Duke | Robert J. Margolis, MD Center for Health Policy

Tenth Annual Sentinel Initiative Public Workshop

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Glossary of Terms

Active Risk Identification and Analysis (ARIA): The U.S. Food and Drug Administration's (FDA) active post-market risk identification and analysis system, which is comprised of pre-defined, parameterized, reusable routine querying tools, combined with the electronic data in the Sentinel Common Data Model. Because ARIA uses parameterized tools and a trusted multi-site distributed database that undergoes continuous quality checks and refreshes, safety analyses can be done more efficiently to conduct medical product safety surveillance to fulfill the mandate in the FDA Amendments Act of 2007.

Biologics Effectiveness and Safety (BEST) Initiative: A system currently being developed to expand and enhance FDA's Center for Biologics Evaluation and Research (CBER) post-market surveillance capabilities. The primary goals of BEST are a) to develop a system using electronic health records (EHR) and claims data sources covering a large proportion of the U.S. population, automated query tools, and additional infrastructure; b) to develop improved automated adverse events data collection, analysis, and reporting techniques for biologics by using methods such as natural language processing and machine learning.

Blood Safety Surveillance Continuous Active Network (BloodSCAN): A subcomponent of the CBER Sentinel Program focusing on surveillance and recipient safety evaluation of blood components and blood-derived products.

Cohort Identification and Descriptive Analysis (CIDA) Tool: CIDA serves as the foundation of the routine querying system, and is responsible for identifying, extracting, and characterizing cohorts of interest from the SDD based on the specification of a number of requester-defined options (e.g., continuous enrollment requirements, incidence criteria, inclusion/exclusion criteria).

FDA-Catalyst: Activities leverage the Sentinel Infrastructure by utilizing the data available through its data partners and supplementing it with data from interventions or interactions with members and/or providers.

Post-licensure Rapid Immunization Safety Monitoring (PRISM): A subcomponent of CBER Sentinel Program focusing on vaccine safety surveillance for evaluation of potential safety signals identified during pre-market and post-market reviews.

Routine Querying Tools (Modular Programs): Sentinel's routine querying tools include modular programs, summary tables, and software toolkits. Modular programs are grouped into three levels:

- **Level 1** modular program queries identify cohorts of interest and, for some cohorts, can perform unadjusted and minimally adjusted (i.e., by Data Partner, age group, sex, and year) analyses.
- **Level 2** modular program queries identify cohorts of interest, perform more complex adjustment for confounding, and generate effect estimates and confidence intervals.

- **Level 3** modular program queries identify cohorts of interest and perform more complex adjustment for confounding repeatedly as part of prospective sequential analysis.

Sentinel Collaborating Institutions: A network of Data and Academic Partners that work with the FDA and Sentinel Coordinating Center to provide access to both healthcare data and scientific, technical, and organizational expertise.

Sentinel Coordinating Center: The Sentinel Coordinating Center includes the Sentinel Operations Center (SOC), comprised of the Applied Surveillance, Scientific Systems, and Administration Divisions housed at the Harvard Pilgrim Health Care Institute (HPHCI), and advisory groups. Both the Sentinel Coordinating Center and the SOC are led by the Sentinel Principal Investigator at HPHCI.

Sentinel Data Partners: Data Partners in the Sentinel System include a diverse group of organizations including academic medical centers, healthcare systems, and health insurance companies. Sentinel Data Partners maintain physical and operational control over electronic data in their existing environments.

Sentinel Infrastructure: The underlying data infrastructure created to enable analysis within the Sentinel System. The Sentinel Infrastructure involves: 1) a distributed data approach in which Data Partners maintain physical and operational control over electronic data in their existing environments; and 2) a Common Data Model consisting of standardized administrative and clinical information across Data Partners. The Sentinel Infrastructure has the potential to allow analysis of the data for other purposes besides safety for the FDA or those outside the FDA.

Sentinel Initiative: A multi-year effort beginning in 2008 to create a national electronic system for monitoring the performance of FDA-regulated medical products to improve the FDA's ability to identify and assess medical product safety issues.

Sentinel System: An active surveillance system that uses routine querying tools and pre-existing electronic healthcare data from multiple sources to monitor the safety of regulated medical products. Subcomponents of the Sentinel System include: ARIA, PRISM, BloodSCAN and STAT.

Surveillance of Tissues and Advanced Therapeutics (STAT): A subcomponent of the CBER Sentinel Program focusing on surveillance and recipient safety evaluation of human cell-, gene-, tissue-based products, other advanced therapies, and antivenins.

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