OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

FOUNDATION FOR THE National Institutes of Health

Observational Medical Outcomes Partnership: Overview and Lessons Learned

Patrick Ryan
OMOP Research Investigator
on behalf of OMOP Research Team

Sentinel Initiative Public Workshop
11 January 2010

Observational Medical Outcomes Partnership

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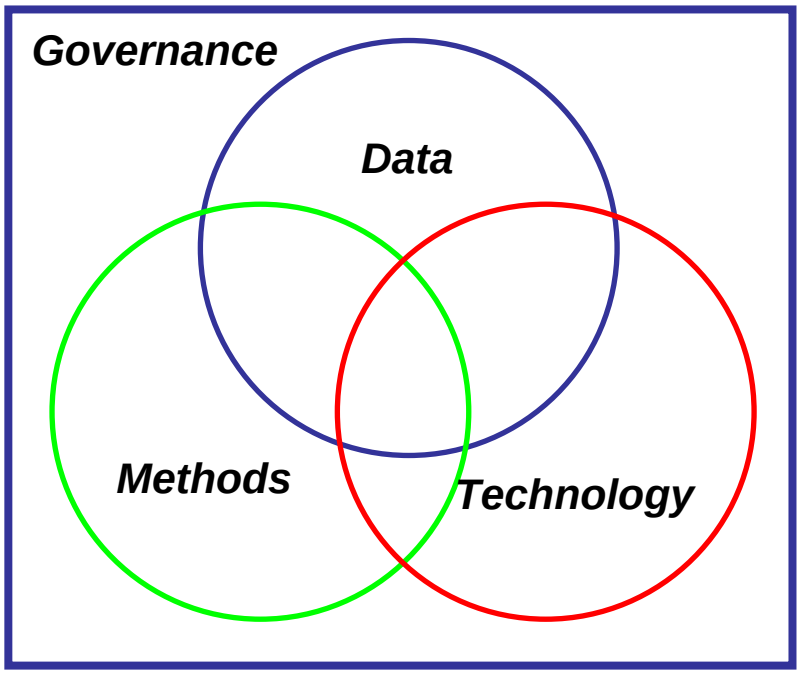
A public-private partnership to serve the public health by testing whether multi-source observational data can improve our ability to assess drug safety and benefits.



- 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

Outstanding questions for active surveillance

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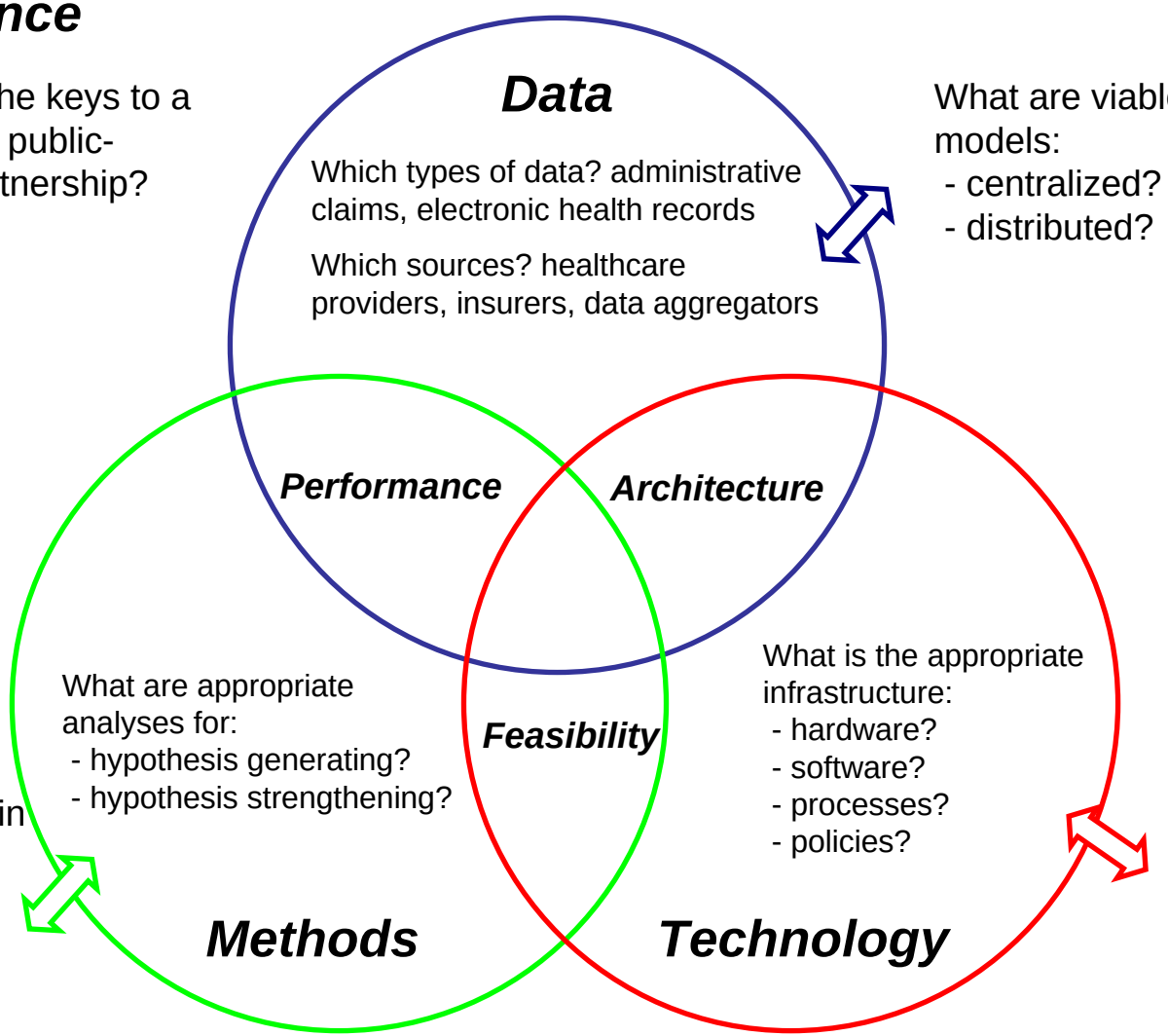
Governance

