Creating any vaccine is a complex process. **Safety is the top priority during all phases of vaccine development, authorization, and use.**

**CAREFUL TESTING**

- Medical experts and the Food and Drug Administration (FDA) oversee the entire vaccine approval process.
- With COVID-19 vaccine trials, researchers have **enrolled far more clinical trial participants than is usually required**, so they can notice and address safety concerns more easily and quickly.

**EMERGENCY USE AUTHORIZATION (EUA)**

During a public health emergency, like the COVID-19 pandemic, the FDA can use its EUA authority to allow the use of certain medical products if they **meet safety and efficacy standards.**

<table>
<thead>
<tr>
<th>PRE-CLINICAL</th>
<th>CLINICAL TRIALS</th>
<th>APPROVAL</th>
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| Laboratory research is done to see if the vaccine could work. | Groups of participants get the vaccine in phases.  
**PHASE 1**  
**PHASE 2**  
**PHASE 3**  
Researchers make sure the vaccine works and is safe. | The FDA reviews data and approves vaccine. |

In an emergency, the FDA can issue an EUA to let people get the vaccine before it is officially approved.

**CONTINUOUS SAFETY MONITORING**

The CDC and the FDA continuously track the safety of vaccines after they are authorized or approved.
CONTINUOUS MONITORING

Clinical trial participants are not the only ones who are monitored after vaccination. There are systems in place that help track common side effects and rare adverse reactions in people who receive any sort of vaccine, including the COVID-19 vaccines. These systems help the CDC and FDA track vaccine safety in real time and make sure vaccines are as safe as possible.

V-safe is a new smartphone-based tool that will make it easy for people to report any health problems or adverse reactions after they get their COVID-19 vaccine. You can learn more about V-safe at: [www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html](http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html)

HOW WERE COVID-19 VACCINES MADE AVAILABLE SO QUICKLY?

No steps were skipped during the development of COVID-19 vaccines. A number of factors allowed safe and effective COVID-19 vaccines to be available quickly.

- Earlier research on other coronaviruses (like SARS and MERS) jump started the COVID-19 vaccine development process.
- Through ground-breaking partnerships between leading medical experts, we were able to build on lessons learned from past pandemics (Zika, Ebola, H1N1) to make the COVID-19 vaccines.
- Medical experts and other key players dedicated their time, effort, and resources to developing a COVID-19 vaccine.
- Issuing an EUA shortened the official process, but did not skip any safety steps. This allowed access to vaccines sooner.
  - For example, the FDA invited more experts to review safety and efficacy data than usual. With all hands on deck, the review process was shortened from months to weeks.

LEARN MORE

From DHS
- Visit our webpage at [www.dhs.wisconsin.gov/covid-19/vaccine.htm](http://www.dhs.wisconsin.gov/covid-19/vaccine.htm)

From CDC