FDA Introduction to Mini-Sentinel Update

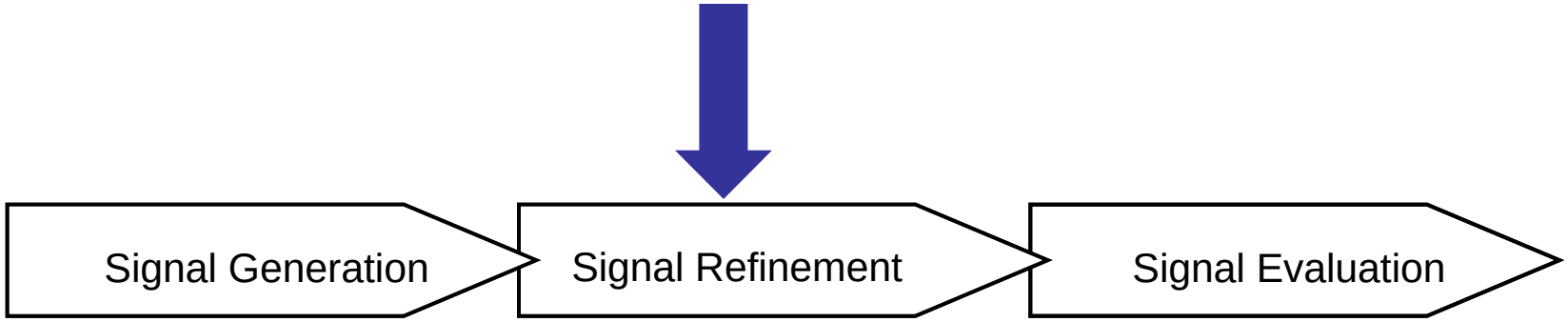
Brookings Active Surveillance Implementation Council
Meeting #2
November 18, 2010

Mini Sentinel

Harvard Pilgrim Healthcare

- Develop the scientific operations needed for the Sentinel Initiative.
- Create a coordinating center with continuous access to automated healthcare data systems, which would have the following capabilities:
  - Provide a "laboratory" for developing and evaluating scientific methodologies that might later be used in a fully-operational Sentinel Initiative.
  - Offer the Agency the opportunity to evaluate safety issues in existing automated healthcare data system(s) and to learn more about some of the barriers and challenges, both internal and external.

Definitions



- Signal generation includes a collection of methods for identifying potential associations between medical products and health outcomes of interest (HOIs)
- Signal refinement is a process for evaluating the magnitude and clinical significance of a suspected association
- Signal evaluation consists of the implementation of a formal epidemiological analysis to more definitively establish or refute causality between exposure to a medical product and the health outcome of interest

Scenarios included in signal refinement

- Concern emerges prior to marketing
  - Safety concern observed in premarket development program
  - Theoretical safety concern based on serious side effects of medical products
- Concern emerges after product has been marketed for a period of time