What are the keys to a successful public-private partnership?



What are viable data access models:
- centralized?
- distributed?

What are appropriate analyses for:
- hypothesis generating?
- hypothesis strengthening?

How to maintain collaborations and engage research community?

What is the appropriate infrastructure:
- hardware?
- software?
- processes?
- policies?

What are best practices for protecting data?

Breadth and diversity of OMOP research community

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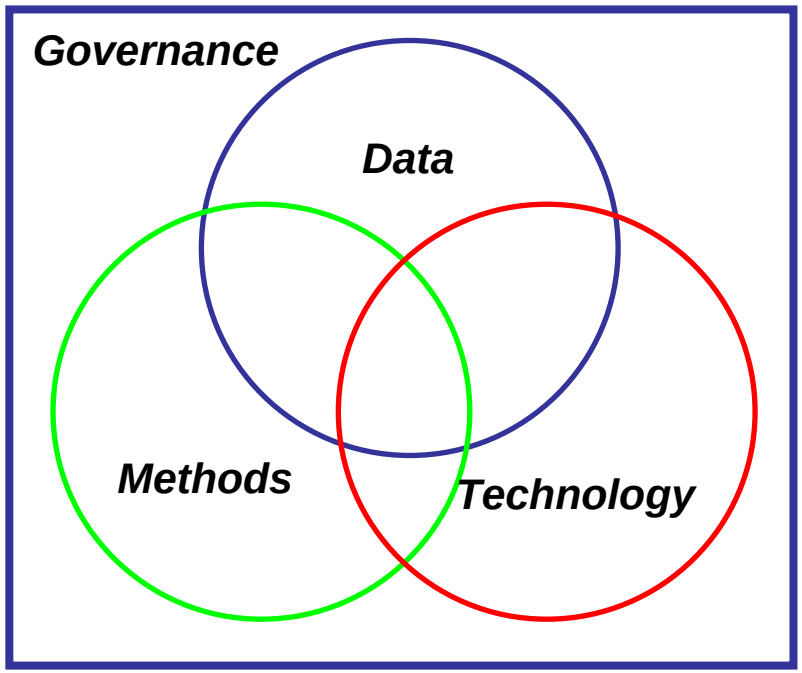
OMOP's research community requires active participation from all key stakeholders, including government, academia, industry, health care organizations, and patient groups.



Governance

- 10 Executive Board members, chaired by FDA and managed by Foundation for NIH
- 21 Advisory Board members
- Led by 5 research investigators and PMO

Methods

- 17 methods collaborators

Data

- 6 distributed partners, 5 central databases

Technology

- 2 data access models, 7 different systems architectures, including Research Lab

Over 100 partners collaborating to advance the science of drug safety!

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 assessment: Provider willingness for data access models

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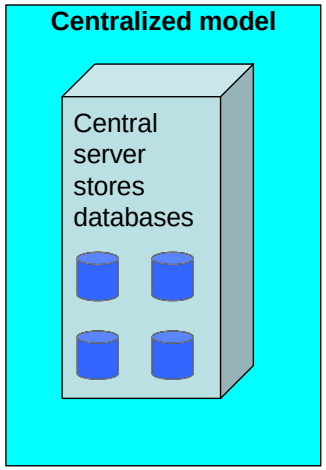
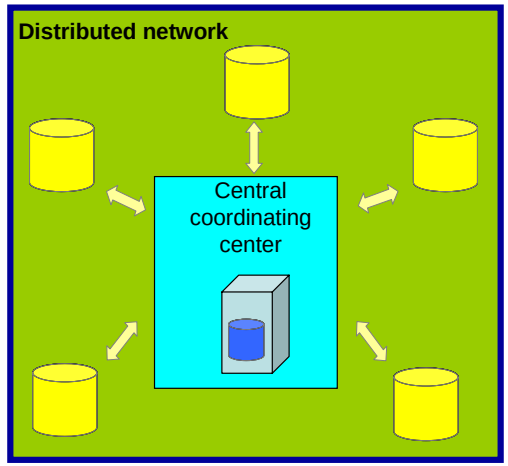
	Organizations (n=21)	Total population (m)
Centralized model: Provide your data externally to load into the Central Research Core IT environment	7	297
Federated model: Facilitate OMOP researchers access to execute queries directly (through firewall)	4	252
Distributed CDM Model: OMOP queries run locally by your research staff	17	470
Distributed protocol model: Develop and run your own queries locally	19	413

Each access model would have access to over 250m lives in aggregate, indicating the FDAAA mandate of 100m persons is achievable under all alternative infrastructures without full participation of potential data sources

