Vaccine Safety Systems

Monitoring System	Data Source	Population Monitored	Management	Key Features	Advantages	Limitations
Vaccine Adverse Event Reporting System (VAERS)	Mandatory reporting by healthcare professionals and vaccine manufacturers for certain post-vaccination events	Nationwide (U.S.)	Managed by FDA and CDC	Early detection system; Passive, voluntary reports; Generates hypotheses; Follow-up for serious cases	Allows anyone to submit reports; Publicly available data	Cannot determine causality; Prone to overreporting and underreporting
Vaccine Safety Datalink (VSD)	Electronic health records from 13 major healthcare organizations nationwide	12.5 million individuals	Managed by CDC in collaboration with health organizations	Active surveillance; Hypothesis testing; Medical record review to confirm results; Strong methodology for vaccine safety studies	Can estimate causal links; Real-time monitoring; High-quality data	May miss adverse events with delayed onset; Primarily covers insured populations
Biologics Effectiveness and Safety System (BEST)	Claims data, electronic health records (EHRs), and combined claims-EHR datasets	100 million individuals	Managed by FDA	Rapid data queries to detect or study adverse events; Can answer targeted vaccine safety questions	Large population base; Can study vaccines' safety in specific subgroups (e.g., those with pre-existing conditions, pregnant people)	Limited pediatric vaccine evaluations; Requires further detailed epidemiological studies for statistical signals
Clinical Immunization Safety Assessment (CISA)	Primarily medical records from healthcare providers	Not specified	Managed by CDC with medical research institutions	Expertise in clinical, immunological, and vaccine safety for in-depth analysis of adverse events	U.S. healthcare providers can request consults for complex vaccine safety questions for specific patients	Limited scope and focus