PT #1.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #2	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
PT #2.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #2.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

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Programmer note: Sort by descending overall frequency by SOC, then PT, then alphabetically by SOC/PT in case of ties.

Table 4.2.2 Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer Note: Repeat Table 4.2.1 for Extension Phase, with Placebo column removed.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.2.3 Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Randomized Treatment Group:					
Treatment Phase:	Placebo		AR1001 10 mg	AR1001 30 mg	
Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
	(N = x)	(N = x)	(N = x)	(N = x)	(N = x)
System Organ Class Preferred Term	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]	# of Subjects n(%) [events]
Subjects with at least one TEAE	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
SOC #1	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
PT #1.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #2	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]	xx (xx.x) [xx]
PT #2.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #2.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

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Programmer note: Sort by descending overall frequency by SOC, then PT, then alphabetically by SOC/PT in case of ties.

Table 4.3.1 Incidence of Non-Serious Treatment Emergent Adverse Events Occurring in 5% or more Subjects by System Organ Class and Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 4.2.1, restricted to non-serious TEAEs occurring in 5% or more of the total column.

Table 4.3.2 Incidence of Non-Serious Treatment Emergent Adverse Events Occurring in 5% or more Subjects by System Organ Class and Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.2.2, restricted to non-serious TEAEs occurring in 5% or more of the total column.

Table 4.3.3 Incidence of Non-Serious Treatment Emergent Adverse Events Occurring in 5% or more Subjects by System Organ Class and Preferred Term: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.2.3, restricted to non-serious TEAEs occurring in 5% or more of the total column.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.4.1 Incidence of Treatment Emergent Adverse Events by Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

Preferred Term	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
PT #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

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Programmer note: Sort by descending overall frequency by PT, then alphabetically by PT in case of ties.

Table 4.4.2 Incidence of Treatment Emergent Adverse Events by Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer Note: Repeat Table 4.4.1 for Extension Phase, with Placebo column removed.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.4.3 Incidence of Treatment Emergent Adverse Events by Preferred Term: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Randomized Treatment Group:					
Treatment Phase:	Placebo		AR1001 10 mg	AR1001 30 mg	
Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
	(N = x)	(N = x)	(N = x)	(N = x)	(N = x)
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)
PT #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

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Programmer note: Sort by descending overall frequency by PT, then alphabetically by PT in case of ties.

Table 4.5.1 Incidence of Serious Adverse Events by System Organ Class and Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 4.2.1, restricted to SAEs.

Table 4.5.2 Incidence of Serious Adverse Events by System Organ Class and Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.2.2, restricted to SAEs.

Table 4.5.3 Incidence of Serious Adverse Events by System Organ Class and Preferred Term: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.2.3, restricted to SAEs.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.6.1 Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Highest Severity: Treatment Phase
(Analysis Set: Safety Population)

System Organ Class Preferred Term Severity	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Subjects with at least one TEAE	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)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.1	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)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	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)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

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Programmer note: Sort by descending overall frequency by SOC, then PT, then alphabetically by SOC/PT if there are ties. Only present severity categories with at least one subject.

Table 4.6.2 Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Highest Severity: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer Note: Repeat Table 4.6.1 for Extension Phase, with Placebo column removed.

Protocol: AR1001-ADP2-US01 AR1001

Table 4.6.3 Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Highest Severity: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Randomized Treatment Group:					
Treatment Phase:	Placebo		AR1001 10 mg	AR1001 30 mg	
Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
	(N = x)	(N = x)	(N = x)	(N = x)	(N = x)
System Organ Class Preferred Term Severity	n (%)	n (%)	n (%)	n (%)	n (%)
Subjects with at least one TEAE	xx (xx.x)	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)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.1	xx (xx.x)	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)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	xx (xx.x)	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)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

Source: SRCNAME
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Programmer note: Sort by descending overall frequency by SOC, then PT, then alphabetically by SOC/PT if there are ties. Only present severity categories with at least one subject.

Table 4.7.1 Incidence of Treatment-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 4.2.1, restricted to Treatment-Related TEAEs. Change the first line to 'Subjects with at least one Treatment-Related TEAE'. Add footnote: "Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related."

Table 4.7.2 Incidence of Treatment-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.2.2, restricted to Treatment-Related TEAEs. Change the first line to 'Subjects with at least one Treatment-Related TEAE'. Add footnote: "Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related."

Table 4.7.3 Incidence of Treatment-Related Treatment Emergent Adverse Events by System Organ Class and Preferred Term: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.2.3, restricted to Treatment-Related TEAEs. Change the first line to 'Subjects with at least one Treatment-Related TEAE'. Add footnote: "Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related."

Table 4.8.1 Incidence of Treatment-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Highest Severity: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 4.6.1, restricted to Treatment-Related TEAEs. Change the first line to 'Subjects with at least one Treatment-Related TEAE'. Add footnote: "Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related."

Table 4.8.2 Incidence of Treatment-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Highest Severity: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.6.2, restricted to Treatment-Related TEAEs. Change the first line to 'Subjects with at least one Treatment-Related TEAE'. Add footnote: "Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related."

Table 4.8.3 Incidence of Treatment-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Highest Severity: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.6.3, restricted to Treatment-Related TEAEs. Change the first line to 'Subjects with at least one Treatment-Related TEAE'. Add footnote: "Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related."

Table 4.9.1 Incidence of Deaths by Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 4.4.1, restricted to Deaths. Change the first line to 'Subjects who Died'. Only create this table if there is at least one death in the study.

Table 4.9.2 Incidence of Deaths by Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.4.2, restricted to Deaths. Change the first line to 'Subjects who Died'. Only create this table if there is at least one death in the study.

Table 4.9.3 Incidence of Deaths by Preferred Term: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 4.4.3, restricted to Deaths. Change the first line to 'Subjects who Died'. Only create this table if there is at least one death in the study.

