

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
PEF (L/s)							
Baseline							
n	29						
Mean (SD)	4.852(2.044)						
Median	4.640						
Min; Max	1.62; 8.69						
Month 6							
n	22	20	20	Absolute change	5.251 (19)	<.001	(0.482,1.121)
Mean (SD)	5.252(1.900)	0.802(0.683)	24.38(21.41)				
Median	5.255	0.670	18.32	% Change	5.093 (19)	<.001	(14.36,34.40)
Min; Max	1.78; 9.37	-0.28; 2.15	-3.34;63.80				
Month 12							
n	30	28	28	Absolute change	3.324 (27)	0.003	(0.285,1.204)
Mean (SD)	5.686(2.212)	0.744(1.185)	20.05(25.10)				
Median	5.770	0.525	10.14	% Change	4.227 (27)	<.001	(10.32,29.78)
Min; Max	2.14;12.50	-0.94; 4.37	-15.9;75.89				
Month 18							
n	8	8	8	Absolute change	1.037 (7)	0.334	(-.475,1.218)
Mean (SD)	4.558(1.866)	0.371(1.012)	9.069(26.13)				
Median	4.335	0.790	17.84	% Change	0.982 (7)	0.359	(-12.8,30.91)
Min; Max	2.31; 7.03	-1.54; 1.40	-40.0;33.59				
Month 24							
n	8	7	7	Absolute change	4.981 (6)	0.002	(1.129,3.308)
Mean (SD)	7.101(1.642)	2.219(1.178)	63.99(53.16)				
Median	6.725	2.510	61.82	% Change	3.185 (6)	0.019	(14.83,113.2)
Min; Max	5.33;10.10	0.73; 4.09	10.11;146.6				

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

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				Change from baseline	t-value (df)	p-value	95% CI
PEF (L/s)							
Month 36							
n	6	6	6	Absolute change	0.076 (5)	0.943	(-1.21,1.283)
Mean (SD)	3.997(2.377)	0.037(1.187)	-4.30(41.70)				
Median	4.300	0.365	6.418	% Change	-.252 (5)	0.811	(-48.1,39.46)
Min; Max	0.67; 6.45	-1.79; 1.22	-58.6;50.00				
Month 48							
n	7	7	7	Absolute change	2.702 (6)	0.035	(0.182,3.675)
Mean (SD)	6.169(1.723)	1.929(1.888)	60.19(72.11)				
Median	6.380	2.100	48.84	% Change	2.209 (6)	0.069	(-6.49,126.9)
Min; Max	4.00; 8.78	-0.12; 5.23	-2.23;201.9				
Last Observation							
n	31	29	29	Absolute change	3.604 (28)	0.001	(0.501,1.819)
Mean (SD)	6.005(2.371)	1.160(1.733)	32.24(56.08)				
Median	6.290	0.730	12.52	% Change	3.096 (28)	0.004	(10.91,53.58)
Min; Max	0.67;12.50	-1.79; 5.23	-58.6;201.9				

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