



**OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP**

FOUNDATION
FOR THE
National Institutes of Health

Observational Medical Outcomes Partnership

**Institute of Medicine of the National Academies
Community Update: Improving the Science of Drug Safety**

September 2, 2009

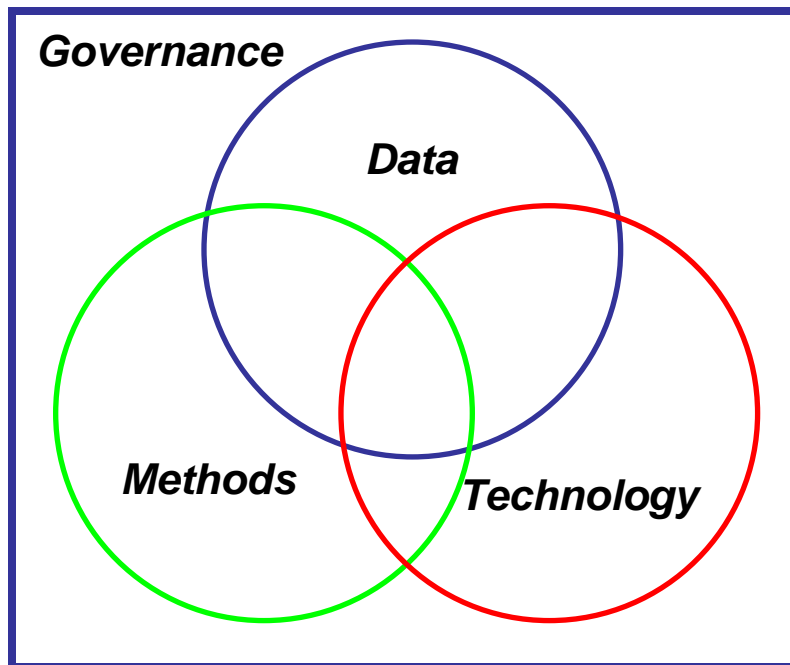
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Observational Medical Outcomes Partnership

A public-private partnership to serve the public health by testing whether multi-source observational data can improve our ability to assess drug safety and benefits.



- Assess the appropriate technology and data infrastructure required for systematic monitoring of observational data
- Develop and test the feasibility and performance of the analysis methods
- Evaluate required governance structures



OMOP Timeline

- **Phase 1: FEASIBILITY OF DATA INFRASTRUCTURE (Feb – July 2009)**
 - Establish a consistent framework to use across disparate observational data sources
 - Establish OMOP Research Community
- **Phase 2: FEASIBILITY OF ANALYSES (Aug – Dec 2009)**
 - Develop and test analysis methods within the OMOP Research Lab and other data environments
 - Establish standard data characterization procedures
 - Implement health outcomes of interest definitions
 - OMOP to facilitate comparisons across databases
- **Phase 3: PERFORMANCE MEASUREMENTS (Jan – July 2010)**
 - Evaluate performance of methods and data in identifying drug safety issues
 - OMOP to facilitate comparisons across databases
- **Phase 4: UTILITY OF ANALYSES & PROCESS (July – Dec 2010)**
 - Assess the effectiveness and usefulness of how the results and comparisons contribute to decision-making



OMOP Research Community

- **OMOP Research Core** - responsible for designing, developing and managing the execution of the approved research proposals
- **OMOP Research Lab** - used to manage analysis process across all data sources within the Research Core
- **Distributed Research Partners** - funded partners performing OMOP research within their own data environments
 - Implement the Common Data Model
 - Collaborate on the design of all studies
 - Execute protocols within their data environment
 - Report back summary analyses into OMOP research lab
 - Support interpretation and publication of results
- The broader scientific community can voluntarily participate in the **OMOP Extended Consortium**



