



## **What does EUA mean?**

EUA stands for **E**mergency **U**se **A**uthorization. The U. S. Food and Drug Administration (FDA) is the government agency responsible for evaluating the safety of all medicines, vaccines, and medical devices before they are given to patients in the US. When there is a public health emergency, such as the COVID-19 pandemic, the FDA undertakes an expedited process of rigorous evaluation called an EUA. The EUA makes it possible to make vaccines and medicines available quickly while maintaining all the necessary steps for a careful and close evaluation of the scientific data.

The FDA has authorized three COVID-19 vaccines for emergency use. The vaccines are:

- Pfizer BioNTech COVID-19 Vaccine
- Moderna COVID-19 Vaccine
- Janssen COVID-19 Vaccine (Johnson & Johnson)

## **Were the COVID-19 vaccines rigorously tested?**

Yes. The FDA carefully evaluated and analyzed the safety and effectiveness data from clinical trials that included tens of thousands of people who received the vaccines. The clinical trials were conducted according to the strict standards set forth by the FDA. FDA scientists and doctors with expertise in vaccine development closely examined the scientific data and other information generated by the studies to determine safety and effectiveness. FDA staff are like your family - they are fathers, mothers, daughters, sons, sisters, brothers and more. They and their families are also directly impacted by the work that they do, and are exactly who you want making these important public health decisions for the United States.

## **Are the COVID-19 vaccines safe and effective?**

Clinical trials data from the COVID-19 vaccines' studies clearly show that the known and potential benefits of the vaccines greatly outweigh the known and potential risks.

Studies' participants received millions of doses of the COVID-19 vaccines and the data shows that serious side-effects following vaccination are very rare. None of the study participants had any serious, life-threatening allergic reactions to the vaccines but a few people who received the vaccines in their community had anaphylaxis (a severe, life-threatening allergic reaction that happens within seconds or minutes of exposure to an allergen). Because of this remote chance of severe allergic reaction, health care providers will ask you to stay at the place where you received a vaccine for 15 to 30 minutes so they can monitor you.

## **Can I see the data showing the COVID-19 vaccine is safe and effective?**

The FDA's analysis of clinical trial data, as well as demographic information about the clinical study volunteers, is available in the FDA Briefing Document for each vaccine. You can see outside experts discuss the data on the advisory committee webcasts. The FDA's reasoning for authorizing each vaccine is available in the FDA Decision Memorandum. Access these resources on the FDA website at <https://tinyurl.com/4t2rbve9>

## **Does the FDA monitor COVID-19 vaccine safety after approval or authorization?**

Yes. The FDA and the CDC (Centers for Disease Control and Prevention) have several systems in place to continually monitor COVID-19 vaccine safety. These systems, rapidly detect and investigate potential safety problems and include:

- The **Vaccine Adverse Event Reporting System (VAERS)** - a central database that collects reports of negative side effects on all vaccines used in the U.S.

- The **v-safe** system – a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for people who receive a COVID-19 vaccine. Access at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

The FDA and CDC also use other systems that obtain data from Electronic Medical Records (EHRs), Medicare and insurance claims and other electronic sources to actively monitor potential negative effects from the COVID-19 vaccines.

### Where can I learn more?

- FDA: COVID-19 Vaccine Safety Surveillance. Access at: <https://tinyurl.com/2vtpcaxz>
- FDA: Emergency Use Authorization for Vaccines Explained. Access at: <https://tinyurl.com/6kbd5pwj>
- FDA. Learn More About COVID-19 Vaccines from the FDA. <https://tinyurl.com/2pr8cpwp>
- FDA. COVID-19 Vaccine Information: <http://www.fda.gov/covid19vaccines>

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Adapted from: FDA website. Access at: <https://www.fda.gov>  
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