

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 (L)							
Baseline							
n	29						
Mean (SD)	2.441(1.000)						
Median	2.320						
Min; Max	0.84; 5.09						
Month 6							
n	21	19	19	Absolute change	2.722 (18)	0.014	(0.049,0.381)
Mean (SD)	2.558(0.972)	0.215(0.344)	10.62(21.03)				
Median	2.610	0.190	11.41	% Change	2.201 (18)	0.041	(0.482,20.76)
Min; Max	0.64; 3.99	-0.38; 0.94	-32.8;53.68				
Month 12							
n	30	28	28	Absolute change	4.576 (27)	<.001	(0.153,0.403)
Mean (SD)	2.793(1.014)	0.278(0.322)	13.56(16.68)				
Median	2.790	0.230	8.271	% Change	4.302 (27)	<.001	(7.094,20.03)
Min; Max	0.77; 5.23	-0.20; 0.85	-12.9;44.21				
Month 18							
n	8	8	8	Absolute change	1.172 ( 7)	0.279	(-.192,0.569)
Mean (SD)	2.340(1.018)	0.189(0.455)	6.639(21.86)				
Median	2.180	0.240	9.992	% Change	0.859 ( 7)	0.419	(-11.6,24.91)
Min; Max	1.15; 3.84	-0.52; 0.88	-30.2;41.31				
Month 24							
n	8	7	7	Absolute change	2.978 ( 6)	0.025	(0.129,1.314)
Mean (SD)	3.424(0.688)	0.721(0.641)	36.25(32.69)				
Median	3.590	0.830	48.26	% Change	2.934 ( 6)	0.026	(6.021,66.49)
Min; Max	2.07; 4.24	-0.02; 1.58	-0.47;78.22				

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

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					Change from baseline	t-value (df)	p-value
FEV1 (L)							
Month 36							
n	6	6	6	Absolute change	0.231 ( 5)	0.827	(-.491,0.587)
Mean (SD)	1.940 (0.986)	0.048 (0.514)	5.436 (36.33)				
Median	1.900	0.080	3.675	% Change	0.367 ( 5)	0.729	(-32.7,43.56)
Min; Max	0.67; 3.54	-0.81; 0.65	-37.9;68.42				
Month 48							
n	7	7	7	Absolute change	3.588 ( 6)	0.012	(0.258,1.367)
Mean (SD)	3.026 (0.710)	0.813 (0.599)	44.75 (41.32)				
Median	3.300	0.670	26.29	% Change	2.866 ( 6)	0.029	(6.539,82.96)
Min; Max	1.86; 3.90	0.22; 1.98	7.14;126.9				
Last Observation							
n	31	29	29	Absolute change	3.490 (28)	0.002	(0.165,0.633)
Mean (SD)	2.864 (1.044)	0.399 (0.615)	21.31 (35.71)				
Median	2.930	0.220	7.143	% Change	3.213 (28)	0.003	(7.724,34.89)
Min; Max	0.67; 5.23	-0.81; 1.98	-37.9;126.9				

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