

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

	Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)
CHEMISTRY												
ALANINE AMINOTRANSFERASE												
Bsln	86	17.6	(9.22)		82	18.0	(8.72)		84	19.2	(10.05)	
Wk 2	83	18.0	(12.53)	0.2 (7.90)	80	20.9	(10.55)	2.8 (8.18)	78	21.0	(8.87)	1.6 (6.83)
Wk 4	79	18.7	(12.91)	0.7 (8.66)	72	17.5	(7.66)	-0.7 (5.08)	72	21.3	(9.51)	2.1 (7.08)
Wk 6	73	17.0	(9.92)	-0.3 (7.78)	62	17.0	(7.98)	-0.8 (4.87)	66	21.2	(9.49)	1.6 (6.11)
Wk 8	72	16.7	(9.34)	-1.1 (5.05)	60	17.6	(7.86)	0.2 (5.45)	56	22.8	(17.49)	3.2 (17.24)
Wk 12	67	18.0	(9.16)	0.0 (8.07)	51	18.5	(12.68)	0.1 (9.27)	50	21.0	(10.18)	0.7 (8.74)
Wk 16	68	17.1	(7.39)	-0.8 (7.94)	42	17.3	(7.51)	0.7 (5.80)	37	19.6	(7.61)	-0.3 (7.58)
Wk 20	65	16.1	(6.56)	-1.9 (7.49)	30	16.7	(6.33)	0.9 (4.77)	31	19.6	(6.82)	-0.3 (8.63)
Wk 24	57	17.9	(15.61)	-0.3 (16.62)	26	18.2	(9.17)	1.6 (5.66)	30	21.0	(8.70)	0.2 (8.25)
Wk 26	57	16.0	(5.98)	-2.1 (7.70)	25	17.8	(9.51)	1.5 (6.26)	27	18.9	(7.02)	-2.0 (7.01)
End[1]	84	18.1	(16.74)	0.4 (15.40)	82	18.3	(8.26)	0.3 (7.25)	80	19.5	(7.44)	0.1 (8.08)
ALBUMIN												
Bsln	86	39.8	(2.81)		82	39.8	(2.56)		84	40.3	(2.84)	
Wk 2	83	38.9	(3.11)	-1.0 (2.49)	80	38.7	(3.17)	-1.1 (2.71)	78	38.9	(2.76)	-1.4 (2.59)
Wk 4	79	38.8	(3.29)	-1.0 (2.69)	72	38.6	(2.80)	-1.2 (2.66)	72	39.1	(3.05)	-1.3 (2.70)
Wk 6	73	39.1	(2.56)	-1.0 (2.25)	62	38.4	(2.60)	-1.2 (2.49)	66	39.5	(2.76)	-1.0 (2.60)
Wk 8	72	39.8	(3.51)	-0.4 (2.70)	60	39.1	(2.93)	-0.5 (2.73)	56	39.8	(2.33)	-0.9 (2.21)
Wk 12	67	39.5	(3.49)	-0.5 (2.31)	51	38.9	(2.18)	-0.9 (2.19)	50	39.8	(2.45)	-0.6 (2.77)
Wk 16	68	40.4	(3.02)	0.4 (2.45)	42	39.1	(2.98)	-0.4 (2.78)	37	39.9	(1.92)	-0.7 (2.76)
Wk 20	65	39.6	(3.47)	-0.5 (2.86)	30	38.6	(2.66)	-1.2 (2.55)	31	39.6	(1.85)	-1.4 (2.86)

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

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Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Wk 24	57	39.7 (3.34)	-0.2 (2.88)	26	40.4 (2.52)	0.4 (2.40)	30	40.5 (2.10)	-0.5 (2.65)		
Wk 26	57	39.8 (3.02)	0.0 (2.26)	25	39.2 (2.39)	-1.0 (2.85)	27	40.0 (2.26)	-1.2 (2.78)		
End[1]	84	39.6 (3.32)	-0.2 (2.69)	82	39.2 (2.97)	-0.5 (2.64)	80	39.8 (2.48)	-0.5 (2.64)		
ALKALINE PHOSPHATASE											
Bsln	86	77.7 (58.11)		81	73.3 (20.72)		83	71.0 (38.85)			
Wk 2	84	77.7 (69.50)	0.1 (15.51)	80	73.0 (21.87)	0.3 (10.25)	78	72.2 (40.22)	-0.1 (8.09)		
Wk 4	82	78.0 (69.43)	0.4 (14.16)	72	73.2 (23.17)	-0.3 (11.12)	72	71.3 (40.65)	-0.7 (6.88)		
Wk 6	75	68.4 (21.53)	-0.4 (10.40)	64	72.7 (23.15)	-1.0 (10.83)	67	71.5 (43.40)	-0.2 (12.65)		
Wk 8	73	70.0 (27.15)	0.0 (10.67)	60	72.9 (23.84)	0.5 (14.09)	56	74.0 (45.60)	0.8 (13.54)		
Wk 12	67	72.1 (32.73)	1.8 (17.18)	52	69.5 (20.55)	-1.5 (9.41)	50	71.9 (46.65)	-1.7 (8.53)		
Wk 16	68	70.6 (29.49)	0.3 (16.98)	42	69.5 (19.43)	-1.7 (8.61)	37	74.7 (54.78)	-1.4 (8.29)		
Wk 20	65	72.6 (37.41)	1.9 (25.77)	31	70.6 (22.20)	-2.2 (9.90)	31	73.5 (55.23)	-2.7 (8.35)		
Wk 24	56	80.6 (68.06)	10.1 (58.71)	27	72.0 (21.80)	-0.4 (8.93)	30	64.4 (17.63)	-2.4 (7.44)		
Wk 26	57	81.0 (79.33)	10.1 (72.41)	25	68.6 (21.08)	-4.1 (10.74)	27	61.9 (16.60)	-3.9 (7.65)		
End[1]	84	84.6 (84.86)	7.1 (49.37)	82	71.6 (23.80)	-1.1 (13.09)	80	70.2 (37.91)	-1.6 (12.00)		
ASPARTATE AMINOTRANSFERASE											
Bsln	86	23.2 (7.50)		82	23.4 (8.24)		84	23.1 (6.61)			
Wk 2	83	23.6 (12.35)	0.2 (8.96)	80	24.7 (8.06)	1.6 (6.53)	78	23.4 (5.20)	0.4 (5.63)		
Wk 4	79	23.9 (14.93)	0.5 (11.33)	72	22.3 (6.75)	-1.4 (6.40)	72	23.8 (5.85)	0.6 (5.75)		
Wk 6	73	22.0 (6.40)	-0.9 (6.38)	62	22.1 (6.11)	-0.4 (4.19)	66	24.1 (7.84)	0.4 (6.10)		
Wk 8	72	22.3 (7.05)	-1.1 (4.84)	60	22.7 (5.95)	0.3 (4.02)	56	25.7 (13.33)	1.6 (13.98)		