1.3.3 Laboratory Data

Protocol: AR1001-ADP2-US01 AR1001

Table 5.1.1 Laboratory Parameters by Visit – Hematology Panel: Treatment Phase
(Analysis Set: Safety Population)

Parameter (unit)	Visit	Statistic	Placebo (N=xxx)	AR1001 10 mg (N=xxx)	AR1001 30 mg (N=xxx)	Total (N=xxx)
Parameter 1 (unit)	Baseline	Actual Value:				
		n	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx
	Week 4	Actual Value:				
		n	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx
		Change From Baseline:				
		n	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx
	Etc.					

Baseline is defined as the last available measurement prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
At each time point, only subjects with a value both at that time point and at baseline are included in the summary.

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Programmer note: Repeat for Week 13 and Week 26. Repeat the parameter at the beginning of each page under column header. Decimal places for each parameter should be determined by the number of significant digits for the individual parameter. The minimum and maximum should have the same number of decimal places as the original value. The mean and median should have the one more decimal place than the original value. The SD should have two more decimal places than the original value. If the original value has 2 or more decimal places, the minimum and maximum should have 2 decimal places and the mean, median, and SD should have 3 decimal places.

Protocol: AR1001-ADP2-US01 AR1001

Table 5.1.2 Laboratory Parameters by Visit – Hematology Panel: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

		Randomized Treatment Group:					
		Treatment Phase:	AR1001 10 mg	AR1001 30 mg	Placebo		
	Study Phase	Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
Parameter (unit)	Visit	Statistic	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)
Parameter 1 (unit)	Treatment Phase						
	Baseline	Actual Value:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
	Week 4	Actual Value:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
		Change From Baseline:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
	Etc.						

Baseline is defined as the last available measurement prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
At each time point, only subjects with a value both at that time point and at baseline are included in the summary.

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Programmer note: Repeat for Treatment Phase – Week 13 and Week 26, Extension Phase –Week 30, Week 39, and Week 52. Repeat the parameter at the beginning of each page under column header. Decimal places for each parameter should be determined by the number of significant digits for the individual parameter. The minimum and maximum should have the same number of decimal places as the original value. The mean and median should have the one more decimal place than the original value. The SD should have two more decimal places than the original value. If the original value has 2 or more decimal places, the minimum and maximum should have 2 decimal places and the mean, median, and SD should have 3 decimal places.

Table 5.2.1 Laboratory Parameters by Visit- Chemistry Panel: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 5.1.1 for the Chemistry Panel.

Table 5.2.2 Laboratory Parameters by Visit- Chemistry Panel: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 5.1.2 for the Chemistry Panel.

Table 5.3.1 Laboratory Parameters by Visit- Urinalysis Panel: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 5.1.1 for the Urinalysis Panel.

Table 5.3.2 Laboratory Parameters by Visit- Urinalysis Panel: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 5.1.2 for the Urinalysis Panel.

Protocol: AR1001-ADP2-US01 AR1001

Table 5.4.1 Shift Table for Laboratory Hematology Data: CTCAE Grading: Treatment Phase
(Analysis Set: Safety Population)

Hemoglobin Increased

		Post-Baseline Highest Grade					
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Treatment	Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n
Placebo	Grade 0 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 1 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 2 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 3 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 4 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Any Grade (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Missing (N=xxx)						
AR1001 10 mg	Grade 0 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 1 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 2 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 3 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 4 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Any Grade (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Missing (N=xxx)						
AR1001 30 mg	Grade 0 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 1 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 2 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 3 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Grade 4 (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Any Grade (N=xxx)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x
	Missing (N=xxx)						

Baseline is defined as the last available measurement prior to the first dose of study drug at Week 0 (Visit 2).
Grading criteria according to Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.
Grade 0 = No Grade, Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe or medically significant but note immediately life threatening, Grade 4 = Life-threatening, Grade 5 = Death.
N = number of subjects who received the treatment and had data in the baseline category with non-missing data Post-Baseline. n = number of subjects in baseline and post-baseline category. % = 100 x n/N.

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Programmer note: repeat for each laboratory test required within Hematology. Add Grade 5 to post-baseline categories shown if there are any deaths for the parameter. For the “Missing” Row, N=”Population N” minus the “Any Grade N”. Only include values from the Treatment Phase.

Table 5.4.2 Shift Table for Laboratory Hematology Data: CTCAE Grading: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 5.4.1 for the Chemistry Panel, including values from the Treatment and Extension Phases.

Table 5.5.1 Shift Table for Laboratory Chemistry Data: CTCAE Grading: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat Table 5.4.1 for the Chemistry Panel.

Table 5.5.2 Shift Table for Laboratory Chemistry Data: CTCAE Grading: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 5.4.1 for the Chemistry Panel, including values from the Treatment and Extension Phases.

1.3.4 Vital Signs

Protocol: AR1001-ADP2-US01 AR1001

Table 6.1.1 Vital Sign Measurements by Visit: Treatment Phase
(Analysis Set: Safety Population)

Parameter (Unit)	Visit	Statistic	Placebo (N=xxx)	AR1001 10 mg (N=xxx)	AR1001 30 mg (N=xxx)	Total (N=xxx)
Systolic Blood Pressure (mmHg)	Baseline	Actual Value:				
		n	xx	xx	xx	xx
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Minimum	xxx.x	xxx.x	xxx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x	xxx.x
			xxx.x	xxx.x	xxx.x	xxx.x
	Week 4	Actual Value:				
		n	xx	xx	xx	xx
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Minimum	xxx.x	xxx.x	xxx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x	xxx.x
			xxx.x	xxx.x	xxx.x	xxx.x
		Change From Baseline:				
		n	xx	xx	xx	xx
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Minimum	xxx.x	xxx.x	xxx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x	xxx.x
			xxx.x	xxx.x	xxx.x	xxx.x
	. . .					

SD = Standard Deviation.
Baseline is defined as last measurement taken prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
At each time point, only subjects with a value both at that time point and at baseline are included in the summary.

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Programmer note: Repeat the above assessments for Week 13, Week 26, and Week 28. Repeat for diastolic blood pressure (mmHg), pulse (bpm), respiratory rate (breaths/min), temperature (°C), and weight (kg). Repeat the parameter at the beginning of each page under column header.

