



COVID-19 Vaccine Safety

U.S. Systems Will Monitor the Safety and Effectiveness of COVID-19 Vaccines After FDA Approval.

Existing Vaccine Safety Monitoring Systems in the U.S.

- ✓ **VACCINE ADVERSE EVENTS REPORTING SYSTEM (VAERS)**
This system looks for any unexpected or unusual patterns that indicate that a vaccine safety issue needs to be researched further. Anyone can report vaccine reactions to VAERS, which means that these adverse events/reactions may or may not be caused by vaccines.

- ✓ **VACCINE SAFETY DATALINK (VSD)**
Collaboration of CDC and 9 health care organizations that monitor safety of vaccines and conduct studies about rare and serious adverse events following vaccination. VSD also used to figure out if side effects identified with VAERS are actually related to vaccination.

- ✓ **CLINICAL IMMUNIZATION SAFETY ASSESSMENT (CISA) PROJECT**
Collaboration between CDC and 7 medical research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety.



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New or Expanded Vaccine Safety Monitoring Systems in the U.S.

- ✓ **V-SAFE**
CDC's new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines.
- ✓ **NATIONAL HEALTHCARE SAFETY NETWORK (NHSN)**
An acute care and long term care facility monitoring system that reports to VAERS.
- ✓ **FDA'S BIOLOGICS EFFECTIVENESS AND SAFETY (BEST) SYSTEM AND FDA'S SENTINEL SYSTEM**
Systems contain administrative and claims-based data for vaccine surveillance and research.
- ✓ **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)' HEALTH DATA**
FDA and CMS collaboration that monitors the CMS health records database.
- ✓ **GENESIS**
NIA/Brown University system to identify and track any adverse events after vaccination for nursing home residents.
- ✓ **HEALTH DATA/SAFETY MONITORING SYSTEMS FROM VETERAN AFFAIRS, DEPARTMENT OF DEFENSE AND INDIAN HEALTH SERVICE**