Table 14.2.2.1.3.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=xx)	mRNA-1273 (N=xx)
Number of Subjects with COVID-19*, n (%)	xx (xx.x)	xx (xx.x)
Number of Subjects Censored, n (%)	xx (xx.x)	xx (xx.x)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		x.xxx (x.xxx, x.xxx)
p-value [2]		0.xxxx
Person-Years [3]	xx.x	xx.x
Incidence Rate per 1,000 Person-Years (95% CI) [4]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Vaccine Efficacy Based on Incidence Rate (95% CI) [5]		x.xxx (x.xxx, x.xxx)

ADTTEA where PPROTFL=Y and PARAMCD='TTCVDC1'
Treatment: TRT01P

Event: count # of subjects with CNSR=0
Censored: count # of subjects with CNSR=1

Person-years: sum AVAL over all subjects for each treatment group, then divided by 365.25

VE (95% CI) based on hazard ratio, IR (95% CI), VE (95% CI) based on IR:
Use mVEHRIR.sas and CALL %VEHRIR(T14020201030101,ADTTEA,%str(PPROTFL='Y' and PARAMCD='TTCVDC1'),TRT01P,AVAL,CNSR);

Output dataset for hazard ratio: VEHR_T14020201030101. VE, VELOW, VEUPP, VEPVAL.
Output dataset for incidence rate: VEIR_T14020201030101. IR, IRLOW, IRUPP, VEIR, VEIRLOW, VEIRUPP.

* wit ve RT-PCR within
14 da days, or positive
Elecs positive RT-PCR or
Elecs
[1] V sing a stratified
C ariate, adjusting
f
[2] 1 .
[3] P earliest positive
R te, whichever is
e
[4] I risk and adjusted
b t method (Poisson
d
[5] V culated using the
e