

Table 14-6.01
Summary Statistics for Continuous Laboratory Values

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

Visit	N	Placebo		Xanomeline Low			Xanomeline High			
		Change from Bsln		Change from Bsln		Change from Bsln		Change from Bsln		
		Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	
Wk 26	57	39.8	(3.02)	0.0	(2.26)	25	39.2	(2.39)	-1.0	(2.85)
End[1]	84	39.6	(3.32)	-0.2	(2.69)	82	39.2	(2.97)	-0.5	(2.64)
ALKALINE PHOSPHATASE										
Bsln	86	77.7	(58.11)			81	73.3	(20.72)		
Wk 2	84	77.7	(69.50)	0.1	(15.51)	80	73.0	(21.87)	0.3	(10.25)
Wk 4	82	78.0	(69.43)	0.4	(14.16)	72	73.2	(23.17)	-0.3	(11.12)
Wk 6	75	68.4	(21.53)	-0.4	(10.40)	64	72.7	(23.15)	-1.0	(10.83)
Wk 8	73	70.0	(27.15)	-0.0	(10.67)	60	72.9	(23.84)	0.5	(14.09)
Wk 12	67	72.1	(32.73)	1.8	(17.18)	52	69.5	(20.55)	-1.5	(9.41)
Wk 16	68	70.6	(29.49)	0.3	(16.98)	42	69.5	(19.43)	-1.7	(8.61)
Wk 20	65	72.6	(37.41)	1.9	(25.77)	31	70.6	(22.20)	-2.2	(9.90)
Wk 24	56	80.6	(68.06)	10.1	(58.71)	27	72.0	(21.80)	-0.4	(8.93)
Wk 26	57	81.0	(79.33)	10.1	(72.41)	25	68.6	(21.08)	-4.1	(10.74)
End[1]	84	84.6	(84.86)	7.1	(49.37)	82	71.6	(23.80)	-1.1	(13.09)
ASPARTATE AMINOTRANSFERASE										
Bsln	86	23.2	(7.50)			82	23.4	(8.24)		
Wk 2	83	23.6	(12.35)	0.2	(8.96)	80	24.7	(8.06)	1.6	(6.53)
Wk 4	79	23.9	(14.93)	0.5	(11.33)	72	22.3	(6.75)	-1.4	(6.40)
Wk 6	73	22.0	(6.40)	-0.9	(6.38)	62	22.1	(6.11)	-0.4	(4.19)
Wk 8	72	22.3	(7.05)	-1.1	(4.84)	60	22.7	(5.95)	0.3	(4.02)
Wk 12	67	22.8	(7.64)	-0.6	(7.06)	51	24.2	(15.87)	1.5	(12.39)
Wk 16	68	22.8	(6.42)	-0.6	(6.43)	42	22.4	(10.34)	0.6	(7.62)
Wk 20	65	21.9	(5.90)	-1.6	(6.07)	30	20.7	(5.74)	0.4	(4.60)
Wk 24	57	25.2	(21.02)	1.2	(20.43)	26	22.4	(10.78)	2.1	(6.58)
Wk 26	57	21.5	(6.99)	-2.5	(7.29)	25	22.1	(11.85)	1.4	(7.69)

[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

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

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

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

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

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

Visit	N	Placebo		Xanomeline Low		Xanomeline High										
		Change from Bsln		Change from Bsln		Change from Bsln										
		Mean	(SD)	Mean	(SD)	Mean	(SD)									
HEMATOLOGY																
BASOPHILS																
Bsln	85	0.1	(-0.04)	81	0.1	(-0.03)	81	0.1	(-0.02)	80	0.0	(0.03)	-0.0	(0.02)		
Wk 2	83	0.0	(-0.02)	-0.0	(0.03)	80	0.1	(-0.03)	-0.0	(0.03)	71	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)	62	0.0	(0.03)	-0.0	(0.03)	
Wk 6	73	0.0	(-0.03)	-0.0	(0.03)	59	0.1	(-0.02)	-0.0	(0.04)	64	0.1	(0.03)	0.0	(0.03)	
Wk 8	72	0.0	(-0.02)	-0.0	(0.03)	50	0.0	(0.02)	-0.0	(0.03)	56	0.1	(0.03)	0.0	(0.02)	
Wk 12	66	0.0	(-0.02)	-0.0	(0.04)	42	0.0	(0.02)	-0.0	(0.03)	37	0.1	(0.03)	-0.0	(0.02)	
Wk 16	68	0.0	(-0.03)	-0.0	(0.04)	30	0.0	(0.02)	-0.0	(0.03)	31	0.0	(0.02)	-0.0	(0.03)	
Wk 20	65	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 24	58	0.0	(-0.03)	-0.0	(0.03)	27	0.1	(0.03)	-0.0	(0.02)	27	0.1	(0.03)	-0.0	(0.03)	
Wk 26	57	0.0	(-0.02)	-0.0	(0.03)	End[1]	84	0.0	(0.03)	-0.0	(0.03)	81	0.1	(0.02)	-0.0	(0.02)
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)	80	0.1	(0.11)	-0.0	(0.07)		
Wk 2	83	0.1	(0.10)	-0.0	(0.09)	71	0.2	(0.17)	0.0	(0.14)	71	0.2	(0.15)	0.0	(0.13)	
Wk 4	79	0.1	(0.13)	-0.0	(0.09)	62	0.2	(0.14)	0.0	(0.11)	64	0.2	(0.28)	0.1	(0.25)	
Wk 6	73	0.1	(0.13)	-0.0	(0.11)	59	0.3	(0.26)	0.2	(0.23)	56	0.2	(0.25)	0.1	(0.19)	
Wk 8	72	0.1	(0.10)	-0.0	(0.10)	50	0.3	(0.21)	0.1	(0.19)	50	0.2	(0.17)	0.1	(0.14)	
Wk 12	66	0.1	(0.09)	-0.0	(0.11)	42	0.2	(0.16)	0.1	(0.13)	37	0.2	(0.21)	0.1	(0.17)	
Wk 16	68	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 20	65	0.1	(0.08)	-0.0	(0.10)	25	0.2	(0.14)	0.0	(0.12)	30	0.2	(0.15)	0.0	(0.13)	
Wk 24	58	0.1	(0.08)	-0.0	(0.09)											