Evaluating alternative data access models

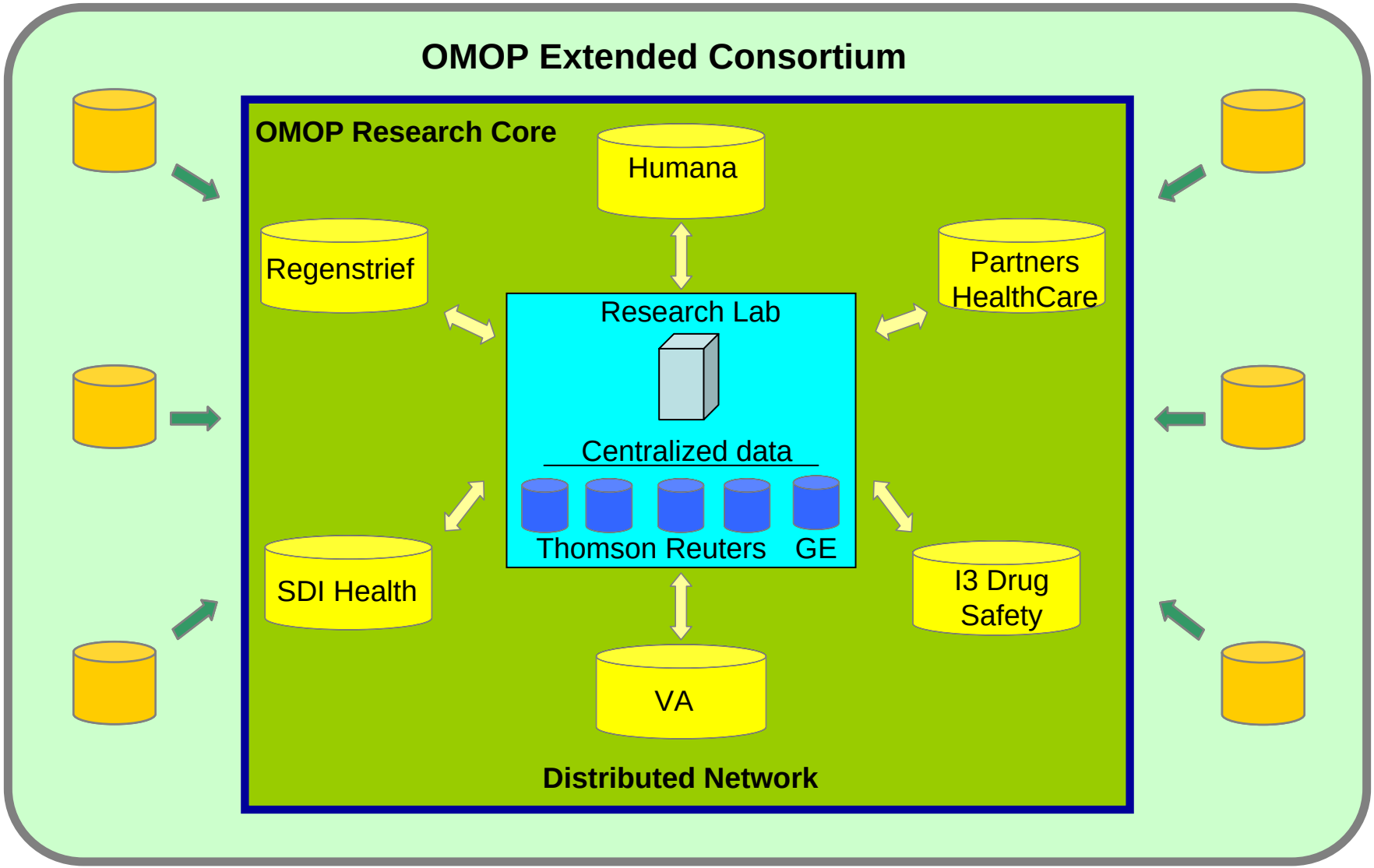




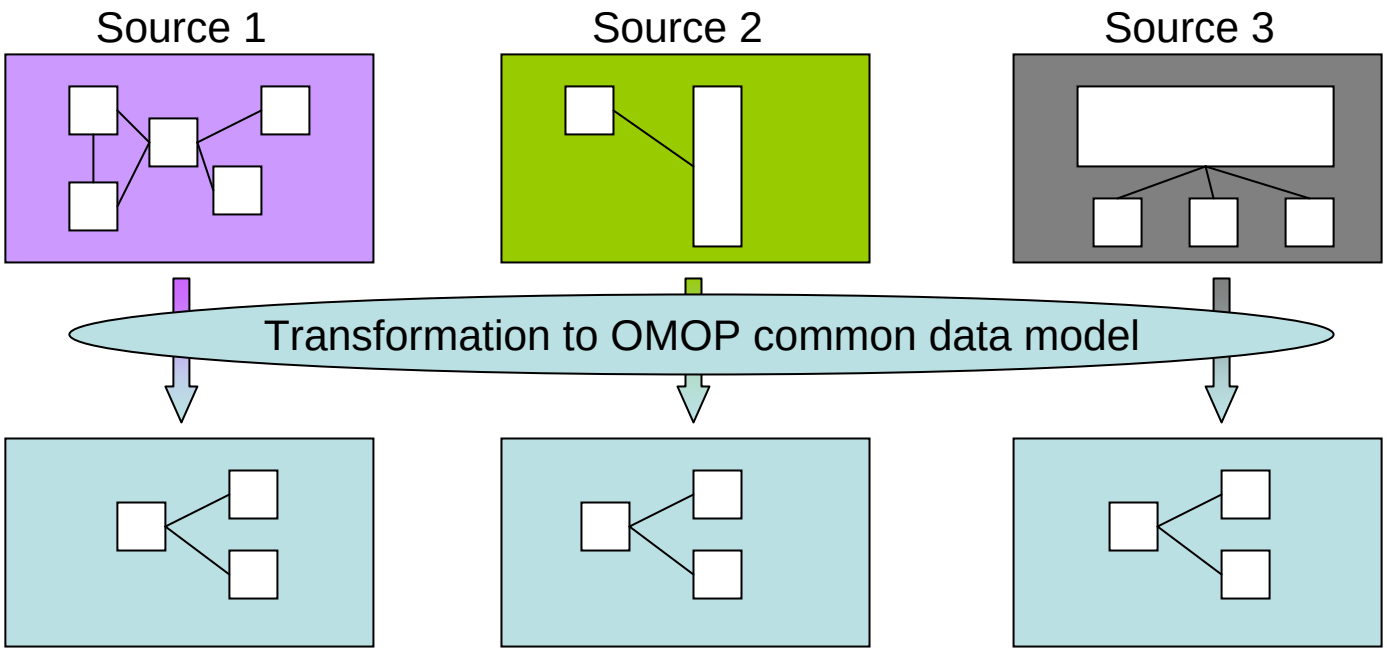
- Central systems architecture (network, hardware, software)
- Data owner provide access to de-identified patient-level data
- One or more databases stored independently (no data pooling)
- Analyses coordinated and conducted by central team across
- Central responsibility for validity of data and analyses

- Data owner conducts patient-level analyses within own systems architecture
- Central coordinating center manages protocol development and aggregates summary analysis results submitted by distributed partners
- Distributed partners assume responsibility for validity of data and analyses