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

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	Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)			
Wk 12	67	22.8 (7.64)	-0.6 (7.06)	51	24.2 (15.87)	1.5 (12.39)	50	23.3 (6.11)	-1.2 (6.26)			
Wk 16	68	22.8 (6.42)	-0.6 (6.43)	42	22.4 (10.34)	0.6 (7.62)	37	23.1 (5.78)	-0.7 (4.17)			
Wk 20	65	21.9 (5.90)	-1.6 (6.07)	30	20.7 (5.74)	0.4 (4.60)	31	24.0 (6.90)	-0.3 (6.18)			
Wk 24	57	25.2 (21.02)	1.2 (20.43)	26	22.4 (10.78)	2.1 (6.58)	30	24.4 (7.29)	-0.2 (5.48)			
Wk 26	57	21.5 (6.99)	-2.5 (7.29)	25	22.1 (11.85)	1.4 (7.69)	27	21.6 (5.71)	-3.1 (4.17)			
End[1]	84	25.1 (21.33)	1.8 (19.03)	82	23.2 (8.21)	-0.3 (8.06)	80	22.7 (6.13)	-0.4 (6.36)			
BILIRUBIN												
Bsln	86	9.7 (3.96)		82	9.4 (4.01)		84	11.0 (5.35)				
Wk 2	83	10.8 (12.26)	1.1 (10.29)	80	9.4 (4.16)	0.0 (3.08)	78	10.4 (3.94)	-0.6 (3.62)			
Wk 4	79	11.1 (13.57)	1.4 (11.65)	72	9.2 (3.84)	-0.3 (2.70)	72	10.9 (5.62)	-0.3 (3.07)			
Wk 6	73	9.6 (3.78)	0.1 (2.88)	62	9.5 (4.03)	0.0 (2.99)	66	10.9 (4.89)	-0.6 (3.18)			
Wk 8	72	9.4 (3.89)	-0.4 (3.43)	60	9.6 (4.72)	0.5 (3.11)	56	10.8 (5.21)	-0.7 (3.21)			
Wk 12	67	9.5 (3.56)	-0.1 (2.83)	51	8.8 (4.15)	0.1 (2.64)	50	11.5 (6.16)	-0.3 (4.78)			
Wk 16	68	10.0 (3.63)	0.2 (2.68)	42	8.8 (3.91)	0.4 (2.14)	37	11.6 (4.89)	-0.7 (4.28)			
Wk 20	65	10.1 (5.19)	0.3 (3.58)	30	8.8 (4.51)	0.3 (2.82)	31	11.8 (8.69)	-0.2 (6.41)			
Wk 24	57	9.4 (3.39)	0.1 (2.75)	26	10.1 (4.44)	1.1 (2.84)	30	12.3 (6.52)	-0.6 (2.89)			
Wk 26	57	10.0 (4.73)	0.4 (3.57)	25	10.2 (6.21)	1.4 (3.44)	27	12.2 (6.82)	-0.6 (5.31)			
End[1]	84	11.2 (13.42)	1.4 (11.28)	82	9.8 (4.29)	0.5 (3.08)	80	11.1 (5.36)	0.0 (3.16)			
CALCIUM												
Bsln	86	2.3 (0.09)		82	2.3 (0.11)		84	2.3 (0.10)				
Wk 2	84	2.3 (0.09)	0.0 (0.10)	80	2.3 (0.12)	0.0 (0.10)	78	2.3 (0.11)	0.0 (0.11)			

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Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Wk 4	82	2.3 (0.09)	0.0 (0.09)	72	2.3 (0.10)	0.0 (0.08)	72	2.3 (0.10)	0.0 (0.10)		
Wk 6	75	2.3 (0.09)	0.0 (0.10)	64	2.3 (0.10)	0.0 (0.08)	67	2.3 (0.09)	0.0 (0.10)		
Wk 8	73	2.3 (0.09)	0.0 (0.09)	60	2.3 (0.12)	0.0 (0.09)	56	2.3 (0.12)	0.0 (0.11)		
Wk 12	67	2.3 (0.09)	0.0 (0.08)	52	2.3 (0.10)	0.0 (0.07)	50	2.3 (0.09)	0.0 (0.09)		
Wk 16	68	2.3 (0.10)	0.0 (0.11)	42	2.3 (0.11)	0.0 (0.08)	37	2.3 (0.11)	0.0 (0.12)		
Wk 20	66	2.3 (0.09)	0.0 (0.09)	31	2.3 (0.10)	0.0 (0.09)	31	2.3 (0.08)	0.0 (0.09)		
Wk 24	57	2.3 (0.09)	-0.1 (0.10)	27	2.3 (0.11)	0.0 (0.12)	30	2.3 (0.10)	-0.1 (0.12)		
Wk 26	57	2.3 (0.10)	0.0 (0.10)	25	2.3 (0.10)	0.0 (0.08)	27	2.3 (0.09)	0.0 (0.10)		
End[1]	84	2.3 (0.09)	0.0 (0.10)	82	2.3 (0.10)	0.0 (0.10)	80	2.3 (0.10)	0.0 (0.11)		
CHLORIDE											
Bsln	86	105.7 (3.19)		82	105.8 (3.25)		83	105.4 (3.33)			
Wk 2	84	106.0 (3.12)	0.3 (3.40)	80	105.6 (3.12)	0.0 (3.44)	77	104.4 (3.49)	-0.8 (3.88)		
Wk 4	82	105.6 (3.53)	-0.1 (4.24)	72	105.5 (2.88)	-0.3 (3.72)	72	105.0 (3.46)	-0.4 (3.94)		
Wk 6	75	105.5 (3.14)	-0.1 (3.61)	64	106.3 (3.07)	0.6 (3.78)	67	105.3 (3.09)	-0.3 (3.47)		
Wk 8	73	106.0 (3.34)	0.3 (3.52)	60	105.6 (3.01)	-0.2 (3.47)	56	105.2 (3.57)	-0.1 (3.71)		
Wk 12	67	105.3 (2.93)	-0.3 (3.75)	52	105.7 (3.21)	-0.4 (3.63)	49	105.2 (2.40)	-0.1 (2.64)		
Wk 16	68	105.5 (3.16)	0.0 (3.57)	42	106.2 (2.93)	0.2 (3.17)	37	105.9 (2.66)	0.6 (2.54)		
Wk 20	65	106.0 (3.68)	0.6 (4.13)	31	106.3 (2.75)	-0.1 (2.41)	31	105.4 (3.03)	-0.2 (3.69)		
Wk 24	57	105.5 (3.14)	-0.1 (3.82)	27	105.3 (2.52)	-1.2 (2.95)	30	105.3 (3.21)	-0.1 (3.06)		
Wk 26	57	106.2 (2.58)	0.8 (3.33)	25	105.7 (2.35)	-0.5 (2.72)	27	105.7 (3.44)	0.4 (2.92)		
End[1]	84	105.6 (3.42)	-0.1 (3.86)	82	105.5 (3.37)	-0.1 (3.31)	80	105.0 (3.20)	-0.5 (3.17)		

