

Table 1: Listing of Clinical 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	Type of Report Location of Study Reports
Phase 1							
Safety Immunogenicity	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	<ul style="list-style-type: none"> • P101 Day 119 CSR (full) • P101 CSR Addendum 1 (Day 209) (addendum) Module 5.3.5.2
Phase 2							
Safety Immunogenicity	mRNA-1273-P201 (NCT04405076)/ Ongoing	<p><u>Primary Safety</u> To evaluate the safety and reactogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart</p> <p><u>Primary Immunogenicity</u> 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.</p>	<u>Part A</u> 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	<ul style="list-style-type: none"> • P201 Primary Analysis CSR (full) • P201 CSR Addendum 1 (End of Part A) (addendum) Module 5.3.5.1

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Phase 3								
Efficacy Safety	mRNA-1273-P301 (NCT04470427)/ Ongoing	<u>Primary Efficacy</u> To demonstrate the efficacy of mRNA-1273 to prevent COVID-19. <u>Primary Safety</u> To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.	Part A					<ul style="list-style-type: none"> • P301 Part A CSR (full) Module 5.3.5.1
			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		
			Part B					<ul style="list-style-type: none"> • P301 CSR Addendum 1 (Part B) (addendum) Module 5.3.5.1
			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)		

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.