R Consortium R Submission Pilot 5 - Summary Tables and Figures

Pilot 5 Team

2025-07-28

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    Xanomeline Low Dose   Xanomeline High Dose
                                    (N=86)          (N=84)                (N=84)
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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\line(N=79)	Xanomeline\li ne Low Dose\line(N=8 1)	Xanomeline\li ne High Dose\line(N=7 4)
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)

Column names: row_label, var1_Placebo, var1_Xanomeline Low Dose,
var1_Xanomeline High Dose

Protocol: CDISCPILOT01
Population: Intent-to-Treat

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	Placebo (N=86)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)

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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 14-3.02

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

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[[1]]
                    Trt N1       Mean1 N2        Mean2 N3        Mean3
1 Xanomeline High Dose 84   5.4 ( 1.34) 31   5.8 ( 1.61) 31   0.2 ( 1.47)
2             Placebo 86   5.6 ( 2.14) 65   5.8 ( 1.50) 65   0.1 ( 2.08)
                    CI
1  0.16 (-0.31, 0.63)
2  0.09 (-0.23, 0.42)


[[2]]
                              comp             mean       p
1 Xanomeline High Dose vs. Placebo  0.07 (-0.50, 0.63)   0.822


[[3]]
                                 rmse
1 Root Mean Squared Error of Change = 1.30
```
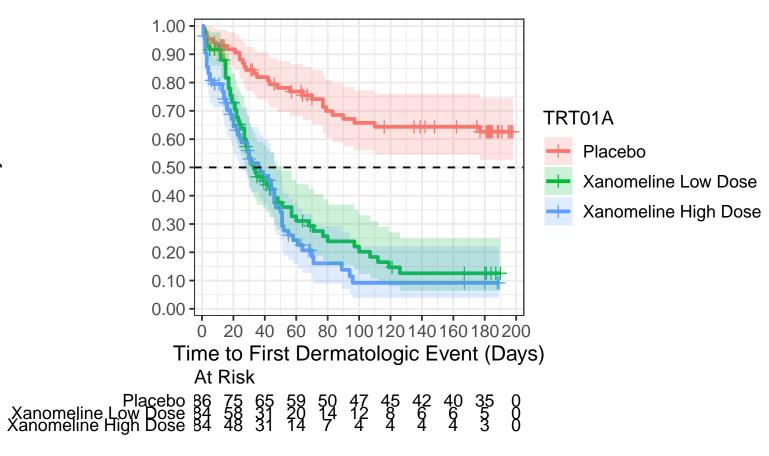
Figure 14-1

Time to Dermatologic Event by Treatment Group

Saving 6.5 x 4.5 in image