

Table 14.2.2.7.1.3 Summary of study specific quality of life questionnaire by scheduled visit and treatment (PPS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days unable to work/study due to VV	Visit 2	n / missing	51 / 1		21 / 0	
		Mean (SD)	0.0 (0.20)		0.0 (0.00)	
		Median	0.0		0.0	
		IQR	0.0		0.0	
		Q1 / Q3	0.0 / 0.0		0.0 / 0.0	
		Min / Max	0 / 1		0 / 0	
	Visit 3	n / missing	51 / 0	50 / 1	20 / 1	20 / 1
		Mean (SD)	0.1 (0.70)	0.1 (0.74)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 5	-1 / 5	0 / 0	0 / 0
	Visit 4	n / missing	49 / 0	48 / 1	19 / 0	19 / 0
		Mean (SD)	0.0 (0.14)	0.0 (0.25)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 1	-1 / 1	0 / 0	0 / 0
	Visit 5	n / missing	47 / 0	46 / 1	19 / 0	19 / 0
		Mean (SD)	0.1 (0.35)	0.0 (0.36)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 2	-1 / 2	0 / 0	0 / 0
	EOS	n / missing	48 / 4	47 / 5	20 / 1	20 / 1
		Mean (SD)	0.0 (0.20)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 1	0 / 0	0 / 0	0 / 0

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; VV = Vulvovaginitis.

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Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days of partial work/study restriction due to VV	Visit 2	n / missing	51 / 1		21 / 0	
		Mean (SD)	0.5 (1.01)		0.5 (1.54)	
		Median	0.0		0.0	
		IQR	0.0		0.0	
		Q1 / Q3	0.0 / 0.0		0.0 / 0.0	
		Min / Max	0 / 4		0 / 6	
	Visit 3	n / missing	51 / 0	50 / 1	20 / 1	20 / 1
		Mean (SD)	0.2 (0.85)	-0.3 (1.25)	0.0 (0.00)	-0.5 (1.57)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 5	-4 / 5	0 / 0	-6 / 0
	Visit 4	n / missing	49 / 0	48 / 1	19 / 0	19 / 0
		Mean (SD)	0.1 (0.37)	-0.4 (0.98)	0.0 (0.00)	-0.3 (1.38)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 2	-4 / 1	0 / 0	-6 / 0
	Visit 5	n / missing	47 / 0	46 / 1	19 / 0	19 / 0
		Mean (SD)	0.4 (1.11)	-0.1 (1.32)	0.6 (1.92)	0.3 (2.45)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 5	-3 / 5	0 / 7	-6 / 7
	EOS	n / missing	48 / 4	47 / 5	20 / 1	20 / 1
		Mean (SD)	0.1 (0.55)	-0.4 (1.17)	0.0 (0.00)	-0.3 (1.34)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 3	-4 / 3	0 / 0	-6 / 0

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; VV = Vulvovaginitis.

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Table 14.2.2.7.1.3 Summary of study specific quality of life questionnaire by scheduled visit and treatment (PPS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Quality of Life during actual episode/visit	Visit 2	n / missing	52 / 0		21 / 0	
		Mean (SD)	4.5 (1.58)		4.5 (2.66)	
		Median	5.0		4.0	
		IQR	1.0		3.0	
		Q1 / Q3	4.0 / 5.0		3.0 / 6.0	
		Min / Max	1 / 8		0 / 10	
	Visit 3	n / missing	51 / 0	51 / 0	21 / 0	21 / 0
		Mean (SD)	5.3 (2.23)	0.8 (2.34)	5.7 (2.48)	1.2 (2.29)
		Median	5.0	1.0	6.0	1.0
		IQR	3.0	3.0	3.0	2.0
		Q1 / Q3	4.0 / 7.0	0.0 / 3.0	4.0 / 7.0	0.0 / 2.0
		Min / Max	1 / 10	-5 / 6	0 / 10	-4 / 5
	Visit 4	n / missing	48 / 1	48 / 1	19 / 0	19 / 0
		Mean (SD)	5.1 (2.27)	0.6 (2.08)	5.3 (2.63)	0.4 (2.97)
		Median	5.0	1.0	5.0	1.0
		IQR	4.0	2.5	3.0	4.0
		Q1 / Q3	3.0 / 7.0	-0.5 / 2.0	4.0 / 7.0	-2.0 / 2.0
		Min / Max	0 / 9	-6 / 5	0 / 10	-6 / 6
	Visit 5	n / missing	47 / 0	47 / 0	19 / 0	19 / 0
		Mean (SD)	5.9 (2.28)	1.4 (2.92)	6.1 (1.99)	1.2 (2.52)
		Median	5.0	1.0	6.0	1.0
		IQR	4.0	5.0	3.0	3.0
		Q1 / Q3	4.0 / 8.0	-1.0 / 4.0	5.0 / 8.0	0.0 / 3.0
		Min / Max	0 / 10	-7 / 7	3 / 10	-3 / 6
	EOS	n / missing	49 / 3	49 / 3	20 / 1	20 / 1
		Mean (SD)	6.4 (1.94)	2.0 (2.47)	6.2 (2.30)	1.5 (1.93)
		Median	6.0	2.0	6.0	1.5
		IQR	3.0	4.0	3.5	3.0
		Q1 / Q3	5.0 / 8.0	0.0 / 4.0	5.0 / 8.5	0.0 / 3.0
		Min / Max	2 / 10	-2 / 8	1 / 10	-3 / 6

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; VV = Vulvovaginitis.

