



# Continuing the Journey of a COVID-19 Vaccine

When the U.S. Food and Drug Administration (FDA) authorizes a COVID-19 vaccine\*, experts may consider recommending them for public use.

## How a COVID-19 vaccine is recommended for public use



The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that advise CDC on the best way to use vaccines to protect the public's health in the United States. Representatives from 30 liaison organizations also bring related immunization expertise to the committee. This group carefully reviews all available data about a COVID-19 vaccine from clinical trials and other studies to develop recommendations for vaccine use. The ACIP continues to review vaccine safety and effectiveness data even after the vaccine is recommended for use and may change or update recommendations based on that data.



### When making recommendations, ACIP considers:

- How safe is the vaccine when given at specific ages?
- How well does the vaccine work at specific ages?
- How serious is the disease this vaccine prevents?
- How many people would get the disease the vaccine prevents if we didn't have the vaccine?



ACIP recommendations are not official until the CDC Director reviews and approves them. These recommendations then become official public health guidance.

\* FDA Vaccine Facts: The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization. [www.fda.gov/media/143890/download](http://www.fda.gov/media/143890/download)

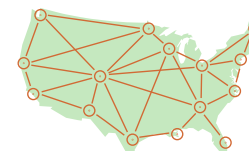
## How a COVID-19 vaccine's safety continues to be monitored

### FDA and CDC closely monitor vaccine safety after the public begins using a 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 is a safety monitoring system that is jointly managed by CDC and FDA.
- 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)

VSD is a collaboration between CDC and 9 integrated healthcare organizations.

- VSD conducts near real-time safety monitoring of vaccines as they are being administered and does vaccine safety research.



#### Clinical Immunization Safety Assessment Project (CISA)

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

- CISA provides vaccine safety expertise to assist U.S. healthcare providers with complex vaccine safety questions about their patients and conducts clinical research studies to better understand vaccine safety.

#### V-safe: After Vaccination Health Checker

V-safe is an active monitoring program for COVID-19 vaccine safety.

- This new smartphone-based tool uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination.
- V-safe also provides second COVID-19 vaccine dose reminders, if needed.



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