

Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions

Español (</emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/preguntas-frecuentes-sobre-la-vacuna-contr-el-covid-19-de-pfizer-biontech>)

Q: What data did the FDA evaluate to support the emergency use authorization of Pfizer-BioNTech COVID-19 Vaccine administered as a primary series for individuals 16 years of age and older?

A: For the December 2020 EUA for Pfizer-BioNTech COVID-19 Vaccine, 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. Based on the scientific evidence available, the FDA concluded that the known and potential benefits of a two-dose primary series of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks for people 16 years of age and older.

Q: How well does Pfizer-BioNTech COVID-19 Vaccine prevent COVID-19 in individuals 16 years of age and older?

A: The data to support the December 2020 EUA of the Pfizer-BioNTech COVID-19 Vaccine include an analysis of 36,523 participants in the ongoing randomized, blinded, 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 data showed that a two-dose series of 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: Does Pfizer-BioNTech COVID-19 Vaccine protect against asymptomatic SARS-CoV-2 infection? (Asymptomatic infection is when someone is infected with SARS-CoV-2 but does not have signs or symptoms of COVID-19.)

A: It is not known if Pfizer-BioNTech COVID-19 Vaccine protects against asymptomatic SARS-CoV-2 infection.

Q: What safety data did the FDA evaluate to authorize the Pfizer-BioNTech COVID-19 Vaccine for emergency use for individuals 16 years of age and older?

A: The available safety data to support the December 2020 EUA include 37,586 of the participants enrolled in an ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants. These participants, 18,801 of whom received the vaccine and 18,785 of whom received saline placebo, were followed for a median of 2 months after receiving the 2nd dose.

The most commonly reported side effects were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. Side effects typically started within two days of vaccination and resolved 1-2 days later. Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose.

The FDA also evaluated additional safety data from the larger database that included participants enrolled later during the study who had shorter follow-up (the total database included 43,448 participants, 21,720 of whom received vaccine and 21,728 of whom received saline placebo). The FDA determined that the findings were similar to those in the population of participants with a median follow-up of 2 months after the second dose.

It is important to note that as a general matter, while some individuals may experience side effects following any vaccination, not every individual's experience will be the same and some people may not experience side effects.

Q: After the FDA granted the emergency use authorization of the Pfizer BioNTech COVID-19 Vaccine were clinical trial participants unblinded so that the placebo recipients could be offered the vaccine?

A: Yes. After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants. These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months.

Q: What data did the FDA evaluate to support Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in individuals 12 through 15 years of age?

A: The available safety data to support the EUA in adolescents in this age group include 2,260 participants ages 12 through 15 years old enrolled in an ongoing randomized, placebo-controlled clinical trial in the United States. Of these, 1,131 adolescent participants received the vaccine and 1,129 received a saline placebo. More than half of the participants were followed for safety for at least two months following the second dose.

The most commonly reported side effects in the adolescent clinical trial participants, which typically lasted 1-3 days, were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain. With the exception of pain at the injection site, more adolescents reported these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose. The side effects in adolescents were consistent with those reported in clinical trial participants 16 years of age and older.

It is important to note that as a general matter, while some individuals may experience side effects following any vaccination, not every individual's experience will be the same and some people may not experience side effects.

The effectiveness data to support the EUA in adolescents 12 through 15 years of age is based on immunogenicity and an analysis of COVID-19 cases. The immune response to the vaccine in 190 participants 12 through 15 years of age was compared to the immune response of 170 participants 16 through 25 years of age. In this analysis the immune response of adolescents was non-inferior to (at least as good as) the immune response of the older participants. An analysis of cases of COVID-19 occurring among participants 12 through 15 years of age seven days after the second dose was also conducted. In this analysis, among participants without evidence of prior infection with SARS-CoV-2, no cases of COVID-19 occurred among 1,005 vaccine recipients and 16 cases of COVID-19 occurred among 978 placebo recipients; the vaccine was 100% effective in preventing COVID-19.

