2.7.6.1 SYNOPSES OF INDIVIDUAL STUDIES

Type of Study	Study Identifier (CT Identifier)/ Study Status[a]	Primary Objective(s) of Study	Study Design	Dose, Test Product(s) Regimen Route of Administration	Number of Participants Exposed	Study Population	Location of Study Report Synopses
Phase 1							
Safety Immuno-genicity	20-0003 (NCT04283461)/ Ongoing	To evaluate the safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart, across 5 dosages in healthy adults	Open-label, dose-ranging	10[b], 25, 50, 100, and 250 µg IM injection mRNA-1273 2 doses, 28 days apart	Total (n= 120) 25 µg (n=35) 50 µg (n=35) 100 µg (n=35) 250 µg (n=15)	Men and nonpregnant women at least 18 years of age, in good health	• P101 Day 119 CSR (synopsis) • P101 CSR Addendum 1 (Day 209) (synopsis) Module 5.3.5.2
Phase 2							
Safety Immuno-genicity	mRNA-1273-P201 (NCT04405076)/ Ongoing	Primary Safety To evaluate the safety and reactogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart Primary Immunogenicity To evaluate the immunogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart, as assessed by the level of specific bAb.	**Part A**				
			Randomized, observer-blind, placebo-controlled	50 or 100 µg IM injection mRNA-1273 or placebo 2 doses, 28 days apart	Total (n=600) 50 µg (n=200) 100 µg (n=200) placebo (n=200)	Men and nonpregnant women at least 18 years of age, in good health	• P201 Primary Analysis CSR (synopsis) • P201 CSR Addendum 1 (End of Part A) (synopsis) Module 5.3.5.1

Type of Study	Study Identifier (CT Identifier)/ Study Status[a]	Primary Objective(s) of Study	Study Design	Dose, Test Product(s) Regimen Route of Administration	Number of Participants Exposed	Study Population	Location of Study Report Synopses
Phase 3							
Efficacy Safety	mRNA-1273-P301 (NCT04470427)/ Ongoing	Primary Efficacy To demonstrate the efficacy of mRNA-1273 to prevent COVID-19. Primary Safety To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.	**Part A**				
			Case-driven, randomized, stratified, observer-blind, placebo-controlled	100 µg of mRNA-1273 or placebo 2 doses, 28 days apart	Total (n=30,346) 100 µg (n=15,184) placebo (n=15,162)	Men and nonpregnant women at least 18 years of age, at appreciable risk of SARS-CoV-2 infection, with a negative history for SARS-CoV-2 infection	• P301 Part A CSR (synopsis) Module 5.3.5.1
			Part B				
			Open-label, observational	100 µg of mRNA-1273 2 doses, 28 days apart[c]	Total (n=12,648) 100 µg (n=12,648)	Men and nonpregnant women at least 18 years of age Must have previously enrolled in mRNA-1273-P301 (Part A participants who had received 1 dose of 100 µg mRNA-1273 or placebo)	• P301 CSR Addendum 1 (Part B) (synopsis) Module 5.3.5.1

Abbreviations: bAb = binding antibody; COVID-19 = coronavirus disease 2019; CSR = clinical study report; IM = intramuscular; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

[a] Participants remain in all studies to all protocol-specified assessments of efficacy, immunogenicity, and safety through the scheduled end of study.
[b] The 10 µg cohort was not enrolled.
[c] 1 dose in some participants: participants who were unblinded at the participant decision visit and who received ONLY 1 dose of mRNA-1273 100 µg in Part A, were eligible to receive a second dose of mRNA-1273 in Part B if they met certain criteria.