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Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
CHOLESTEROL											
Bsln	86	5.8 (1.07)		82	5.7 (1.00)		84	5.8 (1.02)			
Wk 2	84	5.6 (1.02)	-0.1 (0.54)	80	5.6 (0.92)	-0.1 (0.50)	78	5.6 (0.93)	-0.2 (0.53)		
Wk 4	82	5.5 (0.94)	-0.2 (0.57)	72	5.5 (0.97)	-0.2 (0.49)	72	5.5 (1.00)	-0.3 (0.51)		
Wk 6	75	5.6 (0.95)	-0.1 (0.67)	64	5.4 (0.95)	-0.2 (0.55)	67	5.5 (0.91)	-0.3 (0.64)		
Wk 8	73	5.5 (1.02)	-0.2 (0.71)	60	5.5 (0.96)	-0.2 (0.49)	56	5.5 (0.94)	-0.3 (0.54)		
Wk 12	67	5.5 (0.92)	-0.2 (0.57)	52	5.3 (0.90)	-0.3 (0.47)	50	5.4 (0.91)	-0.3 (0.63)		
Wk 16	68	5.6 (0.98)	-0.1 (0.58)	42	5.3 (1.00)	-0.3 (0.48)	37	5.4 (0.94)	-0.2 (0.55)		
Wk 20	66	5.5 (0.94)	-0.2 (0.68)	31	5.2 (0.86)	-0.4 (0.46)	31	5.3 (0.85)	-0.3 (0.49)		
Wk 24	57	5.5 (1.01)	-0.3 (0.68)	27	5.4 (0.94)	-0.2 (0.65)	30	5.3 (0.89)	-0.3 (0.50)		
Wk 26	57	5.5 (0.94)	-0.3 (0.62)	25	5.2 (0.76)	-0.4 (0.64)	27	5.4 (0.90)	-0.2 (0.81)		
End[1]	84	5.5 (1.02)	-0.3 (0.76)	82	5.4 (0.96)	-0.3 (0.56)	80	5.4 (0.89)	-0.4 (0.60)		
CREATINE KINASE											
Bsln	86	86.9 (43.71)		82	100.6 (68.87)		84	104.0 (71.75)			
Wk 2	83	90.3 (66.11)	2.4 (57.72)	80	106.1 (83.92)	6.0 (84.97)	78	93.8 (53.19)	-12.0 (52.92)		
Wk 4	79	96.9 (124.45)	8.3 (116.54)	72	93.2 (51.67)	-7.8 (55.54)	72	100.6 (58.39)	-4.8 (53.80)		
Wk 6	73	88.0 (42.36)	-0.3 (40.55)	62	89.0 (44.29)	-13.7 (59.25)	66	123.5 (227.36)	17.8 (187.17)		
Wk 8	72	93.8 (45.84)	1.2 (46.26)	60	90.0 (39.16)	-8.3 (61.09)	56	91.8 (52.25)	-9.3 (59.25)		
Wk 12	67	101.8 (78.66)	8.9 (67.77)	51	94.7 (53.59)	-7.2 (65.59)	50	96.6 (60.55)	-2.8 (66.47)		
Wk 16	68	104.9 (66.37)	12.7 (52.13)	42	97.5 (56.39)	-6.9 (72.02)	37	86.1 (47.70)	-1.6 (24.32)		
Wk 20	65	93.8 (46.56)	1.0 (42.07)	30	111.6 (137.04)	21.5 (136.75)	31	97.5 (68.57)	6.0 (28.57)		
Wk 24	57	127.4 (207.98)	32.6 (200.00)	26	83.6 (38.60)	0.8 (21.99)	30	90.9 (53.97)	-1.1 (23.40)		

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Visit	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)
Wk 26	57	94.1	(51.03)	2.0 (46.93)	25	69.9	(23.70)	-15.0 (17.45)	27	93.0	(59.94)	1.4 (43.90)
End[1]	84	112.6	(173.34)	24.6 (165.91)	82	98.2	(61.12)	-1.9 (67.09)	80	95.1	(56.32)	-9.9 (60.94)
CREATININE												
Bsln	86	97.7	(17.78)		82	103.5	(20.01)		84	103.7	(19.37)	
Wk 2	84	99.0	(17.51)	1.4 (8.06)	80	106.2	(21.26)	2.3 (10.51)	78	106.3	(21.18)	2.8 (9.50)
Wk 4	82	98.6	(18.56)	1.1 (11.40)	72	105.1	(19.83)	2.0 (8.13)	72	105.8	(20.66)	2.6 (10.43)
Wk 6	75	101.7	(18.46)	3.3 (12.14)	64	104.4	(19.85)	1.7 (9.31)	67	105.8	(20.87)	3.2 (9.94)
Wk 8	73	99.1	(16.07)	0.0 (9.88)	60	104.3	(21.27)	1.8 (7.54)	56	106.1	(22.24)	3.2 (9.14)
Wk 12	67	101.5	(16.53)	2.4 (9.68)	52	101.8	(17.72)	1.8 (7.99)	50	108.2	(20.48)	5.8 (10.95)
Wk 16	68	100.4	(16.43)	1.2 (10.57)	42	98.5	(16.63)	-1.3 (9.29)	37	102.5	(17.86)	2.2 (9.18)
Wk 20	66	100.3	(17.92)	1.3 (11.31)	31	97.2	(17.23)	-1.8 (8.17)	31	103.5	(19.66)	3.1 (11.76)
Wk 24	57	99.3	(15.85)	0.8 (11.37)	27	99.2	(16.14)	1.7 (7.08)	30	100.2	(19.61)	-0.6 (10.36)
Wk 26	57	100.0	(18.46)	2.0 (9.30)	25	99.7	(18.84)	2.9 (8.10)	27	101.8	(18.73)	0.3 (8.31)
End[1]	84	98.5	(16.13)	0.8 (10.77)	82	105.6	(19.79)	1.8 (8.60)	80	104.6	(20.50)	1.4 (10.38)
GAMMA GLUTAMYL TRANSFERASE												
Bsln	86	24.9	(49.75)		82	22.2	(15.57)		84	22.8	(17.71)	
Wk 2	84	24.2	(47.03)	-0.8 (5.52)	80	22.6	(15.52)	0.2 (9.48)	78	23.7	(18.17)	0.6 (8.96)
Wk 4	82	24.5	(48.68)	-0.8 (5.69)	72	21.8	(13.82)	-1.1 (7.51)	72	23.3	(16.08)	0.1 (9.29)
Wk 6	75	19.9	(15.55)	0.3 (6.11)	64	21.9	(13.72)	-0.6 (6.88)	67	21.6	(13.48)	-0.5 (6.74)
Wk 8	73	20.6	(16.38)	0.1 (6.76)	60	23.6	(15.55)	1.1 (11.36)	56	26.8	(29.96)	4.0 (24.63)
Wk 12	67	21.4	(15.04)	0.5 (5.70)	52	21.9	(13.97)	-0.7 (8.80)	50	24.7	(21.26)	1.2 (8.19)

