

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
Numerical Mannose Complex Index (Standard)							
Baseline							
n	7						
Mean (SD)	1.0(0.3)						
Median	1.0						
Min; Max	1; 1						
Month 6							
n	9	7	7	Absolute change	-1.1 (6)	0.309	(-0.4, 0.1)
Mean (SD)	0.8(0.2)	-0.1(0.3)	-8.2(27.4)	% Change	-0.8 (6)	0.458	(-33.6, 17.1)
Median	0.9	-0.1	-15.7				
Min; Max	1; 1	-0; 0	-37; 49				
Month 12							
n	9	7	7	Absolute change	-0.9 (6)	0.399	(-0.3, 0.1)
Mean (SD)	0.9(0.3)	-0.1(0.2)	-7.0(20.0)	% Change	-0.9 (6)	0.392	(-25.5, 11.5)
Median	0.8	0.0	1.8				
Min; Max	0; 2	-0; 0	-32; 15				
Month 18							
n	9	7	7	Absolute change	-0.2 (6)	0.839	(-0.3, 0.2)
Mean (SD)	0.9(0.3)	-0.0(0.3)	-0.6(28.6)	% Change	-0.1 (6)	0.961	(-27.0, 25.9)
Median	0.9	-0.1	-11.0				
Min; Max	1; 2	-0; 0	-40; 37				
Month 48							
n	9	7	7	Absolute change	-0.4 (6)	0.704	(-0.4, 0.3)
Mean (SD)	0.9(0.4)	-0.1(0.4)	-7.7(28.6)	% Change	-0.7 (6)	0.504	(-34.2, 18.8)
Median	0.9	-0.1	-8.6				
Min; Max	0; 2	-0; 1	-40; 47				

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

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

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	Change from baseline	t-Test results		
					t-value (df)	p-value	95% CI
Numerical Mannose Complex Index (Standard)							
Last Observation							
n	9	7	7	Absolute change	-0.4 (6)	0.704	(-0.4, 0.3)
Mean (SD)	0.9(0.4)	-0.1(0.4)	-7.7(28.6)	% Change	-0.7 (6)	0.504	(-34.2, 18.8)
Median	0.9	-0.1	-8.6				
Min; Max	0; 2	-0; 1	-40; 47				

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