OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

Overview
ISPE Mid-Year Symposium

Thomas Scarnecchia
on behalf of OMOP research team
April 12, 2010

OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

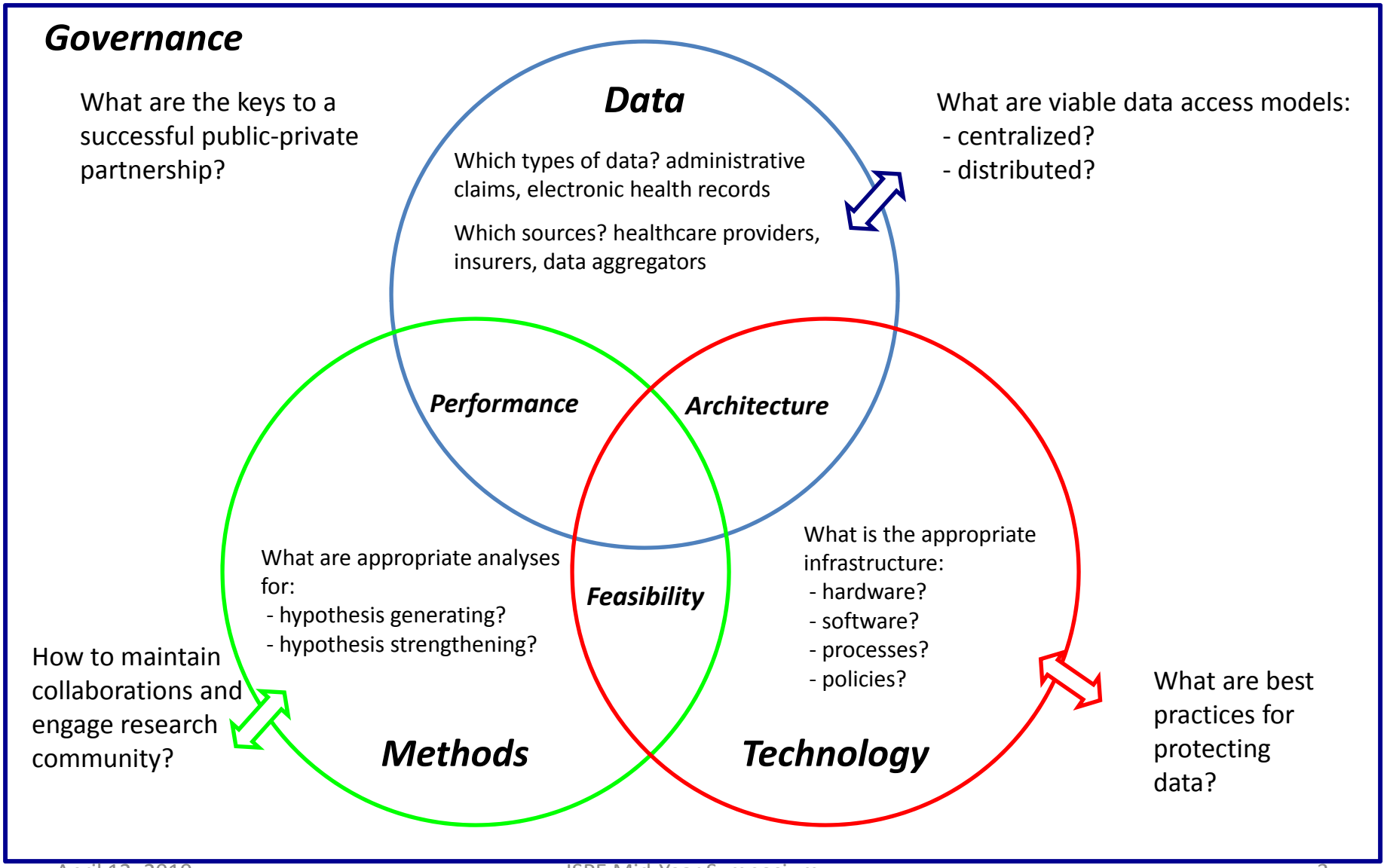
Observational Medical Outcomes Partnership

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

OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

Outstanding questions for active surveillance



OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

Research Investigators

The lead scientists for the OMOP project who guide and participate in the research across all project phases

Marc Overhage, MD, PhD: Director, Medical Informatics and Research Scientist, Regenstrief Institute, Inc.; Regenstrief Professor of Medical Informatics, Indiana University School of Medicine, CEO; President of the Indiana Health Information Exchange