Decimal places for each parameter should be determined by the number of significant digits for the individual parameter. The minimum and maximum should have the same number of decimal places as the original value. The mean and median should have the one more decimal place than the original value. The SD should have two more decimal places than the original value. If the original value has 2 or more decimal places, the minimum and maximum should have 2 decimal places and the mean, median, and SD should have 3 decimal places.

Protocol: AR1001-ADP2-US01 AR1001

Table 6.1.2 Vital Sign Measurements by Visit: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

		Randomized Treatment Group:					
		Treatment Phase:	AR1001 10 mg	AR1001 30 mg	Placebo		
	Study Phase	Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
Parameter (unit)	Visit	Statistic	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)
Systolic Blood Pressure (mmHg)	Treatment Phase						
	Baseline	Actual Value:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
	Week 4	Actual Value:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
		Change From Baseline:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
	Etc.						

SD = Standard Deviation.
Baseline is defined as last measurement taken prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
At each time point, only subjects with a value both at that time point and at baseline are included in the summary.

Source: SRCNAME
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Programmer note: Repeat for Treatment Phase – Week 13, Week 26, and Week 28, Extension Phase – Week 30, Week 39, Week 52, and Week 54. Repeat for diastolic blood pressure (mmHg), pulse (bpm), respiratory rate (breaths/min), temperature (°C), and weight (kg). Repeat the parameter at the beginning of each page under column header. Decimal places for each parameter should be determined by the number of significant digits for the individual parameter. The minimum and maximum should have the same number of decimal places as the original value. The mean and median should have the one more decimal place than the original value. The SD should have two more decimal places than the original value. If the original value has 2 or more decimal places, the minimum and maximum should have 2 decimal places and the mean, median, and SD should have 3 decimal places.

Protocol: AR1001-ADP2-US01 AR1001

Table 6.2.1 Incidence of Treatment-Emergent Potentially Clinically Significant Vital Signs: Treatment Phase
(Analysis Set: Safety Population)

Parameter	Post-baseline Criteria	Placebo (N=xxx) n/N1 (%)	AR1001 10 mg (N=xxx) n/N1 (%)	AR1001 30 mg (N=xxx) n/N1 (%)	Total (N=xxx) n/N1 (%)
Systolic Blood Pressure, increase	≥ xxx and increase from Baseline ≥ xx mmHg	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Systolic Blood Pressure, decrease	≤ xx and decrease from Baseline ≥ xx mmHg	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Diastolic Blood Pressure, increase	≥ xxx and increase from Baseline ≥ xx mmHg	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Diastolic Blood Pressure, decrease	≤ xx and decrease from Baseline ≥ xx mmHg	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
…					

Baseline is defined as last measurement taken prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
n is the number of subjects meeting the Post-baseline Criteria at any time after the first dose of study drug. N1= number of subjects with both post-baseline and baseline data for the parameter. % = 100 x n/N1.

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Programmer note: Replace Parameters and Post-baseline Criteria with criteria in SAP section 7.6.5. Only include values from the Treatment Phase.

Table 6.2.2 Incidence of Treatment-Emergent Potentially Clinically Significant Vital Signs: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 6.2.1, including values from the Treatment and Extension Phases.

1.3.5 Electrocardiogram (ECG)

Protocol: AR1001-ADP2-US01 AR1001

Table 7.1.1 ECG Parameters by Visit: Treatment Phase
(Analysis Set: Safety Population)

Parameter (Unit)	Study Phase Visit	Statistic	Placebo (N=xxx)	AR1001 10 mg (N=xxx)	AR1001 30 mg (N=xxx)	Total (N=xxx)
Heart Rate (beats/min)	Treatment Phase					
	Baseline	Actual Value:				
		n	xx	xx	xx	xx
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Minimum	xxx.x	xxx.x	xxx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x	xxx.x
			xxx.x	xxx.x	xxx.x	xxx.x
	Week 4	Actual Value:				
		n	xx	xx	xx	xx
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Minimum	xxx.x	xxx.x	xxx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x	xxx.x
			xxx.x	xxx.x	xxx.x	xxx.x
		Change From Baseline:				
		n	xx	xx	xx	xx
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Minimum	xxx.x	xxx.x	xxx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x	xxx.x
			xxx.x	xxx.x	xxx.x	xxx.x
	. . .					

SD = Standard Deviation.
Baseline is defined as last measurement taken prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
At each time point, only subjects with a value both at that time point and at baseline are included in the summary.

Source: SRCNAME
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Programmer note: Repeat the above assessments for Week 26. Repeat for PR interval (ms), QRS (ms) duration, QT interval (ms), and QTcF interval (ms). Repeat the parameter at the beginning of each page under column header.

Protocol: AR1001-ADP2-US01 AR1001

Table 7.1.2 ECG Parameters by Visit: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

		Randomized Treatment Group:					
		Treatment Phase:	AR1001 10 mg	AR1001 30 mg	Placebo		
	Study Phase	Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
Parameter (unit)	Visit	Statistic	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)
Heart Rate (beats/min)	Treatment Phase						
	Baseline	Actual Value:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
	Week 4	Actual Value:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
		Change From Baseline:					
		n	xx	xx	xx	xx	xx
		Mean	x.xx	x.xx	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx	x.xx	x.xx
		Minimum	x.xx	x.xx	x.xx	x.xx	x.xx
		Maximum	x.xx	x.xx	x.xx	x.xx	x.xx
	Etc.						

SD = Standard Deviation.
Baseline is defined as last measurement taken prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
At each time point, only subjects with a value both at that time point and at baseline are included in the summary.

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Programmer note: Repeat for Treatment Phase –Week 26, Extension Phase – Week 30 and Week 52. Repeat for PR interval (ms), QRS (ms) duration, QT interval (ms), and QTcF interval (ms). Repeat the parameter at the beginning of each page under column header.