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Wk 16	68	20.8 (13.00)	-0.1 (5.65)	42	22.8 (14.86)	-0.1 (6.38)	37	23.9 (17.79)	-1.3 (6.16)		
Wk 20	66	20.4 (13.90)	-0.5 (5.42)	31	24.1 (17.52)	-0.4 (5.90)	31	22.2 (11.28)	-0.5 (5.98)		
Wk 24	57	22.0 (16.68)	0.5 (10.90)	27	23.7 (14.75)	0.5 (7.28)	30	25.5 (22.64)	-0.9 (6.48)		
Wk 26	57	21.4 (13.91)	-0.4 (7.08)	25	22.0 (15.31)	-1.0 (8.44)	27	23.4 (18.73)	-3.4 (7.97)		
End[1]	84	25.7 (48.78)	0.7 (9.60)	82	22.4 (14.03)	0.3 (10.36)	80	22.3 (15.66)	-0.6 (9.81)		
GLUCOSE											
Bsln	86	5.6 (2.14)		82	5.4 (0.94)		84	5.4 (1.34)			
Wk 2	83	5.6 (1.87)	0.0 (1.37)	80	5.6 (1.75)	0.1 (1.50)	78	6.1 (2.92)	0.7 (2.06)		
Wk 4	79	5.6 (1.87)	0.0 (1.55)	71	5.4 (1.41)	-0.1 (1.09)	72	5.9 (1.84)	0.4 (1.25)		
Wk 6	73	5.7 (2.22)	0.1 (1.37)	62	5.3 (1.34)	-0.1 (1.12)	66	6.0 (2.80)	0.5 (2.20)		
Wk 8	72	5.5 (1.35)	-0.1 (2.09)	59	5.5 (1.76)	0.1 (1.34)	56	5.8 (2.15)	0.2 (1.68)		
Wk 12	67	6.1 (1.97)	0.4 (1.97)	51	5.9 (3.18)	0.4 (2.78)	49	6.0 (2.28)	0.4 (1.64)		
Wk 16	68	5.5 (1.42)	-0.2 (1.69)	42	5.3 (0.83)	-0.2 (0.89)	37	5.9 (2.30)	0.2 (1.74)		
Wk 20	65	5.8 (1.50)	0.1 (2.08)	30	5.7 (1.73)	0.1 (1.39)	31	5.8 (1.61)	0.2 (1.47)		
Wk 24	57	5.7 (1.83)	-0.1 (2.68)	26	5.7 (1.26)	0.2 (0.82)	30	6.0 (1.92)	0.5 (1.94)		
Wk 26	57	5.8 (1.85)	0.0 (1.60)	25	5.5 (1.72)	0.1 (1.35)	27	5.6 (1.01)	0.1 (1.66)		
End[1]	84	5.6 (1.61)	0.0 (2.26)	82	5.4 (1.07)	-0.1 (1.03)	80	5.9 (2.15)	0.5 (1.62)		
PHOSPHATE											
Bsln	86	1.2 (0.15)		81	1.2 (0.11)		83	1.2 (0.15)			
Wk 2	84	1.2 (0.15)	0.0 (0.16)	80	1.2 (0.15)	0.0 (0.16)	78	1.2 (0.18)	0.0 (0.19)		
Wk 4	82	1.1 (0.16)	0.0 (0.17)	71	1.1 (0.14)	0.0 (0.14)	72	1.2 (0.18)	0.0 (0.16)		

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Wk 6	75	1.2 (0.15)	0.0 (0.17)	64	1.2 (0.17)	0.0 (0.17)	67	1.2 (0.15)	0.0 (0.16)		
Wk 8	73	1.1 (0.14)	0.0 (0.13)	60	1.1 (0.16)	0.0 (0.16)	56	1.2 (0.16)	0.0 (0.18)		
Wk 12	67	1.2 (0.16)	0.0 (0.18)	52	1.1 (0.14)	0.0 (0.18)	50	1.1 (0.15)	0.0 (0.17)		
Wk 16	68	1.1 (0.14)	0.0 (0.15)	42	1.1 (0.17)	0.0 (0.19)	37	1.2 (0.17)	0.0 (0.17)		
Wk 20	65	1.2 (0.17)	0.0 (0.15)	31	1.1 (0.13)	0.0 (0.14)	31	1.2 (0.15)	0.0 (0.16)		
Wk 24	56	1.2 (0.15)	0.0 (0.16)	27	1.2 (0.19)	0.1 (0.19)	30	1.1 (0.17)	0.0 (0.17)		
Wk 26	57	1.2 (0.15)	0.0 (0.18)	25	1.1 (0.17)	0.0 (0.17)	27	1.2 (0.19)	0.0 (0.20)		
End[1]	84	1.2 (0.17)	0.0 (0.18)	82	1.2 (0.17)	0.0 (0.18)	80	1.2 (0.16)	0.0 (0.17)		
POTASSIUM											
Bsln	86	4.3 (0.43)		81	4.3 (0.34)		82	4.3 (0.41)			
Wk 2	84	4.2 (0.41)	0.0 (0.37)	80	4.3 (0.41)	0.0 (0.38)	77	4.3 (0.40)	0.0 (0.46)		
Wk 4	82	4.2 (0.37)	-0.1 (0.38)	71	4.3 (0.40)	-0.1 (0.36)	72	4.2 (0.37)	-0.1 (0.46)		
Wk 6	75	4.3 (0.33)	0.0 (0.41)	64	4.3 (0.39)	-0.1 (0.41)	67	4.2 (0.32)	-0.1 (0.44)		
Wk 8	73	4.2 (0.37)	-0.1 (0.43)	60	4.3 (0.39)	0.0 (0.38)	56	4.2 (0.39)	0.0 (0.50)		
Wk 12	67	4.2 (0.41)	0.0 (0.46)	52	4.2 (0.42)	-0.2 (0.40)	49	4.2 (0.26)	-0.1 (0.39)		
Wk 16	68	4.2 (0.41)	0.0 (0.46)	42	4.3 (0.33)	-0.1 (0.35)	37	4.3 (0.27)	0.0 (0.35)		
Wk 20	64	4.3 (0.46)	0.0 (0.44)	31	4.3 (0.36)	0.0 (0.44)	31	4.3 (0.37)	0.0 (0.40)		
Wk 24	56	4.3 (0.44)	0.1 (0.44)	27	4.3 (0.41)	0.0 (0.35)	30	4.2 (0.42)	0.0 (0.50)		
Wk 26	57	4.2 (0.38)	0.0 (0.34)	25	4.3 (0.40)	0.0 (0.36)	27	4.3 (0.39)	0.0 (0.54)		
End[1]	84	4.3 (0.43)	0.0 (0.41)	82	4.3 (0.43)	-0.1 (0.39)	80	4.2 (0.36)	-0.1 (0.47)		

PROTEIN

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

	Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)
Bsln	86	70.5	(4.72)		82	70.4	(4.29)		84	71.0	(4.24)	
Wk 2	84	69.2	(4.93)	-1.3 (4.53)	80	69.5	(4.48)	-0.9 (3.63)	78	69.5	(4.31)	-1.6 (3.91)
Wk 4	82	69.0	(4.18)	-1.6 (3.93)	72	68.8	(4.30)	-1.5 (3.97)	72	69.8	(4.54)	-1.4 (3.90)
Wk 6	75	69.6	(3.95)	-1.2 (4.01)	64	68.8	(4.33)	-1.3 (4.17)	67	70.2	(4.28)	-1.1 (4.10)
Wk 8	73	70.5	(5.20)	-0.4 (4.35)	60	69.2	(3.95)	-0.9 (3.71)	56	70.6	(3.78)	-1.0 (3.57)
Wk 12	67	70.0	(4.28)	-0.6 (3.86)	52	69.3	(4.98)	-0.8 (3.62)	50	70.4	(3.83)	-1.0 (4.11)
Wk 16	68	71.2	(4.57)	0.4 (4.39)	42	69.3	(4.79)	-0.5 (4.27)	37	70.5	(4.93)	-1.0 (4.57)
Wk 20	66	70.0	(4.92)	-1.1 (4.53)	31	68.7	(4.82)	-1.3 (3.88)	31	69.5	(4.15)	-1.8 (4.13)
Wk 24	57	70.1	(4.33)	-0.8 (4.81)	27	70.9	(6.11)	0.7 (4.03)	30	70.7	(3.47)	-0.7 (3.83)
Wk 26	57	70.4	(4.48)	-0.5 (4.56)	25	69.4	(5.29)	-1.1 (4.26)	27	69.4	(4.89)	-2.5 (4.01)
End[1]	84	70.2	(4.26)	-0.3 (4.35)	82	70.1	(4.95)	-0.4 (3.97)	80	70.4	(3.91)	-0.7 (3.63)
SODIUM												
Bsln	86	140.3	(2.74)		82	140.0	(2.61)		83	140.0	(3.11)	
Wk 2	84	140.4	(2.62)	0.0 (3.35)	80	139.6	(2.47)	-0.3 (2.86)	77	139.1	(2.74)	-0.6 (2.87)
Wk 4	82	139.9	(2.74)	-0.4 (3.58)	72	140.1	(2.40)	0.2 (3.16)	72	139.7	(2.75)	-0.3 (3.39)
Wk 6	75	140.3	(2.58)	0.0 (3.08)	64	140.6	(2.69)	0.8 (3.25)	67	140.1	(2.61)	-0.2 (3.23)
Wk 8	73	140.7	(2.48)	0.4 (3.33)	60	140.4	(2.58)	0.6 (3.33)	56	140.5	(3.15)	0.3 (3.79)
Wk 12	67	140.4	(2.39)	0.2 (2.98)	52	141.1	(2.77)	1.1 (3.06)	49	140.2	(2.39)	-0.1 (2.79)
Wk 16	68	141.1	(2.37)	0.9 (3.10)	42	141.0	(2.62)	1.2 (2.93)	37	141.6	(2.96)	1.4 (3.18)
Wk 20	65	141.2	(2.53)	1.1 (3.01)	31	141.4	(2.53)	1.6 (3.42)	31	141.8	(3.87)	1.2 (3.61)
Wk 24	57	141.7	(2.23)	1.6 (3.27)	27	141.5	(2.12)	1.2 (3.12)	30	141.6	(2.99)	1.0 (3.10)
Wk 26	57	142.6	(2.25)	2.5 (2.90)	25	142.1	(2.08)	1.9 (3.13)	27	142.4	(3.07)	1.9 (3.43)