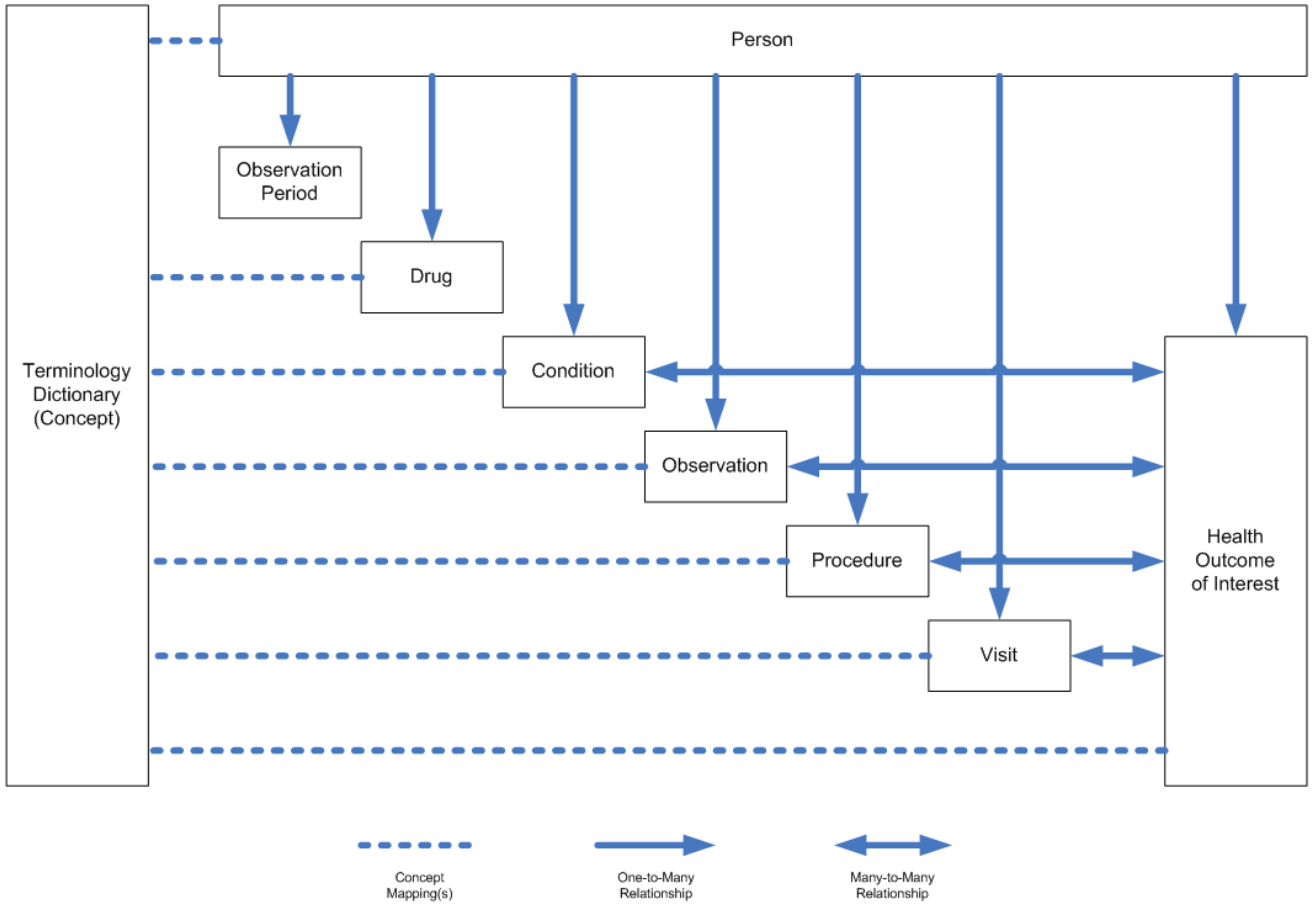
Diversity across OMOP data community



Role of common data model in OMOP Analysis process



Establishing a common data model

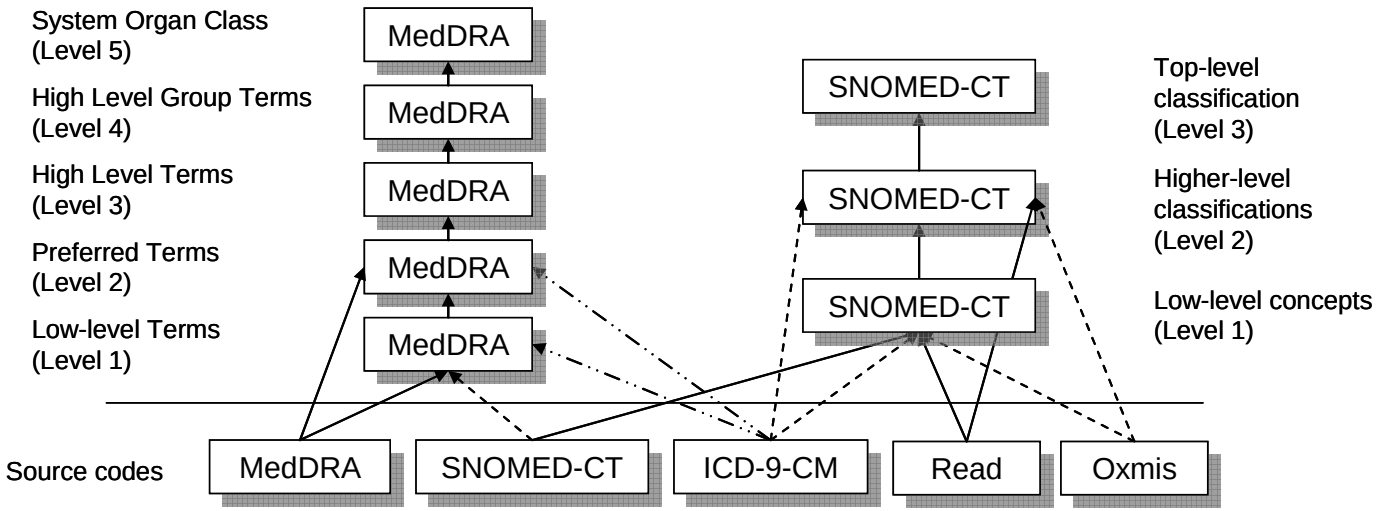


