Table 14.3/10

Change in Laboratory Events: Shift in NCI-CTC Grade from Baseline to Worst Post-Baseline Level **Safety Event Patients**

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Lab Parameter	Lab Event	Baseline Grade	N	0	1	2	3	4	Other (value > ULN)
Sodium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	31	26(83.9%)	2(6.5%)	(00.0%)	(00.0%)	(00.0%)	3(9.7%)
	High	1-4	1	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	1(100.0%)
Pottasium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	1	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	31	28(90.3%)	2(6.5%)	(00.0%)	(00.0%)	(00.0%)	1(3.2%)
	High	1-4	1	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	1(100.0%)
Magnesium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	6	(00.0%)	5(83.3%)	1(16.7%)	(00.0%)	(00.0%)	(00.0%)
		0	27	20(74.1%)	6(22.2%)	(00.0%)	(00.0%)	(00.0%)	1(3.7%)
Alkaline Phosphatase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	2	1(50.0%)	1(50.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	31	27(87.1%)	3(9.7%)	1(3.2%)	(00.0%)	(00.0%)	(00.0%)
Aspartate Aminotransferase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	2	(00.0%)	2(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	31	24(77.4%)	6(19.4%)	1(3.2%)	(00.0%)	(00.0%)	(00.0%)
Alanine Aminotransferase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	4	2(50.0%)	2(50.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	29	23(79.3%)	3(10.3%)	2(6.9%)	1(3.4%)	(00.0%)	(00.0%)

Change in Laboratory Events: Shift in NCI-CTC Grade from Baseline to Worst Post-Baseline Level **Safety Event Patients**

Lab Parameter				Post-Baseline NCI CTCAE Grade								
	Lab Event	Baseline Grade	N	0	1	2	3	4	Other (value > ULN)			
Bilirubin (umol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		1	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		0	33	33(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
Blood Urea Nitrogen (mmol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		2	3	(00.0%)	(00.0%)	3(100.0%)	(00.0%)	(00.0%)	(00.0%)			
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		0	29	20(69.0%)	5(17.2%)	4(13.8%)	(00.0%)	(00.0%)	(00.0%)			
Creatinine (umol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		1	2	(00.0%)	2(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			
		0	31	26(83.9%)	5(16.1%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)			

Table 14.3/10

Change in Laboratory Events: Shift in NCI-CTC Grade from Baseline to Worst Post-Baseline Level **Safety Event Patients**

Treatment: Placebo

Lab Parameter	Lab Event	Baseline Grade	N	0	1	2	3	4	Other (value > ULN)
Sodium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	30	22(73.3%)	4(13.3%)	(00.0%)	1(3.3%)	(00.0%)	3(10.0%)
	High	1-4	1	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
Pottasium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	29	25(86.2%)	2(6.9%)	(00.0%)	(00.0%)	(00.0%)	2(6.9%)
	High	1-4	1	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
Magnesium (mmol/L)	Low	4	1	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	7	(00.0%)	7(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	21	14(66.7%)	5(23.8%)	(00.0%)	(00.0%)	(00.0%)	2(9.5%)
	High	1-4	1	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
Alkaline Phosphatase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	3	1(33.3%)	2(66.7%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		0	28	25(89.3%)	3(10.7%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
Aspartate Aminotransferase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	3	2(66.7%)	(00.0%)	1(33.3%)	(00.0%)	(00.0%)	(00.0%)
		0	28	18(64.3%)	8(28.6%)	2(7.1%)	(00.0%)	(00.0%)	(00.0%)
Alanine Aminotransferase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)
		1	2	(00.0%)	1(50.0%)	1(50.0%)	(00.0%)	(00.0%)	(00.0%)

Change in Laboratory Events: Shift in NCI-CTC Grade from Baseline to Worst Post-Baseline Level **Safety Event Patients**

Treatment: Placebo

				Post-Baseline NCI CTCAE Grade							
Lab Parameter	Lab Event	Baseline Grade	N	0	1	2	3	4	Other (value > ULN)		
		0	29	20(69.0%)	7(24.1%)	2(6.9%)	(00.0%)	(00.0%)	(00.0%)		
Bilirubin (umol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	30	30(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
Blood Urea Nitrogen (mmol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	1	(00.0%)	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	6	1(16.7%)	5(83.3%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	24	18(75.0%)	2(8.3%)	4(16.7%)	(00.0%)	(00.0%)	(00.0%)		
Creatinine (umol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	30	25(83.3%)	5(16.7%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		

Table 14.3/10

Change in Laboratory Events: Shift in NCI-CTC Grade from Baseline to Worst Post-Baseline Level **Safety Event Patients**

				Post-Baseline NCI CTCAE Grade							
Lab Parameter	Lab Event	Baseline Grade	N	0	1	2	3	4	Other (value > ULN)		
Sodium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	31	26(83.9%)	2(6.5%)	(00.0%)	(00.0%)	(00.0%)	3(9.7%)		
	High	1-4	1	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	1(100.0%)		
Pottasium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	1	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	31	28(90.3%)	2(6.5%)	(00.0%)	(00.0%)	(00.0%)	1(3.2%)		
	High	1-4	1	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	1(100.0%)		
Magnesium (mmol/L)	Low	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	6	(00.0%)	5(83.3%)	1(16.7%)	(00.0%)	(00.0%)	(00.0%)		
		0	27	20(74.1%)	6(22.2%)	(00.0%)	(00.0%)	(00.0%)	1(3.7%)		
Alkaline Phosphatase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	2	1(50.0%)	1(50.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	31	27(87.1%)	3(9.7%)	1(3.2%)	(00.0%)	(00.0%)	(00.0%)		
Aspartate Aminotransferase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	2	(00.0%)	2(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	31	24(77.4%)	6(19.4%)	1(3.2%)	(00.0%)	(00.0%)	(00.0%)		
Alanine Aminotransferase (U/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	4	2(50.0%)	2(50.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	29	23(79.3%)	3(10.3%)	2(6.9%)	1(3.4%)	(00.0%)	(00.0%)		

Table 14.3/10 Change in Laboratory Events: Shift in NCI-CTC Grade from Baseline to Worst Post-Baseline Level **Safety Event Patients**

				Post-Baseline NCI CTCAE Grade							
Lab Parameter	Lab Event	Baseline Grade	N	0	1	2	3	4	Other (value > ULN)		
Bilirubin (umol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	33	33(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
Blood Urea Nitrogen (mmol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	3	(00.0%)	(00.0%)	3(100.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	1	(00.0%)	1(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	29	20(69.0%)	5(17.2%)	4(13.8%)	(00.0%)	(00.0%)	(00.0%)		
Creatinine (umol/L)	High	4	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		3	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		2	0	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		1	2	(00.0%)	2(100.0%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		
		0	31	26(83.9%)	5(16.1%)	(00.0%)	(00.0%)	(00.0%)	(00.0%)		