FDA's Mini-Sentinel program
Status report

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Deliverables*

- Organizational model
  - Coordinating center, distributed data partners, content expertise
- Principles and Policies
- Data
  - Administrative, claims, EHR (inpatient, outpatient)
  - Query capability
  - Ability to link across sources
- Methods development
- Active surveillance
  - Ongoing evaluation of new products
  - One time evaluation of older products for which a question arises
  - Impact of FDA regulatory action

* Five years

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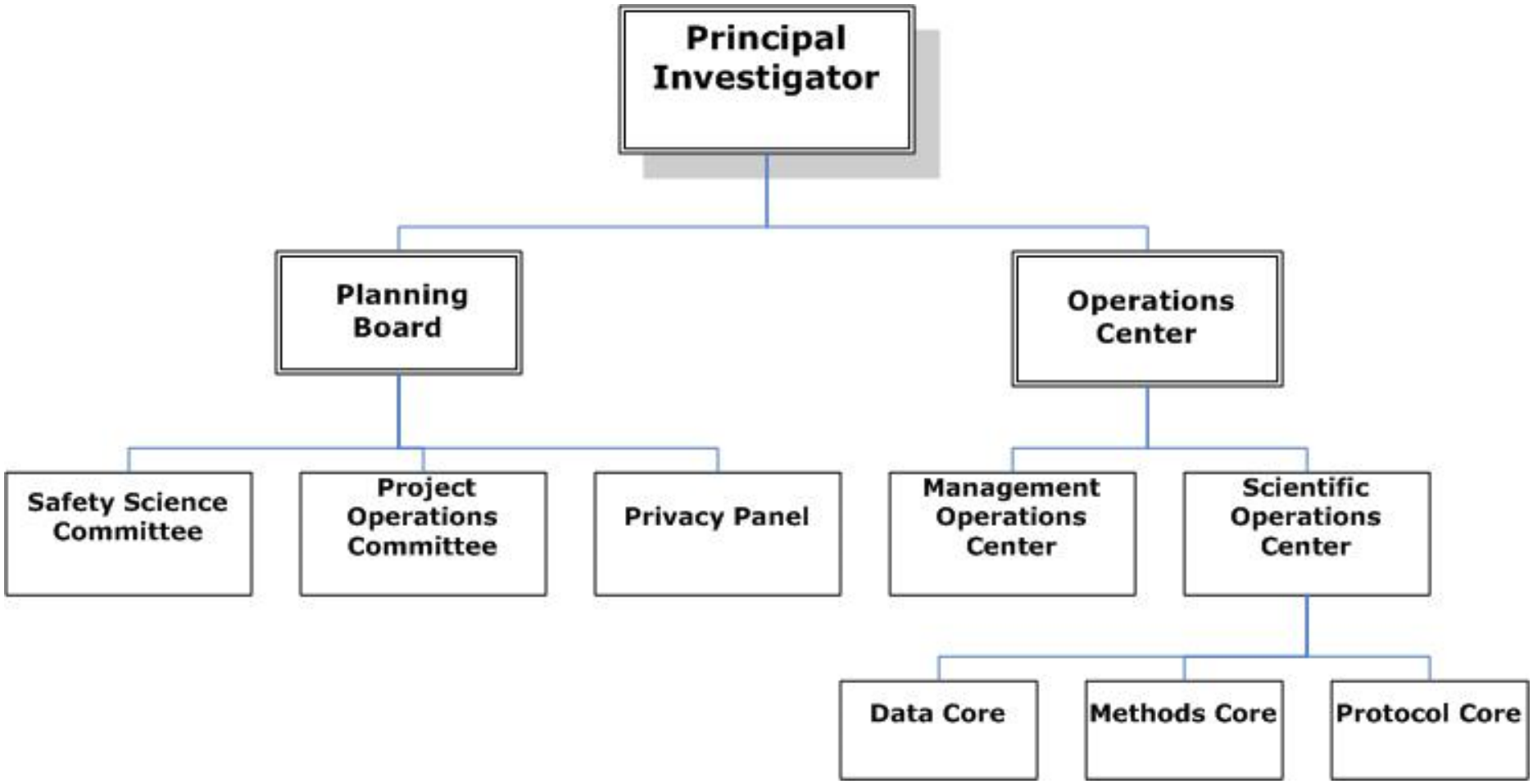
Coordinating Center



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Distributed data partners

Additional Partners

CRITICAL PATH INSTITUTE
Improving the Path for Innovative Therapies

AHIP
America's Health Insurance Plans

The University of Iowa COLLEGE OF PUBLIC HEALTH

UAB

Risk Sciences INTERNATIONAL

UIC

RUTGERS
Institute for Health

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Content expertise

~200, including:

- All Vaccine Safety Datalink Principal Investigators
- 12 AHRQ CERTs PIs
- 9 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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Principles/Policies

- Public health practice, not research
- Minimize transfer of protected health information and proprietary data
- Data partners participate voluntarily
- Maximize transparency
- Public availability of “workproduct”
  - Tools, methods, protocols, computer programs
  - Findings
- Confidentiality
- Conflict of Interest for individuals

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Data

- Developed and implemented a Common Data Model
- Created Mini-Sentinel Distributed Database v1, encompassing quality checked administrative and claims for **69 million individuals**
- Performed data inventory → prioritized list of data needs

