

Table 14.2.16: Summary of FEV₁ Percentage of Predicted Normal Value on Day 42

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 42	T15': 15 Min Post-Dose	Actual Values	n	149	151	148	150
			Mean (SD)	73.2 (12.9)	74.3 (13.2)	72.5 (12.6)	72.1 (11.6)
			95% CI [1]	71.1 - 75.3	72.2 - 76.4	70.5 - 74.6	70.3 - 74.0
			Median	74.0	76.0	73.5	73.0
			Min - Max	30 - 106	30 - 105	24 - 97	41 - 97
Day 42	T30': 30 Min Post-Dose	Actual Values	n	152	150	148	152
			Mean (SD)	74.5 (12.9)	75.5 (13.0)	74.4 (12.2)	73.2 (11.7)
			95% CI [1]	72.5 - 76.6	73.4 - 77.6	72.4 - 76.3	71.4 - 75.1
			Median	75.0	76.0	75.5	73.5
			Min - Max	34 - 104	31 - 109	44 - 97	42 - 100
Day 42	T45': 45 Min Post-Dose	Actual Values	n	150	151	148	149
			Mean (SD)	75.1 (12.9)	76.3 (12.9)	74.7 (12.5)	74.0 (11.8)
			95% CI [1]	73.0 - 77.2	74.3 - 78.4	72.7 - 76.8	72.1 - 75.9
			Median	76.0	78.0	76.0	73.0
			Min - Max	29 - 107	36 - 107	29 - 100	42 - 100
Day 42	T1H: 1 Hour Post-Dose	Actual Values	n	153	151	147	151
			Mean (SD)	75.6 (12.8)	76.6 (12.6)	75.2 (12.7)	74.5 (11.7)
			95% CI [1]	73.5 - 77.6	74.5 - 78.6	73.1 - 77.3	72.6 - 76.3
			Median	76.0	76.0	76.0	74.0
			Min - Max	31 - 105	35 - 107	30 - 100	41 - 107

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 42	T2H: 2 Hours Post-Dose	Actual Values	n	153	152	149	152
			Mean (SD)	76.5 (13.6)	77.5 (12.7)	76.5 (13.1)	75.0 (12.2)
			95% CI [1]	74.4 - 78.7	75.4 - 79.5	74.4 - 78.6	73.0 - 77.0
			Median	78.0	78.0	78.0	75.0
			Min - Max	27 - 109	36 - 111	28 - 105	40 - 111
Day 42	T3H: 3 Hours Post-Dose	Actual Values	n	153	152	149	152
			Mean (SD)	76.1 (14.1)	77.1 (12.8)	76.4 (12.7)	74.3 (12.5)
			95% CI [1]	73.9 - 78.4	75.0 - 79.1	74.4 - 78.5	72.3 - 76.3
			Median	77.0	78.0	78.0	75.0
			Min - Max	31 - 105	33 - 106	38 - 102	39 - 108
Day 42	T4H: 4 Hours Post-Dose	Actual Values	n	152	151	148	152
			Mean (SD)	75.1 (13.1)	76.2 (12.8)	75.2 (12.6)	73.6 (12.3)
			95% CI [1]	73.0 - 77.2	74.2 - 78.3	73.2 - 77.3	71.6 - 75.5
			Median	76.0	78.0	77.0	74.5
			Min - Max	35 - 100	32 - 107	32 - 101	38 - 109
Day 42	T6H: 6 Hours Post-Dose	Actual Values	n	153	151	149	152
			Mean (SD)	73.3 (13.3)	74.1 (13.0)	73.3 (13.0)	72.1 (12.4)
			95% CI [1]	71.2 - 75.5	72.0 - 76.2	71.2 - 75.4	70.1 - 74.1
			Median	75.0	76.0	74.0	72.0
			Min - Max	32 - 101	38 - 101	30 - 104	39 - 103
Day 42	T8H: 8 Hours Post-Dose	Actual Values	n	152	152	148	151
			Mean (SD)	71.5 (13.0)	72.6 (13.3)	72.2 (13.0)	70.2 (12.5)
			95% CI [1]	69.4 - 73.6	70.5 - 74.7	70.1 - 74.3	68.2 - 72.2
			Median	72.5	75.0	73.5	71.0
			Min - Max	28 - 100	29 - 105	28 - 100	36 - 105

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 42	T11H30': 11 Hours and 30 Min Post-Dose	Actual Values	n	154	150	147	152
			Mean (SD)	69.7 (13.1)	70.4 (13.4)	69.3 (13.3)	68.6 (12.4)
			95% CI [1]	67.6 - 71.8	68.2 - 72.5	67.2 - 71.5	66.6 - 70.6
			Median	71.0	71.5	71.0	69.5
			Min - Max	27 - 100	31 - 101	25 - 97	38 - 100
Day 42	T12H: 12 Hours Post-Dose	Actual Values	n	154	150	149	152
			Mean (SD)	69.7 (13.0)	69.7 (12.8)	69.9 (12.8)	68.9 (12.2)
			95% CI [1]	67.6 - 71.8	67.6 - 71.8	67.8 - 72.0	66.9 - 70.8
			Median	70.0	71.0	72.0	71.0
			Min - Max	32 - 100	26 - 98	25 - 95	37 - 98