Protocol: AR1001-ADP2-US01 AR1001

Table 7.2.1 Incidence of Treatment-Emergent Potentially Clinically Significant ECG Values: Treatment Phase
(Analysis Set: Safety Population)

		Placebo	AR1001 10 mg	AR1001 30 mg	Total
	Post-baseline	(N=xxx)	(N=xxx)	(N=xxx)	(N=xxx)
Parameter	Criteria	n/N1 (%)	n/N1 (%)	n/N1 (%)	n/N1 (%)
QTcF Prolongation	>= xxx msec if < xxx msec at baseline and >= xx msec change from baseline	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
	>= xxx msec if >= xxx msec at baseline and >= xx msec change from baseline	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
	Increase from baseline is >= xx msec	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)

…

Baseline is defined as last measurement taken prior to the first dose of study drug on Day 1 (Week 0, Visit 2).
n is the number of subjects meeting the Post-baseline Criteria at any time after the first dose of study drug. N1= number of subjects with both post-baseline and baseline data for the parameter. % = 100 x n/N1.

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Programmer note: Replace Parameters and Post-baseline Criteria with criteria in SAP section 7.6.6. Only include values from the Treatment Phase.

Table 7.2.2 Incidence of Treatment-Emergent Potentially Clinically Significant ECG Values: Both Phases
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat Table 7.2.1, including values from the Treatment and Extension Phases.

1.3.6 Prior and Concomitant Medications

Protocol: AR1001-ADP2-US01 AR1001

Table 8.1.1 Prior Medications by WHO Drug Class and Preferred Term
(Analysis Set: Safety Population)

WHO Drug Class Preferred Term	Placebo (N = x) n (%)	AR1001 10 mg (N = x) n (%)	AR1001 30 mg (N = x) n (%)	Total (N = x) n (%)
Subjects with at least one Prior Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				

WHO = World Health Organization.

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Programmer note: Sort by decreasing overall incidence in drug class, then preferred term, then alphabetically by drug class and preferred term to break ties.

Protocol: AR1001-ADP2-US01 AR1001

Table 8.1.2 Prior Medications by WHO Drug Class and Preferred Term
(Analysis Set: Safety Population Enrolled in Extension Phase)

Randomized Treatment Group:					
Treatment Phase:	Placebo		AR1001 10 mg	AR1001 30 mg	
Extension Phase:	AR1001 10 mg	AR1001 30 mg	AR1001 10 mg	AR1001 30 mg	Total
	(N = x)	(N = x)	(N = x)	(N = x)	(N = x)
WHO Drug Class Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)
Subjects with at least one Prior Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT #1.2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					

WHO = World Health Organization.

Source: SRCNAME
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Programmer note: Sort by decreasing overall incidence in drug class, then preferred term, then alphabetically by drug class and preferred term to break ties.

Table 8.2.1 Concomitant Medications by WHO Drug Class and Preferred Term: Treatment Phase
(Analysis Set: Safety Population)

Programmer note: Repeat table 8.1.1 for concomitant medications. Only include medications taken during the Treatment Phase.

Table 8.2.2 Concomitant Medications by WHO Drug Class and Preferred Term: Extension Phase
(Analysis Set: Safety Population Enrolled in Extension Phase)

Programmer note: Repeat table 8.1.2 for concomitant medications. Only include medications taken during the Extension Phase.

2. DATA LISTINGS

2.1 Subject Disposition and Demographics

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.1 Subject Disposition and Demographic Data
(Analysis Set: All Screened Subjects)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race / Ethnicity [a]	Height (cm) / Weight (kg) / BMI (kg/m²)	Randomized / Consented / Consent Date	Subject Study Status (Last Contact Study Day) [b]
xxx-xxxx Placebo Treated	xx/F/B/NH	xx/xx.x/xx.x	Yes/Yes/ yyyy-mm-dd	Completed Study (xxx)
xxx-xxxx AR1001 10 mg Treated	xx/M/W/H	xx/xx.x/xx.x	Yes/Yes/ yyyy-mm-dd	Discontinued Participant lost to follow-Up (xxx)
xxx-xxxx AR1001 30 mg Treated	xx/F/A/NH	xx/xx.x/xx.x	Yes/Yes/ yyyy-mm-dd	Discontinued Occurrence of Adverse Event (xxx)
xxx-xxxx NA Not Treated	xx/M/O/NH	xx/xx.x/xx.x	No/Yes/ yyyy-mm-dd	Discontinued Screen Failure (NA)

NA = Not Applicable
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported. Ethnicity: H = Hispanic or Latino; NH = Not Hispanic or Latino; NR = Not Reported.
[b] Date of Last Contact is per eCRF for subjects lost to follow-up, and date of last visit otherwise. Study Day is only calculated for treated subjects.

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Listing 1.2 NIA-AA Criteria – Probable AD Dementia
(Analysis Set: All Screened Subjects)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Visit	Criteria	Response
xxx-xxxx Placebo Treated	xx/M/B	Visit 1	All-Cause Dementia	
			1 Interfere with ability to function at work or in usual activities	Yes
			2 Represent a decline from previous levels of functioning	No
			3 Are not explained by delirium or a major psychiatric disorder	Yes
			4 Cognitive Impairment is detected and diagnosed through a combination of:	
			a history-taking from the patient and a knowledgeable informant	No
			b cognitive assessment ("bedside" mental status or neuropsych testing)	Yes
			5 Cognitive or behavioural impairment involves ≥ 2 of the following 5 domains	
			a impaired ability to acquire and remember new information	Yes
			b impaired reasoning and handling of complex tasks, poor judgement	No
			c impaired visuospatial abilities	Yes
			d impaired language functions	No
			e changes in personality, behavior, or comportment	Yes
			AD Dementia	
			1 Insidious onset (gradual over months to years)	Yes
			2 Clear-cut history of worsening of cognition by report or observation	No
			3 Initial, most prominent cognitive deficits	Amnestic presentation
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	Visit 1		
xxx-xxxx AR1001 30 mg Treated	xx/M/B	Visit 1		

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

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Listing 1.3 Early Withdrawal from the Study
(Analysis Set: All Randomized Subjects)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of First Dose	Date of Last Dose (Study Day)	Date of Last Contact [b] (Study Day)	Reason for Early Termination
xxx-xxxx Placebo Treated	xx/F/B	yyyy-mm-dd	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Participant lost to follow-up
xxx-xxxx AR1001 10 mg Treated	xx/M/W	yyyy-mm-dd	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Administrative or other reasons according to Sponsor decision
xxx-xxxx AR1001 30 mg Treated	xx/F/A	yyyy-mm-dd	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Occurrence of Adverse Event: <Preferred Term>
xxx-xxxx NA Not Treated	xx/M/O	NA	NA	yyyy-mm-dd (NA)	Screen Failure

NA = Not Applicable
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] Date of Last Contact is per eCRF for subjects lost to follow-up, and date of last visit otherwise. Study Day is only calculated for treated subjects.