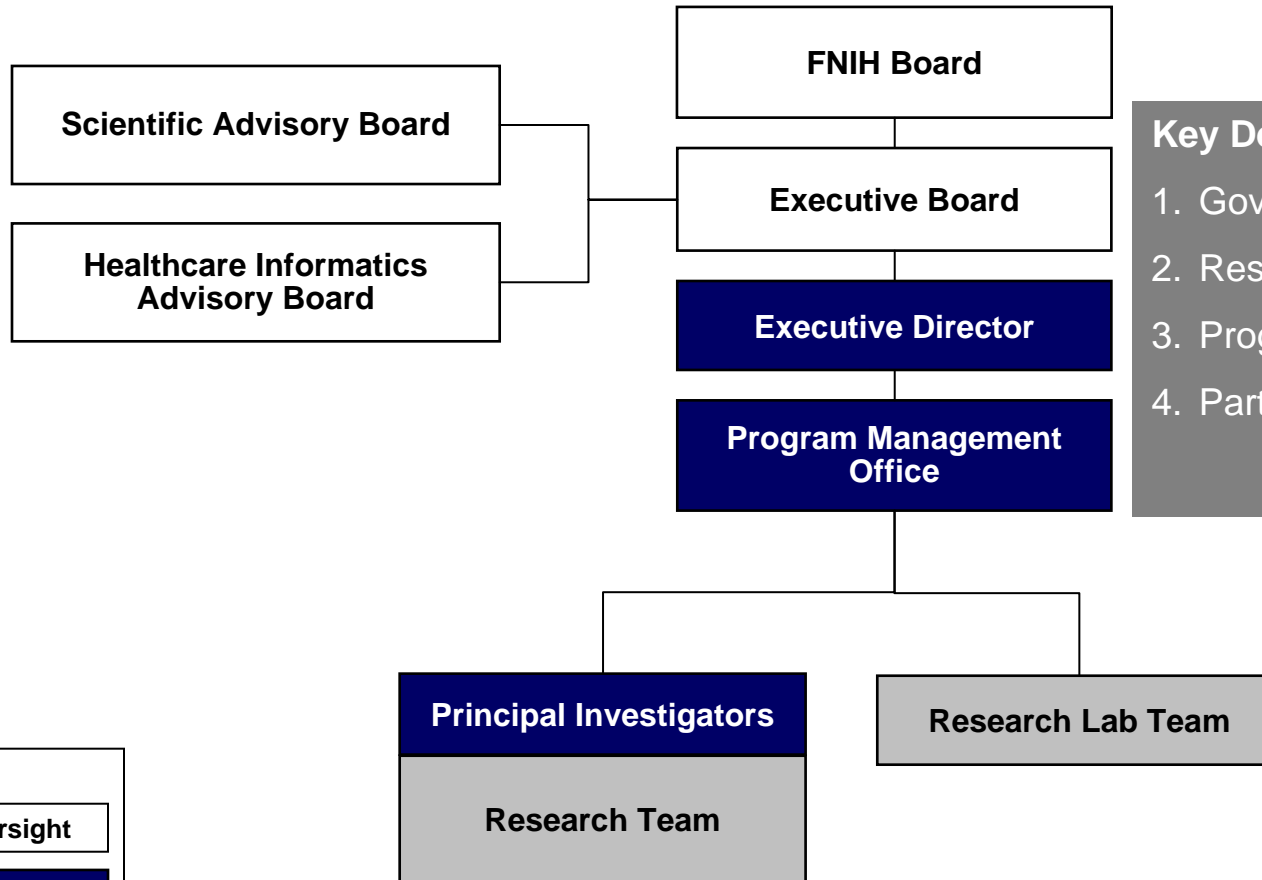
Enabling Methods Research and Development

- Develop new methods
- Implement and standardize existing approaches
- Adapt and apply techniques from other domains
- Evaluate the performance across disparate data sources

Analysis Method
Epidemiology designs
Cohort
Case-control
Case-crossover
Self-controlled case series
Sequential methods
Maximized sequential probability ratio test
Conditional Sequential Sampling Procedure
Disproportionality Analysis
Proportional reporting ratio
Multi-item Gamma Poisson Shrinker
Bayesian screening
Bayesian confidence propagation neural network
Adjusted residual score
Other methods
Local Control
Tree-based scan statistic
Statistical relational learning
Bayesian Logistic Regression
Information-theoretic similarity measure
Temporal pattern discovery
Other analytical considerations
Propensity score adjustment
False discovery rate
Matching and stratification

