

Table 14.2.2.7.1.1 Summary of EQ-5D dimensions by scheduled visit and treatment (PPS)

EQ-5D Dimension	Scheduled visit	Option	Statistics	IMUNOR	PLACEBO
Mobility	Visit 2		N	52	21
		I have no problems walking	n (%)	49 (94.2)	21 (100)
		I have slight problems walking	n (%)	3 (5.8)	
	Visit 3		N	51	21
		I have no problems walking	n (%)	47 (92.2)	18 (85.7)
		I have slight problems walking	n (%)	4 (7.8)	3 (14.3)
	Visit 4		N	49	19
		I have no problems walking	n (%)	47 (95.9)	18 (94.7)
		I have slight problems walking	n (%)	2 (4.1)	1 (5.3)
	Visit 5		N	47	19
		I have no problems walking	n (%)	46 (97.9)	19 (100)
		I have slight problems walking	n (%)	1 (2.1)	
	EOS		N	52	21
		I have no problems walking	n (%)	47 (94.0)	18 (90.0)
		I have slight problems walking	n (%)	3 (6.0)	1 (5.0)
		I have moderate problems walking	n (%)		1 (5.0)
		Missing	n (%)	2	1
Self-care	Visit 2		N	52	21
		I have no problems washing or dressing myself	n (%)	52 (100)	21 (100)
	Visit 3		N	51	21
		I have no problems washing or dressing myself	n (%)	51 (100)	20 (95.2)
		I have slight problems washing or dressing myself	n (%)		1 (4.8)
	Visit 4		N	49	19
		I have no problems washing or dressing myself	n (%)	48 (98.0)	19 (100)
		I have slight problems washing or dressing myself	n (%)	1 (2.0)	
	Visit 5		N	47	19
		I have no problems washing or dressing myself	n (%)	47 (100)	19 (100)
	EOS		N	52	21
		I have no problems washing or dressing myself	n (%)	50 (100)	19 (95.0)
		I have slight problems washing or dressing myself	n (%)		1 (5.0)
		Missing	n (%)	2	1

% = Percentage of subjects out of corresponding N; EOS = End of Study visit; N = Total number of patients at visit; n = Number of subjects within specified category; PPS = Per Protocol Set.

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EQ-5D Dimension	Scheduled visit	Option	Statistics	IMUNOR	PLACEBO
Usual activities	Visit 2		N	52	21
		I have no problems doing my usual activities	n (%)	50 (96.2)	20 (95.2)
		I have slight problems doing my usual activities	n (%)	2 (3.8)	1 (4.8)
	Visit 3		N	51	21
		I have no problems doing my usual activities	n (%)	50 (98.0)	18 (85.7)
		I have slight problems doing my usual activities	n (%)	1 (2.0)	3 (14.3)
	Visit 4		N	49	19
		I have no problems doing my usual activities	n (%)	46 (93.9)	18 (94.7)
		I have slight problems doing my usual activities	n (%)	3 (6.1)	1 (5.3)
	Visit 5		N	47	19
		I have no problems doing my usual activities	n (%)	47 (100)	19 (100)
	EOS		N	52	21
		I have no problems doing my usual activities	n (%)	47 (94.0)	17 (85.0)
		I have slight problems doing my usual activities	n (%)	3 (6.0)	3 (15.0)
		Missing	n (%)	2	1
Pain/discomfort	Visit 2		N	52	21
		I have no pain or discomfort	n (%)	39 (75.0)	14 (66.7)
		I have slight pain or discomfort	n (%)	12 (23.1)	4 (19.0)
		I have moderate pain or discomfort	n (%)	1 (1.9)	3 (14.3)
	Visit 3		N	51	21
		I have no pain or discomfort	n (%)	40 (78.4)	16 (76.2)
		I have slight pain or discomfort	n (%)	10 (19.6)	4 (19.0)
		I have moderate pain or discomfort	n (%)	1 (2.0)	1 (4.8)
	Visit 4		N	49	19
		I have no pain or discomfort	n (%)	36 (73.5)	15 (78.9)
		I have slight pain or discomfort	n (%)	10 (20.4)	4 (21.1)
		I have moderate pain or discomfort	n (%)	3 (6.1)	
	Visit 5		N	47	19
		I have no pain or discomfort	n (%)	36 (76.6)	18 (94.7)
		I have slight pain or discomfort	n (%)	11 (23.4)	
		I have moderate pain or discomfort	n (%)		1 (5.3)
	EOS		N	52	21
		I have no pain or discomfort	n (%)	39 (78.0)	17 (85.0)
		I have slight pain or discomfort	n (%)	8 (16.0)	3 (15.0)
		I have moderate pain or discomfort	n (%)	3 (6.0)	
		Missing	n (%)	2	1

% = Percentage of subjects out of corresponding N; EOS = End of Study visit; N = Total number of patients at visit; n = Number of subjects within specified category; PPS = Per Protocol Set.

