

THE COVID-19 VACCINE:
As essential as you are.

I GOT MY COVID-19 VACCINE!

Add one more layer of protection to keep you and your family safe.

cdc.gov/coronavirus/vaccines
health.mil/COVIDvaccine

CHAT with TRICARE

TRICARE
COVID-19 VACCINATION
GET THE FACTS

Have questions about the COVID-19 vaccine?

Join us for Chat with TRICARE, a live Q&A on our Facebook page.

Feb. 18, 2021 | 2-3 p.m. ET

How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

PHASE 1	PHASE 2	PHASE 3
<p>20-100 healthy volunteers</p> <ul style="list-style-type: none"> Is this vaccine safe? Does this vaccine seem to work? Are there any serious side effects? How is the size of the dose related to side effects? 	<p>several hundred volunteers</p> <ul style="list-style-type: none"> What are the most common short-term side effects? How are the volunteers' immune systems responding to the vaccine? 	<p>hundreds or thousands of volunteers</p> <ul style="list-style-type: none"> How do people who get the vaccine and people who do not get the vaccine compare? Is the vaccine safe? Is the vaccine effective? What are the most common side effects?

FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.
 Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.
 The FDA inspects manufacturing facilities regularly to ensure quality and safety.

FOR MORE INFORMATION, VISIT [HTTPS://WWW.FDA.GOV/CBER](https://www.fda.gov/cber)



How a vaccine's safety continues to be monitored

FDA and CDC closely monitor vaccine safety after the public begins using the vaccine.

The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

Vaccine Adverse Event Reporting System (VAERS)

VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.

Vaccine Safety Datalink (VSD) and Post-Licensure Rapid Immunization Safety Monitoring (PRISM)

Two networks of healthcare organizations across the U.S.

- VSD can analyze healthcare information from over 24 million people.
- PRISM can analyze healthcare information from over 190 million people.

Scientists use these systems to actively monitor vaccine safety.

Clinical Immunization Safety Assessment Project (CISA)

CISA is a collaboration between CDC and 7 medical research centers.

- Vaccine safety experts assist U.S. healthcare providers with complex vaccine safety questions about their patients.
- CISA conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).

FOR MORE INFORMATION, VISIT [HTTPS://WWW.CDC.GOV/VACCINESAFETY](https://www.cdc.gov/vaccinesafety)