

Table 14.2.2.7.1.2 Summary of EQ-5D summary index and EQ-VAS by scheduled visit and treatment (PPS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ Overall Health (VAS)	Visit 2	n / missing	52 / 0		21 / 0	
		Mean (SD)	86.1 (12.07)		83.2 (12.39)	
		Median	90.0		80.0	
		IQR	15.0		20.0	
		Q1 / Q3	80.0 / 95.0		75.0 / 95.0	
		Min / Max	45 / 100		60 / 100	
	Visit 3	n / missing	51 / 0	51 / 0	21 / 0	21 / 0
		Mean (SD)	83.1 (16.14)	-3.0 (19.33)	84.0 (11.90)	0.9 (11.80)
		Median	85.0	0.0	85.0	0.0
		IQR	15.0	15.0	10.0	14.0
		Q1 / Q3	80.0 / 95.0	-10.0 / 5.0	80.0 / 90.0	-4.0 / 10.0
		Min / Max	30 / 100	-65 / 50	45 / 100	-30 / 30
	Visit 4	n / missing	49 / 0	49 / 0	19 / 0	19 / 0
		Mean (SD)	86.4 (13.05)	0.6 (14.34)	88.7 (8.63)	4.1 (10.30)
		Median	90.0	0.0	90.0	0.0
		IQR	10.0	15.0	10.0	14.0
		Q1 / Q3	85.0 / 95.0	-5.0 / 10.0	85.0 / 95.0	-4.0 / 10.0
		Min / Max	50 / 100	-45 / 40	70 / 100	-10 / 25
	Visit 5	n / missing	47 / 0	47 / 0	19 / 0	19 / 0
		Mean (SD)	86.4 (12.06)	0.2 (16.77)	89.2 (10.04)	4.6 (13.59)
		Median	90.0	0.0	90.0	0.0
		IQR	15.0	15.0	5.0	15.0
		Q1 / Q3	80.0 / 95.0	-10.0 / 5.0	90.0 / 95.0	-5.0 / 10.0
		Min / Max	50 / 100	-30 / 50	60 / 100	-20 / 35
	EOS	n / missing	50 / 2	50 / 2	20 / 1	20 / 1
		Mean (SD)	85.0 (16.19)	-1.3 (19.17)	87.6 (16.31)	3.5 (16.82)
		Median	90.0	0.0	90.0	2.5
		IQR	10.0	15.0	5.0	12.5
		Q1 / Q3	85.0 / 95.0	-10.0 / 5.0	90.0 / 95.0	0.0 / 12.5
		Min / Max	20 / 100	-65 / 50	30 / 100	-45 / 33

BL = Baseline; EOS = End of Study visit; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; missing = Number of subjects at visit with missing value; PPS = Per Protocol Set; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VAS = Visual analogue scale.

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Table 14.2.2.7.1.2 Summary of EQ-5D summary index and EQ-VAS by scheduled visit and treatment (PPS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ-5D Summary Index	Visit 2	n / missing	52 / 0		21 / 0	
		Mean (SD)	0.965 (0.0559)		0.954 (0.0678)	
		Median	1.000		1.000	
		IQR	0.063		0.084	
		Q1 / Q3	0.937 / 1.000		0.916 / 1.000	
		Min / Max	0.81 / 1.00		0.79 / 1.00	
	Visit 3	n / missing	51 / 0	51 / 0	21 / 0	21 / 0
		Mean (SD)	0.962 (0.0675)	-0.002 (0.0673)	0.954 (0.0854)	0.000 (0.0645)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.000	0.063	0.021
		Q1 / Q3	0.937 / 1.000	0.000 / 0.000	0.937 / 1.000	0.000 / 0.021
		Min / Max	0.72 / 1.00	-0.29 / 0.17	0.65 / 1.00	-0.24 / 0.10
	Visit 4	n / missing	49 / 0	49 / 0	19 / 0	19 / 0
		Mean (SD)	0.970 (0.0531)	0.007 (0.0480)	0.973 (0.0522)	0.010 (0.0558)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.000	0.063	0.000
		Q1 / Q3	0.937 / 1.000	0.000 / 0.000	0.937 / 1.000	0.000 / 0.000
		Min / Max	0.81 / 1.00	-0.16 / 0.12	0.83 / 1.00	-0.14 / 0.15
	Visit 5	n / missing	47 / 0	47 / 0	19 / 0	19 / 0
		Mean (SD)	0.974 (0.0478)	0.011 (0.0491)	0.987 (0.0300)	0.024 (0.0646)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.015	0.000	0.063
		Q1 / Q3	0.937 / 1.000	0.000 / 0.015	1.000 / 1.000	0.000 / 0.063
		Min / Max	0.83 / 1.00	-0.14 / 0.17	0.92 / 1.00	-0.08 / 0.21
	EOS	n / missing	50 / 2	50 / 2	20 / 1	20 / 1
		Mean (SD)	0.963 (0.0739)	-0.001 (0.0621)	0.958 (0.0909)	-0.001 (0.0772)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.000	0.029	0.014
		Q1 / Q3	0.937 / 1.000	0.000 / 0.000	0.971 / 1.000	0.000 / 0.014
		Min / Max	0.72 / 1.00	-0.21 / 0.17	0.66 / 1.00	-0.24 / 0.15

BL = Baseline; EOS = End of Study visit; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; missing = Number of subjects at visit with missing value; PPS = Per Protocol Set; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VAS = Visual analogue scale.

