PFIZER-BIONTECH COVID-19 VACCINE TRIAL OVERVIEW

Our Path to Developing an Investigational COVID-19 Vaccine

In the fight against COVID-19, a vaccine is a critical part of addressing the global health crisis by decreasing rates of infection, disease and death worldwide. Pfizer and BioNTech leveraged decades of scientific expertise to design and execute a rigorous Phase 3 clinical trial program to make our investigational COVID-19 vaccine available as quickly and safely as possible.

The landmark Phase 3 clinical trial began in late July 2020, recruiting participants aged 12 and over, and completed enrollment of 46,331 participants in January 2021. On December 11, 2020, the U.S. Food and Drug Administration (FDA) authorized the Pfizer-BioNTech COVID-19 vaccine for emergency use.

The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheet at www.cvdvaccine.com (https://web.archive.org/web/20210301062516/http://www.cvdvaccine.com/).

Developing an investigational breakthrough vaccine to help prevent COVID-19 is only possible through the dedicated work of thousands of individuals and those who volunteer to take part in research. We are grateful to each of 153 clinical trial investigators and their study teams who are partnering with us in this effort and to all of the participants who volunteered to help make a difference for society. Participants 16 years and older that originally received the placebo have the option to receive the investigational vaccine while staying in the study through our Vaccine Transition Option. Vaccine doses for placebo recipients have been secured, and our aim is that that all participants 16 years and older who received the placebo will have the opportunity to receive their first dose of the investigational vaccine within the study by March 1, 2021, if they choose.

Trial Enrollment

The clinical trial has enrolled **46,331** participants at **153 clinical trial** sites around the world.

Trial Geography

Our trial sites are located in **Argentina, Brazil, Germany, Turkey, South Africa** and the **United States.**

Participant Diversity

Approximately **42%** of overall and **30%** of U.S. participants have diverse backgrounds.

Participants	Overall Study	U.S. Only
Asian	5%	6%
Black	10%	10%
Hispanic/Latinx	26%	13%
Native American	1.0%	1.3%

49.1% of participants are male and **50.9%** are female

Participant Age

Ages 12-15	2,259
Ages 16-17	754
Ages 18-55	25,427
Ages 56+	17,879

Vaccine Transition Option

As of Wednesday, February 24 at 5:30 pm ET, **16,904** of participants who received placebo have received their first dose and **11,807** have received their second dose.

What's Next

In February 2021, we began a global Phase 2/3 study to evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) in preventing COVID-19 in healthy pregnant women 18 years of age and older. We plan to enroll approximately 4,000 healthy pregnant women in the U.S., Canada, Argentina, Brazil, Chile, Mozambique, South Africa, U.K., and Spain. After a participant's infant is born, she will be unblinded and those who were in the placebo group will be given the opportunity to receive the vaccine. Additional information about the study can be found at www.clinicaltrials.gov (https://web.archive.org/web/20210301062516/http://www.clinicaltrials.gov/) under the identifier NCT04754594.

Pfizer and BioNTech also initiated an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) to understand the effect of a booster on immunity against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants. The study will draw upon participants from the Phase 1 study in the United States who will be offered the opportunity to receive a 30 µg booster of the current vaccine 6 to 12 months after receiving their initial two-dose regimen. The study is part of the Companies' clinical development strategy to determine the effectiveness of a third dose including against evolving variants. To be prepared for any potential future strain changes, Pfizer and BioNTech are in ongoing discussions with regulatory authorities regarding a registration-enabling clinical study to evaluate a variant-specific vaccine having a modified mRNA sequence. This study would use a new construct of the Pfizer-BioNTech vaccine based on the B.1.351 lineage, first identified in South Africa. This could position the Companies to update the current vaccine quickly if the need arises to protect against COVID-19 from circulating strains. In keeping with the updated guidance issued by the FDA regarding emergency use of vaccines to prevent COVID-19 which provides recommendations for evaluating a modified vaccine to address variants, the Companies are hoping to pursue the validation of future modified mRNA vaccines with a regulatory pathway similar to what is currently in place for flu vaccines.

Pfizer and BioNTech expect to start additional studies in children between the ages of 5 and 11 over the next couple of months, and in children younger than 5 later in 2021. The Companies are also planning studies to further evaluate the vaccine in people with compromised immune systems.

FREQUENTLY ASKED QUESTIONS

The Investigational Vaccine

The Clinical Trials

Commitment to Safety

Commitment to Diversity

DEVELOPMENT MILESTONES

February 25, 2021

Pfizer and BioNTech Initiate a Study as Part of Broad Development Plan to Evaluate COVID-19 Booster and New Vaccine Variants

View Press Release (https://web.archive.org/web/20210301062516/https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-study-part-broad-development)

December 21, 2020 - 2 PM

Pfizer and BioNTech Receive Authorization in the European Union for COVID-19 Vaccine

View Press Release (https://web.archive.org/web/20210301062516/https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-receive-authorization-european-union)

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Learn more about progress on our path to develop a COVID-19 vaccine.

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It is with great pride and joy – and even a little relief – that I can say that our request for Emergency Use Authorization for our potential COVID-19 vaccine is now in the FDA's hands. This is a historic day for science. It took just 248 days to get from the day we announced our plans to...

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The results demonstrate that our r vaccine can help prevent COVID-19 of people who receive it.

For additional information about Pfizer, please see our filings with the U.S. Securities and Exchange Commission, including the information provided in the sections captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results".

(/web/20210301062516/https://www.pfizer.com/)