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.

<table>
<thead>
<tr>
<th>Pre-clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Review</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab studies &amp; animals</td>
<td>20-100 volunteers</td>
<td>Hundreds of volunteers</td>
<td>Thousands of volunteers</td>
<td>FDA &amp; ACIP* review data &amp; approve it</td>
<td>Everyone who gets vaccinated</td>
</tr>
</tbody>
</table>

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.
What is an mRNA vaccine?

An mRNA vaccines give our cells instructions on how to make a protein that triggers an immune response. Our immune response produces antibodies that protect us from getting infected. mRNA vaccines do not put a weakened or inactivated virus into our bodies and cannot give someone COVID-19. Our cells break down and get rid of the mRNA as soon as it is finished using the instructions. The vaccine does not affect or interact with our DNA in any way.

The benefit of mRNA vaccines, like all vaccines, is that those vaccinated gain protection against COVID-19 without ever having to risk the serious consequences of getting sick with COVID-19.

Where can I learn more about the vaccine?

**DHS:**

**CDC:**