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Table 14.2.2.7.1.1 Summary of EQ-5D dimensions by scheduled visit and treatment (PPS)

EQ-5D Dimension	Scheduled visit	Option	Statistics	IMUNOR	PLACEBO
Anxiety/depression	Visit 2		N	52	21
		I am not anxious or depressed	n (%)	43 (82.7)	16 (76.2)
		I am slightly anxious or depressed	n (%)	8 (15.4)	4 (19.0)
		I am moderately anxious or depressed	n (%)	1 (1.9)	1 (4.8)
	Visit 3		N	51	21
		I am not anxious or depressed	n (%)	42 (82.4)	18 (85.7)
		I am slightly anxious or depressed	n (%)	7 (13.7)	2 (9.5)
		I am moderately anxious or depressed	n (%)	1 (2.0)	1 (4.8)
		I am severely anxious or depressed	n (%)	1 (2.0)	
	Visit 4		N	49	19
		I am not anxious or depressed	n (%)	46 (93.9)	17 (89.5)
		I am slightly anxious or depressed	n (%)	2 (4.1)	2 (10.5)
		I am moderately anxious or depressed	n (%)	1 (2.0)	
	Visit 5		N	47	19
		I am not anxious or depressed	n (%)	41 (87.2)	17 (89.5)
		I am slightly anxious or depressed	n (%)	5 (10.6)	2 (10.5)
		I am moderately anxious or depressed	n (%)	1 (2.1)	
	EOS		N	52	21
		I am not anxious or depressed	n (%)	43 (86.0)	17 (85.0)
		I am slightly anxious or depressed	n (%)	6 (12.0)	
		I am moderately anxious or depressed	n (%)		3 (15.0)
		I am severely anxious or depressed	n (%)	1 (2.0)	
		Missing	n (%)	2	1

% = Percentage of subjects out of corresponding N; EOS = End of Study visit; N = Total number of patients at visit; n = Number of subjects within specified category; PPS = Per Protocol Set.

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Table 14.2.2.7.2.1 Summary of EQ-5D dimensions by scheduled visit and treatment (FAS)

EQ-5D Dimension	Scheduled visit	Option	Statistics	IMUNOR	PLACEBO
Mobility	Visit 2		N	90	46
		I have no problems walking	n (%)	87 (96.7)	44 (95.7)
		I have slight problems walking	n (%)	3 (3.3)	2 (4.3)
	Visit 3		N	88	46
		I have no problems walking	n (%)	84 (95.5)	42 (93.3)
		I have slight problems walking	n (%)	4 (4.5)	3 (6.7)
		Missing	n (%)		1
	Visit 4		N	83	43
		I have no problems walking	n (%)	81 (97.6)	42 (97.7)
		I have slight problems walking	n (%)	2 (2.4)	1 (2.3)
	Visit 5		N	79	42
		I have no problems walking	n (%)	78 (98.7)	39 (92.9)
		I have slight problems walking	n (%)	1 (1.3)	3 (7.1)
	EOS		N	90	46
		I have no problems walking	n (%)	79 (94.0)	43 (95.6)
		I have slight problems walking	n (%)	5 (6.0)	1 (2.2)
		I have moderate problems walking	n (%)		1 (2.2)
		Missing	n (%)	6	1
Self-care	Visit 2		N	90	46
		I have no problems washing or dressing myself	n (%)	90 (100)	45 (97.8)
		I have slight problems washing or dressing myself	n (%)		1 (2.2)
	Visit 3		N	88	46
		I have no problems washing or dressing myself	n (%)	88 (100)	44 (97.8)
		I have slight problems washing or dressing myself	n (%)		1 (2.2)
		Missing	n (%)		1
	Visit 4		N	83	43
		I have no problems washing or dressing myself	n (%)	82 (98.8)	43 (100)
		I have slight problems washing or dressing myself	n (%)	1 (1.2)	
	Visit 5		N	79	42
		I have no problems washing or dressing myself	n (%)	79 (100)	42 (100)
	EOS		N	90	46
		I have no problems washing or dressing myself	n (%)	84 (100)	44 (97.8)
		I have slight problems washing or dressing myself	n (%)		1 (2.2)
		Missing	n (%)	6	1

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Table 14.2.2.7.2.1 Summary of EQ-5D dimensions by scheduled visit and treatment (FAS)

