Q&A for Comirnaty (COVID-19 Vaccine mRNA)

How did the FDA arrive at the decision to approve Comirnaty (COVID-19 Vaccine mRNA)? What is different now when compared to the December 2020 authorization of Pfizer-BioNTech COVID-19 Vaccine?

FDA conducted a thorough evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty before making a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

The EUA (https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial in approximately 18,000 individuals who received the vaccine and approximately 18,000 who received a placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. The duration of safety follow-up for the vaccinated and placebo participants was a median of two months after receiving the second dose.

Follow-up data from this ongoing clinical trial was analyzed by FDA to determine the safety and effectiveness of Comirnaty. The updated analysis to determine effectiveness for individuals 16 years of age and older included approximately 20,000 Comirnaty and 20,000 placebo recipients who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Overall, the vaccine was 91% effective, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The safety was evaluated in approximately 22,000 Comirnaty and 22,000 placebo recipients 16 years of age and older. More than half of the vaccine and placebo recipients were followed for safety for at least four months after the second dose. After issuance of the EUA, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty. Overall, in blinded and unblinded follow-up, approximately 12,000 Comirnaty recipients have been followed for at least 6 months.

What are the most commonly reported side effects by those who received Comirnaty (COVID-19 Vaccine mRNA)?

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

How safe and effective is Comirnaty (COVID-19 Vaccine mRNA)?

Overall, the vaccine was 91% effective in preventing COVID-19 disease, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

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The FDA conducted a rigorous evaluation of the of post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of Pfizer-BioNTech COVID-19 Vaccine and determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information (/media/151707/download) includes a warning about these risks.

Will the emergency use authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine remain in effect after the approval?

The EUA will continue to cover adolescents 12 through 15 years of age (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use) and the administration of a third dose to certain immunocompromised individuals 12 years of age and older. Additionally, for logistical reasons, the EUA will continue to cover the use of the Pfizer-BioNTech COVID 19 Vaccine in individuals 16 years of age and older; this use is also now approved.

How is Comirnaty (COVID-19 VACCINE, mRNA) related to the PFIZER-BIONTECH COVID-19 VACCINE?

The FDA-approved Pfizer-BioNTech product Comirnaty (/vaccines-blood-biologics/comirnaty) (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers (/media/144414/download) provides additional information about both the approved and authorized vaccine.

After 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?

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.