Source: SRCNAME
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2.1.1 Protocol Deviations

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.4 Major Protocol Deviations
(Analysis Set: All Randomized Subjects)

Subject ID	Treatment	Treatment Status	Age / Gender / Race [a]	Major Protocol Deviation
xxx-xxxx	Placebo	Treated	xx/M/B	xxxx
xxx-xxxx	AR1001 10 mg	Untreated	xx/F/W	xxxx
xxx-xxxx	AR1001 30 mg	Treated	xx/M/B	xxxx

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

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Protocol: AR1001-ADP2-US01 AR1001

Listing 1.5 Violation of Inclusion/Exclusion Criteria
(Analysis Set: All Randomized Subjects)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Failed Criteria
xxx-xxxx Placebo Treated	xx/M/B	IC 1: xxx EC 3: xxx
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	EC 2: xxx
xxx-xxxx AR1001 30 mg Treated	xx/M/B	IC 1: xxx EC 3: xxx

IC = Inclusion Criterion; EC = Exclusion Criterion.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

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Programmer note: Include IC/EC, then criterion number, then ‘: ‘, and the text description of the failed criterion. Only present subjects with at least one failed IC/EC in this table

2.1.2 Subjects Excluded from Analysis Populations

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.6 Subjects Excluded from Analysis Populations
(Analysis Set: All Randomized Subjects)

Subject ID Randomized Treatment Treatment Status	ITT	PP	Safety	Population Excluded	Reason for Exclusion
xxx-xxxx Placebo Treated	Yes	No	No	PP	<80% Treatment Compliance
				Safety	No post-dose safety measurements
xxx-xxxx AR1001 10 mg Treated	Yes	No	Yes	PP	Did not complete Visit 5
xxx-xxxx AR1001 30 mg Treated	No	No	Yes	ITT	No post-dose efficacy measurements
				PP	Did not complete Visit 5
xxx-xxxx NA Not Treated	No	No	No	ITT	Never treated
				PP	Never treated
				Safety	Never treated

ITT = Intent to Treat; PP = Per-Protocol

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Programmer note: More details on derivation of reason for exclusion TBD.

2.1.3 Baseline Characteristics

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.7 Disease Characteristics
(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age at AD Diagnosis (years)	Time Since AD Diagnosis (years)	Global Deterioration Scale for Assessment of Primary Degenerative Dementia scale
xxx-xxxx Placebo Treated	55	3.3	6
xxx-xxxx AR1001 10 mg Treated	72	1.2	5
xxx-xxxx AR1001 30 mg Treated	60	2.5	4
xxx-xxxx NA Not Treated	51	7.0	7

AD = Alzheimer's Disease

Source: SRCNAME
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Listing 1.8 Baseline Efficacy Endpoints
(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	ADAS-Cog 13	MMSE-2: BV	MMSE-2: SV	NPI	GDS	QOL-AD-Family Version	QOL-AD-Participant Version
xxx-xxxx Placebo Treated	xx.xx	xx	xx	xxx	xx	xx	xx
xxx-xxxx AR1001 10 mg Treated	xx.xx	xx	xx	xxx	xx	xx	xx
xxx-xxxx AR1001 30 mg Treated	xx.xx	xx	xx	xxx	xx	xx	xx
xxx-xxxx NA Not Treated	xx.xx	xx	xx	xxx	xx	xx	xx

ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive Subscale; MMSE-2: BV = Mini-mental status examination, 2nd Edition: Brief Version; MMSE-2: SV = Mini-mental status examination, 2nd Edition: Standard Version; NPI = Neuropsychiatric Inventory; GDS = Geriatric Depression Scale; QOL-AD = Quality of Life in Alzheimer's Disease

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.9 Medical and Surgical History
(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	System Organ Class	Condition / Surgery (Preferred Term)	Start Date	End Date	Ongoing at Baseline
xxx-xxxx Placebo Treated	xx/M/B	xxxxxx	xxxxxx (xxxxx)	yyyy-mm-dd	yyyy-mm-dd	
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	xxxxxx	xxxxxx (xxxxx)	yyyy-mm		Yes
xxx-xxxx AR1001 30 mg Treated	xx/M/B	xxxxxx	xxxxxx (xxxxx)	Unknown	yyyy	

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.2 Efficacy

2.2.1 ADAS-Cog 13

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.10 ADAS-Cog 13

(Analysis Set: ITT Population)

			Item Number															
Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assessment / Start Time / End Time / Visit	1 - Trial 1 [b]	1 - Trial 2 [b]	1 - Trial 3 [b]	Parti-cipant Score [b]	2 [b]	3 [b]	4 [b]	5 [b]	6 [b]	7 [b]	8 [b]	9 [b]	10 [b]	11 [b]	12 [b]	13 [b]
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	x	x	x	x.xx	x	x	x	x	x	x	x	x	x	x	x	x
		yyyy-mm-dd / hh:mm / hh:mm / Visit 3	x	x	x	x.xx	x	x	x	x	x	x	x	x	x	x	x	x
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	x	x	x	x.xx	x	x	x	x	x	x	x	x	x	x	x	x
		yyyy-mm-dd / hh:mm / hh:mm / Visit 4	x	x	x	x.xx	x	x	x	x	x	x	x	x	x	x	x	x
xxx-xxxx AR1001 30 mg Treated	xx/M/B		x	x	x	x.xx	x	x	x	x	x	x	x	x	x	x	x	x

