

**Table 14.2.16.1 Summary of CHAQ VAS pain - by timepoint - FAS**

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	Change from baseline	t-Test results		
					t-value (df)	p-value	95% CI
CHAQ Pain (0-3)							
Baseline							
n	32						
Mean (SD)	0.618 (0.731)						
Median	0.465						
Min; Max	0.00; 2.52						
Month 6							
n	24	23	16	Absolute change	1.587 (22)	0.127	(-.079,0.593)
Mean (SD)	0.895 (0.911)	0.257 (0.776)	45.77 (138.8)				
Median	0.690	0.000	8.824	% Change	1.319 (15)	0.207	(-28.2,119.7)
Min; Max	0.00; 2.94	-0.99; 2.46	-72.7;512.5				
Month 12							
n	31	30	20	Absolute change	1.122 (29)	0.271	(-.122,0.418)
Mean (SD)	0.761 (0.931)	0.148 (0.723)	3.697 (107.3)				
Median	0.210	0.030	-4.17	% Change	0.154 (19)	0.879	(-46.5,53.91)
Min; Max	0.00; 2.55	-1.44; 1.80	-100;320.0				
Month 18							
n	9	9	5	Absolute change	0.370 ( 8)	0.721	(-.314,0.434)
Mean (SD)	0.407 (0.409)	0.060 (0.487)	122.3 (380.0)				
Median	0.360	0.000	-50.0	% Change	0.720 ( 4)	0.512	( -350,594.1)
Min; Max	0.00; 1.14	-0.66; 0.72	-79.2;800.0				
Month 24							
n	10	9	6	Absolute change	-1.69 ( 8)	0.129	(-.929,0.143)
Mean (SD)	0.339 (0.458)	-.393 (0.697)	-46.0 (60.21)				
Median	0.105	0.000	-64.4	% Change	-1.87 ( 5)	0.120	( -109,17.23)
Min; Max	0.00; 1.29	-1.83; 0.24	-100;38.10				

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

Note 2: n may be lower for the percent change from baseline because of baseline values of zero.

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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
CHAQ Pain (0-3)							
Month 36							
n	7	7	7	Absolute change	-1.38 ( 6)	0.216	(-.688,0.191)
Mean (SD)	0.390(0.326)	-.249(0.476)	32.61(198.2)				
Median	0.300	-.150	-33.3	% Change	0.435 ( 6)	0.678	( -151,215.9)
Min; Max	0.12; 1.02	-0.87; 0.42	-86.2;466.7				
Month 48							
n	9	9	5	Absolute change	0.246 ( 8)	0.812	(-.529,0.656)
Mean (SD)	0.443(0.644)	0.063(0.771)	51.69(202.7)				
Median	0.210	0.000	0.000	% Change	0.570 ( 4)	0.599	( -200,303.4)
Min; Max	0.00; 1.59	-1.14; 1.59	-100;400.0				
Last Observation							
n	33	32	21	Absolute change	-1.52 (31)	0.139	(-.407,0.060)
Mean (SD)	0.431(0.616)	-.173(0.647)	-17.0(109.8)				
Median	0.180	0.015	-44.2	% Change	-.711 (20)	0.485	(-67.0,32.94)
Min; Max	0.00; 2.55	-1.83; 1.59	-100;400.0				

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

Note 2: n may be lower for the percent change from baseline because of baseline values of zero.