

Table 14.2.20 Summary of MRI / MRS - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
ADC Standard (10 ⁻⁶ mm2/s)							
Baseline							
n	9						
Mean (SD)	856.1 (91.7)						
Median	849.0						
Min; Max	749; 1063						
Month 6							
n	9	9	9	Absolute change	0.8 (8)	0.461	(-13.6, 27.4)
Mean (SD)	863.0 (86.2)	6.9 (26.7)	0.9 (3.2)				
Median	871.0	7.0	0.8	% Change	0.9 (8)	0.413	(-1.5, 3.3)
Min; Max	765; 1055	-32; 44	-4; 5				
Month 12							
n	9	9	9	Absolute change	-0.8 (8)	0.443	(-36.8, 17.7)
Mean (SD)	846.6 (86.9)	-9.6 (35.5)	-1.0 (4.2)				
Median	841.0	-7.0	-0.9	% Change	-0.7 (8)	0.491	(-4.2, 2.2)
Min; Max	760; 1038	-74; 32	-9; 4				
Month 18							
n	9	9	9	Absolute change	-0.5 (8)	0.614	(-51.0, 32.1)
Mean (SD)	846.7 (86.5)	-9.4 (54.0)	-0.9 (6.1)				
Median	850.0	-8.0	-0.9	% Change	-0.5 (8)	0.658	(-5.6, 3.7)
Min; Max	711; 985	-78; 97	-7; 11				
Month 48							
n	9	9	9	Absolute change	-0.4 (8)	0.699	(-38.3, 27.0)
Mean (SD)	850.4 (63.4)	-5.7 (42.4)	-0.3 (4.5)				
Median	855.0	-3.0	-0.3	% Change	-0.2 (8)	0.830	(-3.8, 3.2)
Min; Max	753; 976	-87; 48	-8; 6				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMANO2.

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Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
ADC Standard (10^-							
6mm2/s) Last							
n	9	9	9	Absolute change	-0.4 (8)	0.699	(-38.3, 27.0)
Observed SD	850.4 (63.4)	-5.7 (42.4)	-0.3(4.5)				
Median	855.0	-3.0	-0.3	% Change	-0.2 (8)	0.830	(-3.8, 3.2)
Min; Max	753; 976	-87; 48	-8; 6				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMANO2.