Judy Racoosin, MD, MPH: Sentinel Initiative Scientific Lead, US Food and Drug Administration

Paul Stang, PhD, FISPE: Senior Director, Epidemiology, Johnson & Johnson Pharmaceutical Research and Development

Abraham G. Hartzema PharmD, MSPH, PhD, FISPE: Professor and Eminent Scholar, Pharmaceutical Outcomes & Policy, Perry A. Foote Chair in Health Outcomes Research, University of Florida College of Pharmacy

Patrick Ryan: Manager Drug Development Sciences, GlaxoSmithKline R&D

OMOP Co-Investigator

David Madigan, PhD: Professor of Statistics, Columbia University

OMOP Methods Lead

OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

OMOP research community

OMOP's research community requires active participation from all key stakeholders, including government, academia, industry, health care organizations, and patient groups.

Governance

- 10 Executive Board members, chaired by FDA and managed by Foundation for NIH
- 21 Advisory Board members
- Led by 6 research investigators and Program Management Office

Methods

- 17 methods collaborators

Data

- 5 active distributed partners
- 5 central databases included in the OMOP Research Lab
- Simulated, claims and EHR datasets

Technology

- Secure virtual research lab
- 2 data access models
- 6 different systems architectures

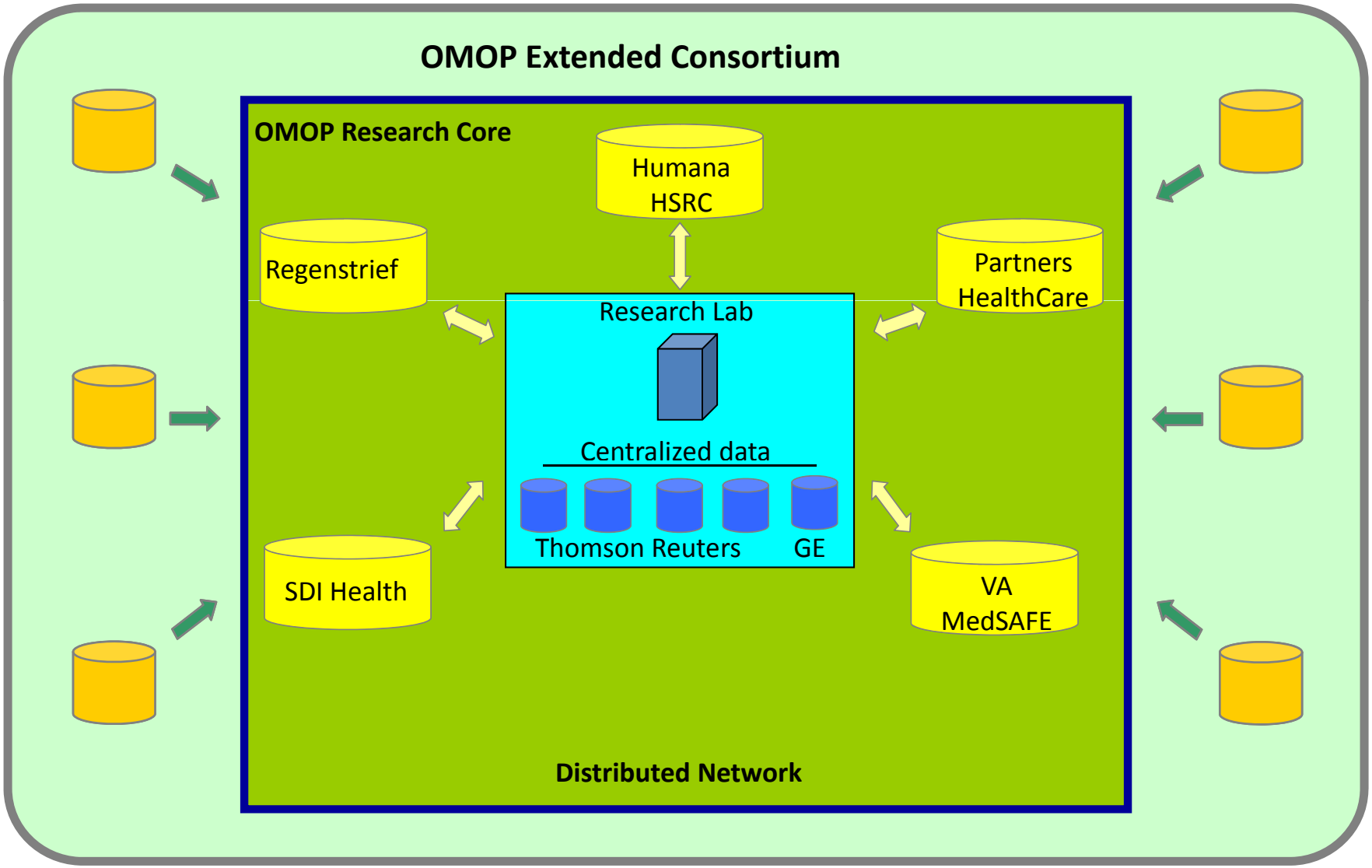
Over 100 researchers involved!

OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

OMOP Research Phases

- **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 data community



OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

Methods Library

Disproportionality analysis

- Proportional reporting ratio
- Multi-item Gamma Poisson Shrinker
- Bayesian confidence propagation neural network
- Temporal pattern discovery

Other novel approaches? OMOP Cup outreach effort

Exposure-based approaches

- Cohort Screening
- Incident user designs
- High dimensional propensity scoring
- Local control

Sequential methods

- Maximized sequential probability ratio test
- Conditional sequential sampling procedure

Case-based approaches

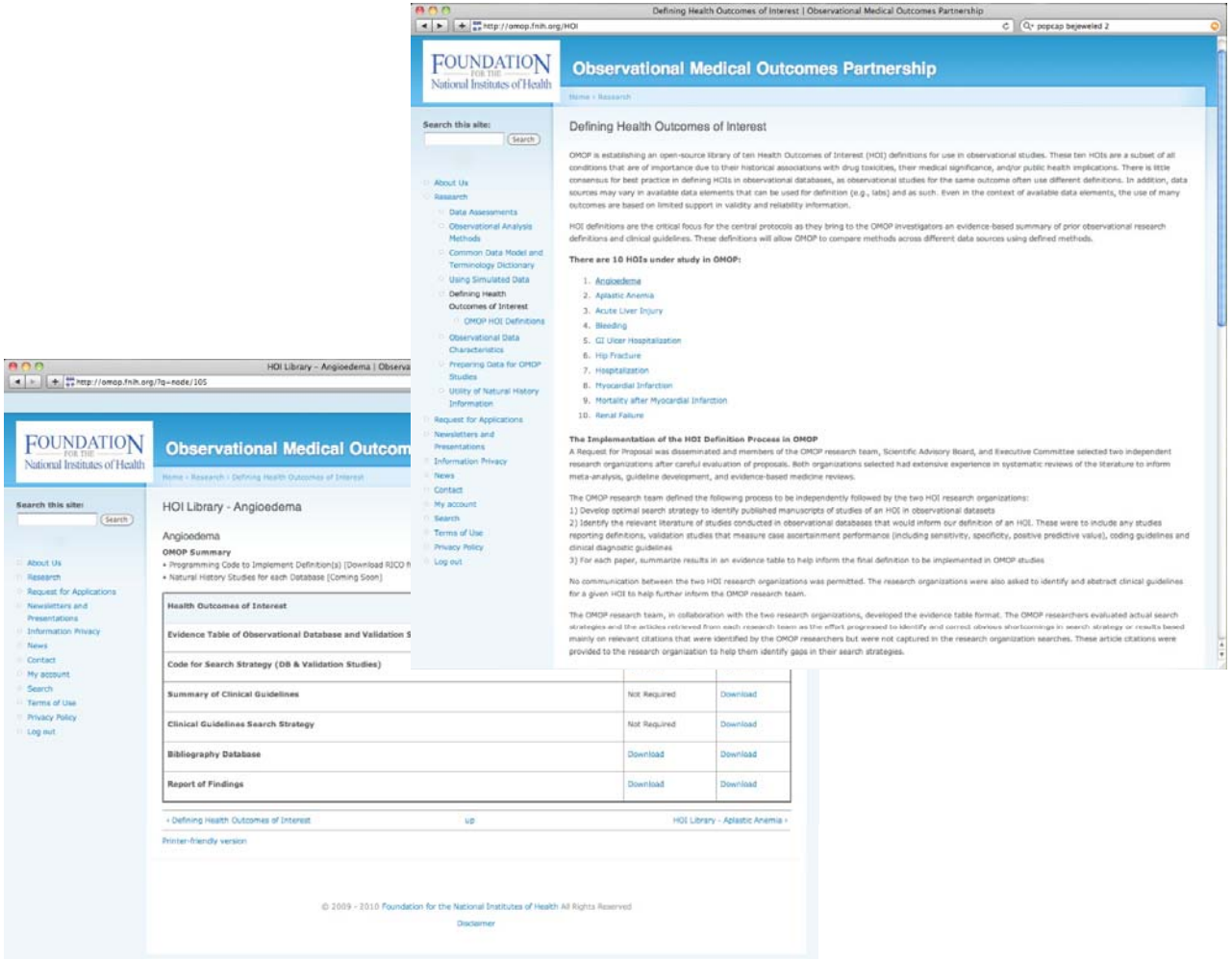
- Case-control surveillance
- Case-crossover
- Self-controlled case series

