

Table 14.3.1.4.1.4.1  
Summary of Duration (Days) of Solicited Adverse Reaction After First Injection  
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
<b>Solicited Adverse Reactions</b>			
n	7285	13317	20602
Mean (SD)	3.9 (5.51)	3.9 (4.33)	3.9 (4.78)
Median	2.0	3.0	3.0
Min, Max	1, 191	1, 193	1, 193
<b>Solicited Local Adverse Reactions</b>			
n	3009	12765	15774
Mean (SD)	2.2 (3.07)	2.8 (2.37)	2.7 (2.53)
Median	1.0	2.0	2.0
Min, Max	1, 55	1, 72	1, 72
<b>Pain</b>			
n	2665	12688	15353
Mean (SD)	1.9 (2.44)	2.5 (1.68)	2.4 (1.85)
Median	1.0	2.0	2.0
Min, Max	1, 55	1, 69	1, 69
<b>Erythema (Redness)</b>			
n	77	445	522
Mean (SD)	4.2 (6.21)	2.8 (4.05)	3.0 (4.46)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days of the first 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	65	935	1000
Mean (SD)	6.9 (8.76)	2.2 (2.71)	2.5 (3.62)
Median	2.0	1.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	722	1553	2275
Mean (SD)	2.3 (3.03)	2.5 (3.53)	2.5 (3.38)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 69	1, 69
Solicited Systemic Adverse Reactions			
n	6397	8316	14713
Mean (SD)	3.8 (5.63)	3.5 (4.97)	3.7 (5.27)
Median	2.0	2.0	2.0
Min, Max	1, 188	1, 193	1, 193
Fever			
n	44	112	156
Mean (SD)	1.6 (1.17)	1.3 (1.05)	1.4 (1.09)
Median	1.0	1.0	1.0
Min, Max	1, 8	1, 8	1, 8

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Solicited Systemic Adverse Reactions (Cont.)			
Headache			
n	4026	4950	8976
Mean (SD)	2.6 (3.09)	2.5 (2.67)	2.6 (2.87)
Median	1.0	1.0	1.0
Min, Max	1, 85	1, 46	1, 85
Fatigue			
n	4133	5636	9769
Mean (SD)	3.3 (4.55)	3.1 (4.10)	3.2 (4.30)
Median	2.0	2.0	2.0
Min, Max	1, 131	1, 92	1, 131
Myalgia			
n	2069	3442	5511
Mean (SD)	3.1 (4.14)	2.6 (3.74)	2.8 (3.90)
Median	1.0	1.0	1.0
Min, Max	1, 55	1, 75	1, 75
Arthralgia			
n	1784	2510	4294
Mean (SD)	3.8 (7.58)	3.1 (6.79)	3.4 (7.13)
Median	2.0	1.0	1.0
Min, Max	1, 188	1, 193	1, 193

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Solicited Systemic Adverse Reactions (Cont.)			
Nausea/Vomiting			
n	1075	1262	2337
Mean (SD)	2.0 (2.32)	1.9 (1.92)	2.0 (2.11)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 24	1, 35
Chills			
n	878	1251	2129
Mean (SD)	1.9 (2.16)	1.7 (1.89)	1.8 (2.01)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 28	1, 35

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