EQ-5D Dimension	Scheduled visit	Option	Statistics	IMUNOR	PLACEBO
Usual activities	Visit 2		N	90	46
		I have no problems doing my usual activities	n (%)	87 (96.7)	41 (89.1)
		I have slight problems doing my usual activities	n (%)	3 (3.3)	5 (10.9)
	Visit 3		N	88	46
		I have no problems doing my usual activities	n (%)	85 (96.6)	41 (91.1)
		I have slight problems doing my usual activities	n (%)	2 (2.3)	4 (8.9)
		I have moderate problems doing my usual activities	n (%)	1 (1.1)	
		Missing	n (%)		1
	Visit 4		N	83	43
		I have no problems doing my usual activities	n (%)	78 (94.0)	41 (95.3)
		I have slight problems doing my usual activities	n (%)	4 (4.8)	2 (4.7)
		I have moderate problems doing my usual activities	n (%)	1 (1.2)	
	Visit 5		N	79	42
		I have no problems doing my usual activities	n (%)	79 (100)	38 (90.5)
		I have slight problems doing my usual activities	n (%)		4 (9.5)
	EOS		N	90	46
		I have no problems doing my usual activities	n (%)	79 (94.0)	40 (88.9)
		I have slight problems doing my usual activities	n (%)	4 (4.8)	5 (11.1)
		I have moderate problems doing my usual activities	n (%)	1 (1.2)	
		Missing	n (%)	6	1
Pain/discomfort	Visit 2		N	90	46
		I have no pain or discomfort	n (%)	67 (74.4)	31 (67.4)
		I have slight pain or discomfort	n (%)	22 (24.4)	11 (23.9)
		I have moderate pain or discomfort	n (%)	1 (1.1)	4 (8.7)
	Visit 3		N	88	46
		I have no pain or discomfort	n (%)	65 (73.9)	34 (75.6)
		I have slight pain or discomfort	n (%)	19 (21.6)	10 (22.2)
		I have moderate pain or discomfort	n (%)	4 (4.5)	1 (2.2)
		Missing	n (%)		1
	Visit 4		N	83	43
		I have no pain or discomfort	n (%)	61 (73.5)	33 (76.7)
		I have slight pain or discomfort	n (%)	16 (19.3)	10 (23.3)
		I have moderate pain or discomfort	n (%)	5 (6.0)	
		I have severe pain or discomfort	n (%)	1 (1.2)	
	Visit 5		N	79	42
		I have no pain or discomfort	n (%)	59 (74.7)	30 (71.4)
		I have slight pain or discomfort	n (%)	18 (22.8)	10 (23.8)
		I have moderate pain or discomfort	n (%)	2 (2.5)	2 (4.8)
	EOS		N	90	46
		I have no pain or discomfort	n (%)	62 (73.8)	34 (75.6)
		I have slight pain or discomfort	n (%)	18 (21.4)	10 (22.2)
		I have moderate pain or discomfort	n (%)	3 (3.6)	1 (2.2)
		I have severe pain or discomfort	n (%)	1 (1.2)	
		Missing	n (%)	6	1

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Table 14.2.2.7.2.1 Summary of EQ-5D dimensions by scheduled visit and treatment (FAS)

EQ-5D Dimension	Scheduled visit	Option	Statistics	IMUNOR	PLACEBO
Anxiety/depression	Visit 2		N	90	46
		I am not anxious or depressed	n (%)	73 (81.1)	36 (78.3)
		I am slightly anxious or depressed	n (%)	14 (15.6)	8 (17.4)
		I am moderately anxious or depressed	n (%)	2 (2.2)	2 (4.3)
		I am severely anxious or depressed	n (%)	1 (1.1)	
	Visit 3		N	88	46
		I am not anxious or depressed	n (%)	69 (78.4)	38 (84.4)
		I am slightly anxious or depressed	n (%)	14 (15.9)	6 (13.3)
		I am moderately anxious or depressed	n (%)	3 (3.4)	1 (2.2)
		I am severely anxious or depressed	n (%)	2 (2.3)	
		Missing	n (%)		1
	Visit 4		N	83	43
		I am not anxious or depressed	n (%)	76 (91.6)	38 (88.4)
		I am slightly anxious or depressed	n (%)	5 (6.0)	5 (11.6)
		I am moderately anxious or depressed	n (%)	1 (1.2)	
		I am severely anxious or depressed	n (%)	1 (1.2)	
	Visit 5		N	79	42
		I am not anxious or depressed	n (%)	65 (82.3)	34 (81.0)
		I am slightly anxious or depressed	n (%)	11 (13.9)	7 (16.7)
		I am moderately anxious or depressed	n (%)	2 (2.5)	1 (2.4)
		I am severely anxious or depressed	n (%)	1 (1.3)	
	EOS		N	90	46
		I am not anxious or depressed	n (%)	70 (83.3)	39 (86.7)
		I am slightly anxious or depressed	n (%)	11 (13.1)	3 (6.7)
		I am moderately anxious or depressed	n (%)		3 (6.7)
		I am severely anxious or depressed	n (%)	3 (3.6)	
		Missing	n (%)	6	1

% = Percentage of subjects out of corresponding N; EOS = End of Study visit; FAS = Full Analysis Set; N = Total number of patients at visit; n = Number of subjects within specified category.

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