

Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
ADSL.SAR2FL=Y Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	ADAR.ATOXGRN>0	Overall				Total (N=xxx) n (%)
		Placebo (N=xxx) n (%)	ADSL.TRT01A	50 µg (N=xxx) n (%)	mRNA-1273 100 µg (N=xxx) n (%)	
Solicited Adverse Reactions - N1	ADAR.AVALC NOT MISSING	xxx		xxx	xxx	xxx
Any Solicited Adverse Reactions		xxx (xx.x)		xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
95% CI		xx.x, xx.x		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Grade 1	ADAR.ATOXGR	xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Solicited Local Adverse Reactions - N1		xxx		xxx	xxx	xxx
Any Solicited Local Adverse Reactions		xxx (xx.x)		xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
95% CI		xx.x, xx.x		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Grade 1		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4		xx (xx.x)		xx (xx.x)	xx (xx.x)	xx (xx.x)

Including all symptom events: Pain, Erythema, Swelling, Lymphadenopathy, etc.

ADAR.PARAM

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010102.sas DDMMM2020 HH:MM Database Lock Date: DDMMM2020