- Developed with broad stakeholder input
- Designed to accommodate disparate types of data (claims and EHRs)
- Applied successfully across OMOP data community

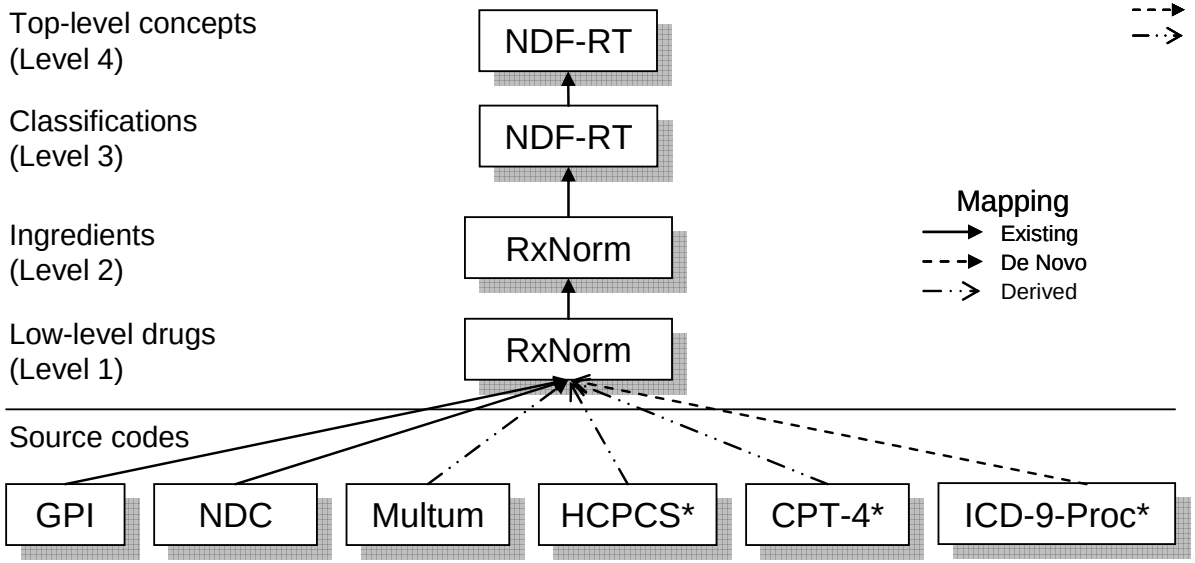
http://omop.fnih.org/CDMandTerminologies

