



## COVID-19

## ACT NOW!



# Why CDC Measures Vaccine Effectiveness

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After the U.S. Food and Drug Administration (FDA) approves a vaccine or authorizes a vaccine for emergency use, experts continue to assess vaccine effectiveness—or how a vaccine works in real-world conditions. The goal is to understand how a vaccine protects people outside of strict clinical trial settings.

CDC and other partners will continue to assess how COVID-19 vaccines work in real-world conditions. Assessing how vaccines work in the real-world is important to:

- Learn if vaccines offer the same protection seen in clinical trials.
- Adjust vaccine recommendations, as needed.
- Learn why and how often breakthrough cases (people getting sick after vaccination) occur.
- Learn how vaccines protect against COVID-19 variants.
- Inform vaccine policy and widespread vaccine distribution.
- Inform future development of improved vaccine technologies.

## Clinical trial results show COVID-19 vaccines are effective.

[Clinical trials](#) provide data and information about how well a vaccine prevents an infectious disease and about how safe it is. FDA evaluates these data, as well as manufacturing information, to assess the safety and effectiveness of vaccines. FDA then decides whether to approve a vaccine or authorize it for emergency use in the United States.

However, more assessments take place after a vaccine is either approved or authorized for emergency use by FDA. The goal of these assessments is to understand more about the protection a vaccine provides under real-world conditions, outside of strict clinical trial settings.

# Real-World COVID-19 Vaccine Effectiveness Can Differ

CDC and partners [will continue to assess the effectiveness of COVID-19 vaccines](#) approved or authorized for emergency use by FDA and recommended for public use in the United States. These real-world assessments will compare groups of people who do and don't get vaccinated and people who do and don't get COVID-19 to assess how COVID-19 vaccines are working to protect people.

Many factors can affect how a vaccine works in real-world conditions. These factors include:

- **Host factors** such as people not included in clinical trials who may respond differently to the vaccine
- **Virus factors** such as variants
- **Programmatic factors** such as following dosing schedules or storing and handling vaccines properly

Understanding how COVID-19 vaccines work in real-world conditions will allow CDC, FDA, and other partners to ensure vaccines offer real-world protection against COVID-19.

## Related Pages

- [Vaccine Effectiveness Presentation](#) ↗ at the Oct. 22, 2020, FDA Vaccines and Related Biological Products Advisory Committee Meeting
- [FDA's Center for Biologics Evaluation and Research Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness \[399 KB, 27 pages\]](#) ↗
- [COVID-19 Vaccine Effectiveness Research](#)
- [Ensuring the Safety of COVID-19 Vaccines in the United States](#)
- [Key Things to Know about COVID-19 Vaccines](#)
- [Food and Drug Administration COVID-19 Vaccines](#) ↗
- [Combat COVID: Information about Clinical Trials](#) ↗

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