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

	Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)
End[1]	84	141.5	(2.74)	1.1 (3.51)	82	141.1	(2.65)	1.3 (3.09)	80	140.5	(3.22)	0.5 (3.50)
URATE												
Bsln	86	285.0	(74.45)		82	300.7	(77.78)		84	302.2	(78.01)	
Wk 2	84	284.0	(68.72)	-1.8 (50.16)	80	305.8	(74.25)	1.0 (40.56)	78	301.7	(81.96)	-2.7 (33.85)
Wk 4	82	285.6	(69.22)	-0.6 (35.59)	72	299.5	(79.44)	-3.7 (38.80)	72	291.4	(79.28)	-9.5 (42.17)
Wk 6	75	288.0	(68.73)	-1.1 (38.24)	64	298.1	(74.46)	-6.2 (30.89)	67	291.6	(74.82)	-9.8 (34.48)
Wk 8	73	285.6	(65.63)	-5.1 (36.28)	60	290.9	(71.15)	-15.6 (30.49)	56	291.6	(76.76)	-11.2 (35.13)
Wk 12	67	291.1	(70.07)	3.2 (40.20)	52	290.3	(63.20)	-11.5 (31.83)	50	294.2	(78.84)	-9.0 (36.29)
Wk 16	68	285.8	(68.72)	-3.6 (41.33)	42	288.8	(58.78)	-12.9 (39.98)	37	284.1	(80.47)	-19.9 (36.13)
Wk 20	66	301.9	(73.43)	12.1 (40.18)	31	279.7	(58.71)	-16.5 (44.34)	31	295.1	(85.89)	-9.6 (43.81)
Wk 24	57	293.5	(73.47)	4.6 (42.98)	27	274.9	(57.72)	-19.2 (31.26)	30	288.5	(88.37)	-19.4 (50.03)
Wk 26	57	291.9	(74.43)	5.1 (44.39)	25	279.3	(60.01)	-13.6 (39.12)	27	301.1	(86.31)	-12.6 (47.68)
End[1]	84	290.5	(73.86)	4.7 (46.43)	82	298.3	(80.54)	-3.1 (37.11)	80	292.4	(80.83)	-10.5 (42.35)
UREA NITROGEN												
Bsln	86	5.5	(1.39)		82	6.4	(1.97)		84	5.8	(1.88)	
Wk 2	84	5.8	(1.51)	0.3 (1.17)	80	6.6	(1.82)	0.3 (1.53)	78	6.0	(2.06)	0.3 (1.36)
Wk 4	82	5.9	(1.47)	0.3 (1.11)	72	6.4	(1.63)	0.0 (1.37)	72	5.9	(1.87)	0.3 (1.30)
Wk 6	75	6.1	(1.42)	0.5 (1.16)	64	6.4	(1.76)	-0.1 (1.32)	67	6.0	(2.06)	0.3 (1.43)
Wk 8	73	5.6	(1.58)	0.0 (1.22)	60	6.3	(1.92)	0.0 (0.95)	56	5.9	(1.93)	0.1 (1.25)
Wk 12	67	5.9	(1.61)	0.2 (1.24)	52	6.2	(1.49)	0.0 (1.45)	50	5.9	(1.76)	0.1 (1.50)
Wk 16	68	5.8	(1.60)	0.2 (1.28)	42	6.0	(1.62)	-0.2 (1.25)	37	5.7	(1.92)	0.2 (1.29)

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Wk 20	66	5.8 (1.53)	0.1 (1.28)	31	5.6 (1.57)	-0.6 (1.39)	31	5.9 (2.25)	0.2 (1.50)		
Wk 24	57	5.9 (1.32)	0.3 (1.24)	27	6.0 (2.07)	0.0 (1.37)	30	5.3 (1.92)	-0.3 (1.37)		
Wk 26	57	6.1 (1.62)	0.4 (1.36)	25	5.7 (1.93)	-0.3 (1.14)	27	5.9 (2.47)	0.3 (1.40)		
End[1]	84	5.9 (1.38)	0.3 (1.20)	82	6.6 (1.95)	0.2 (1.37)	80	5.7 (1.97)	0.0 (1.57)		
HEMATOLOGY											
BASOPHILS											
Bsln	85	0.1 (0.04)		81	0.1 (0.03)		81	0.1 (0.02)			
Wk 2	83	0.0 (0.02)	0.0 (0.03)	80	0.1 (0.03)	0.0 (0.03)	80	0.0 (0.03)	0.0 (0.02)		
Wk 4	79	0.0 (0.02)	0.0 (0.03)	71	0.0 (0.03)	0.0 (0.03)	71	0.0 (0.02)	0.0 (0.02)		
Wk 6	73	0.0 (0.03)	0.0 (0.03)	62	0.0 (0.03)	0.0 (0.03)	64	0.1 (0.03)	0.0 (0.03)		
Wk 8	72	0.0 (0.02)	0.0 (0.03)	59	0.1 (0.02)	0.0 (0.04)	56	0.1 (0.03)	0.0 (0.02)		
Wk 12	66	0.0 (0.02)	0.0 (0.04)	50	0.0 (0.02)	0.0 (0.03)	50	0.1 (0.03)	0.0 (0.02)		
Wk 16	68	0.0 (0.03)	0.0 (0.04)	42	0.0 (0.02)	0.0 (0.03)	37	0.1 (0.03)	0.0 (0.02)		
Wk 20	65	0.0 (0.03)	0.0 (0.03)	30	0.0 (0.02)	0.0 (0.03)	31	0.0 (0.02)	0.0 (0.03)		
Wk 24	58	0.0 (0.03)	0.0 (0.03)	25	0.0 (0.03)	0.0 (0.02)	30	0.1 (0.02)	0.0 (0.02)		
Wk 26	57	0.0 (0.02)	0.0 (0.03)	25	0.0 (0.03)	0.0 (0.02)	27	0.1 (0.03)	0.0 (0.03)		
End[1]	84	0.0 (0.03)	0.0 (0.03)	82	0.0 (0.03)	0.0 (0.03)	81	0.1 (0.02)	0.0 (0.02)		
EOSINOPHILS											
Bsln	85	0.1 (0.12)		81	0.1 (0.12)		81	0.1 (0.10)			
Wk 2	83	0.1 (0.10)	0.0 (0.09)	80	0.2 (0.17)	0.0 (0.14)	80	0.1 (0.11)	0.0 (0.07)		
Wk 4	79	0.1 (0.13)	0.0 (0.09)	71	0.2 (0.14)	0.0 (0.11)	71	0.2 (0.15)	0.0 (0.13)		