Standardizing terminologies to accommodate disparate observational data sources

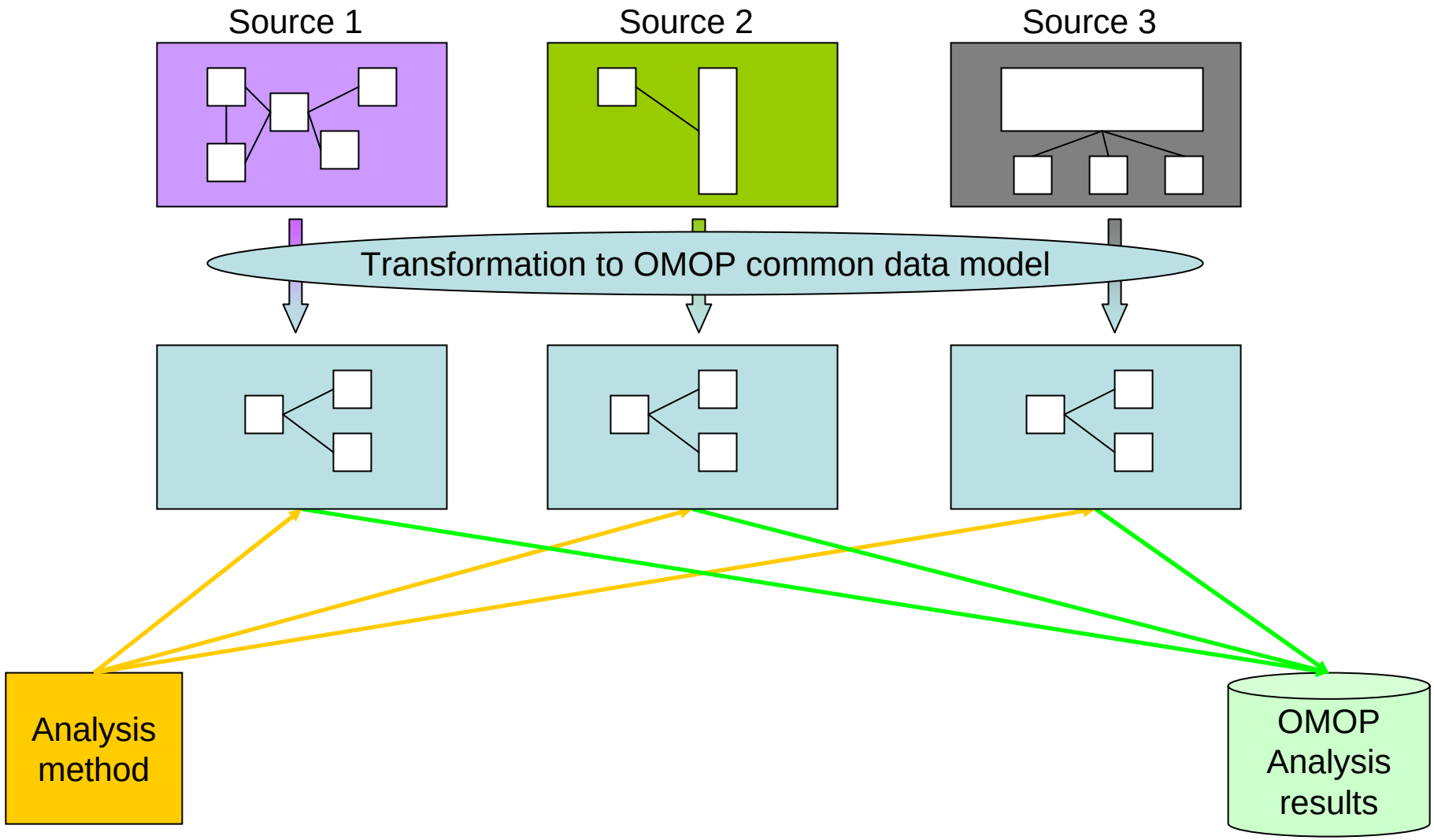
Standardizing conditions:



Standardizing drugs:



Role of common data model in OMOP Analysis process



Heart of OMOP's methodological research: Assessing the diversity in analysis methods

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Disproportionality analysis

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

Other novel approaches? OMOP Cup

Exposure-based approaches

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

Sequential methods

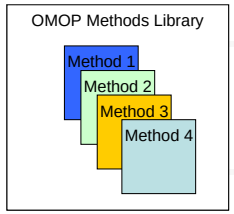
- Maximized sequential probability ratio test
- Conditional sequential sampling procedure
- Bayesian logistic regression
- Statistical relational learning