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Table 14.2.2.7.2.2 Summary of EQ-5D summary index and EQ-VAS by scheduled visit and treatment (FAS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ Overall Health (VAS)	Visit 2	n / missing	90 / 0		46 / 0	
		Mean (SD)	85.7 (11.68)		84.7 (13.07)	
		Median	90.0		85.0	
		IQR	15.0		15.0	
		Q1 / Q3	80.0 / 95.0		80.0 / 95.0	
		Min / Max	45 / 100		40 / 100	
	Visit 3	n / missing	88 / 0	88 / 0	45 / 1	45 / 1
		Mean (SD)	83.7 (15.16)	-1.9 (16.94)	85.1 (11.87)	0.3 (15.63)
		Median	85.0	0.0	85.0	0.0
		IQR	15.0	15.0	15.0	20.0
		Q1 / Q3	80.0 / 95.0	-10.0 / 5.0	80.0 / 95.0	-10.0 / 10.0
		Min / Max	30 / 100	-65 / 50	45 / 100	-40 / 60
	Visit 4	n / missing	83 / 0	83 / 0	43 / 0	43 / 0
		Mean (SD)	85.3 (13.75)	-0.3 (14.14)	88.4 (8.29)	2.9 (12.65)
		Median	90.0	0.0	90.0	0.0
		IQR	15.0	15.0	10.0	15.0
		Q1 / Q3	80.0 / 95.0	-5.0 / 10.0	85.0 / 95.0	-5.0 / 10.0
		Min / Max	40 / 100	-50 / 40	70 / 100	-15 / 50
	Visit 5	n / missing	79 / 0	79 / 0	42 / 0	42 / 0
		Mean (SD)	86.1 (13.30)	0.0 (17.20)	84.9 (13.00)	-0.6 (16.21)
		Median	90.0	0.0	90.0	0.0
		IQR	15.0	16.0	15.0	15.0
		Q1 / Q3	80.0 / 95.0	-6.0 / 10.0	80.0 / 95.0	-5.0 / 10.0
		Min / Max	20 / 100	-75 / 50	55 / 100	-40 / 35
	EOS	n / missing	84 / 6	84 / 6	45 / 1	45 / 1
		Mean (SD)	85.9 (15.76)	0.0 (17.23)	88.0 (12.65)	2.9 (15.71)
		Median	90.0	0.0	90.0	0.0
		IQR	10.0	15.0	16.0	15.0
		Q1 / Q3	85.0 / 95.0	-5.0 / 10.0	80.0 / 96.0	-5.0 / 10.0
		Min / Max	20 / 100	-65 / 50	30 / 100	-45 / 45

BL = Baseline; EOS = End of Study visit; FAS = Full Analysis Set; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; missing = Number of subjects at visit with missing value; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VAS = Visual analogue scale.

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Table 14.2.2.7.2.2 Summary of EQ-5D summary index and EQ-VAS by scheduled visit and treatment (FAS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ-5D Summary Index	Visit 2	n / missing	90 / 0		46 / 0	
		Mean (SD)	0.962 (0.0626)		0.951 (0.0745)	
		Median	1.000		1.000	
		IQR	0.063		0.084	
		Q1 / Q3	0.937 / 1.000		0.916 / 1.000	
		Min / Max	0.67 / 1.00		0.70 / 1.00	
	Visit 3	n / missing	88 / 0	88 / 0	45 / 1	45 / 1
		Mean (SD)	0.956 (0.0703)	-0.006 (0.0680)	0.962 (0.0691)	0.011 (0.0702)
		Median	1.000	0.000	1.000	0.000
		IQR	0.071	0.000	0.063	0.021
		Q1 / Q3	0.930 / 1.000	0.000 / 0.000	0.937 / 1.000	0.000 / 0.021
		Min / Max	0.72 / 1.00	-0.29 / 0.17	0.65 / 1.00	-0.24 / 0.24
	Visit 4	n / missing	83 / 0	83 / 0	43 / 0	43 / 0
		Mean (SD)	0.965 (0.0674)	0.005 (0.0643)	0.973 (0.0532)	0.019 (0.0699)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.000	0.063	0.063
		Q1 / Q3	0.937 / 1.000	0.000 / 0.000	0.937 / 1.000	0.000 / 0.063
		Min / Max	0.66 / 1.00	-0.28 / 0.17	0.81 / 1.00	-0.14 / 0.24
	Visit 5	n / missing	79 / 0	79 / 0	42 / 0	42 / 0
		Mean (SD)	0.966 (0.0607)	0.005 (0.0548)	0.957 (0.0630)	0.001 (0.0842)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.015	0.078	0.021
		Q1 / Q3	0.937 / 1.000	0.000 / 0.015	0.922 / 1.000	-0.021 / 0.000
		Min / Max	0.65 / 1.00	-0.17 / 0.17	0.73 / 1.00	-0.21 / 0.21
	EOS	n / missing	84 / 6	84 / 6	45 / 1	45 / 1
		Mean (SD)	0.953 (0.0986)	-0.008 (0.0952)	0.962 (0.0717)	0.009 (0.0817)
		Median	1.000	0.000	1.000	0.000
		IQR	0.063	0.000	0.063	0.028
		Q1 / Q3	0.937 / 1.000	0.000 / 0.000	0.937 / 1.000	0.000 / 0.028
		Min / Max	0.32 / 1.00	-0.68 / 0.17	0.66 / 1.00	-0.24 / 0.24

BL = Baseline; EOS = End of Study visit; FAS = Full Analysis Set; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; missing = Number of subjects at visit with missing value; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VAS = Visual analogue scale.

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