



# **FDA's Sentinel Initiative — A National Strategy for Monitoring Medical Product Safety**



*Judith A. Racoosin, MD, MPH  
Sentinel Initiative Scientific Lead  
Office of Critical Path Programs  
Office of the Commissioner, FDA*



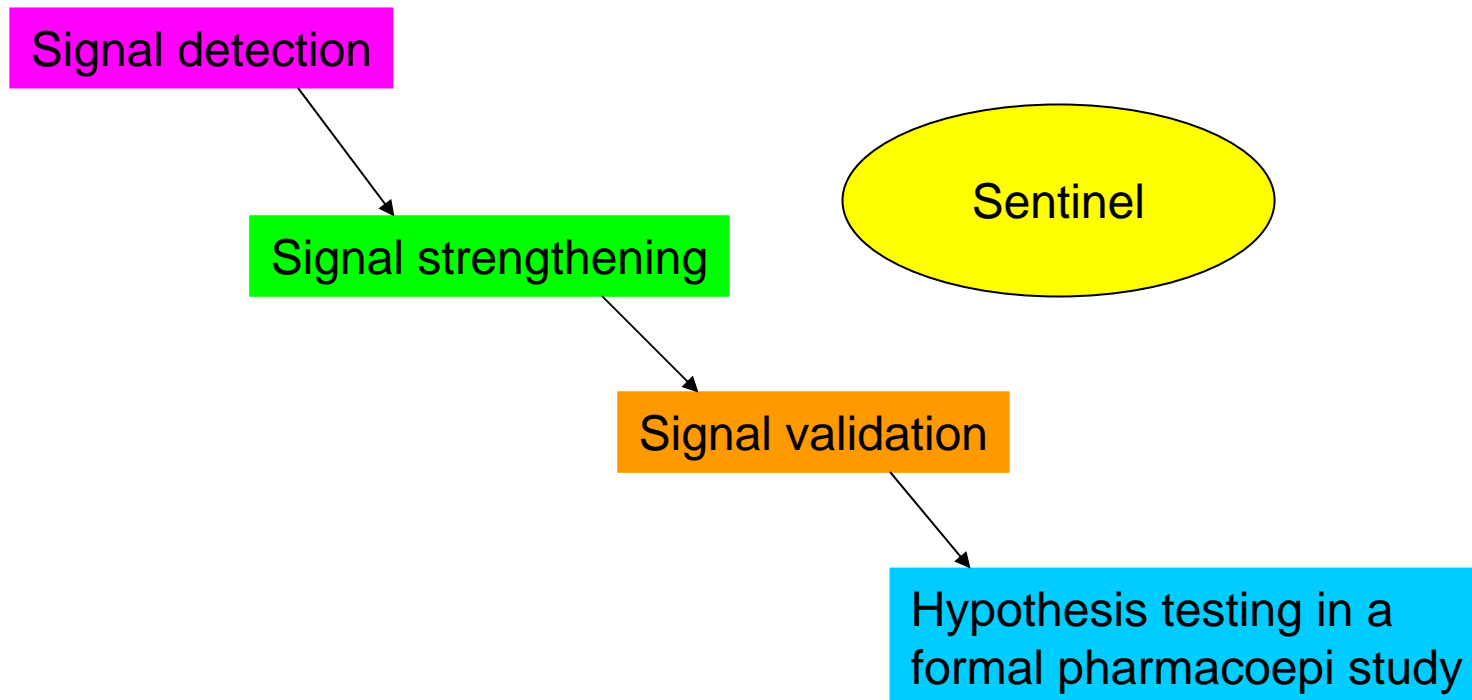
# Agenda

- Sentinel Initiative Overview
- Progress to date
- Next steps

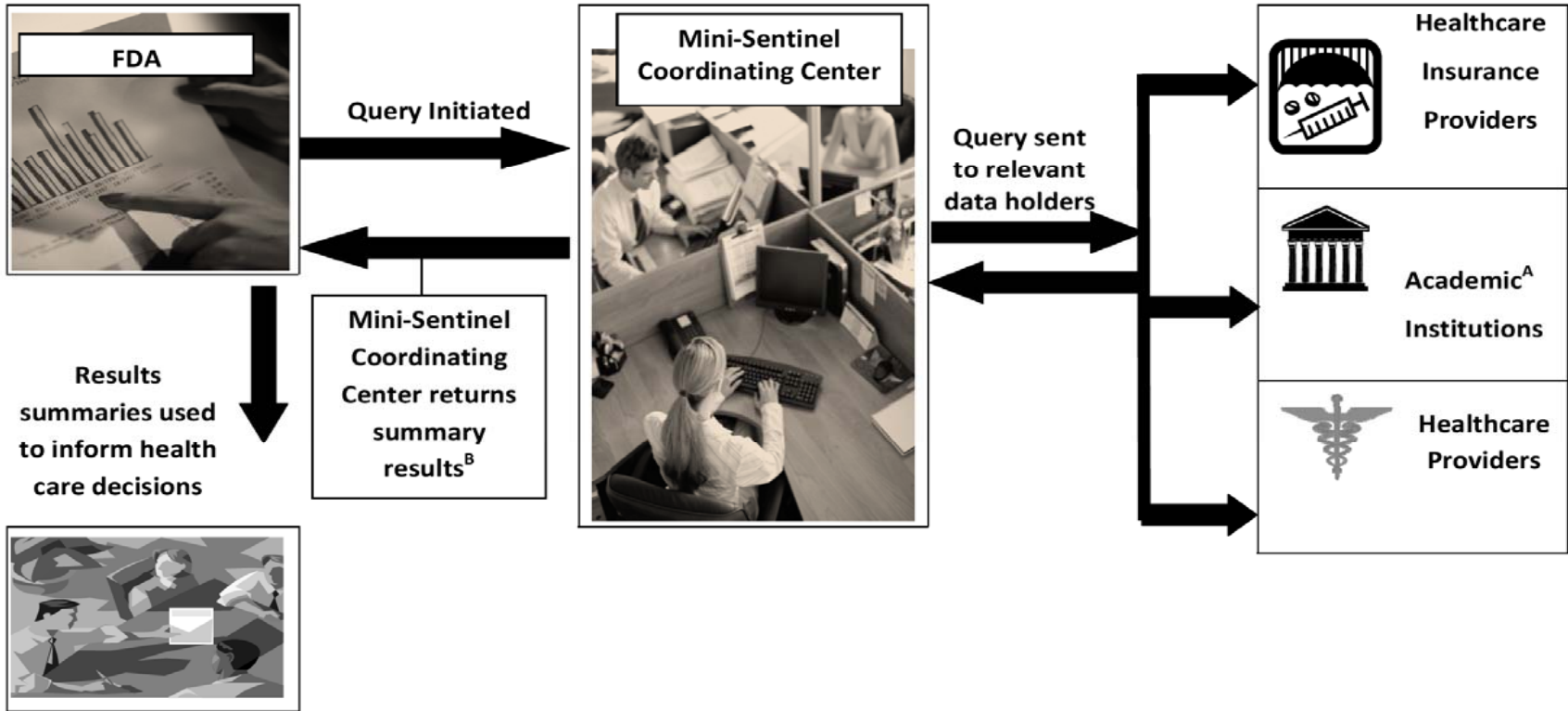
# Sentinel Overview

- Develop an active electronic safety monitoring system to
  - Strengthen FDA's ability to monitor postmarket performance of medical products
  - Augment, not replace, existing safety monitoring systems
  - Enable FDA to access existing automated healthcare data by partnering with data holders (e.g., insurance companies with large claims databases, owners of electronic health records, others)

# Evaluation of postmarket safety issues



## Overview of the Mini-Sentinel Query Process



A. Only those academic institutions with automated data will be recipients of queries.

B. No entities will have access to protected health information that they do not already hold. Instead, those whose queries are accepted by the **Mini-Sentinel Coordinating Center** for processing will receive results summaries from analyses conducted by each data holder that receives and agrees to respond to those queries. Results summaries will not include protected health information.

