

About the COVID-19 Clinical Trials



COVID-19 vaccines were developed through the federal government's [Operation Warp Speed](#). The goal of Operation Warp Speed was to produce and distribute millions of vaccine doses while ensuring the safety and efficacy of the vaccines. Clinical trials are a critical step in ensuring vaccine safety and efficacy.

COVID-19 Vaccine Development Stages

Strict rules were followed before approval was granted to move to the next stage.

Exploratory Research and Discovery Stage

Researchers investigated what kinds of safe vaccines were possible and how to make them in the lab.

Pre-clinical Stage

Pre-clinical studies were conducted in animals to understand the effects that the vaccines may have in live cells and tissues before testing in humans.

For most vaccines, these first two stages take many years. For COVID-19, scientists had already been studying the best ways to make vaccines for two similar viruses: SARS-CoV and MERS-CoV. This pre-existing knowledge was used to help develop the COVID-19 vaccines.

Clinical Trials Stage

Testing in people began ONLY after careful evaluation of the results of the laboratory and pre-clinical work. Researchers then tested the vaccines with human volunteers to determine if they were safe, prevented disease or caused any side effects.

PHASE 1 TRIALS	PHASE 2 TRIALS	PHASE 3 TRIALS
<i>Small group of volunteers</i>	<i>Larger group of volunteers</i>	<i>Thousands of volunteers, diverse populations</i>
Goals: Determine 1) whether vaccines triggered an immune response in the body and 2) what dose is effective and safe.	Goals: Refine vaccine dosage to determine the best frequency for maximum disease protection and benefit for most people.	Goals: Evaluate vaccine safety and effectiveness in the general population.

Approximately half of the trial participants received the COVID-19 vaccine, while the rest received a placebo. Researchers compared the number of people who received the vaccine and tested positive or got sick with COVID-19 to those who did not receive the vaccine and tested positive or got sick with COVID-19. Vaccine developers and federal regulators carefully followed all the usual rules to ensure participant safety.

COVID-19 Vaccine Clinical Trials



The Pfizer-BioNTech and Moderna vaccines are now being distributed for use in the United States. In clinical trials, these vaccines provided a high degree of protection to those who received them.

Manufacturer	Phase 3 Clinical Trial Participants	Vaccine Efficacy	Safety and Side Effects	FDA Emergency Use Authorization (EUA)
Pfizer-BioNTech Start Date: July 27, 2020	43,433 adults age 18 and older from six countries: United States, Germany, Turkey, South Africa, Brazil, and Argentina 42% of all participants and 30% of U.S. participants have diverse backgrounds	95% efficacy after 2 doses 94% in adults age 65 and older	162 cases of COVID-19 in the placebo group; eight cases among participants who were vaccinated 10 cases of severe COVID-19 in the placebo group; one case among participants who were vaccinated Vaccine safety and efficacy were consistent across all subgroups	December 11, 2020
Moderna Start Date: July 27, 2020	30,400 adults 18 or older from the United States: <ul style="list-style-type: none"> • 25% aged 65 and older • 63% white • 20% Latinx • 10% Black • 4% Asian American 	94.1% efficacy after 2 doses 95% efficacy for people ages 18-64	185 cases of COVID-19 in the placebo group; 11 cases among participants who were vaccinated 30 cases of severe COVID-19 in the placebo group; no cases among those vaccinated Vaccine safety and efficacy were consistent across all subgroups	December 18, 2020

GET MORE INFORMATION

For more COVID-19 vaccine information, visit covidlink.maryland.gov/content/vaccine