

Table 14.2.6.1 Summary of Pulmonary Functions - 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
FEV1 (%)							
Baseline							
n	29						
Mean (SD)	83.8 ( 17.6)						
Median	83.4						
Min; Max	50; 119						
Month 6							
n	21	19	19	Absolute change	1.0 (18)	0.341	( -3.9, 10.6)
Mean (SD)	88.0 ( 18.0)	3.4 ( 15.0)	6.0 ( 20.1)				
Median	89.0	3.0	4.4	% Change	1.3 (18)	0.211	( -3.7, 15.6)
Min; Max	46; 125	-38; 25	-39; 42				
Month 12							
n	30	28	28	Absolute change	2.1 (27)	0.043	( 0.1, 8.4)
Mean (SD)	90.4 ( 18.3)	4.3 ( 10.6)	6.1 ( 14.1)				
Median	90.0	5.0	6.2	% Change	2.3 (27)	0.030	( 0.6, 11.6)
Min; Max	49; 136	-24; 26	-26; 37				
Month 18							
n	8	8	8	Absolute change	-0.3 ( 7)	0.757	(-17.1, 13.0)
Mean (SD)	79.1 ( 24.5)	-2.1 ( 18.0)	-2.8 ( 23.8)				
Median	81.5	1.5	1.9	% Change	-0.3 ( 7)	0.751	(-22.7, 17.1)
Min; Max	37; 112	-29; 22	-35; 34				
Month 24							
n	8	7	7	Absolute change	2.8 ( 6)	0.030	( 1.9, 26.4)
Mean (SD)	102.1 ( 16.3)	14.1 ( 13.2)	19.6 ( 18.4)				
Median	105.5	12.0	17.6	% Change	2.8 ( 6)	0.030	( 2.6, 36.6)
Min; Max	75; 119	0; 34	0; 48				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.

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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
FEV1 (%)							
Month 36							
n	6	6	6	Absolute change	-0.7 ( 5)	0.505	(-27.9, 15.7)
Mean (SD)	68.2 ( 28.1)	-6.1 ( 20.8)	-8.2 ( 30.1)				
Median	68.5	-1.5	-2.0	% Change	-0.7 ( 5)	0.534	(-39.8, 23.4)
Min; Max	35; 115	-32; 15	-47; 28				
Month 48							
n	7	7	7	Absolute change	1.0 ( 6)	0.368	(-10.9, 25.4)
Mean (SD)	92.6 ( 15.1)	7.2 ( 19.6)	10.8 ( 26.0)				
Median	94.0	10.0	11.9	% Change	1.1 ( 6)	0.314	(-13.2, 34.8)
Min; Max	64; 106	-19; 30	-23; 47				
Last Observation							
n	31	29	29	Absolute change	1.2 (28)	0.226	( -2.4, 9.9)
Mean (SD)	88.3 ( 22.6)	3.7 ( 16.2)	5.1 ( 22.9)				
Median	94.0	4.0	3.4	% Change	1.2 (28)	0.241	( -3.6, 13.8)
Min; Max	35; 121	-32; 34	-47; 48				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.