R Consortium R Submission Pilot 5 - Summary Tables and Figures

Pilot5 Team

2025-09-29

Note : In Pilot 5, following the same approach as Pilot1, 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

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Protocol: CDISCPILOT01
Population: Intent-to-Treat
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	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	76.00	77.50	76.00
Min - Max	52.00 - 89.00	51.00 - 88.00	56.00 - 88.00
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	162.60	162.60	165.10
Min - Max	137.20 - 185.40	135.90 - 195.60	146.10 - 190.50
Baseline Weight (kg)			
Mean (sd)	62.76 (12.77)	67.28 (14.12)	70.00 (14.65)
Median	60.55	64.90	69.20
Min - Max	34.00 - 86.20	45.40 - 106.10	41.70 - 108.00
Baseline BMI (kg/m^2)			
Mean (sd)	23.64 (3.67)	25.06 (4.27)	25.35 (4.16)
Median	23.40	24.30	24.80
Min - Max	15.10 - 33.30	17.70 - 40.10	13.70 - 34.50
MMSE Total			
Mean (sd)	18.05 (4.27)	17.87 (4.22)	18.51 (4.16)
Median	19.50	18.00	20.00
Min - Max	10.00 - 23.00	10.00 - 24.00	10.00 - 24.00

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Program: tlf-demographic.r
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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.

Table 14-3.02

Primary Endpoint Analysis: Glucose (mmol/L) - Summary at Week 20 - LOCF

ANCOVA of Change from Baseline at Week 20

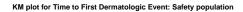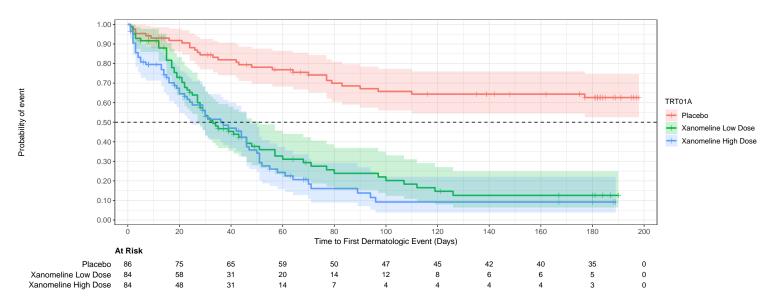| Treatment	Baseline[a]		Week 20		Change from Baseline		
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	LS Mean (95% CI)[b]
Xanomeline High Dose	84	5.4 (1.34)	31	5.8 (1.61)	31	0.2 (1.47)	0.16 (-0.31, 0.63)
Placebo	86	5.6 (2.14)	65	5.8 (1.50)	65	0.1 (2.08)	0.09 (-0.23, 0.42)
Pairwise Comparison	Difference in LS Mean (95% CI)[b]						p-Value
Xanomeline High Dose vs. Placebo	0.07 (-0.50, 0.63)						0.822
Root Mean Squared Error of Change = 1.30							

[a] Table is based on participants who have observable data at Baseline and Week 20.
[b] Based on an Analysis of covariance (ANCOVA) model with treatment and baseline value as covariates
CI = Confidence Interval, LS = Least Squares, SD = Standard Deviation

Figure 14-1

Time to Dermatologic Event by Treatment Group

KM plot for Time to First Dermatologic Event: Safety population

At Risk											
Placebo	86	75	65	59	50	47	45	42	40	35	0
Xanomeline Low Dose	84	58	31	20	14	12	8	6	6	5	0
Xanomeline High Dose	84	48	31	14	7	4	4	4	4	3	0

Program: tlf–kmplot.r [2025–09–11 12:59:06.233846]