

ADAR where SAR1FL='Y' and
ATPTREF='Vaccination 1'
Treatment: TRT01A

Table 14.3.1.1.1.1
Cited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection

S 95% CI:
Main: Use mclopper.sas
Any AR: call %clopper(datain=ADAR, vac=('Vaccination 1'),
S sar=SAR1FL, sec='AR', dataout=yyy);
Any local AR: call %clopper(datain=ADAR, vac=('Vaccination
1'), sar=SAR1FL, sec='LAR', dataout=yyy);
Any systemic AR: call %clopper(datain=ADAR,
vac=('Vaccination 1'), sar=SAR1FL, sec='SAR', dataout=yyy);
Specify yyy as the output name, 95% CI will be yyy.LowerCL,
yyy.UpperCL.

S
Grade 1
Grade 2
Grade 3
Grade 4
Grade 3 or Above
Pain - N1
Any
Grade 1
Grade 2
Grade 3
Grade 4
Grade 3 or Above

CI = Confidence intervals. N1 = Number of exposed subjects
Percentages are based on the number of exposed subjects
95% CI is calculated using the Clopper-Pearson method
Toxicity grade for Erythema (Redness) is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39.0 - 39.4 C; G4 = 39.5 - 39.9 C
Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39.0 - 39.4 C; G4 = 39.5 - 39.9 C
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N1: Count #of subject with ATOXGRN>. for each param
Use ADAR.ATOXGR for all other summaries for each param
Any: Count #of subject with ATOXGRN>0
Grade: Count #of subject with maximum grade, for 'Grade 3 or Above', count
number of subjects with ATOXGRN>=3
Any AR: Count #of subject with ATOXGRN>. for any param
Any: Count #of subject with ATOXGRN>0 for any param
Any Local AR: Count #of subject with ATOXGRN>. where PARCAT1=LOCAL
Any: Count #of subject with ATOXGRN>0 where PARCAT1=LOCAL
Pain: PARAMCD=PAIN
Erythema: PARAMCD=ERYTHDIA
Swelling: PARAMCD=SWELLDIA
Axillary Swelling or Tenderness: PARAMCD=LYMPH
Any Systemic AR: Count #of subject with ATOXGRN>. where PARCAT1=SYSTEMIC
Any: Count #of subject with ATOXGRN>0 where PARCAT1=SYSTEMIC
Fever: PARAMCD=FEVER
Headache: PARAMCD=HEADACHE
Fatigue: PARAMCD=FATIGUE
Myalgia: PARAMCD=MYALGIA
Arthralgia: PARAMCD=ARTHRA LG
Nausea: PARAMCD=NAUSEA

Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=xx) n (%)	mRNA-1273 (N=xx) n (%)	Total (N=xx) n (%)
Erythema (Redness) - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Swelling (Hardness) - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Axillary Swelling or Tenderness - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. 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.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 – 50 mm; G2 = 51 – 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 – 38.4 C; G2 = 38.5 – 38.9 C; G3 = 39 – 40 C; G4 = > 40 C.

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Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=xx) n (%)	mRNA-1273 (N=xx) n (%)	Total (N=xx) n (%)
Solicited Systemic Adverse Reactions - N1	xx	xx	xx
Any Solicited Systemic Adverse Reactions	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fever - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Headache - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. 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.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 – 50 mm; G2 = 51 – 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 – 38.4 C; G2 = 38.5 – 38.9 C; G3 = 39 – 40 C; G4 = > 40 C.

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Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=xx) n (%)	mRNA-1273 (N=xx) n (%)	Total (N=xx) n (%)
Fatigue - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Myalgia - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Arthralgia - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. 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.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 – 50 mm; G2 = 51 – 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 – 38.4 C; G2 = 38.5 – 38.9 C; G3 = 39 – 40 C; G4 = > 40 C.

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Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction	Placebo	mRNA-1273	Total
Category	(N=xx)	(N=xx)	(N=xx)
Grade	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chills - N1	xx	xx	xx
Any	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 or Above	xx (xx.x)	xx (xx.x)	xx (xx.x)

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