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

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Opportunities

- FDAAA
- Emerging technologies and data sources
- National will
- Increasing recognition that partnering among sectors can be extremely productive

Sentinel Initiative

- Develop a national electronic safety monitoring system
  - Strengthen FDA's ability to monitor postmarket performance of medical products
  - 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)

- Will augment, not replace, existing safety monitoring systems

Potential Capabilities of Sentinel

- Safety issues may be identified and evaluated in near real-time
- Sentinel expands current 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 may 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
- ’08 – ’09: Foundational work on privacy, governance and data sources completed
- Fall ’09: Launched “Mini-sentinel”
- On-going: Broad stakeholder outreach

- Managing expectations - Sentinel will be implemented in stages and will necessarily evolve

Contracts

(reports on Sentinel Website)

- 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

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, SAMHSA, and CPSC

Observational Medical Outcomes Partnership

http://omop.fnih.gov

- 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

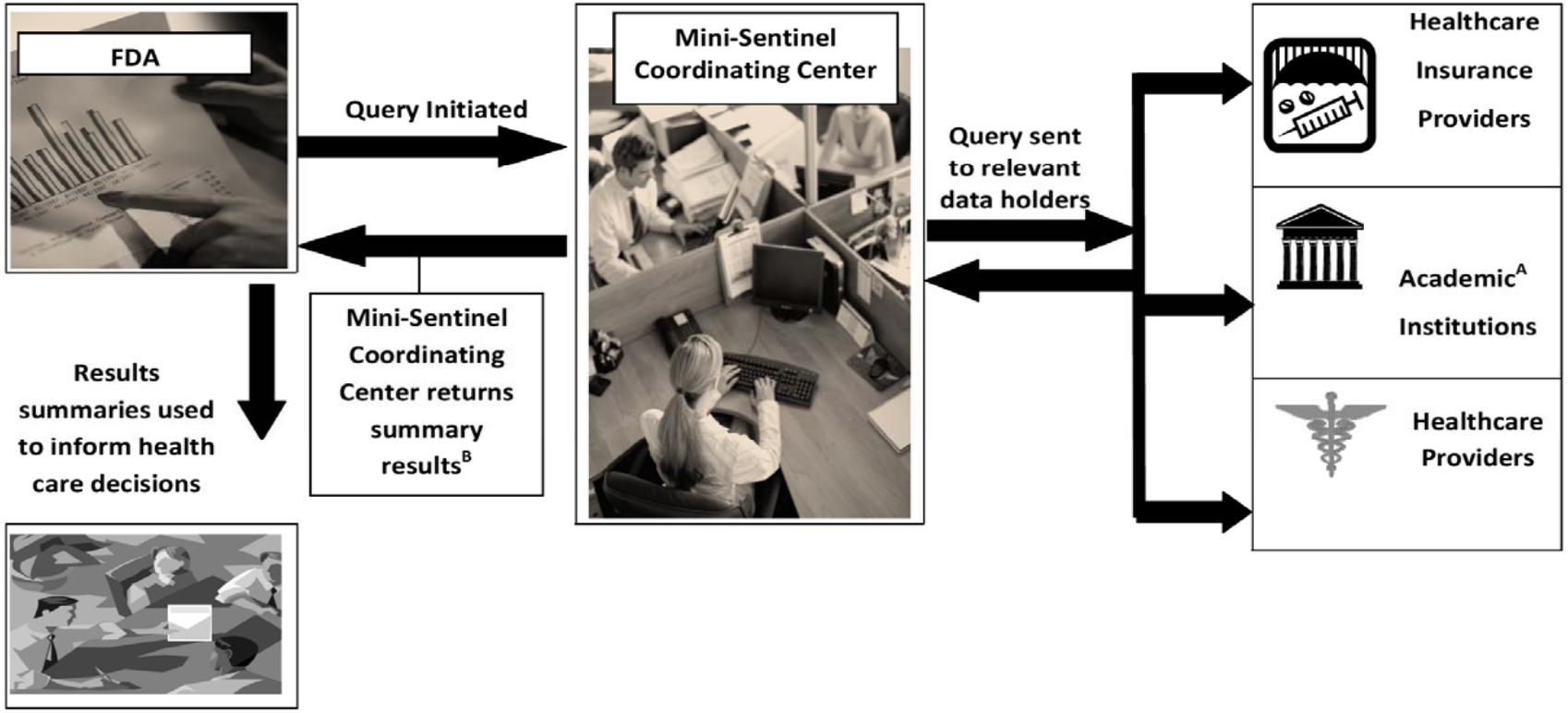
- **Europe**
  - **European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP)**
    - Create a “network of excellence” consisting of research and medical-care centers, healthcare databases, electronic registries and existing networks to strengthen postmarketing monitoring to 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

Harvard Pilgrim Healthcare

- 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

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.

Convener on Active Medical Product Surveillance

Brookings Institution

- Expert stakeholder conferences
  - Nov 23, 2009: Distributed Data Networks
  - March 2010: Privacy issues
- Public Workshop
  - Jan 11, 2010
- Medical Product Surveillance “Roundtables”
  - Update on Sentinel Initiative: Oct 2009
  - Learnings from H1N1 vaccine surveillance: Dec 2009
- Active Surveillance Implementation Meetings

Broader Questions

- How will Sentinel interface with related national efforts
  - Non-federal safety surveillance and research
  - CER
  - Data standards development
  - Privacy and security
- What might a national infrastructure look like and how will it be governed
- How to keep these efforts aligned with modernizing the clinical trials enterprise

Lessons Learned to Date

- Clear articulation of scope is critical
- Broad, inclusive process is vital
- Managing expectations is key (aka patience)
- Build what we can today with a constant focus on what we will need, and can achieve, in the future