COVID-19 Vaccine Safety

In the U.S., the Food and Drug Administration (FDA), the Advisory Committee on Immunization Practices (ACIP), and the Centers for Disease Control and Prevention (CDC) make sure all vaccines are safe and effective before approving them and continue to monitor their safety after approval.

Safety is the top priority during all phases of vaccine development, authorization or approval, and use.

Pre-clinical	Phase 1	Phase 2	Phase 3	Review	Phase 4
Lab studies & animals	20-100 volunteers	Hundreds of volunteers	Thousands of volunteers	FDA & ACIP* review data & approve it	Everyone who gets vaccinated

In an emergency, FDA can issue an Emergency Use Authorization (EUA) to let people get a vaccine before all the trials are complete.

- An EUA ensures that the best medical products are available as soon as possible, while still making sure that scientific and safety standards are met.
- The FDA only grants emergency use authorization of COVID-19 vaccines with current phase 3 trial data showing the vaccine is safe and effective.

Vaccine Safety Monitoring

After a vaccine gets authorized with an EUA or fully approved, CDC and FDA will continue to track the safety of COVID-19 vaccines for many years.

- V-safe, a new smartphone-based health checker, will make it even easier for people to report any health problems after they get their COVID-19 vaccine.
- Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program that has been used to detect possible safety issues with vaccines for many years.
  - Anyone can, but doctors must, report adverse events (possible side effects or health problems) that occur after vaccination using VAERS.
- Clinical Immunization Safety Assessment (CISA) Project researches vaccine safety in special populations and helps U.S. clinicians answer vaccine safety questions about specific patients.

Learn more about COVID-19 vaccines at https://www.dhs.wisconsin.gov/covid-19/vaccine.htm.