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**
- 10-100 healthy volunteers
- Goal: determine if the vaccine is safe.
- FDA licenses the vaccine only if it's safe and effective.

**PHASE 2**
- Several hundred volunteers
- Goal: determine if the vaccine is safe and effective.
- The FDA sets guidelines to ensure quality.

**PHASE 3**
- Hundreds or thousands of volunteers
- Goal: determine if the vaccine is safe and has benefits that outweigh risks.

How a vaccine's safety continues to be monitored

FDA and CDC closely monitor vaccine safety. The purpose of monitoring is to track if adverse events (possible side effects) are consistent with prior monitoring. Monitoring a vaccine as it is licensed helps ensure that the benefits of vaccination outweigh risks.

**Vaccine Adverse Event Reporting System (VAERS)**
VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including patients, 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 30 million people.
- PRISM can analyze healthcare information from over 100 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 assess U.S. healthcare providers with example immunizations to identify safety questions about their patients.
- CISA conducts clinical research studies to better understand vaccine safety and effectiveness.

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

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

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

www.tricare.mil/coronavirus