

ADAE where SAFFL='Y' and
D28FL='Y' and TRTEMFL='Y'
Treatment: TRT01A

Table 14.3.1.7.1.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection
Safety Set

	Placebo (N=xx) n (%)	mRNA-1273 (N=xx) n (%)	Total (N=xx) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	xx (xx.)		
Serious	xx (xx.)		
Fatal	xx (xx.)		
Medically-Attended	xx (xx.)		
Leading to Discontinuation from Study Vaccine	xx (xx.)		
Leading to Discontinuation from Participation in the Study	xx (xx.)		
Severe	xx (xx.)		
Unsolicited TEAEs Related to Study Vaccination			
All	xx (xx.)		
Serious	xx (xx.)		
Fatal	xx (xx.)		
Medically-Attended	xx (xx.)		
Leading to Discontinuation from Study Vaccine	xx (xx.)		
Leading to Discontinuation from Participation in the Study	xx (xx.)		
Severe	xx (xx.)		

Count number of unique subjects with non-missing AETERM

At least one records

At least one AESER='Y'

At least one AEOUT=FATAL

At least one AEMAFL='Y'

At least one AEACN contains WITHDRAWN

At least one AEDISFL='Y'

At least one AESEV='SEVERE'

Subset with ARELN=2, then count number of unique subjects with

At least one records

At least one AESER='Y'

At least one AEOUT=FATAL

At least one AEMAFL='Y'

At least one AEACN contains WITHDRAWN

At least one AEDISFL='Y'

At least one AESEV='SEVERE'

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.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070101.sas 10JUN2021 07:58