

Table 14.2.5.1 Summary of FVC (%) - 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
FVCP (%)							
Baseline							
n	29						
Mean (SD)	84.9 (18.6)						
Median	91.0						
Min; Max	50; 119						
Month 6							
n	22	20	20	Absolute change	1.1 (19)	0.304	(-3.4, 10.4)
Mean (SD)	87.1 (18.6)	3.5 (14.7)	6.1 (20.3)				
Median	88.5	5.5	7.1	% Change	1.3 (19)	0.194	(-3.4, 15.6)
Min; Max	43; 116	-36; 29	-38; 48				
Month 12							
n	30	28	28	Absolute change	2.7 (27)	0.011	(1.6, 11.5)
Mean (SD)	93.2 (20.8)	6.6 (12.8)	8.5 (16.5)				
Median	97.5	8.0	8.4	% Change	2.7 (27)	0.011	(2.1, 14.9)
Min; Max	45; 127	-25; 40	-29; 50				
Month 18							
n	8	8	8	Absolute change	0.9 (7)	0.403	(-7.3, 16.0)
Mean (SD)	84.8 (23.6)	4.4 (13.9)	5.0 (20.9)				
Median	84.5	7.0	7.7	% Change	0.7 (7)	0.520	(-12.5, 22.5)
Min; Max	35; 116	-16; 22	-31; 36				
Month 24							
n	8	7	7	Absolute change	2.9 (6)	0.028	(2.5, 29.8)
Mean (SD)	106.1 (18.0)	16.1 (14.8)	20.7 (18.5)				
Median	108.5	16.0	21.1	% Change	3.0 (6)	0.025	(3.6, 37.9)
Min; Max	74; 130	-4; 36	-4; 41				

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

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					Change from baseline	t-value (df)	p-value
FVCP (%)							
Month 36							
n	6	6	6	Absolute change	1.3 (5)	0.243	(-5.2, 16.4)
Mean (SD)	78.8(22.0)	5.6(10.3)	7.6(15.2)				
Median	72.0	6.0	7.5	% Change	1.2 (5)	0.277	(-8.4, 23.5)
Min; Max	56; 116	-8; 17	-12; 28				
Month 48							
n	7	7	7	Absolute change	1.8 (6)	0.114	(-4.4, 31.9)
Mean (SD)	98.3(12.4)	13.7(19.6)	19.8(28.4)				
Median	98.0	12.0	12.1	% Change	1.8 (6)	0.116	(-6.5, 46.1)
Min; Max	78; 112	-17; 43	-18; 62				
Last Observation							
n	31	29	29	Absolute change	2.9 (28)	0.007	(2.4, 13.7)
Mean (SD)	93.1(21.7)	8.1(14.8)	10.5(20.9)				
Median	95.0	7.0	7.2	% Change	2.7 (28)	0.011	(2.6, 18.5)
Min; Max	35; 130	-17; 43	-31; 62				

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