Submit report(s) of adverse events following vaccination.

The FDA & CDC sort the reports in terms of their severity. The FDA defines a severe adverse event as one that results in one of the following or necessitates surgical or medical intervention to preclude one of the following:

- Congenital Anomalies
- Hospitalization
- Permanent Disability
- Life Threatening Condition
- Death

VAERS

RCA (launched by VSD) monitors AE in real-time based upon:
- VAERS reports
- Data from pre-licensure studies
- Concerns published

FDA & CDC conduct case studies of serious events.

FDA & CDC conduct case studies of events with high public attention.

Gather data from the Vaccine Safety Datalink.

Is there adequate information?

- No.
- Yes.

Is the rate of AE higher than in the unvaccinated?

- No.
- Yes.

Are instances of AEs high?

- No.
- Yes.

The occurrence is not connected to the vaccine.

- No.
- Yes.

The manufacturers and FDA request (or the FDA orders) to withdraw or recall the vaccine.

FDA & CDC conduct more studies.

FDA & CDC compare reports to similar events in other vaccinations based on sex and age.

Index of Acronyms

AE – Adverse Events
CDC – Centers for Disease Control and Prevention
FDA – Food and Drug Administration
RCA – Rapid Cycle Analysis
VSD – Vaccine Safety Datalink