

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change	N	Mean (SD)	Change	N	Mean (SD)	Change		
			from Bsln Mean (SD)			from Bsln Mean (SD)			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)		
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)		

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
			Change from Bsln			Change from Bsln			Change from Bsln		
Visit	N	Mean (SD)	Mean (SD)	N	Mean (SD)	Mean (SD)	N	Mean (SD)	Mean (SD)		
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)	-0.6 (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	70.3 (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)		
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)		

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

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High				
				Change from Bsln				Change from Bsln				Change from Bsln
Visit	N	Mean (SD)	Mean (SD)	N	Mean (SD)	Mean (SD)	N	Mean (SD)	Mean (SD)	N	Mean (SD)	Mean (SD)
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)	79	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)	71	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	55	9.4 (3.39)	0.1 (2.75)	25	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]	82	11.2 (13.42)	1.4 (11.28)	80	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)			
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)			

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

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Summary Statistics for Continuous Laboratory Values

Visit	Placebo			Xanomeline Low			Xanomeline High		
	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)
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)
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)

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

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Visit	Placebo			Xanomeline Low			Xanomeline High		
	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)
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)
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)

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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)	
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)	
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)	70	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)	

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change	N	Mean (SD)	Change	N	Mean (SD)	Change		
			from Bsln			from Bsln			from Bsln		
			Mean (SD)			Mean (SD)			Mean (SD)		
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)		
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)		

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Visit	Placebo			Xanomeline Low			Xanomeline High		
	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)
PROTEIN									
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	140.5 (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)
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)

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Visit	Placebo			Xanomeline Low			Xanomeline High		
	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)
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)
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)

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change	N	Mean (SD)	Change	N	Mean (SD)	Change		
			from Bsln Mean (SD)			from Bsln Mean (SD)			from Bsln Mean (SD)		
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)		
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)		

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo					Xanomeline Low					Xanomeline High				
Visit	N	Change from Bsln			N	Change from Bsln			N	Change from Bsln				
		Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	Mean (SD)						
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														
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)					

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo					Xanomeline Low					Xanomeline High				
Visit	N	Change from Bsln			N	Change from Bsln			N	Change from Bsln				
		Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	Mean (SD)						
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)			
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)			

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
Visit	N	Mean (SD)	Change	N	Mean (SD)	Change	N	Mean (SD)	Change		
			from Bsln Mean (SD)			from Bsln Mean (SD)			from Bsln Mean (SD)		
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)		
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)		

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Placebo				Xanomeline Low				Xanomeline High			
			Change from Bsln Mean (SD)			Change from Bsln Mean (SD)			Change from Bsln Mean (SD)		
Visit	N	Mean (SD)		N	Mean (SD)		N	Mean (SD)			
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)		
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	6.5 (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)	-0.1 (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)		

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

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_lb_cont.sas

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Table 14-6.01
Summary Statistics for Continuous Laboratory Values

Visit	Placebo			Xanomeline Low			Xanomeline High		
	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)
MONOCYTES									
Bsln	85	0.4 (0.15)		81	0.5 (0.16)		81	0.4 (0.12)	
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)

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