

R Consortium R Submission Pilot 5 - Summary Tables and Figures

Pilot5 Team

2026-01-07

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

Warning in lapply(d[dbl_cols], as.double): NAs introduced by coercion
Warning in lapply(d[dbl_cols], as.double): NAs introduced by coercion

Protocol: CDISCPILOT01
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 | 76.00 | 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 |

Program: tlf-demographic.r
2026-01-07 19:37:03.11848

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.

Source: <run interactively>

19:19 Wednesday, January 07, 2026

Table 14-3.02

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

ANCOVA of Change from Baseline at Week 20

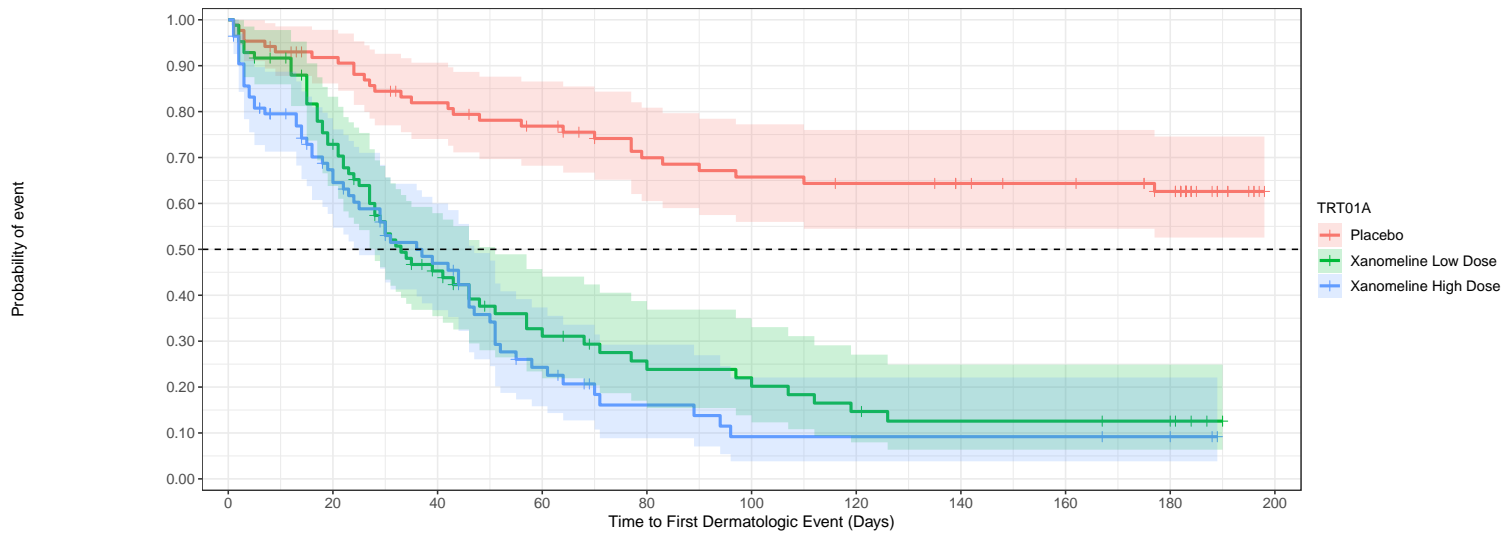
| | Baseline ^a | | Week 20 | | Change from Baseline | | |
|--|-----------------------|-------------|---|-------------|----------------------|-------------|-------------------------------|
| Treatment | N | Mean (SD) | N | Mean (SD) | N | Mean (SD) | LS Mean (95% CI) ^b |
| Xanomeline High Dose | 84 | 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 | | | | | | | |

Table generated on: 2026-01-07 19:19:04.70865
Source: [pilot5: adam-adsl; adlbc]

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 |