# How does Sentinel complement what we are already doing?

- Safety issues can be identified and evaluated in near real-time
- Sentinel expands the capacity for evaluating safety issues
  - Improved access to subgroups, special populations
  - Improved precision of risk estimates due to expanded number of populations available for study
- Active surveillance can identify an increased risk of common AEs (e.g., MI, fracture) that health care providers may not suspect are related to medical products

## A Work in Progress

May '08: Sentinel Initiative launched with release of initial report

- A long-term project; will be implemented in stages and will necessarily evolve
- Currently working on the “how and what”

# Contracts

- **Scientific Operations**

Defining and Evaluating Possible Database Models

Evaluation of Existing Methods for Safety Signal Identification

Evaluation of Timeliness of Medical Product Uptake in Healthcare Systems

- **Data and Infrastructure**

Evaluation of Potential Data Sources for Sentinel Initiative

Evaluation of Potential Data Sources for Blood and Tissue Products

Evaluation of Potential Orthopedic Device Implant Registries

- **Governance**

Developing a Governance and Operations Structure for Sentinel Initiative

- **Stakeholder Outreach/ Privacy Issues**

Engagement of Patients, Consumers, and Health Care Professionals



# Communication

- Efforts to provide information on status of initiative and obtain input from stakeholders
  - Website  
<http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm>
  - Public outreach
  - Internal meetings

# Federal Activities

- Collaborations with CMS, DoD, and VA
  - SafeRx project with CMS to develop near-real time active surveillance methods using Medicare data
  - Several ongoing projects within medical product Centers to evaluate potential medical product-adverse event signals and develop active surveillance and statistical methodologies
- Federal Partners Working Group
  - Share information and discuss issues related to complementary efforts being carried out by the various Agencies within the Federal government
  - Participants include FDA, ONC, NIH, CDC, CMS, DoD, VA, AHRQ, IHS, HRSA, OHRP, and CPSC

# Observational Medical Outcomes Partnership (OMOP)

- Public-Private Partnership with FNIH, FDA, and PhRMA
- Conducts experiments to assess value, feasibility, and utility of observational data to identify and evaluate the safety risks and potential benefits of prescription drugs
- Tests approaches for creating the infrastructure for accessing and managing required data
- Enables the evaluation of a possible governance model, consisting of an Executive Board, and Scientific and Technical Advisory Boards

# International Discussions

- **Europe**
  - **European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP)**
    - Create a “network of excellence” consisting of research and medical-care centers, healthcare databases, electronic registries and existing networks to strengthen postmarketing monitoring to facilitate the conduct of safety related postapproval studies
  - **IMI Topic 6/PROTECT**
    - To develop and validate tools and methods that will enhance AE data collection, active signal detection, create standards for pharmacoepi studies, and means to integrate all data know about a product for evaluation of risk:benefit
  - **EU-ADR**
    - Design, develop and validate a computerized system that exploits data from electronic healthcare records and biomedical databases for the *early detection of adverse drug reactions*; complementary to existing systems, have more power and detect signals earlier
- **Canada**
  - **Drug Safety and Effectiveness Network (DSEN)**
    - Enable research by linking researchers through a new virtual network, creating a national agenda of research based on priorities identified by decision-makers, provide funding for research to assess the risks and benefits of drug products that are on the market.
- **Japan**
  - **Utilization of Electronic Medical Records and Claims Data in Pharmacovigilance**
    - Secure access to EMR database including claim data to assess drug safety through ADR incidence survey and using a pharmacoepi approach

# Mini Sentinel

- **Develop a coordinating center for a distributed system**
  - Access three or more health data environments with varied attributes to conduct analyses
  - Convene a Planning Board to develop governing documents and establish a Safety Science Committee charged with the day-to-day operations
  - Develop a means for secure communication with contracted data holders
  
- **Evaluate emerging methods in safety science**
  - Develop epidemiological and statistical methodologies for signal detection signal strengthening, and signal validation
  - Test such methodologies in the evaluation of FDA-identified medical product-adverse event pairs of concern

# Federal Partners Collaboration

- An active surveillance initiative via intra-agency agreements with CMS, VA, DoD
- Identify medical product – AE pairs to evaluate
- Evolve active surveillance methodologies
- Evaluate interpretability of query findings resulting from a decentralized analytic approach

# Engaging External Stakeholders: Convener on Active Medical Product Surveillance

- Expert stakeholder conferences
  - Nov 23, 2009: Distributed Data Networks
- Public Workshop
  - Jan 11, 2010 (tentative)
- Medical Product Surveillance “Roundtables”
  - First scheduled for Oct 30, 2009
- Active Surveillance Implementation Meetings



# Questions?