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High				
Visit	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)
Wk 6	73	0.1	(0.13)	0.0 (0.11)	62	0.2	(0.21)	0.1 (0.16)	64	0.2	(0.28)	0.1 (0.25)
Wk 8	72	0.1	(0.10)	0.0 (0.10)	59	0.3	(0.26)	0.2 (0.23)	56	0.2	(0.25)	0.1 (0.19)
Wk 12	66	0.1	(0.09)	0.0 (0.11)	50	0.3	(0.21)	0.1 (0.19)	50	0.2	(0.17)	0.1 (0.14)
Wk 16	68	0.1	(0.08)	0.0 (0.10)	42	0.2	(0.16)	0.1 (0.13)	37	0.2	(0.21)	0.1 (0.17)
Wk 20	65	0.1	(0.08)	0.0 (0.10)	30	0.2	(0.19)	0.1 (0.16)	31	0.1	(0.11)	0.0 (0.12)
Wk 24	58	0.1	(0.08)	0.0 (0.09)	25	0.2	(0.14)	0.0 (0.12)	30	0.2	(0.15)	0.0 (0.13)
Wk 26	57	0.1	(0.10)	0.0 (0.11)	25	0.2	(0.15)	0.0 (0.13)	27	0.1	(0.10)	0.0 (0.09)
End[1]	84	0.1	(0.08)	0.0 (0.10)	82	0.2	(0.17)	0.0 (0.14)	81	0.2	(0.20)	0.1 (0.18)
ERY. MEAN CORPUSCULAR HB CONCENTRATION												
Bsln	85	20.6	(0.87)		80	20.2	(0.98)		80	20.5	(0.87)	
Wk 2	83	20.3	(0.77)	-0.3 (1.00)	80	20.3	(0.85)	0.0 (1.04)	80	20.4	(0.74)	0.0 (0.98)
Wk 4	77	20.2	(0.78)	-0.4 (1.01)	69	20.2	(0.72)	0.0 (0.94)	70	20.5	(0.71)	-0.1 (0.90)
Wk 6	72	20.5	(0.77)	-0.2 (0.98)	60	20.1	(0.84)	-0.2 (0.99)	65	20.4	(0.89)	-0.2 (1.00)
Wk 8	71	20.3	(0.68)	-0.2 (0.85)	56	20.2	(0.83)	0.0 (0.92)	56	20.5	(0.76)	-0.1 (0.93)
Wk 12	65	20.3	(0.74)	-0.3 (0.96)	49	20.3	(0.68)	0.0 (0.99)	50	20.5	(0.76)	-0.1 (1.03)
Wk 16	68	20.2	(0.75)	-0.4 (1.02)	42	20.0	(0.82)	-0.2 (1.02)	37	20.4	(0.83)	-0.2 (1.11)
Wk 20	64	20.3	(0.80)	-0.3 (0.94)	30	20.0	(0.85)	-0.4 (0.91)	31	20.3	(0.88)	-0.3 (1.22)
Wk 24	58	20.1	(0.89)	-0.5 (1.01)	25	20.3	(0.91)	-0.3 (0.95)	30	20.4	(0.85)	-0.3 (1.29)
Wk 26	56	20.3	(0.99)	-0.4 (1.16)	25	19.9	(0.94)	-0.6 (1.09)	27	20.2	(0.92)	-0.6 (1.12)
End[1]	83	20.2	(0.85)	-0.4 (0.99)	82	20.2	(0.81)	0.0 (0.98)	81	20.4	(0.78)	-0.1 (1.08)

ERY. MEAN CORPUSCULAR HEMOGLOBIN

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Bsln	85	1.9 (0.12)		81	1.9 (0.09)		81	1.9 (0.13)			
Wk 2	83	1.9 (0.11)	0.0 (0.07)	80	1.9 (0.09)	0.0 (0.07)	80	1.9 (0.13)	0.0 (0.07)		
Wk 4	79	1.9 (0.12)	0.0 (0.07)	71	1.9 (0.09)	0.0 (0.07)	71	1.9 (0.13)	0.0 (0.06)		
Wk 6	73	1.9 (0.13)	0.0 (0.08)	62	1.9 (0.08)	0.0 (0.05)	65	1.9 (0.13)	0.0 (0.08)		
Wk 8	72	1.9 (0.12)	0.0 (0.06)	59	1.9 (0.09)	0.0 (0.06)	56	1.9 (0.10)	0.0 (0.07)		
Wk 12	66	1.9 (0.12)	0.0 (0.06)	50	1.9 (0.09)	0.0 (0.05)	50	1.9 (0.09)	0.0 (0.07)		
Wk 16	68	1.9 (0.12)	0.0 (0.05)	42	1.9 (0.10)	0.0 (0.07)	37	1.9 (0.11)	0.0 (0.08)		
Wk 20	65	1.9 (0.11)	0.0 (0.06)	30	1.9 (0.08)	0.0 (0.06)	31	1.9 (0.12)	0.0 (0.08)		
Wk 24	58	1.9 (0.12)	0.0 (0.06)	25	1.9 (0.09)	0.0 (0.06)	30	1.9 (0.13)	0.0 (0.09)		
Wk 26	57	1.9 (0.12)	0.0 (0.07)	25	1.9 (0.08)	0.0 (0.08)	27	1.9 (0.12)	0.0 (0.08)		
End[1]	84	1.9 (0.12)	0.0 (0.07)	82	1.9 (0.09)	0.0 (0.06)	81	1.9 (0.13)	0.0 (0.07)		
ERY. MEAN CORPUSCULAR VOLUME											
Bsln	85	92.9 (5.69)		80	94.6 (4.90)		80	93.3 (5.91)			
Wk 2	83	94.1 (5.31)	1.2 (3.93)	80	94.6 (4.12)	0.2 (3.57)	80	93.4 (5.93)	0.2 (3.91)		
Wk 4	77	94.6 (5.87)	1.7 (3.47)	69	95.1 (4.22)	0.6 (3.69)	70	93.0 (5.52)	0.0 (3.69)		
Wk 6	72	94.2 (6.21)	1.3 (3.79)	60	95.2 (4.51)	0.7 (3.68)	65	94.0 (6.61)	0.6 (3.99)		
Wk 8	71	94.3 (5.51)	1.5 (3.27)	56	94.9 (3.97)	0.6 (3.35)	56	94.4 (4.77)	0.4 (4.03)		
Wk 12	65	94.2 (5.66)	1.6 (3.81)	49	95.1 (4.17)	0.9 (3.91)	50	94.9 (4.90)	0.8 (4.20)		
Wk 16	68	94.1 (6.01)	1.7 (4.07)	42	95.8 (5.17)	1.2 (4.18)	37	94.7 (6.27)	0.6 (5.05)		
Wk 20	64	93.3 (5.58)	1.3 (4.14)	30	95.4 (5.43)	2.0 (3.29)	31	95.1 (5.91)	0.9 (5.12)		
Wk 24	58	93.9 (5.90)	1.6 (3.85)	25	94.3 (3.85)	0.8 (3.94)	30	95.0 (5.99)	0.7 (4.97)		
Wk 26	56	93.9 (6.40)	1.7 (4.48)	25	95.8 (4.33)	2.6 (3.70)	27	95.4 (6.19)	1.2 (3.93)		