ADAS-Cog 13 = Alzheimer's Disease Assessment Scale-cognitive subscale.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] 1 - Trial 1 = Word Recall Task Trial 1, 1 - Trial 2 = Word Recall Task Trial 2, 1 - Trial 3 = Word Recall Task Trial 3, Participant Score = Participant's score, 2 = Commands, 3 = Construction Praxis, 4 = Delayed Recall, 5 = Naming Task, 6 = Ideational Praxis, 7 = Orientation, 8 = Word Recognition, 9 = Remembering Word Recognition Test Instructions, 10 = Spoken Language Ability, 11 = Comprehension of Spoken Language, 12 = Word-Finding Difficulty in Spontaneous Speech, 13 = Concentration/Distractibility.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.2.2 ADCS-CGIC

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.11 ADCS-CGIC

(Analysis Set: ITT Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assessment / Start Time / End Time / Visit	Clinical Impression of Change from Baseline
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	
			2 - Moderate Improvement
		yyyy-mm-dd / hh:mm / hh:mm / Visit 3	
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	
		yyyy-mm-dd / hh:mm / hh:mm / Visit 4	5 - Minimal Worsening
xxx-xxxx AR1001 30 mg Treated	xx/M/B		

ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change; NA = Not applicable.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.2.3 MMSE-2

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.12 MMSE-2

(Analysis Set: ITT Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assessment / Start Time / End Time / Visit	Assessment of Level of Consciousness	1 [b]	2 [b]	3 [b]	4 [b]	BV Total Raw Score	5 [b]	6 [b]	7 [b]	8 [b]	9 [b]	10 [b]	11 [b]	SV Total Raw Score
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	Drowsy	x	x	x	x	xx	x	x	x	x	x	x	x	xx
		yyyy-mm-dd / hh:mm / hh:mm / Visit 3	Alert	x	x	x	x	xx	x	x	x	x	x	x	x	xx
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	Alert	x	x	x	x	xx	x	x	x	x	x	x	x	xx
		yyyy-mm-dd / hh:mm / hh:mm / Visit 4	Stupor	x	x	x	x	xx	x	x	x	x	x	x	x	xx
xxx-xxxx AR1001 30 mg Treated	xx/M/B															

MMSE-2 = Mini-mental status examination, 2nd Edition; BV = Brief Version; SV = Standard Version.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

[b] 1 = Registration, 2 = Orientation to time, 3 = Orientation to place, 4 = Recall, 5 = Attention and Calculation, 6 = Naming, 7 = Repetition, 8 = Comprehension, 9 = Reading, 10 = Writing, 11 = Drawing.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.2.4 NPI

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.13 NPI

(Analysis Set: ITT Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assess-ment / Start Time / End Time / Visit	Symptom	Frequency	Severity	Distress
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	A. Delusions	Often	Mild	Minimal
			B. Hallucinations	Frequently	Severe	Mild
			C. Agitation/Aggression			
			D. Depression/Dysphoria	…	…	…
			E. Anxiety			
			F. Elation/Euphoria			
			G. Apathy/Indifference			
			H. Disinhibition			
			I. Irritability/Liability			
			J. Aberrant Motor Behavior			
			K. Sleep			
			L. Appetite and Eating Disorders			
		yyyy-mm-dd / hh:mm / hh:mm / Visit 3	…			
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2 yyyy-mm-dd / hh:mm / hh:mm / Visit 4				
xxx-xxxx AR1001 30 mg Treated	xx/M/B					

NPI = Neuropsychiatric Inventory; NA = Not applicable.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
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2.2.5 GDS

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.14 GDS

(Analysis Set: ITT Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assessment / Start Time / End Time / Visit	1 [b]	2 [b]	3 [b]	4 [b]	5 [b]	6 [b]	7 [b]	8 [b]	9 [b]	10 [b]	11 [b]	12 [b]	13 [b]	14 [b]	15 [b]	Total Score
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	Yes	No	Yes	No	…											2
		yyyy-mm-dd / hh:mm / hh:mm / Visit 3	No	Yes	No	Yes	…											4
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2																
		yyyy-mm-dd / hh:mm / hh:mm / Visit 4																
xxx-xxxx AR1001 30 mg Treated	xx/M/B																	

GDS = Geriatric Depression Scale.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] 1 = Are you basically satisfied with your life?, 2 = Have you dropped many of your activities and interests?, 3 = Do you feel that your life is empty?, 4 = Do you often get bored?, 5 = Are you in good spirits most of the time?, 6 = Are you afraid that something bad is going to happened to you?, 7 = Do you feel happy most of the time?, 8 = Do you often feel helpless?, 9 = Do you prefer to stay at home, rather than going out and doing new things?, 10 = Do you feel you have more problems with memory than most?, 11 = Do you think it is wonderful to be alive now?, 12 = Do you feel pretty worthless the way you are now?, 13 = Do you feel full of energy?, 14 = Do you feel that your situation is hopeless?, 15 = Do you think that most people are better off than you are?.

