

## R Consortium R Submission Pilot 1 - Summary Tables and Figures

**Note:** In this pilot, different open-source packages were used when generating each of the 4 analysis outputs to test wider use case scenarios. The outputs were formatted differently intentionally to cover different company specific formatting choices.

**Table 14-2.01**

### Summary of Demographic and Baseline Characteristics

Protocol: CDISCPIL0T01  
Population: Intent-to-Treat

	Placebo (N=86)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)
Age			
Mean (sd)	75.21 (8.59)	75.67 (8.29)	74.38 (7.89)
Median	76	77.5	76
Min - Max	52 - 89	51 - 88	56 - 88
Pooled Age Group 1			
<65	14	8	11
65-80	42	47	55
>80	30	29	18
Race			
WHITE	78	78	74
BLACK OR AFRICAN AMERICAN	8	6	9
AMERICAN INDIAN OR ALASKA NATIVE	0	0	1
Baseline Height (cm)			
Mean (sd)	162.57 (11.52)	163.43 (10.42)	165.82 (10.13)
Median	162.6	162.6	165.1
Min - Max	137.2 - 185.4	135.9 - 195.6	146.1 - 190.5
Baseline Weight (kg)			
Mean (sd)	62.76 (12.77)	67.28 (14.12)	70 (14.65)
Median	60.55	64.9	69.2
Min - Max	34 - 86.2	45.4 - 106.1	41.7 - 108
Baseline BMI (kg/m^2)			
Mean (sd)	23.64 (3.67)	25.06 (4.27)	25.35 (4.16)
Median	23.4	24.3	24.8
Min - Max	15.1 - 33.3	17.7 - 40.1	13.7 - 34.5
MMSE Total			
Mean (sd)	18.05 (4.27)	17.87 (4.22)	18.51 (4.16)
Median	19.5	18	20
Min - Max	10 - 23	10 - 24	10 - 24

Program: tlf\_demographic.Rmd  
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Table 14-3.01

## Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF

Protocol: CDISCPilot01  
Population: Efficacy

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Table 14-3.01  
Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF

	Placebo (N=79)	Xanomeline Low Dose (N=81)	Xanomeline High Dose (N=74)
Baseline			
n	79	81	74
Mean (SD)	24.1 (12.19)	24.4 (12.92)	21.3 (11.74)
Median (Range)	21.0 ( 5;61)	21.0 ( 5;57)	18.0 ( 3;57)
Week 24			
n	79	81	74
Mean (SD)	26.7 (13.79)	26.4 (13.18)	22.8 (12.48)
Median (Range)	24.0 ( 5;62)	25.0 ( 6;62)	20.0 ( 3;62)
Change from Baseline			
n	79	81	74
Mean (SD)	2.5 ( 5.80)	2.0 ( 5.55)	1.5 ( 4.26)
Median (Range)	2.0 (-11;16)	2.0 (-11;17)	1.0 ( -7;13)
p-value(Dose Response) [1][2]			0.245
p-value(Xan - Placebo) [1][3]		0.569	0.233
Diff of LS Means (SE)		-0.5 (0.82)	-1.0 (0.84)
95% CI		(-2.1;1.1)	(-2.7;0.7)
p-value(Xan High - Xan Low) [1][3]			0.520
Diff of LS Means (SE)			-0.5 (0.84)
95% CI			(-2.2;1.1)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site group as factors and baseline value as a covariate.

[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable

[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

17:21 Tuesday, February 01, 2022

**Table 14-3.02**

**Primary Endpoint Analysis: CIBIC+ - Summary at Week 24 - LOCF**

**ANCOVA of Change from Baseline at Week 20**

	Baseline <sup>a</sup>		Week 20		Change from Baseline		
Treatment	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	LS Mean (95% CI) <sup>b</sup>
Xanomeline High Dose	84	5.4 ( 1.34)	31	5.8 ( 1.61)	31	0.2 ( 1.47)	0.16 (-0.31, 0.63)
Placebo	86	5.6 ( 2.14)	65	5.8 ( 1.50)	65	0.1 ( 2.08)	0.09 (-0.23, 0.42)
Pairwise Comparison			Difference in LS Mean (95% CI) <sup>b</sup>				p-Value
Xanomeline High Dose vs. Placebo			0.07 (-0.50, 0.63)				0.822
Root Mean Squared Error of Change = 1.30							
<sup>a</sup> Table is based on participants who have observable data at Baseline and Week 20.							
<sup>b</sup> Based on an Analysis of covariance (ANCOVA) model with treatment and baseline value as covariates							
CI = Confidence Interval, LS = Least Squares, SD = Standard Deviation							

Source: [pilot1 wrappers: adam-adsl; adlbc]

Figure 14-1

Time to Dermatologic Event by Treatment Group