Q: What data did the FDA evaluate to support Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in individuals 5 through 11 years of age?

A: The effectiveness of the Pfizer-BioNTech COVID-19 in this age group is based on the clinical trial results that previously demonstrated the vaccine effective in preventing COVID-19 in individuals 16 years of age and older and data from an ongoing randomized, placebo-controlled study that has enrolled approximately 4,700 children 5 through 11 years of age. The study is being conducted in the U.S., Finland, Poland and Spain. Children in the vaccine group received two doses of the Pfizer-BioNTech COVID-19 Vaccine. The FDA analyzed data that compared the immune response of 264 participants from this study to the immune response of 253 participants 16 through 25 years of age who had two doses of the vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The dose of Pfizer-BioNTech COVID-19 Vaccine used in study participants 5 through 11 years of age was lower than that used in study participants 16 through 25 years of age. The immune responses of the younger age participants were comparable to the older participants.

For the study in children 5 through 11 years of age, FDA also conducted a preliminary analysis of cases of COVID-19 occurring seven days after the second dose. In this analysis, among participants without evidence of prior infection with SARS-CoV-2, 3 cases of COVID-19 occurred among 1,305 vaccine recipients and 16 cases of COVID-19 occurred among 663 placebo recipients; the vaccine was 90.7% effective in preventing COVID-19.

The available safety data to support the EUA include more than 4,600 participants (3,100 vaccine, 1,538 placebo) ages 5 through 11 years enrolled in the ongoing study. In this trial, a total of 1,444 vaccine recipients were followed for safety for at least 2 months after the second dose.

Commonly reported side effects in the clinical trial included injection site pain (sore arm), redness and swelling, fatigue, headache, muscle and/or joint pain, chills, fever, swollen lymph nodes, nausea and decreased appetite. More children reported side effects after the second dose than after the first dose. Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within one to two days.

The Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age is administered as a two-dose primary series, 3 weeks apart, but is a lower dose than that used for individuals 12 years of age and older.

Q: Who may receive a booster dose of the Pfizer-BioNTech COVID-19 Vaccine authorized by the FDA?

A: The FDA amended the emergency use authorization for the Pfizer-BioNTech COVID-19 Vaccine to allow for the use of a single booster dose administered at least 5 months after completing a primary series of Pfizer-BioNTech COVID-19 Vaccine or Comirnaty in individuals 12 years of age and older.

Pfizer-BioNTech COVID-19 Vaccine is administered as a two-dose primary series in individuals 5 years of age and older, as a third primary series for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Q: What information did FDA evaluate to authorize a third primary series dose in certain immunocompromised individuals?

A: For individuals 12 years of age and older, the FDA evaluated safety and immune response data from a study in which a third dose of Pfizer-BioNTech COVID-19 Vaccine was administered to 99 individuals who had undergone a solid organ transplantation. FDA determined that in the individuals studied, a third dose appears to be only moderately effective in increasing potentially protective antibodies. Based on available data, FDA authorized a third primary series dose of the vaccine for individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For individuals 5 through 11 years of age with certain kinds of immunocompromise, safety is inferred from data in healthy children 5 through 11 years of age who were vaccinated with the two-dose primary series, and effectiveness of the vaccine in this age group is extrapolated from data in immunocompromised adult vaccine recipients.

Q: What safety and effectiveness data did FDA evaluate to support the November 2021 authorization for emergency use of administration of a single vaccine booster dose of Pfizer-BioNTech COVID-19 Vaccine for individuals 18 years of age and older?

A: FDA analyzed safety and immune response data from a subset of participants from the original clinical trial of the Pfizer-BioNTech COVID-19 Vaccine. The immune responses of approximately 200 participants 18 through 55 years of age who received a single vaccine booster dose approximately 6 months after their second dose were assessed. The antibody response against a Wuhan-like SARS-CoV-2 virus one month after a booster dose of the vaccine compared to the response one month after the two-dose primary series in the same individuals demonstrated a booster response.

