

Table 14.3.1.4.1.4.2
Summary of Duration (Days) of Solicited Adverse Reaction After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited Adverse Reactions			
n	6255	13556	19811
Mean (SD)	4.2 (8.86)	4.4 (7.83)	4.4 (8.17)
Median	2.0	3.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	2757	13029	15786
Mean (SD)	2.4 (6.54)	3.3 (3.35)	3.1 (4.10)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 155	1, 212
Pain			
n	2486	12964	15450
Mean (SD)	2.1 (5.05)	3.1 (2.51)	2.9 (3.09)
Median	1.0	3.0	3.0
Min, Max	1, 165	1, 154	1, 165
Erythema (Redness)			
n	68	1274	1342
Mean (SD)	3.9 (5.27)	2.7 (2.71)	2.8 (2.90)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 39	1, 39

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Duration is calculated as the last day - the first day + 1 when the solicited adverse reaction was reported starting within the 7 days of injection.

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Solicited Local Adverse Reactions (Cont.)			
Swelling (Hardness)			
n	60	1807	1867
Mean (SD)	4.3 (5.33)	2.5 (2.09)	2.6 (2.28)
Median	1.0	2.0	2.0
Min, Max	1, 31	1, 31	1, 31
Axillary Swelling or Tenderness			
n	571	2092	2663
Mean (SD)	3.3 (11.71)	2.7 (5.35)	2.8 (7.21)
Median	1.0	2.0	2.0
Min, Max	1, 212	1, 155	1, 212
Solicited Systemic Adverse Reactions			
n	5343	11678	17021
Mean (SD)	4.2 (8.91)	3.7 (8.00)	3.9 (8.30)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	43	2276	2319
Mean (SD)	1.5 (1.92)	1.1 (0.46)	1.1 (0.53)
Median	1.0	1.0	1.0
Min, Max	1, 13	1, 9	1, 13

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Solicited Systemic Adverse Reactions (Cont.)			
Headache			
n	3427	8637	12064
Mean (SD)	2.9 (5.24)	2.7 (4.95)	2.8 (5.03)
Median	1.0	2.0	2.0
Min, Max	1, 175	1, 196	1, 196
Fatigue			
n	3418	9607	13025
Mean (SD)	3.7 (8.47)	3.0 (6.59)	3.2 (7.14)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	1824	8529	10353
Mean (SD)	4.0 (10.05)	2.3 (4.32)	2.6 (5.80)
Median	2.0	1.0	2.0
Min, Max	1, 175	1, 170	1, 175
Arthralgia			
n	1579	6303	7882
Mean (SD)	4.5 (10.29)	2.5 (4.88)	2.9 (6.39)
Median	2.0	1.0	1.0
Min, Max	1, 175	1, 185	1, 185

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Solicited Systemic Adverse Reactions (Cont.)			
Nausea/Vomiting			
n	941	2794	3735
Mean (SD)	2.2 (6.05)	1.9 (3.78)	2.0 (4.47)
Median	1.0	1.0	1.0
Min, Max	1, 175	1, 176	1, 176
Chills			
n	813	6500	7313
Mean (SD)	2.5 (7.70)	1.5 (2.35)	1.6 (3.40)
Median	1.0	1.0	1.0
Min, Max	1, 175	1, 158	1, 175

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