

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 (Grey)							
Baseline							
n	9						
Mean (SD)	1.0 (0.5)						
Median	0.8						
Min; Max	1; 2						
Month 6							
n	9	9	9	Absolute change	0.2 (8)	0.860	(-0.3, 0.3)
Mean (SD)	1.1 (0.2)	0.0 (0.4)	16.2 (38.0)	% Change	1.3 (8)	0.236	(-13.0, 45.4)
Median	1.0	0.1	17.7				
Min; Max	1; 2	-1; 0	-32; 69				
Month 12							
n	9	9	9	Absolute change	0.3 (8)	0.771	(-0.2, 0.3)
Mean (SD)	1.1 (0.5)	0.0 (0.3)	12.8 (38.7)	% Change	1.0 (8)	0.351	(-16.9, 42.5)
Median	0.9	0.1	16.9				
Min; Max	1; 2	-1; 0	-52; 68				
Month 18							
n	9	9	9	Absolute change	-0.6 (8)	0.540	(-0.3, 0.2)
Mean (SD)	1.0 (0.3)	-0.1 (0.3)	3.3 (28.6)	% Change	0.3 (8)	0.739	(-18.7, 25.3)
Median	0.9	0.1	11.3				
Min; Max	1; 2	-0; 0	-31; 56				
Month 48							
n	9	9	9	Absolute change	-1.0 (8)	0.329	(-0.5, 0.2)
Mean (SD)	0.9 (0.3)	-0.2 (0.4)	-4.5 (34.1)	% Change	-0.4 (8)	0.705	(-30.7, 21.7)
Median	0.8	0.1	5.6				
Min; Max	1; 1	-1; 0	-47; 58				

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
Numerical Mannose Complex Index							
(Grey) Last Observation							
n	9	9	9	Absolute change	-1.0 (8)	0.329	(-0.5, 0.2)
Mean (SD)	0.9(0.3)	-0.2(0.4)	-4.5(34.1)				
Median	0.8	0.1	5.6	% Change	-0.4 (8)	0.705	(-30.7, 21.7)
Min; Max	1; 1	-1; 0	-47; 58				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMAN02.