Safety was evaluated in 306 participants 18 through 55 years of age and 12 participants 65 years of age and older who were followed for an average of over two months. The most commonly reported side effects by the clinical trial participants who received the booster dose of the vaccine were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, and chills. Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series.

The authorization for emergency use of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine in individuals who completed primary vaccination with a different FDA-authorized or approved COVID-19 vaccine (heterologous booster dose) is based on the above-mentioned data as well as immunogenicity data from a clinical trial that evaluated a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine (151 participants), a Janssen COVID-19 Vaccine (156 participants), or a Pfizer-BioNTech COVID-19 Vaccine (151 participants) received a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. A booster response to the Pfizer-BioNTech COVID-19 Vaccine was demonstrated regardless of vaccine used for primary vaccination.

Q: What information did FDA evaluate to authorize a single booster dose of Pfizer-BioNTech COVID-19 Vaccine for individuals 16 and 17 years of age?

A: The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 and 17 years of age is based on the FDA's previous analysis of immune response data that supported use of a booster dose in individuals 18 years of age and older.

The FDA also undertook an evaluation of the benefits and risks. In the time since Pfizer initially submitted safety and effectiveness data on a single booster dose following the two-dose primary series to the FDA, additional real-world data have become available on the increasing number of cases of COVID-19 in the U.S. and on the risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. Based on an analysis of real-world data from Israel and the United States, FDA determined that the risks of myocarditis and pericarditis following third doses of the Pfizer-BioNTech COVID-19 Vaccine given to 16 and 17 year old males (who are among the population

at highest risk for vaccine-associated myocarditis and pericarditis) appear to be lower than the risks after the second primary series dose. The FDA has determined that the benefits of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine or Comirnaty outweigh the risks of myocarditis and pericarditis in individuals 16 and 17 years of age to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death.

Q: What information did FDA evaluate to authorize a single booster dose of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 through 15 years of age and lower the booster dose interval from 6 months to 5 months for all individuals 12 years of and older?

A: The FDA reviewed: prepublications; accepted publications; published publications; real world evidence on the safety of booster doses provided by the Israeli Ministry of Health, which includes data from over 6,300 individuals 12 to 15 years of age who received a Pfizer-BioNTech COVID-19 Vaccine booster dose at least 5 months following completion of the primary series, noting no cases of myocarditis or pericarditis reported; and real-world evidence data from approximately 4.7 million third (booster) doses of the Pfizer-BioNTech COVID-19 Vaccine given to individuals 16 years of age and older at least 5 months after the primary series. Based on the totality of the scientific evidence available, FDA concluded that a homologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective and that the known and potential benefits of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine following completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks in individuals 12 years of age and older when given at least 5 months following the primary series.

Q: For the September 2021 emergency use authorization of a booster dose, did FDA evaluate data pertaining to the effectiveness of a primary series of the vaccine during the time the Delta variant of SARS-CoV-2 was surging?

A: An analysis compared the rates of COVID-19 accrued during the current Delta surge among original clinical trial participants who completed the two-dose vaccination series early in the clinical trial, to those who completed the two-dose series later in the study because they were originally randomized to the placebo group and received the vaccine later. The analysis showed that during the study period of July and August 2021, the incidence of COVID-19 was higher among the participants who completed their vaccine series earlier, compared to participants who completed the vaccine series later. FDA determined that the rate of breakthrough COVID-19 reported during this time period translates to a modest decrease in the efficacy of the vaccine among those vaccinated earlier, equivalent to one to five percent.

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

A: Yes. Among the participants in the study that the FDA evaluated for the December 2020 authorization, relatively few confirmed COVID-19 cases occurred overall among clinical study participants with evidence of SARS-CoV-2 infection prior to vaccination.

Current scientific evidence suggests that individuals previously infected with SARS-CoV-2, including individuals who have had COVID-19, may be at risk of reinfection and developing COVID-19 again and could benefit from vaccination. Furthermore, available data suggest that the safety profile of the vaccine in previously infected individuals is just as favorable as in previously uninfected individuals.

