Table 14.3.1.7.2
Summary of Unsolicited TEAE from Day 1 to End of Part A
Safety Set ADSL.SAFFL=Y

Where ADSL.SAFFL=Y and TRT01AN in (1, 2, 3)	Overall			
		mRNA-1273		
	Placebo (N=XXX) n (%)	50 µg (N=XXX) n (%)	100 µg (N=XXX) n (%)	Total (N=XXX) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination	Select Records Where ADAE.TRTEMFL=Y			
All	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious ADAE.AESER=Y	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatal ADAE.AEOUT=FATAL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medically-Attended ADAE.MAAEFL=Y	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Discontinuation from Study Vaccine ADAE.AEACN=DRUG WITHDRAWN	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Study Discontinuation ADAE.AEDISFL=Y	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe ADAE.AESEV=SEVERE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unsolicited TEAEs Related to Study Vaccination	Select Records Where ADAE.TRTEMFL=Y and AEREL="RELATED			
All	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medically-Attended	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Discontinuation from Study Vaccine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Study Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.

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Table 14.3.1.7.2
Summary of Unsolicited TEAE from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
	Placebo (N=XXX) n (%)	50 µg (N=XXX) n (%)	100 µg (N=XXX) n (%)	Total (N=XXX) n (%)	Placebo (N=XXX) n (%)	50 µg (N=XXX) n (%)	100 µg (N=XXX) n (%)	Total (N=XXX) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination								
All	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medically-Attended	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Discontinuation from Study Vaccine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Study Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unsolicited TEAEs Related to Study Vaccination								
All	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medically-Attended	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Discontinuation from Study Vaccine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Leading to Study Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.

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