[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	N	Placebo		Xanomeline Low			Xanomeline High			
		Change from Bsln		Change from Bsln		Change from Bsln		Change from Bsln		
		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)
End[1]	84	0.1	(-0.08)	-0.0	(0.10)	82	0.2	(-0.17)	0.0	(0.14)
ERY. MEAN CORPUSCULAR HB CONCENTRATION										
Bsln	85	20.6	(0.87)			80	20.2	(0.98)		
Wk 2	83	20.3	(0.77)	-0.3	(1.00)	80	20.3	(0.85)	0.0	(1.04)
Wk 4	77	20.2	(0.78)	-0.4	(1.01)	69	20.2	(0.72)	-0.0	(0.94)
Wk 6	72	20.5	(0.77)	-0.2	(0.98)	60	20.1	(0.84)	-0.2	(0.99)
Wk 8	71	20.3	(0.68)	-0.2	(0.85)	56	20.2	(0.83)	-0.0	(0.92)
Wk 12	65	20.3	(0.74)	-0.3	(0.96)	49	20.3	(0.68)	-0.0	(0.99)
Wk 16	68	20.2	(0.75)	-0.4	(1.02)	42	20.0	(0.82)	-0.2	(1.02)
Wk 20	64	20.3	(0.80)	-0.3	(0.94)	30	20.0	(0.85)	-0.4	(0.91)
Wk 24	58	20.1	(0.89)	-0.5	(1.01)	25	20.3	(0.91)	-0.3	(0.95)
Wk 26	56	20.3	(0.99)	-0.4	(1.16)	25	19.9	(0.94)	-0.6	(1.09)
End[1]	83	20.2	(0.85)	-0.4	(0.99)	82	20.2	(0.81)	-0.0	(0.98)
ERY. MEAN CORPUSCULAR HEMOGLOBIN										
Bsln	85	1.9	(0.12)			81	1.9	(0.09)		
Wk 2	83	1.9	(0.11)	-0.0	(0.07)	80	1.9	(0.09)	0.0	(0.07)
Wk 4	79	1.9	(0.12)	-0.0	(0.07)	71	1.9	(0.09)	0.0	(0.07)
Wk 6	73	1.9	(0.13)	0.0	(0.08)	62	1.9	(0.08)	0.0	(0.05)
Wk 8	72	1.9	(0.12)	0.0	(0.06)	59	1.9	(0.09)	0.0	(0.06)
Wk 12	66	1.9	(0.12)	0.0	(0.06)	50	1.9	(0.09)	0.0	(0.05)
Wk 16	68	1.9	(0.12)	-0.0	(0.05)	42	1.9	(0.10)	-0.0	(0.07)
Wk 20	65	1.9	(0.11)	-0.0	(0.06)	30	1.9	(0.08)	0.0	(0.06)
Wk 24	58	1.9	(0.12)	-0.0	(0.06)	25	1.9	(0.09)	-0.0	(0.06)
Wk 26	57	1.9	(0.12)	-0.0	(0.07)	25	1.9	(0.08)	-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

Visit	N	Placebo		Xanomeline Low				Xanomeline High							
		Change from Bsln		Change from Bsln		Change from Bsln		Change from Bsln		Change from Bsln					
		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

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

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

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