Q: If a person has received 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.

Q: How can we be so sure about the effectiveness of the Pfizer-BioNTech COVID-19 Vaccine when people participating in the trial were doing some level of mitigation (whether personal or government recommended)?

A: In a randomized, blinded clinical trial, participants are not aware of whether they received vaccine or placebo. Therefore, any mitigation efforts would have affected those who received vaccine and placebo equally. The relatively high number of COVID-19 cases occurring among placebo recipients suggests that any mitigation efforts among trial participants may not have been very effective.

Q: Did clinical trial participation include members of racial or ethnic groups at greater risk from COVID-19?

A: Yes. In the study that FDA evaluated for the December 2020 authorization, overall, among the total participants who received either Pfizer-BioNTech COVID-19 Vaccine or placebo, 9.1 percent were Black or African American, 28.0 percent were Hispanic/Latino, 4.3 percent were Asian, and 0.5 percent were American Indian/Alaska native.

Q: Can pregnant or breastfeeding women receive Pfizer-BioNTech COVID-19 Vaccine?

A: There is no contraindication to receipt of the vaccine for pregnant or breastfeeding women. Pregnant or breastfeeding women should discuss potential benefits and risks of vaccination with their healthcare provider.

Q: At the time of the December 2020 authorization, what information was available about serious adverse events that occurred during the clinical trial in individuals 16 years of age and older?

A: Serious adverse events, while uncommon (<1.0%), were observed at slightly higher numerical rates in the vaccine study group compared to the saline placebo study group, both overall and for certain specific adverse events occurring in very small numbers. These represented common medical events

that occur in the general population at similar frequency. Upon further review by the FDA, these imbalances do not raise a safety concern, nor do they suggest a causal relationship to vaccination for the vast majority of reported serious adverse events.

Serious adverse events considered by the FDA to be plausibly related to the vaccine or vaccination procedure were one case of shoulder injury at the vaccination site and one case of swollen lymph node in the armpit opposite the vaccination arm.

No safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.

Q. What information is available about myocarditis and pericarditis following vaccination with Pfizer-BioNTech COVID-19 Vaccine?

A. Post-authorization safety surveillance data pertaining to myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose of the Pfizer-BioNTech COVID-19 Vaccine, with the observed risk being higher in males under 40 years of age than in females or older males. The observed risk is highest in males 12 through 17 years of age.

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for the Pfizer-BioNTech COVID-19 Vaccine includes a warning about the risk of myocarditis and pericarditis, and the Vaccine Information Fact Sheet for Recipients and Caregivers include information about myocarditis and pericarditis. The Vaccine Information Fact Sheet for Recipients and Caregivers notes that vaccine recipients should seek medical attention right away if they experience any of the following symptoms after vaccination:


- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Q: Are vaccination providers required to report side effects?

A: Yes. Providers administering Pfizer-BioNTech COVID-19 Vaccine must report to the Vaccine Adverse Event Reporting System (VAERS) and are encouraged to report to Pfizer Inc. the following information associated with the administration of the vaccine of which they become aware:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Q: Must vaccination providers give a hard copy of the authorized Vaccine Information Fact Sheet for Recipients and Caregivers to the individual when they get each dose of their vaccine?

A: The EUA requires vaccination providers, prior to the individual receiving the vaccine, to communicate to the recipient or their caregiver information consistent with the “Vaccine Information Fact Sheet for Recipients and Caregivers,” and either to provide a copy of the Vaccine Information Fact Sheet for Recipients and Caregivers (<https://www.fda.gov/media/144414/download>) or to direct the individual to the website <https://www.cvdvaccine.com> (<https://www.cvdvaccine.com/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) to obtain the fact sheet.

Q: Can the Pfizer-BioNTech COVID-19 Vaccine and Comirnaty be used interchangeably?

A: The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for older individuals. The Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age should not be used interchangeably with Comirnaty.