Potential steps in signal refinement

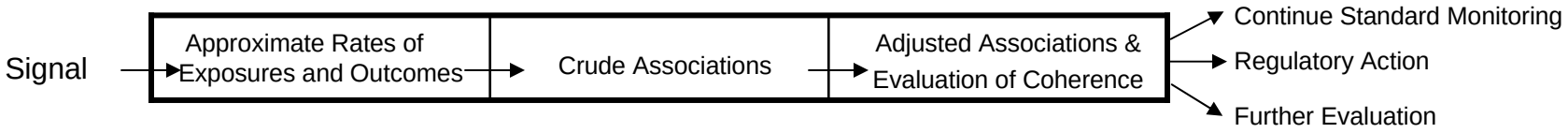
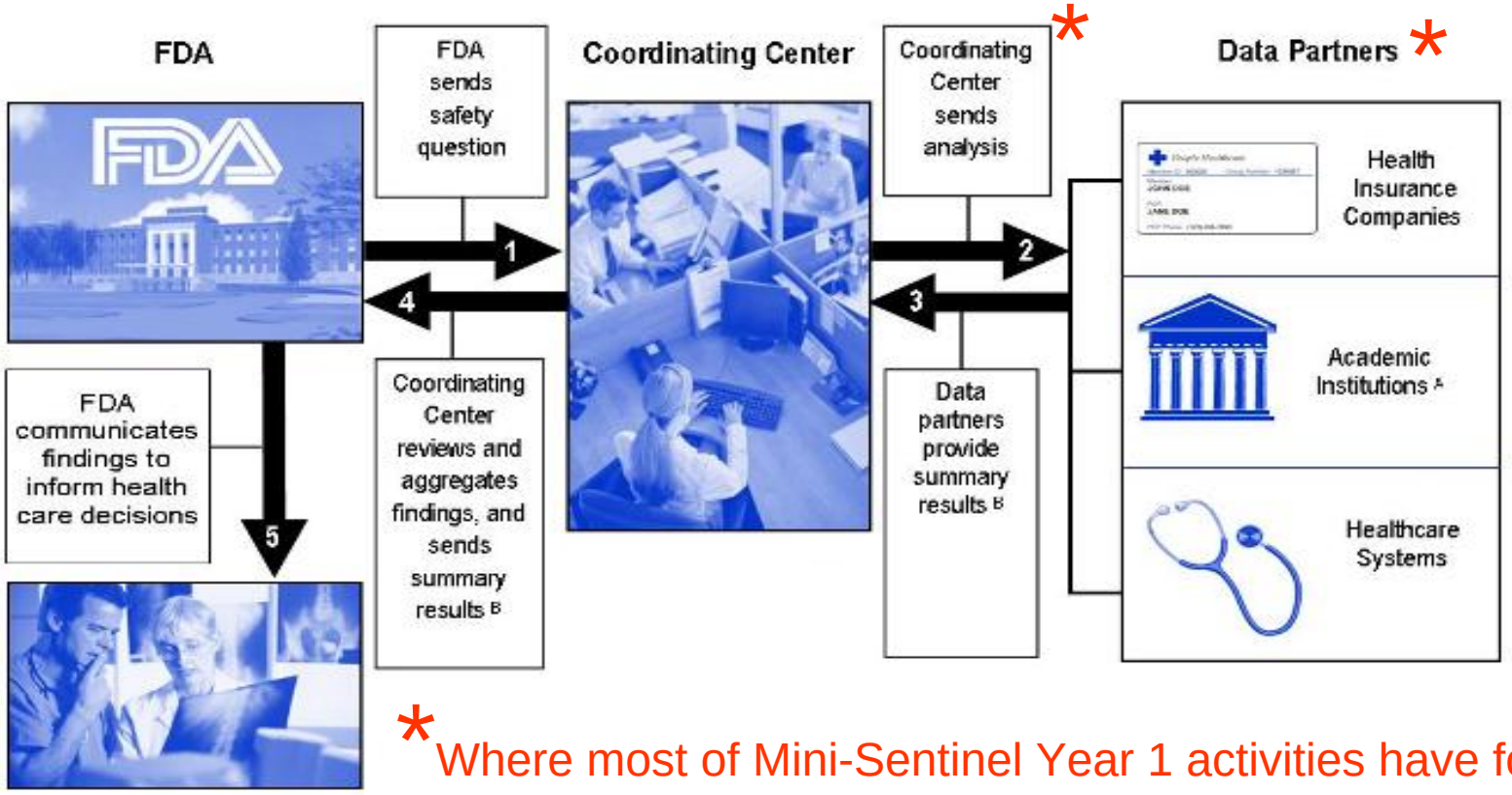


Figure 1: Overview of the Mini-Sentinel Safety Question Evaluation Process



*Where most of Mini-Sentinel Year 1 activities have focused

A. Only those academic institutions with electronic healthcare data will receive safety questions for evaluation.

B. Data partners will provide summary results from analyses conducted within their secure data environments. Those summary results will not include directly identifiable health information.