Case-based approaches

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

OMOP Methods Library at: http://omop.fnih.org/MethodsLibrary

OMOP Methods Library



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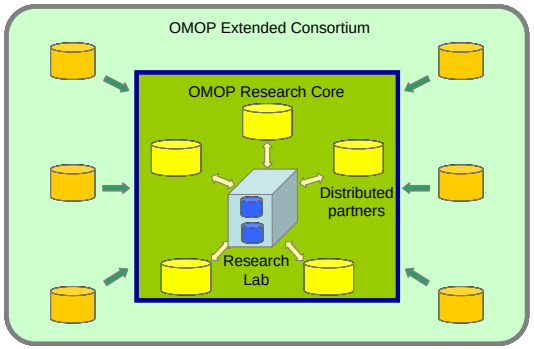
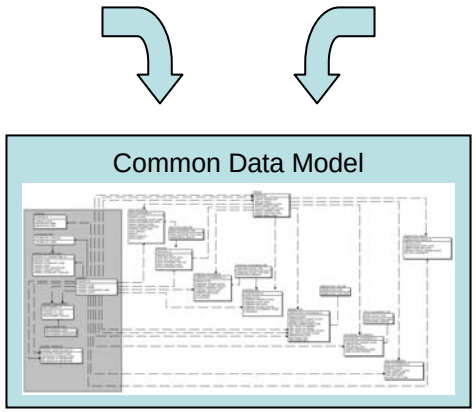
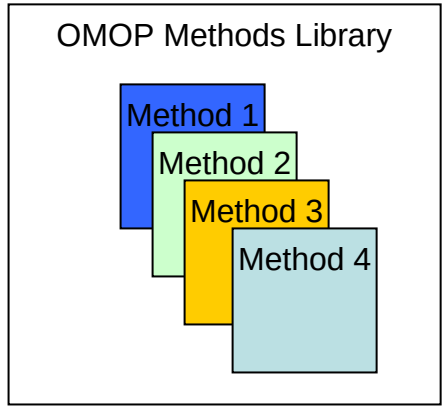
- Standardized procedures are being developed to analyze *any* drug and *any* condition
- All programs being made publicly available to promote transparency and consistency in research
- Methods will be evaluated in OMOP research against specific test case drugs and Health Outcomes of Interest

OMOP Methods Library at: http://omop.fnih.org/MethodsLibrary

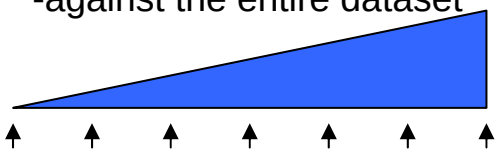
OMOP research experiment workflow







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



Health Outcomes of Interest
1. Angioedema
2. Aplastic Anemia
3. Acute Liver Injury
4. Bleeding
5. GI Ulcer Hospitalization
6. Hip Fracture
7. Hospitalization
8. Myocardial Infarction
9. Mortality after MI
10. Renal Failure

Drugs
1. ACE Inhibitors
2. Amphotericin B
3. Antibiotics
4. Antiepileptics
5. Benzodiazapines
6. Beta blockers
7. Bisphosphonates
8. Tricyclic antidepressants
9. Typical antipsychotics
10. Warfarin

Testing in each source:
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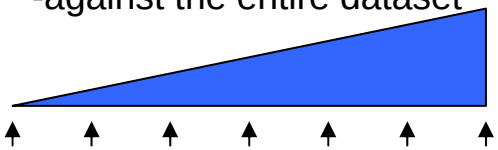

Non-specified conditions

-All outcomes in condition terminology

-'Labeled events' as reference
-Warning
-Precautions
-Adverse Reactions
-Postmarketing Experience

Contact information

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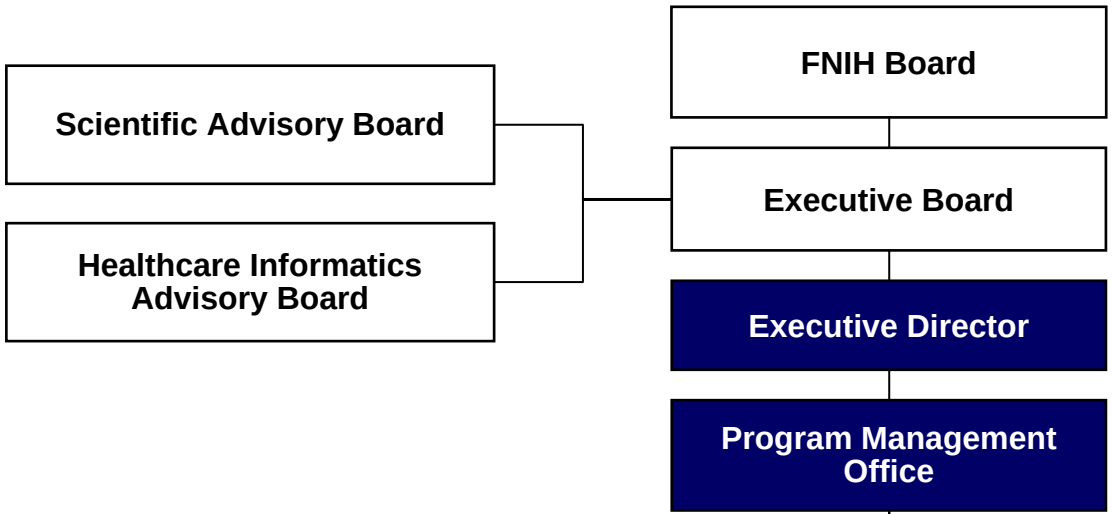
OMOP website: http://omop.fnih.org
OMOP Cup website: http://omopcup.orwik.com

Backups

Partnership Structure

Governance Provided by an Executive Board

Scientific and Informatics advisory boards inform decisions



- Industry, academic and other external resources
- System integrator team, ED and PMO oversight

Key
- Oversight
- Dedicated

Key Design Elements:

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

Executive Board

A multi-stakeholder group, the OMOP Executive Board oversees the operation of the Partnership.

