VAERS is CDC and FDAs frontline vaccine monitoring system. Anyone (healthcare professionals, manufacturers, general public) can send a report into VAERS through an electronic online submission process. These reports are received, processed and they are reviewed by certified coders that assign codes based on the description that's given by the person reporting. They go into a large database which is updated daily. It is made available to CDC and FDA.

- Reports can be classified as serious or non-serious. The code of Federal Regulation defines "serious" as: death, life threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomalies, or birth defects. If any of those conditions get checked, the report is classified as serious adverse event.
- It is important to remember, that classification as a serious report does not mean those adverse events were caused by the vaccine. Some of those adverse events may be true adverse reactions or they may be coincidental events and not related to vaccination.
- For reports classified as serious, CDC requests and reviews all the available medical records: hospital records, clinic records, interviews healthcare providers as needed, examines death certificates, and autopsy reports.
- VAERS is not designed to determine if the vaccine caused the reported adverse event. The determination of the cause of serious adverse events, is done by healthcare providers; the determination of the cause of death, is done by the certifying official who completes the death certificate or the pathologist who conducts the autopsy.
- VAERS is designed to be an early warning system. It looks for unusual patterns of rare and serious adverse events and alerts CDC experts to potential vaccine safety concerns, known as safety signals.
- Statistical methods are used to determine if a potential safety signal exists in VAERS. If a safety concern is detected by VAERS, more detailed, quantitative analyses are conducted using more robust analytic systems, such as the Vaccine Safety Datalink. Such analyses can determine if a statistically meaningful association exists between the vaccine and the adverse event in question. Should a safety issue be established with the vaccine, the FDA and vaccine manufacturer can work toward an appropriate solution, depending upon what the specific safety concern is (e.g., a problem with a specific lot, a manufacturing issue, the vaccine itself).