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

	Placebo						Xanomeline Low						Xanomeline High					
Visit	N	Mean	(SD)	Change from Bsln Mean (SD)		N	Mean	(SD)	Change from Bsln Mean (SD)		N	Mean	(SD)	Change from Bsln Mean (SD)				
End[1]	83	94.4	(5.93)	1.4	(4.07)	82	95.0	(3.98)	0.6	(3.83)	81	93.8	(6.14)	0.7	(4.40)			
ERYTHROCYTES																		
Bsln	85	4.5	(0.45)			81	4.5	(0.42)			81	4.7	(0.47)					
Wk 2	83	4.4	(0.40)	-0.1	(0.22)	80	4.4	(0.43)	-0.1	(0.27)	80	4.6	(0.47)	-0.1	(0.22)			
Wk 4	79	4.4	(0.45)	-0.1	(0.25)	71	4.4	(0.38)	-0.2	(0.30)	71	4.5	(0.49)	-0.1	(0.25)			
Wk 6	73	4.4	(0.37)	-0.1	(0.24)	62	4.3	(0.38)	-0.2	(0.27)	65	4.5	(0.50)	-0.1	(0.24)			
Wk 8	72	4.4	(0.41)	-0.1	(0.26)	59	4.4	(0.34)	-0.2	(0.24)	56	4.5	(0.45)	-0.1	(0.19)			
Wk 12	66	4.4	(0.44)	-0.1	(0.26)	50	4.3	(0.32)	-0.2	(0.20)	50	4.6	(0.47)	-0.1	(0.27)			
Wk 16	68	4.5	(0.41)	0.0	(0.27)	42	4.3	(0.36)	-0.1	(0.24)	37	4.6	(0.44)	-0.2	(0.26)			
Wk 20	65	4.5	(0.41)	-0.1	(0.30)	30	4.3	(0.32)	-0.1	(0.21)	31	4.5	(0.50)	-0.2	(0.30)			
Wk 24	58	4.4	(0.45)	-0.1	(0.23)	25	4.4	(0.38)	-0.1	(0.19)	30	4.6	(0.58)	-0.1	(0.24)			
Wk 26	57	4.4	(0.42)	0.0	(0.25)	25	4.4	(0.35)	-0.1	(0.20)	27	4.5	(0.47)	-0.2	(0.27)			
End[1]	84	4.4	(0.43)	-0.1	(0.27)	82	4.4	(0.38)	-0.2	(0.25)	81	4.6	(0.49)	-0.1	(0.22)			
HEMATOCRIT																		
Bsln	85	0.4	(0.04)			80	0.4	(0.04)			80	0.4	(0.04)					
Wk 2	83	0.4	(0.04)	0.0	(0.03)	80	0.4	(0.04)	0.0	(0.03)	80	0.4	(0.04)	0.0	(0.03)			
Wk 4	77	0.4	(0.04)	0.0	(0.03)	69	0.4	(0.04)	0.0	(0.03)	70	0.4	(0.04)	0.0	(0.03)			
Wk 6	72	0.4	(0.04)	0.0	(0.03)	60	0.4	(0.04)	0.0	(0.03)	65	0.4	(0.04)	0.0	(0.03)			
Wk 8	71	0.4	(0.04)	0.0	(0.03)	56	0.4	(0.03)	0.0	(0.02)	56	0.4	(0.03)	0.0	(0.03)			
Wk 12	65	0.4	(0.04)	0.0	(0.03)	49	0.4	(0.03)	0.0	(0.02)	50	0.4	(0.04)	0.0	(0.03)			
Wk 16	68	0.4	(0.04)	0.0	(0.03)	42	0.4	(0.03)	0.0	(0.03)	37	0.4	(0.03)	0.0	(0.04)			

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)
Wk 20	64	0.4 (0.04)	0.0 (0.03)	30	0.4 (0.03)	0.0 (0.02)	31	0.4 (0.04)	0.0 (0.04)		
Wk 24	58	0.4 (0.04)	0.0 (0.03)	25	0.4 (0.04)	0.0 (0.02)	30	0.4 (0.04)	0.0 (0.04)		
Wk 26	56	0.4 (0.04)	0.0 (0.03)	25	0.4 (0.04)	0.0 (0.03)	27	0.4 (0.04)	0.0 (0.03)		
End[1]	83	0.4 (0.04)	0.0 (0.03)	82	0.4 (0.04)	0.0 (0.03)	81	0.4 (0.04)	0.0 (0.03)		
HEMOGLOBIN											
Bsln	85	8.6 (0.83)		81	8.6 (0.77)		81	8.9 (0.78)			
Wk 2	83	8.4 (0.76)	-0.2 (0.42)	80	8.4 (0.76)	-0.2 (0.46)	80	8.7 (0.83)	-0.2 (0.42)		
Wk 4	79	8.4 (0.82)	-0.2 (0.44)	71	8.4 (0.78)	-0.3 (0.50)	71	8.6 (0.78)	-0.2 (0.45)		
Wk 6	73	8.4 (0.77)	-0.2 (0.44)	62	8.3 (0.76)	-0.3 (0.46)	65	8.6 (0.75)	-0.3 (0.44)		
Wk 8	72	8.5 (0.76)	-0.2 (0.46)	59	8.3 (0.71)	-0.3 (0.39)	56	8.7 (0.73)	-0.3 (0.39)		
Wk 12	66	8.4 (0.83)	-0.2 (0.42)	50	8.3 (0.69)	-0.3 (0.34)	50	8.8 (0.79)	-0.3 (0.42)		
Wk 16	68	8.5 (0.73)	-0.1 (0.46)	42	8.3 (0.69)	-0.2 (0.42)	37	8.7 (0.70)	-0.3 (0.47)		
Wk 20	65	8.4 (0.80)	-0.2 (0.51)	30	8.2 (0.63)	-0.2 (0.46)	31	8.7 (0.79)	-0.4 (0.46)		
Wk 24	58	8.3 (0.82)	-0.2 (0.40)	25	8.4 (0.69)	-0.2 (0.36)	30	8.9 (0.85)	-0.3 (0.36)		
Wk 26	57	8.4 (0.80)	-0.2 (0.47)	25	8.3 (0.67)	-0.3 (0.39)	27	8.7 (0.74)	-0.5 (0.39)		
End[1]	84	8.4 (0.78)	-0.2 (0.44)	82	8.4 (0.69)	-0.2 (0.44)	81	8.7 (0.79)	-0.2 (0.36)		
LEUKOCYTES											
Bsln	85	6.9 (1.76)		81	6.6 (1.95)		81	6.5 (1.54)			
Wk 2	83	6.5 (1.55)	-0.4 (1.40)	80	6.9 (1.99)	0.2 (1.37)	80	6.5 (1.59)	-0.1 (1.18)		
Wk 4	79	6.4 (1.63)	-0.4 (1.17)	71	6.8 (2.12)	0.1 (1.53)	71	6.6 (1.42)	0.1 (1.21)		
Wk 6	73	6.5 (1.57)	-0.4 (1.36)	62	6.9 (1.99)	0.1 (1.14)	65	7.0 (1.84)	0.4 (1.65)		