Q: Can you describe the mRNA technology of the Pfizer-BioNTech COVID-19 Vaccine? Are there any safety concerns considering the “newness” of this technology?

A: The Pfizer-BioNTech COVID-19 Vaccine contains messenger RNA (mRNA) which is genetic material. The vaccine contains a synthetic piece of mRNA that instructs cells in the body to make the distinctive "spike" protein of the SARS-CoV-2 virus. When vaccinated, the body produces copies of the spike protein, which alone does not cause disease, and the immune system learns to react defensively, producing an immune response against SARS-CoV-2.

FDA scientists have expertise with this technology as it has been used to develop other preventive investigational vaccines that have been tested in human clinical trials. The FDA does not have specific safety concerns with a vaccine that utilizes this technology.

Q: Can the Pfizer-BioNTech COVID-19 Vaccine cause infertility in women?

A: There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-

CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; many people have no symptoms or only mild disease, while some have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death. The Pfizer-BioNTech COVID-19 vaccine is a mRNA vaccine. It contains a piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in formation of the placenta.

Q: What materials about the Pfizer-BioNTech COVID-19 Vaccine is the FDA making available to vaccine providers and vaccine recipients?

The FDA makes numerous materials about the Pfizer-BioNTech COVID-19 Vaccine available to the public. These materials include fact sheets, materials covering regulatory information, frequently asked questions, press releases, translations and more. All the materials about the Pfizer-BioNTech COVID-19 Vaccine can be found on the [Comirnaty and Pfizer-BioNTech COVID-19 Vaccine webpage \(/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines\)](#). In addition, the FDA posts all the materials for the COVID-19 vaccine emergency use authorizations on the [Emergency Use Authorization webpage \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization\)](#).

Q: How is additional safety monitoring being conducted for the Pfizer-BioNTech COVID-19 Vaccine?

A: The company has a pharmacovigilance plan that was assessed by FDA to monitor the safety of the Pfizer-BioNTech COVID-19 Vaccine. The pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plan also includes other activities aimed at monitoring the safety of the Pfizer-BioNTech COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

Responsibility for additional post-authorization vaccine safety monitoring is shared primarily by the FDA and the U.S. Centers for Disease Control and Prevention (CDC), along with other agencies involved in healthcare delivery. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program aims to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. There are multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government has a well-established post-authorization/post-approval vaccine safety monitoring infrastructure that has been scaled up to meet the needs of a large-scale COVID-19 vaccination program. The U.S. government – in partnership with health systems, academic centers, and private sector partners – is using multiple existing vaccine safety monitoring systems to monitor COVID-19 vaccines in the post-authorization/approval period. Some of these systems are the Vaccine Adverse Event Reporting System ([VAERS \(/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/vaccine-adverse-events\)](#)), the Vaccine Safety Datalink ([VSD](#)

(<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>), the Biologics Effectiveness and Safety (BEST (<https://www.bestinitiative.org/>)) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)) Initiative, and Medicare claims data.

Q: Now that FDA has approved and authorized COVID-19 vaccines, what happens to other vaccines being studied for the prevention of COVID-19?

A: The FDA believes it is important for clinical trials for other COVID-19 vaccines to continue or initiate. It is important to have a portfolio of COVID-19 vaccines available to be able to vaccinate our population.

Q: Who made the decision to authorize the Pfizer-BioNTech COVID-19 Vaccine for emergency use?

A: FDA career scientists and physicians in the Center for Biologics Evaluation and Research made a determination that the emergency use authorization request met the criteria for issuing an EUA. The FDA's former chief scientist, Rear Adm. Denise Hinton, signed the letter of authorization.

Q: How are you educating the public about the safety and effectiveness of the Pfizer-BioNTech COVID-19 Vaccine?

A: The FDA has embarked on an education campaign via social media, consumer content, media interviews, engagement with stakeholders and more to help the public understand our regulatory and scientific processes. These engagements will continue.