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Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, Food and Drug Administration
Chair, Observational Medical Outcomes Partnership Executive Board

Rebecca Burkholder
Vice President of Health Policy, The National Consumers League

Sherine Gabriel, MD, MSc
Professor of Medicine and Epidemiology, The Mayo Clinic

Cynthia Gilman, JD
Special Assistant to the President for Advancement of Cancer Research and Collaborative Partnerships, Henry Jackson Foundation

Jesse L. Goodman, MD, MPH
Chief Scientist and Deputy Commissioner for Science and Public Health (acting),
Food and Drug Administration

Ronald L. Krall, MD
Former Senior Vice President and Chief Medical Officer, GlaxoSmithKline

Richard Platt, MD, MSc
Professor and Chair of the Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care

Stephen Spielberg, MD, PhD
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Brian Strom, MD, MPH
George S. Pepper Professor of Public Health and Preventive Medicine; Professor of Biostatistics and Epidemiology, Medicine, and Pharmacology; Chair, Department of Biostatistics and Epidemiology; Director, Center for Clinical Epidemiology and Biostatistics; Vice Dean for Institutional Affairs, University of Pennsylvania School of Medicine
Senior Advisor to the Provost for Global Health Initiatives, University of Pennsylvania

David Wheadon, MD
Senior Vice President, Pharmaceutical Research and Manufacturers of America (PhRMA)

Research Investigators

The Principal Investigators (PIs) are the lead scientists for the OMOP project and guide and participate in the research across all four project phases

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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

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

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

Patrick Ryan: Manager Drug Development Sciences, GlaxoSmithKline R&D
OMOP Co-Investigator

Foundation for the NIH Program Staff

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Executive Director, OMOP

Emily Welebob, RN, MS
Senior Program Manager, Research

Christian Reich, MD, PhD
Senior Program Manager, Technology

OMOP Statistics and Programming Team

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David Madigan, PhD
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OMOP Methods Lead

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Hayflinger Analytic Services

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Ron Mantha
Ephir, Inc.

Carlos Alzola
Data Insights

Emmanuel Angel
Angelic Productions

Reed George
etera solutions

Eric Lantz
University of Wisconsin-Madison

Advisory Boards

A Scientific Advisory Board (SAB) will provide independent review of and expert input into the scientific aspects of OMOP's activities.

- Elizabeth Andrews, RTI Health Solutions
- Andrew Bate, Pfizer
- Jesse Berlin, Johnson & Johnson
- Robert Davis, Kaiser Permanente
- Steve Findlay, Consumer Union
- Sean Hennessy, University of Pennsylvania
- Mike Katz, FDA patient representative
- Allen Mitchell, Boston University
- David Page, University of Wisconsin
- Ken Rothman, RTI Health Solutions
- Judy Staffa, FDA
- Alec Walker, WHISCON

A Health Informatics Advisory Board (HIAB) will provide independent review and expert input into the OMOP's technology governance and project requirements related to privacy and security, terminology and coding, data and data models.

- Col. Kevin Abbott
- Jeff Brown, Harvard Medical School
- Stan Huff, Intermountain Healthcare
- Diane MacKinnon, IBM (retired)
- Ken Mandl, Harvard University
- Clem McDonald, National Library of Medicine
- David Memel, Klaipeda Consulting
- Mitra Rocca, FDA
- Joy Pritts, Georgetown University
- Rob Thwaites, United BioSource Corporation

Research Collaborators: Data and Infrastructure

as of 11/12/09

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Organization	Team Leader	Activity
Computer Sciences Corporation	Dan Foltz	Research Lab
Department of Veterans Affairs Center for Medication Safety	Fran Cunningham, PharmD	Distributed Partner
GE Healthcare	Michael Lieberman, MD	Research Lab
i3 Drug Safety	Arnold Chan, M.D., Sc.D.	Distributed Partner
Indiana University - Regenstrief Institute	J. Marc Overhage, MD, PhD	Distributed Partner
Partners HealthCare System	Shawn Murphy, MD, PhD	Distributed Partner
ProSanos Corporation	Stephanie Reisinger	Simulated Data
SDI Health	Gregory Hess, MD, MBA, MSc	Distributed Partner
Thomson Reuters	Stella Chang, MPH	Research Lab
University of Miami-Humana Health Services Research Center	Vinit Nair, BS Pharm., MS, RPh	Distributed Partner

Research Collaborators: Methods

as of 11/12/09

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Organization	Team Leader	Activity
Columbia University	David Madigan, PhD	Methods Lead
Eli Lilly and Company	Karin L. Benoit	Methods Partner
GPRD Group of the MHRA	John Parkinson, BSc, PhD	Methods Partner
Harvard Pilgrim Health Care Institute	Lingling Li, PhD	Methods Partner
Indiana University - Regenstrief Institute	Siu L. Hui, PhD	Methods Partner
M Alan Brookhart, PhD and SAS Institute	M. Alan Brookhart, PhD	Methods Partner
Merck Research Laboratories	Dr. A. Lawrence Gould	Methods Partner
ProSanos Corporation	Stephanie Reisinger	Methods Partner
Risk Benefit Statistics LLC	Robert L. (Bob) Obenchain, PhD, FASA	Methods Partner
RTI International	Suzanne L. West, MPH, PhD	HOI Library
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United BioSource Corporation	Matthew W. Reynolds, PhD	HOI Library
University of North Carolina at Chapel Hill	Stacie Dusetzina	HOI Library
University of Utah	Brian Sauer, PhD	Methods Partner
University of Wisconsin-Madison	David Page, PhD	Methods Partner
Uppsala Monitoring Center	Niklas Norén, PhD	Methods Partner

ENGELBERG CENTER for Health Care Reform at BROOKINGS

Sentinel Initiative Public Workshop

Monday, January 11, 2010