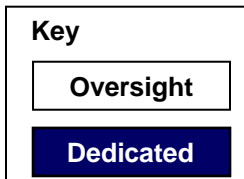


Governance



Key Design Elements:

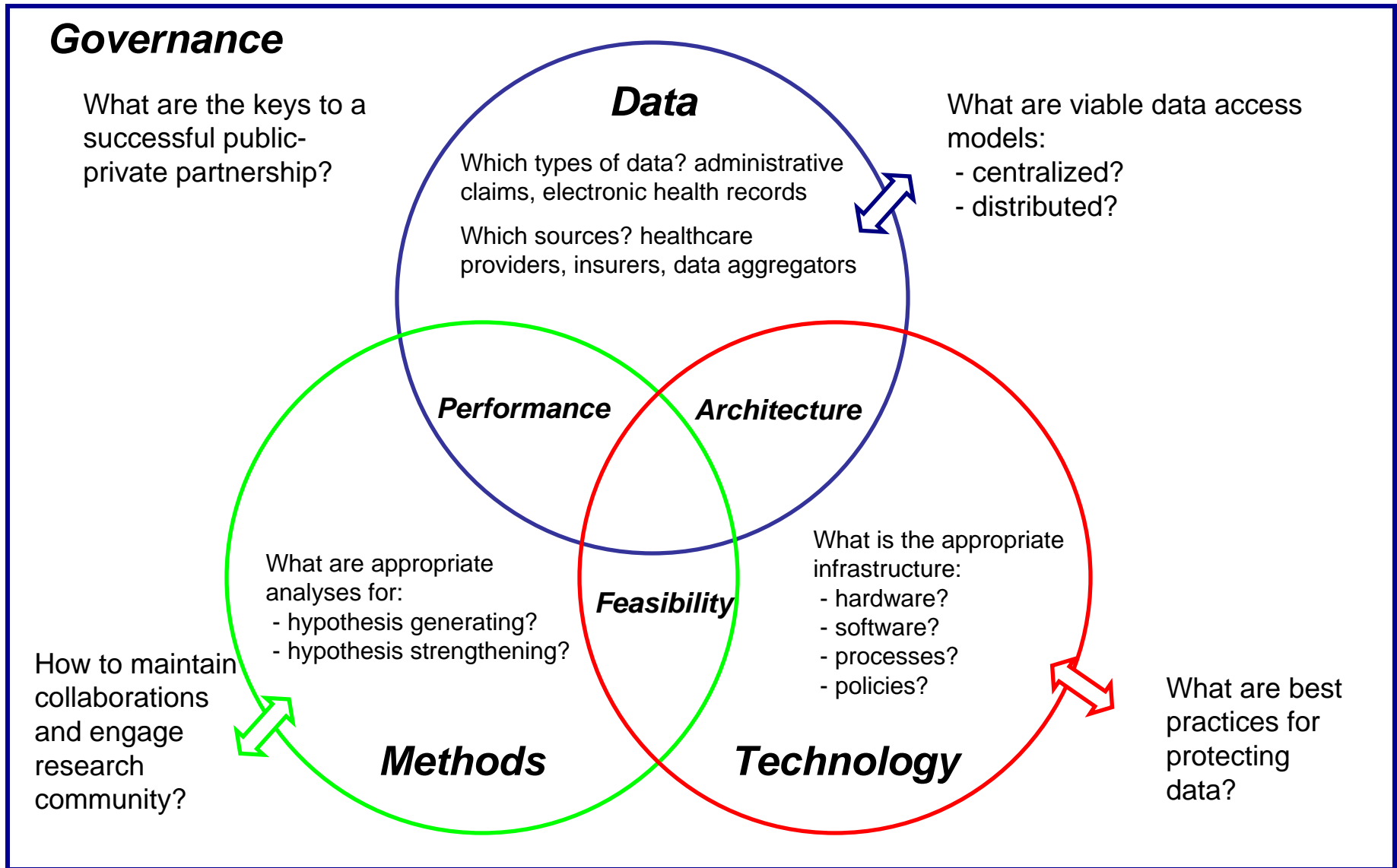
1. Governance and Oversight
2. Research Leadership
3. Program Management
4. Partners & Collaborators



- Industry, academic and other external resources



Outstanding questions for active surveillance





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