FDA's Mini-Sentinel program

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My assignment

- What are Mini-Sentinel's objectives?
- What deliverables are expected within the next two years?
- Which major challenges for scale-up to the Sentinel System will be addressed?

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Objectives

- Provide a “laboratory” to *develop and evaluate policies, procedures, scientific methods, program operations, and costs* to inform a fully operational Sentinel Initiative
- Allow FDA to use existing automated healthcare data systems to:
  - *Evaluate safety issues*
  - *Evaluate impact of FDA actions*

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Organizations

- America's Health Insurance Plans
- CIGNA Healthcare
- Cincinnati Children's Hospital Medical Center
- Critical Path Institute
- Brigham and Women's Hospital
  - Division of Pharmacoepidemiology and Pharmacoeconomics
  - Division of General Medicine
- Duke U School of Medicine
- HMO Research Network:

  Group Health Research Institute
  Harvard Pilgrim Health Care Institute
  Henry Ford Research Foundation
  HealthPartners Research Foundation
  Lovelace Clinic Foundation
  Marshfield Clinic Research Foundation
  Meyers Primary Care Inst(UMass / Fallon)
- HealthCore, Inc
- Humana - Miami Health Services Research Center
- Kaiser Permanente:

  Colorado, Georgia, Hawaii, Mid-Atlantic, N. California, Northwest, Ohio, and S. California regions
- Outcome Sciences, Inc
- Risk Sciences International
- Rutgers University Inst for Health
- U of Alabama at Birmingham
- U of Illinois at Chicago
- U of Iowa College of Public Health
- U of Pennsylvania School of Medicine
- Vanderbilt U School of Medicine
- Weill Cornell Medical College

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Investigators

~200, including:

- All Vaccine Safety Datalink Principal Investigators
- 12 AHRQ CERTs PIs
- 7 AHRQ DEcIDE center PIs
- 12 current/former FDA advisory committee members
- 3 IOM “Future of Drug Safety” committee members
- 4 International Society of Pharmacoepidemiology presidents
- Critical Path Institute leadership

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Data Environments

- 60 million individuals (administrative & claims)
- 10 million also have EMRs
- 88 inpatient facilities
- Device and disease registries

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2-year Deliverables*

- Coordination
- Principles and Policies
- Communications
- Data
- Statistical methods
- Training for FDA personnel
- Assessment
  - Medical product safety
  - Impact of FDA actions

* Year 2 workplan not yet finalized

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Deliverables: Coordination

- Operations Center
- Cores for data, methods, protocol
- Privacy panel

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Deliverables: Principles/Policies

- Public health practice, not research
- Minimize transfer of private information
- Data partners participate voluntarily
- Maximum feasible transparency
- Public availability of “workproduct”
  - Tools, methods, protocols, software
  - Findings
- Confidentiality
- Conflict of Interest
- & cetera

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Deliverables: Communication

- Public website
- Secure data transfer capacity

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Deliverables: Data

- Common Data Model
  - administrative data, claims (year 1)
  - vital signs, outpatient laboratory test results (year 2)
- Distributed Dataset containing 60 million people*
- Ability to query data
  - Standardized summary data
  - Modular programs that run against patient level data
  - Ad-hoc feasibility and project-specific programs
- Ability to retrieve/review full text hospital records

* Vital signs and test results for 5-10 million

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Patent
Linamar


WENGER

Deliverables: Methods

Improved statistical methods for:

- Case mix adjustment (confounding)
- Adding information as it accumulates (sequential analysis)
- Case-based methods

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Deliverables: Training

- Seminars at FDA
- FDA personnel as visiting scientific collaborators at Coordinating Center

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Deliverables: Safety assessment

- Active surveillance
  - Myocardial infarction following oral hypoglycemics
  - Influenza vaccine adverse events
  - TBD
- Rapid response to FDA queries

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Challenges that will be addressed 1*

- Organizational model
  - Coordinating center, content expertise, distributed data partners
  - Creating a stable system in the face of unpredictable funding
- Principles and Policies
  - Public health practice (includes ensuring data acquired for this purpose is not used for other purposes)
  - ? access by entities other than FDA
- Active surveillance
  - Common and rare adverse events
  - Framing surveillance as quantitative estimation of safety

* Five years

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Challenges that will be addressed 2*

- Data
  - Administrative, claims, EHR (inpatient, outpatient)
  - Ability to link across sources
- Stretch goal – use for other purposes

* Five years

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Challenges that will remain

- Accommodating HIT developments
  - Evolving data standards
  - New data types, e.g., personal health records
- Balancing intrinsic tensions
  - Sensitivity vs spurious signals
  - Confidentiality vs transparency
- Managing expectations
  - Understanding and communicating the strengths and limitations of these data and methods

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