- Bayesian logistic regression
- Statistical relational learning

OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

Health Outcomes of Interest Library

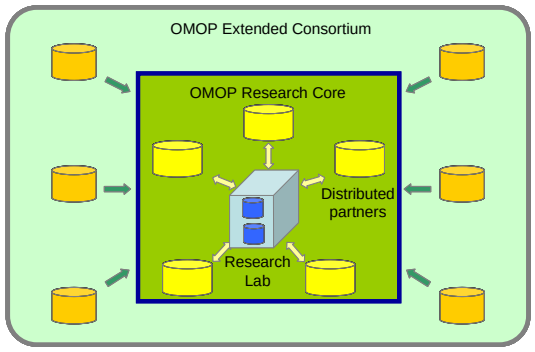
- Identified need for open-source library of definitions:
  - more than 1 per Health Outcomes of Interest (HOI)
  - literature review strategies
  - evidence tables
  - Software code to implement definitions
- OMOP is testing a process for defining HOIs
- Welcome contributions to the library



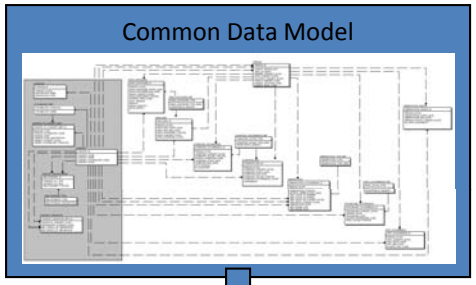
http://omop.fnih.org/HOI

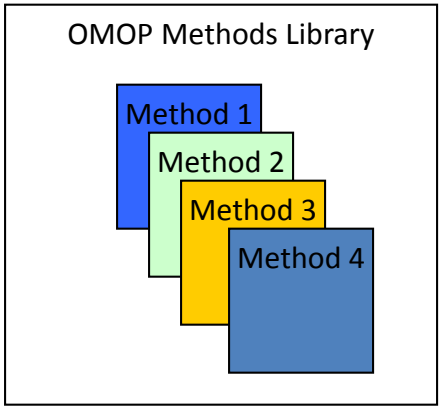
OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

OMOP research experiment workflow



Testing in each source:
-accumulating over time
-against the entire dataset





Testing in each source:
-accumulating over time
-against the entire dataset

Monitoring of Health Outcomes of Interest (HOIs)
- Angioedema
- Aplastic Anemia
- Acute Liver Injury
- Bleeding
- GI Ulcer Hospitalization
- Hip Fracture
- Hospitalization
- Myocardial Infarction
- Mortality after MI
- Renal Failure

Drugs
- ACE Inhibitors
- Amphotericin B
- Antibiotics
- Antiepileptics
- Benzodiazepines
- Beta blockers
- Bisphosphonates
- Tricyclic antidepressants
- Typical antipsychotics
- Warfarin

Identification of non-specified associations
- All outcomes in condition terminology
- 'Labeled events' as reference
  - Warning
  - Precautions
  - Adverse Reactions
  - Post Marketing Experience

OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP

Summary

- OMOP is designed to provide and test:
  - Broad stakeholder participation
  - Transparency in an open innovation model
  - Development of reproducible processes in data and analyses
  - Standards for data models, terminologies, and methods
  - A public-private partnership governance structure with support from advisory boards
  - Empirical evidence that will inform appropriate use and best practices

FOUNDATION FOR THE National Institutes of Health

Thank you

http://omop.fnih.org