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)		
Wk 8	72	6.5 (1.70)	-0.3 (1.28)	59	7.1 (1.88)	0.3 (1.26)	56	6.9 (1.95)	0.4 (1.64)		
Wk 12	66	6.3 (1.28)	-0.5 (1.09)	50	6.8 (2.03)	0.2 (0.97)	50	6.6 (1.51)	0.0 (1.21)		
Wk 16	68	6.4 (1.50)	-0.5 (1.29)	42	6.6 (2.11)	0.2 (1.44)	37	6.8 (1.72)	-0.1 (1.37)		
Wk 20	65	6.4 (1.77)	-0.5 (1.40)	30	6.5 (1.94)	0.1 (1.24)	31	6.6 (1.67)	-0.2 (1.21)		
Wk 24	58	6.7 (1.77)	-0.2 (1.37)	25	6.3 (1.84)	0.0 (1.16)	30	6.7 (1.80)	-0.1 (1.16)		
Wk 26	57	6.4 (1.47)	-0.4 (1.24)	25	6.1 (1.93)	-0.3 (1.15)	27	6.7 (1.78)	-0.2 (1.42)		
End[1]	84	6.6 (1.80)	-0.2 (1.32)	82	6.8 (2.17)	0.1 (1.35)	81	6.7 (1.76)	0.2 (1.37)		
LYMPHOCYTES											
Bsln	85	1.8 (0.57)		81	1.8 (0.57)		81	1.7 (0.52)			
Wk 2	83	1.7 (0.50)	-0.1 (0.37)	80	1.8 (0.66)	0.0 (0.45)	80	1.7 (0.50)	0.0 (0.38)		
Wk 4	79	1.7 (0.56)	0.0 (0.38)	71	1.8 (0.67)	0.0 (0.49)	71	1.7 (0.50)	0.0 (0.44)		
Wk 6	73	1.8 (0.58)	0.0 (0.41)	62	1.9 (0.64)	0.1 (0.47)	64	1.7 (0.48)	0.0 (0.44)		
Wk 8	72	1.8 (0.67)	0.0 (0.44)	59	1.9 (0.65)	0.1 (0.45)	56	1.7 (0.50)	0.0 (0.36)		
Wk 12	66	1.7 (0.58)	-0.1 (0.42)	50	1.8 (0.58)	-0.1 (0.45)	50	1.6 (0.47)	0.0 (0.37)		
Wk 16	68	1.7 (0.58)	-0.1 (0.42)	42	1.8 (0.63)	-0.1 (0.34)	37	1.7 (0.62)	0.0 (0.41)		
Wk 20	65	1.7 (0.50)	-0.1 (0.45)	30	1.7 (0.59)	-0.1 (0.50)	31	1.7 (0.59)	0.0 (0.36)		
Wk 24	58	1.8 (0.65)	0.0 (0.48)	25	1.8 (0.56)	0.0 (0.37)	30	1.7 (0.56)	0.0 (0.37)		
Wk 26	57	1.8 (0.59)	0.0 (0.43)	25	1.7 (0.62)	-0.1 (0.39)	27	1.8 (0.61)	0.1 (0.50)		
End[1]	84	1.8 (0.59)	0.0 (0.46)	82	1.8 (0.62)	0.0 (0.46)	81	1.6 (0.54)	0.0 (0.38)		
MONOCYTES											
Bsln	85	0.4 (0.15)		81	0.5 (0.16)		81	0.4 (0.12)			

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

	Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)	N	Mean	(SD)	Change from Bsln Mean (SD)
Wk 2	83	0.4	(0.15)	0.0 (0.14)	80	0.5	(0.16)	0.0 (0.13)	80	0.4	(0.15)	0.0 (0.12)
Wk 4	79	0.4	(0.12)	0.0 (0.11)	71	0.5	(0.17)	0.0 (0.15)	71	0.4	(0.13)	0.0 (0.13)
Wk 6	73	0.4	(0.15)	0.0 (0.13)	62	0.5	(0.19)	0.0 (0.16)	64	0.5	(0.15)	0.0 (0.13)
Wk 8	72	0.4	(0.14)	0.0 (0.14)	59	0.5	(0.14)	0.0 (0.14)	56	0.5	(0.15)	0.0 (0.14)
Wk 12	66	0.4	(0.13)	0.0 (0.13)	50	0.5	(0.15)	0.0 (0.12)	50	0.4	(0.15)	0.0 (0.11)
Wk 16	68	0.5	(0.15)	0.0 (0.17)	42	0.5	(0.16)	0.0 (0.12)	37	0.5	(0.16)	0.0 (0.14)
Wk 20	65	0.5	(0.16)	0.0 (0.15)	30	0.5	(0.13)	0.0 (0.13)	31	0.5	(0.17)	0.0 (0.18)
Wk 24	58	0.5	(0.17)	0.0 (0.17)	25	0.5	(0.19)	0.0 (0.11)	30	0.5	(0.18)	0.0 (0.12)
Wk 26	57	0.4	(0.14)	0.0 (0.14)	25	0.4	(0.17)	0.0 (0.12)	27	0.5	(0.14)	0.0 (0.13)
End[1]	84	0.5	(0.17)	0.0 (0.17)	82	0.5	(0.17)	0.0 (0.13)	81	0.5	(0.15)	0.0 (0.12)
PLATELET												
Bsln	84	250.3 (65.52)			79	233.8 (58.58)			81	227.7 (54.74)		
Wk 2	83	246.2 (57.55)		-4.4 (36.21)	78	247.4 (59.37)		9.1 (46.36)	80	238.2 (59.77)		8.4 (31.55)
Wk 4	78	243.8 (54.30)		-7.4 (40.04)	70	239.2 (57.80)		5.7 (39.75)	70	238.3 (49.60)		9.8 (29.21)
Wk 6	73	250.8 (58.97)		-3.3 (36.82)	62	238.3 (55.74)		3.5 (43.39)	63	239.1 (56.79)		9.2 (37.82)
Wk 8	72	246.0 (66.61)		-6.2 (42.35)	59	245.4 (60.21)		5.1 (46.18)	55	236.9 (70.88)		11.0 (48.13)
Wk 12	65	241.9 (53.71)		-12.8 (42.62)	50	238.8 (49.49)		1.9 (24.69)	49	236.1 (53.03)		9.1 (34.47)
Wk 16	68	241.8 (55.65)		-13.7 (43.45)	41	244.5 (57.60)		2.8 (32.93)	37	230.9 (58.00)		5.3 (25.87)
Wk 20	65	248.4 (60.70)		-8.4 (30.42)	30	240.7 (64.07)		7.3 (42.65)	30	235.1 (65.46)		2.3 (22.80)
Wk 24	57	238.8 (51.89)		-11.3 (35.06)	24	249.7 (63.44)		1.8 (33.48)	29	238.3 (67.53)		4.5 (26.74)
Wk 26	56	247.6 (60.11)		-2.7 (41.73)	25	241.3 (57.16)		-1.9 (38.84)	27	237.4 (67.14)		0.3 (26.99)
End[1]	84	241.5 (59.49)		-8.5 (35.55)	82	236.7 (63.56)		1.1 (36.31)	81	233.8 (60.79)		4.1 (35.89)

[1] Last observed value while on treatment (prior to or at Week 24)

Source: programs/t-14-6-01.R

19:30 Tuesday, June 16, 2020