Source: SRCNAME

Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.2.6 QOL-AD- Family Version

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.15 QOL-AD- Family Version

(Analysis Set: ITT Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assess-ment / Start Time / End Time / Visit	Evaluation	Score	Comments
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	1 Physical health	x	xxxxxxxxxxxxxx
			2 Energy	x	
			3 Mood	x	
			4 Living situation	x	
			5 Memory	x	
			6 Family	x	
			7 Marriage	x	
			8 Friends	x	
			9 Self as a whole	x	
			10 Ability to do chores around the house	x	
			11 Ability to do things for fun	x	
			12 Money	x	
			13 Life as a whole	x	
			Informant's score of subject's QOL	xx	
		yyyy-mm-dd / hh:mm / hh:mm / Visit 5	…		
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2			
		yyyy-mm-dd / hh:mm / hh:mm / Visit 5			
xxx-xxxx AR1001 30 mg Treated	xx/M/B				

QOL-AD- Family Version = Quality of Life in Alzheimer's Disease - Family Version.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.2.7 QOL-AD- Participant Version

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.16 QOL-AD- Participant Version

(Analysis Set: ITT Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Date of Assessment / Start Time / End Time / Visit	Evaluation	Score	Comments
xxx-xxxx Placebo Treated	xx/M/B	yyyy-mm-dd / hh:mm / hh:mm / Visit 2	1 Physical health	x	xxxxxxxxxxxxxx
			2 Energy	x	
			3 Mood	x	
			4 Living situation	x	
			5 Memory	x	
			6 Family	x	
			7 Marriage	x	
			8 Friends	x	
			9 Self as a whole	x	
			11 Ability to do things for fun	x	
			12 Money	x	
			13 Life as a whole	x	
			Subject's own QOL rating	xx	
		yyyy-mm-dd / hh:mm / hh:mm / Visit 5	…		
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	yyyy-mm-dd / hh:mm / hh:mm / Visit 2 yyyy-mm-dd / hh:mm / hh:mm / Visit 5			
xxx-xxxx AR1001 30 mg Treated	xx/M/B				

QOL-AD- Participant Version = Quality of Life in Alzheimer's Disease - Participant Version.
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

2.3 Dosing

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.17 Study Drug Exposure

(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Visit	Were Treatment Kits Dispensed to the Subject?	Date of Dispensing	Kit number(s) dispensed	Were treatment kits dispensed at the previous visit returned by the subject at this visit?	Number of dose returned from bottle A	Number of dose returned from bottle B	Were any missed doses reported by the subject during the preceding treatment period?	Number of dose missed from bottle A	Number of dose missed from bottle B	Study Drug Duration (Days) [b]
xxx-xxxx Placebo Treated	xx/M/B	2	Yes	yyyy-mm-dd	xx, xx		x	X	Yes	x	X	xx
		3	Yes	yyyy-mm-dd	xx, xx	Yes	x	X	Yes	x	X	
xxx-xxxx AR1001 10 mg Untreated	xx/F/W	2	Yes	yyyy-mm-dd	xx, xx		x	X	Yes	x	X	xx
		4	Yes	yyyy-mm-dd	xx, xx	Yes	x	x	Yes	x	x	
xxx-xxxx AR1001 30 mg Treated	xx/M/B		No			No			No			

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] Study Drug Duration (Days) = (last date of dispensing – first date of dispensing) + 1

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Note to Programmer: For Study Drug Duration, calculate as ((last date of dispensing – first date of dispensing) + 1). Only present duration at the first visit for each subect.

2.4 Safety Data

2.4.1 Adverse Events

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.18 Adverse Events

(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	SOC	Verbatim AE (Preferred Term)	Start Date (Study Day) / End Date	Duration (days) [b]	TEAE / SAE	Severity	Related	Study Drug Action	Treatment Given?	Outcome
xxx-xxxx Placebo Treated	xx/M/B	xxxxxx	xxxxxxx (xxxxxxx)	yyyy-mm-dd (xx)/ yyyy-mm-dd	xx	Yes/ No	Mild	NR	None	Yes	Resolving
							Mod. Sev.	Rel.	Int.		

Mod. = Moderate; Sev. = Severe; Rel. = Related; NR = Not Related; Int. = Interrupted; DC = Permanently Discontinued.
[a] Sex: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] Duration of Event (days) = End Date – Start Date + 1.
Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related. AEs that are Not Related include AEs reported as Unlikely related or Not related.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, onset date, then verbatim AE.

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.19 Adverse Events Leading to Premature Discontinuation of Study Drug

(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	SOC	Verbatim AE (Preferred Term)	Start Date (Study Day) / End Date	Duration (days) [b]	TEAE / SAE	Severity	Related	Study Drug Action	Treatment Given?	Outcome
xxx-xxxx Placebo Treated	xx/M/B	xxxxxx	xxxxxxx (xxxxxxx)	yyyy-mm-dd (xx)/ yyyy-mm-dd	xx	Yes/ No	Mild Mod. Sev.	NR Rel.	None Int.	Yes	Resolving

Mod. = Moderate; Sev. = Severe; Rel. = Related; NR = Not Related; Int. = Interrupted; DC = Permanently Discontinued.
[a] Sex: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] Duration of Event (days) = End Date – Start Date + 1.
Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related. AEs that are Not Related include AEs reported as Unlikely related or Not related.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, onset date, then verbatim AE.

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.20 Serious Adverse Events

(Analysis Set: Safety Population)

SOC / Verbatim AE (Preferred Term)	Start Date (Study Day) / End Date	Duration (days) [b]	Date Event Became Serious / Most Recent Dose of Study Drug Prior to SAE	Treatment Emergent ? / Severity / Related	Study Drug Action / Treatment Given ? / Outcome	If Study Drug Interrupted Date Stopped / Did AE Abate / Date Restarted / Did AE Reoccur	If Study Drug Discontinued Date of Last Dose	Serious Criteria	If Death, Date of Death / Autopsy Performed	If Hospitalization / Prolongation of Existing Hospitalization, Admission Date / Discharge Date
Subject ID (Randomized Treatment/Treatment Status) Age/Gender/Race [a]: xxx-xxxx (Placebo/Treated) xx/M/B										
xxxxxx / xxxxxxx (xxxxxxx)	yyyy-mm-dd (xx)/ yyyy-mm-dd	xx	yyyy-mm-dd / yyyy-mm-dd	Yes / Mild / NR	None / Yes / Resolving	yyyy-mm-dd / Yes yyyy-mm-dd / No	yyyy-mm-dd	Death / Hospitalization/Prolongation of Existing Hospitalization	yyyy-mm-dd / Yes	yyyy-mm-dd / yyyy-mm-dd

Mod. = Moderate; Sev. = Severe; Rel. = Related; NR = Not Related; Int. = Interrupted; DC = Permanently Discontinued.
[a] Sex: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] Duration of Event (days) = End Date – Start Date + 1.
Treatment Related AEs include AEs reported as Definitely related, Probably related, or Possibly related. AEs that are Not Related include AEs reported as Unlikely related or Not related.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, onset date, then verbatim AE.