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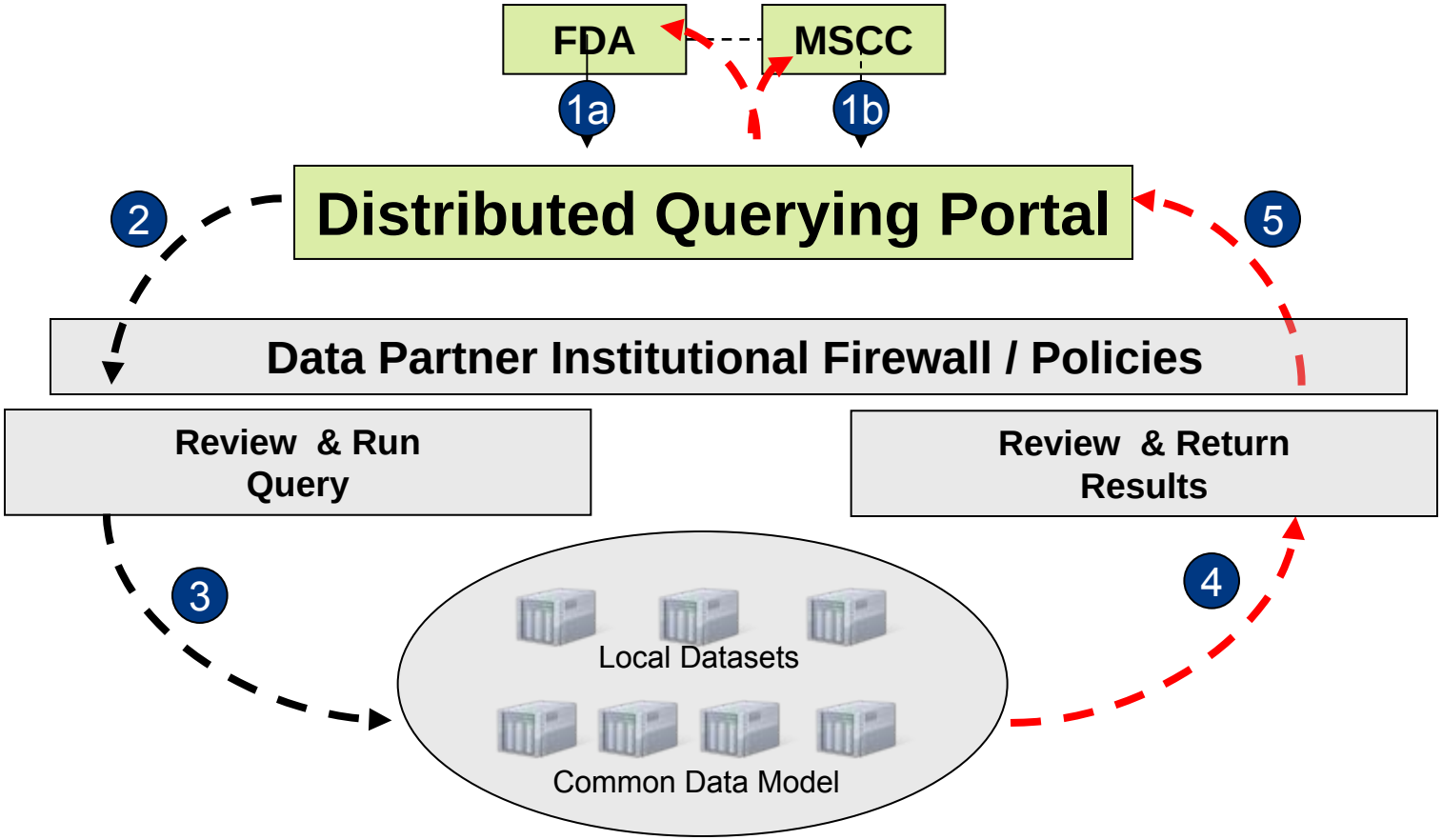
Distributed Querying



1a- Query directly submitted by FDA to the Distributed Querying Portal
1b- Query submitted by MSCC to Distributed Querying Portal on behalf of FDA
2- Data Partners retrieve the query on the Distributed Querying Portal
3- Data partners review and run query
4- Data partners review results
5- Data partners return results to Distributed Querying Portal for review by FDA and\or MSCC

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Active surveillance

- Created framework for safety surveillance study designs and a prioritized list of gaps
- Designed protocol for active surveillance of acute myocardial infarction following oral hypoglycemics
- Designed protocol to validate acute myocardial infarction using full text records.
  - Implementation under way!

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Methods development

- Epidemiology methods
  - Literature review completed for algorithms to identify 20 outcomes using coded health data
- Statistical methods (under way)
  - Better adjustment for confounding
  - Case based methods
  - Regression methods for sequential analysis

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Communication

www.minisentinel.org

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Next steps – active surveillance

- Drugs
  - Implement active surveillance protocol for acute MI related to oral hypoglycemics
  - Evaluate emerging safety issues for
    - New molecular entities (newly approved drugs)
    - Drugs that have been marketed for >2 years
  - Evaluate the impact of regulatory actions (e.g., restricted distribution)
- Vaccines (PRISM)
  - Develop sustainable successor to ad hoc active surveillance system developed for H1N1 vaccine safety surveillance by HHS, FDA, & CDC
  - Institute safety monitoring for a vaccine
  - Link to state immunization registries
  - Identify complementary data sources

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Next steps – data and methods

- Data
  - Update distributed data set quarterly
  - Add blood pressure, height, weight, tobacco use
  - Add selected laboratory test results
  - Evaluate methods for obtaining EHR data
- Methods
  - Test anonymous linkage between data partners
  - Develop additional statistical methods
  - Assess comparability of Mini-Sentinel data to national data sources

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