

Table 14.2.16: Summary of FEV₁ Percentage of Predicted Normal Value on Day 1

Day	Time Point			Foster 400/24 µg + CHF5259 100 µg (N=157)	Foster 400/24 µg + CHF5259 50 µg (N=156)	Foster 400/24 µg + CHF5259 25 µg (N=152)	Foster 400/24 µg (N=153)
Day 1	T15': 15 Min Post-Dose	Actual Values	n	155	152	148	153
			Mean (SD)	71.6 (11.8)	72.5 (13.0)	71.9 (12.6)	71.2 (12.0)
			95% CI [1]	69.8 - 73.5	70.4 - 74.6	69.8 - 73.9	69.3 - 73.2
			Median	72.0	73.0	72.0	71.0
			Min - Max	43 - 102	28 - 98	39 - 102	34 - 106
Day 1	T30': 30 Min Post-Dose	Actual Values	n	157	154	148	151
			Mean (SD)	73.4 (11.7)	74.5 (12.3)	74.0 (12.4)	73.0 (12.3)
			95% CI [1]	71.5 - 75.2	72.6 - 76.5	72.0 - 76.0	71.0 - 74.9
			Median	74.0	76.0	75.0	73.0
			Min - Max	45 - 103	28 - 99	42 - 100	34 - 109
Day 1	T45': 45 Min Post-Dose	Actual Values	n	153	153	147	151
			Mean (SD)	74.4 (11.9)	75.4 (12.3)	74.4 (12.5)	74.0 (12.1)
			95% CI [1]	72.5 - 76.3	73.4 - 77.3	72.4 - 76.5	72.0 - 75.9
			Median	75.0	77.0	76.0	74.0
			Min - Max	46 - 113	33 - 96	43 - 104	41 - 113
Day 1	T1H: 1 Hour Post-Dose	Actual Values	n	154	153	150	152
			Mean (SD)	75.3 (11.7)	75.6 (12.4)	75.7 (12.1)	74.2 (12.3)
			95% CI [1]	73.4 - 77.2	73.6 - 77.6	73.7 - 77.6	72.2 - 76.2
			Median	76.5	76.0	77.0	74.5
			Min - Max	44 - 104	31 - 102	45 - 101	39 - 113

Day	Time Point			Foster 400/24 µg + CHF5259 100 µg (N=157)	Foster 400/24 µg + CHF5259 50 µg (N=156)	Foster 400/24 µg + CHF5259 25 µg (N=152)	Foster 400/24 µg (N=153)
Day 1	T2H: 2 Hours Post-Dose	Actual Values	n	156	153	150	153
			Mean (SD)	76.4 (12.3)	76.5 (12.6)	76.8 (12.8)	75.4 (13.1)
			95% CI [1]	74.5 - 78.4	74.5 - 78.5	74.8 - 78.9	73.3 - 77.5
			Median	77.0	77.0	77.0	76.0
			Min - Max	44 - 105	33 - 103	44 - 104	39 - 109
Day 1	T3H: 3 Hours Post-Dose	Actual Values	n	156	153	150	152
			Mean (SD)	76.4 (12.5)	76.3 (12.0)	77.0 (12.9)	74.7 (13.2)
			95% CI [1]	74.4 - 78.4	74.4 - 78.3	74.9 - 79.1	72.6 - 76.9
			Median	77.5	78.0	77.0	76.0
			Min - Max	29 - 107	32 - 99	45 - 105	39 - 112
Day 1	T4H: 4 Hours Post-Dose	Actual Values	n	155	153	149	152
			Mean (SD)	75.6 (12.8)	75.6 (12.3)	76.2 (13.5)	74.2 (13.0)
			95% CI [1]	73.6 - 77.6	73.7 - 77.6	74.0 - 78.3	72.1 - 76.3
			Median	77.0	78.0	77.0	75.0
			Min - Max	31 - 104	31 - 97	44 - 122	37 - 112
Day 1	T6H: 6 Hours Post-Dose	Actual Values	n	155	152	150	151
			Mean (SD)	74.4 (12.6)	74.1 (12.6)	74.2 (13.4)	72.5 (13.5)
			95% CI [1]	72.4 - 76.4	72.1 - 76.2	72.0 - 76.4	70.4 - 74.7
			Median	76.0	76.0	76.0	73.0
			Min - Max	42 - 101	33 - 99	37 - 105	35 - 113
Day 1	T8H: 8 Hours Post-Dose	Actual Values	n	156	152	150	151
			Mean (SD)	72.6 (11.9)	72.5 (12.7)	73.0 (13.1)	70.9 (13.0)
			95% CI [1]	70.7 - 74.5	70.4 - 74.5	70.9 - 75.1	68.8 - 73.0
			Median	73.0	74.0	74.0	70.0
			Min - Max	41 - 99	29 - 98	34 - 101	28 - 112

Day	Time Point			Foster 400/24 µg + CHF5259 100 µg (N=157)	Foster 400/24 µg + CHF5259 50 µg (N=156)	Foster 400/24 µg + CHF5259 25 µg (N=152)	Foster 400/24 µg (N=153)
Day 1	T11H30': 11 Hours and 30 Min Post-Dose	Actual Values	n	155	153	150	149
			Mean (SD)	69.8 (11.8)	70.0 (12.8)	69.8 (13.3)	69.7 (12.8)
			95% CI [1]	67.9 - 71.7	67.9 - 72.0	67.7 - 72.0	67.6 - 71.8
			Median	71.0	71.0	71.0	70.0
			Min - Max	29 - 97	27 - 96	32 - 106	41 - 117
Day 1	T12H: 12 Hours Post-Dose	Actual Values	n	156	153	150	149
			Mean (SD)	69.9 (12.5)	69.6 (13.0)	70.0 (13.1)	69.4 (12.4)
			95% CI [1]	67.9 - 71.9	67.5 - 71.7	67.9 - 72.1	67.4 - 71.4
			Median	72.0	71.0	72.0	70.0
			Min - Max	29 - 104	25 - 95	35 - 104	40 - 108