2.4.2 Columbia Suicide Severity Rating Scale (C-SSRS)

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.21 C-SSRS

(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Visit	Assessment Date / Start Time / End Time (Study Day)	Assessment Timeframe	Question	Response
xxx-xxxx Placebo Treated	xx/M/B	Screening	yyyy-mm-dd/ hh:mm (xx)	Lifetime	Suicidal Ideation – 1. Wish to be Dead	Yes: xxxx

C-SSRS = Columbia Suicide Severity Rating Scale
[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, assessment date, timeframe (Lifetime/Past 6 months/Since last visit) then question (as asked in the assessment). If a question has a free text description, please append it to the response followed by ':' (e.g. Yes: drawn to high places). Only report values which are answered 'Yes'.

2.4.3 Laboratory Parameters

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.22 Laboratory Parameters – Hematology Panel

(Analysis Set: Safety Population)

Subject ID (Randomized Treatment/Treatment Status) Age/Gender/Race [a]: xxx-xxxx (Placebo/Treated) xx/M/B

Visit	Date of Collection (Study Day)	Lab Parameter (unit)	Value	Normal Range Low - High	Reported Flag [b]	Baseline Value	Change from Baseline
Screening	yyyy-mm-dd (xx)	xxxxx (xxx)	xx.xxx	xxx - xxx	CL	xx.xxx	x.xxx

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] L = Low; H = High; LN = Low Normal; N = Normal; HN = High Normal.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, collection date, then lab parameter. Report SI result if available, otherwise original.

Listing 1.23 Laboratory Parameters – Chemistry Panel

(Analysis Set: Safety Population)

Programmer note: Repeat Listing 1.21 for the Chemistry Panel.

Listing 1.24 Laboratory Parameters – Urinalysis Panel

(Analysis Set: Safety Population)

Programmer note: Repeat Listing 1.21 for the Urinalysis Panel.

2.4.4 Vital Signs

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.25 Vital Signs

(Analysis Set: Safety Population)

Subject ID (Randomized Treatment/Treatment Status) Age/Gender/Race [a]: xxx-xxxx (Placebo/Treated) xx/M/B

Visit	Date of Assessment (Study Day)	Parameter (unit)	Value	Baseline Value	Change from Baseline
Screening	yyyy-mm-dd (xx)	xxxxx (xxx)	xx.xxx	xx.xxx	x.xxx

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, visit, collection date, then parameter.

2.4.5 Electrocardiogram (ECG)

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.26 ECG

(Analysis Set: Safety Population)

Visit	Date of Assessment (Study Day)	Parameter (unit)	Value [b]	Baseline Value [b]	Change from Baseline
Subject ID (Randomized Treatment/Treatment Status) Age/Gender/Race [a]: xxx-xxxx (Placebo/Treated) xx/M/B					
Screening	yyyy-mm-dd (xx)	xxxxx (xxx)	xx.xxx	xx.xxx	x.xxx

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.
[b] ECG Interpretation: 1: Normal; 2: Abnormal, not clinically significant; 3: Abnormal, clinically significant.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, visit, collection date, then parameter. For ECG Interpretation do not present Change from Baseline at any visit.

2.4.6 Physical Examination

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.27 Physical Examination

(Analysis Set: Safety Population)

Visit	Was Physical Examination Performed	Date of Examination (Study Day)	If No, Reason not Performed
Subject ID (Randomized Treatment/Treatment Status) Age/Gender/Race [a]: xxx-xxxx (Placebo/Treated) xx/M/B			
Screening	Yes	yyyy-mm-dd (xx)	xxxxx

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, then examination date.

2.4.7 Pregnancy Test

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.28 Pregnancy Test

(Analysis Set: Safety Population)

Visit	Date of Test (Study Day)	Test Result
Subject ID (Randomized Treatment/Treatment Status) Age/Gender/Race [a]: xxx-xxxx (Placebo/Treated) xx/M/B		
Screening	yyyy-mm-dd (xx)	Negative

[a] Gender: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, visit, then test date.

2.4.8 Prior and Concomitant Medications

Protocol: AR1001-ADP2-US01 AR1001

Listing 1.29 Prior and Concomitant Medications

(Analysis Set: Safety Population)

Subject ID Randomized Treatment Treatment Status	Age / Gender / Race [a]	Medication Verbatim Term (Preferred Term)	Route (Other Route, Specify)	Frequency (Other Frequency, Specify)	Indication	Medication Start Date (Study Day) / End Date (Study Day) / Ongoing	Duration (Days)	Prior / Concomitant (Treatment Phase) / Concomitant (Extension Phase)
xxx-xxxx Placebo xxx xxx	xx/M/B	xxxxxxxxxxxx (xxxxxxxxxxxxx)	ORAL	PRN	xxxxxxxxxxxxxxxxx	yyyy-mm-dd (xx) / yyyy-mm-dd (xx)	xx	Yes/Yes/No
		xxxxxxxxxxxx (xxxxxxxxxxxxx)	OTHER: Transdermal	OTHER: Once a year	xxxxxxxxxxxxxxxxx	yyyy-mm-dd (xx) / Ongoing		Yes/Yes/Yes

[a] Sex: M = Male; F = Female. Race: AIAN = American Indian or Alaska Native; A = Asian; B = Black or African American; NHPI = Native Hawaiian or Pacific Islander; W = White; O = Other; MULT = Multiple races reported; UNK = Unknown; NR = Not Reported.

Source: SRCNAME
Program:/sasdir/PGNAME.sas Version yyyy-mm-dd hh:mm (Page x of y)

Programmer note: Sort by subject, medication start date, then medication verbatim term. Do not present a study day if the date is partially complete (year only or year and month only).