

# Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](#))) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19 ([/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19](#))) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine ([/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine](#)) to be distributed in the U.S.

## Q: What data did the FDA use to make the decision to authorize Pfizer-BioNTech COVID-19 Vaccine for emergency use?

**Q: What data is available to the public to review?**

A: The data used to authorize the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older includes:

• **Individual study data and analysis:** A briefing document made available in connection with the December 10, 2020, meeting of the Vaccines and Related Biological Products Advisory Committee. FDA evaluated and analyzed the safety and effectiveness data from clinical trials conducted in tens of thousands of study participants and manufacturing information submitted by Pfizer-BioNTech. FDA has determined that the totality of the available data provides clear evidence that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 and support that the known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people 16 years of age and older, including healthy individuals.

• **Prescribing Information:** The Letter of Authorization, Fact Sheets and Full EUA Prescribing Information are posted ([/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine](#)) on FDA's web site. FDA has also posted the review memo ([/media/144416/download](#)) for Pfizer-BioNTech COVID-19 Vaccine, which summarizes FDA's review of the safety and effectiveness data, including clinical data, submitted in support of the request for emergency use authorization.

## Q: How well does Pfizer-BioNTech COVID-19 Vaccine prevent COVID-19?

A: The data to support the EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who completed the 2-dose vaccination regimen and did not have evidence of SARS-CoV-2 infection through 7 days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received saline placebo. The vaccine was 95 percent effective in preventing COVID-19 disease among these clinical trial participants with 8

COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group. Of these 170 COVID-19 cases, 1 in the vaccine group and 3 in the placebo group were classified as severe.

**Q: How long will the Pfizer-BioNTech COVID-19 Vaccine provide protection?**

A: Data are not yet available to inform about the duration of protection that the vaccine will provide.

**Q: Is the the Pfizer-BioNTech COVID-19 Vaccine effective at reducing the severity of COVID-19?**

A: To date, only a small number of severe cases have occurred during the study, which makes it difficult to evaluate whether the vaccine reduces the severity of COVID-19. Pfizer-BioNTech COVID-19 vaccine is authorized to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

**Q: Can people who have already had COVID-19 get the Pfizer-BioNTech COVID-19 Vaccine?**

A: Among all study participants, 3% had evidence of infection prior to vaccination, and among participants with evidence of infection prior to vaccination, more confirmed COVID-19 cases occurred in the placebo group compared with the vaccine group. While relatively few confirmed COVID-19 cases occurred overall among participants with evidence of infection prior to vaccination, available data suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

**Q: If a person has received the the Pfizer-BioNTech COVID-19 Vaccine, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?**

A: Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if the Pfizer-BioNTech COVID-19 Vaccine will reduce such transmission.