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Table 14.2.2.7.2.3 Summary of study specific quality of life questionnaire by scheduled visit and treatment (FAS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days unable to work/study due to VV	Visit 2	n / missing	87 / 3		46 / 0	
		Mean (SD)	0.0 (0.15)		0.0 (0.15)	
		Median	0.0		0.0	
		IQR	0.0		0.0	
		Q1 / Q3	0.0 / 0.0		0.0 / 0.0	
		Min / Max	0 / 1		0 / 1	
	Visit 3	n / missing	87 / 1	85 / 3	44 / 2	44 / 2
		Mean (SD)	0.1 (0.54)	0.0 (0.57)	0.0 (0.30)	0.0 (0.30)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 5	-1 / 5	0 / 2	0 / 2
	Visit 4	n / missing	83 / 0	81 / 2	43 / 0	43 / 0
		Mean (SD)	0.0 (0.24)	0.0 (0.30)	0.1 (0.50)	0.1 (0.53)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 2	-1 / 2	0 / 3	-1 / 3
	Visit 5	n / missing	79 / 0	77 / 2	40 / 2	40 / 2
		Mean (SD)	0.1 (0.27)	0.0 (0.28)	0.3 (1.04)	0.3 (0.93)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 2	-1 / 2	0 / 5	0 / 4
	EOS	n / missing	81 / 9	79 / 11	44 / 2	44 / 2
		Mean (SD)	0.1 (0.37)	0.0 (0.34)	0.0 (0.15)	0.0 (0.22)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 3	0 / 3	0 / 1	-1 / 1

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; VV = Vulvovaginitis.

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Table 14.2.2.7.2.3 Summary of study specific quality of life questionnaire by scheduled visit and treatment (FAS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days of partial work/study restriction due to VV	Visit 2	n / missing	87 / 3		46 / 0	
		Mean (SD)	0.6 (1.49)		1.0 (2.42)	
		Median	0.0		0.0	
		IQR	0.0		0.0	
		Q1 / Q3	0.0 / 0.0		0.0 / 0.0	
		Min / Max	0 / 7		0 / 10	
	Visit 3	n / missing	87 / 1	85 / 3	44 / 2	44 / 2
		Mean (SD)	0.3 (1.14)	-0.4 (1.58)	0.2 (0.66)	-0.8 (2.47)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 6	-7 / 5	0 / 3	-10 / 1
	Visit 4	n / missing	83 / 0	81 / 2	43 / 0	43 / 0
		Mean (SD)	0.4 (1.27)	-0.3 (1.69)	0.3 (0.98)	-0.7 (2.54)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 8	-6 / 7	0 / 5	-10 / 3
	Visit 5	n / missing	79 / 0	77 / 2	41 / 1	41 / 1
		Mean (SD)	0.4 (1.20)	-0.3 (1.49)	0.6 (1.69)	-0.4 (3.01)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 7	-6 / 5	0 / 7	-10 / 7
	EOS	n / missing	81 / 9	79 / 11	44 / 2	44 / 2
		Mean (SD)	0.4 (1.28)	-0.3 (1.48)	0.0 (0.21)	-0.9 (2.42)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 7	-6 / 4	0 / 1	-10 / 0

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; VV = Vulvovaginitis.

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Table 14.2.2.7.2.3 Summary of study specific quality of life questionnaire by scheduled visit and treatment (FAS)

Variable	Scheduled visit	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Quality of Life during actual episode/visit	Visit 2	n / missing	89 / 1		46 / 0	
		Mean (SD)	4.3 (1.73)		4.3 (2.19)	
		Median	5.0		4.0	
		IQR	2.0		3.0	
		Q1 / Q3	3.0 / 5.0		3.0 / 6.0	
		Min / Max	0 / 8		0 / 10	
	Visit 3	n / missing	88 / 0	87 / 1	45 / 1	45 / 1
		Mean (SD)	5.1 (2.30)	0.9 (2.39)	5.4 (2.45)	1.0 (2.40)
		Median	5.0	1.0	5.0	1.0
		IQR	4.0	2.0	3.0	2.0
		Q1 / Q3	3.0 / 7.0	0.0 / 2.0	4.0 / 7.0	0.0 / 2.0
		Min / Max	1 / 10	-5 / 8	0 / 10	-4 / 7
	Visit 4	n / missing	82 / 1	82 / 1	43 / 0	43 / 0
		Mean (SD)	5.4 (2.42)	1.2 (2.49)	5.3 (2.57)	0.9 (2.84)
		Median	5.0	1.0	5.0	1.0
		IQR	3.0	3.0	3.0	4.0
		Q1 / Q3	4.0 / 7.0	0.0 / 3.0	4.0 / 7.0	-1.0 / 3.0
		Min / Max	0 / 10	-6 / 9	0 / 10	-6 / 7
	Visit 5	n / missing	79 / 0	79 / 0	42 / 0	42 / 0
		Mean (SD)	5.8 (2.32)	1.5 (2.77)	6.3 (1.95)	1.8 (2.33)
		Median	5.0	2.0	6.0	2.0
		IQR	4.0	4.0	3.0	4.0
		Q1 / Q3	4.0 / 8.0	0.0 / 4.0	5.0 / 8.0	0.0 / 4.0
		Min / Max	0 / 10	-7 / 8	3 / 10	-3 / 6
	EOS	n / missing	83 / 7	82 / 8	45 / 1	45 / 1
		Mean (SD)	6.2 (2.29)	1.9 (2.39)	6.3 (2.38)	1.9 (2.47)
		Median	6.0	2.0	6.0	2.0
		IQR	3.0	4.0	3.0	3.0
		Q1 / Q3	5.0 / 8.0	0.0 / 4.0	5.0 / 8.0	0.0 / 3.0
		Min / Max	2 / 10	-2 / 8	1 / 10	-4 / 8

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; VV = Vulvovaginitis.

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