

OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

OMOP Overview and Insights

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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



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

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

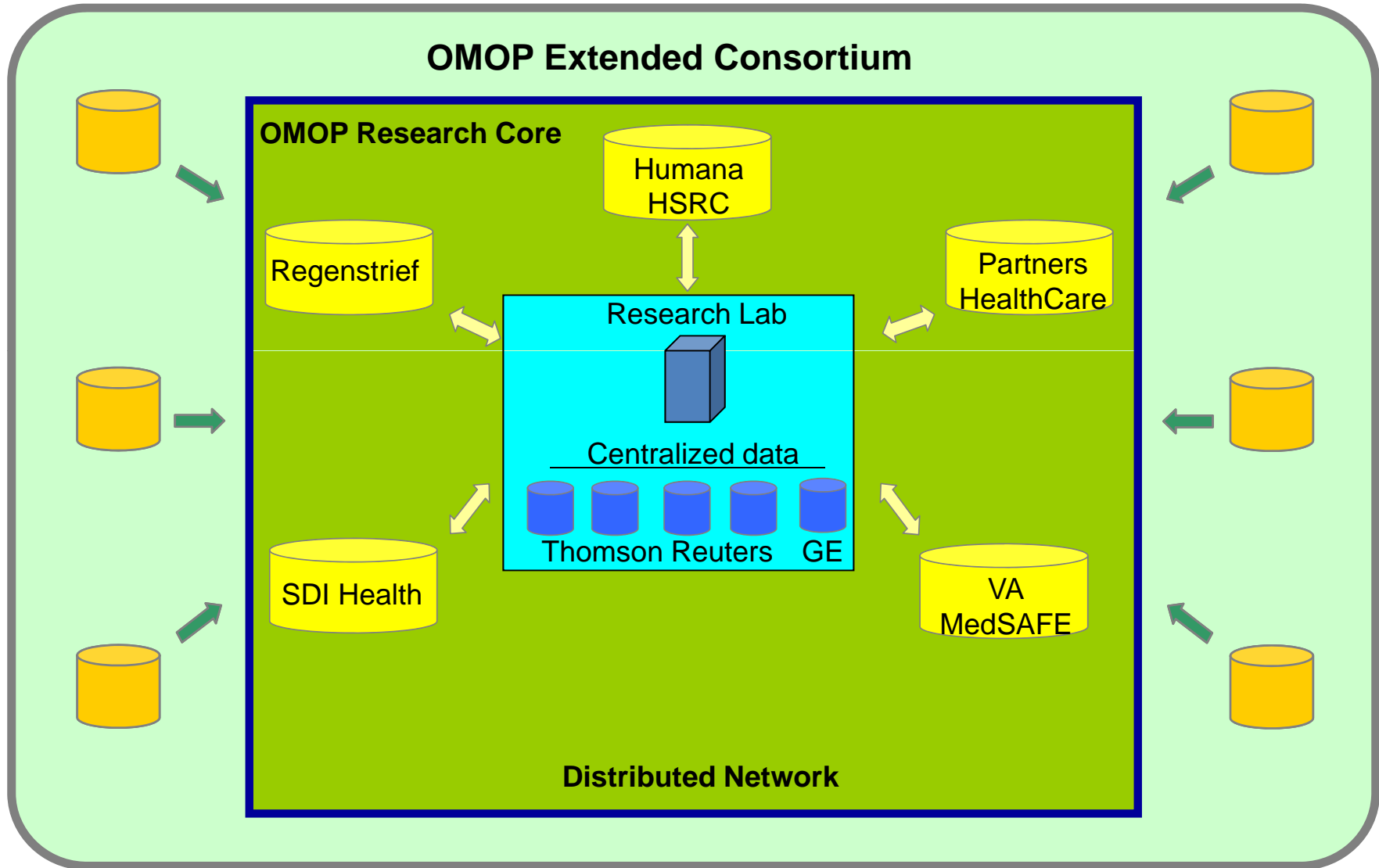
Over 100 researchers involved



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



OMOP's Methods Landscape

Disproportionality Analysis

	<i>AE j = Yes</i>	<i>AE j = No</i>
Drug <i>i</i> = Yes	<i>a</i> =20	<i>b</i> =100
Drug <i>i</i> = No	<i>c</i> =100	<i>d</i> =1080

- Distinct Patients
 - SRS
 - Modified SRS
- X
- MGPS
 - BCPNN
 - PRR
 - Chi
 - etc.
- X
- Stratified

- Temporal Pattern Discovery (WHO)

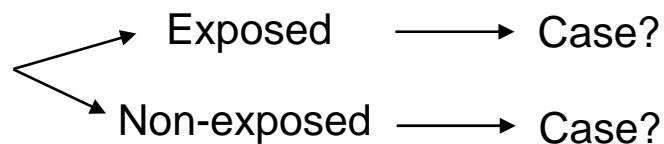
Sequential Methods

	<i>AE j = Yes</i>	<i>AE j = No</i>
Drug <i>i</i> = Yes	<i>a</i> =20	
Drug <i>i</i> = No		

← Compare to baseline Poisson

- Maximized Sequential Probability Ratio Test (MaxSPRT)
- Conditional Sequential Sampling Procedure (CSSP)

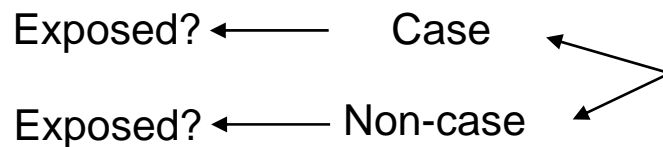
Exposure Based Methods



- Observational Screening
- HSIU Cohort Method
- Incident User Designs
- High-Dimensional Propensity Scoring
- Local Control

OMOP's Methods Landscape

Case Based Methods



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

Other Methods

- Hi-Dimensional logistic regression
- Statistical relational learning

Future Methods

- Multivariate self-controlled case series
- Case-time control
- Lasso propensity scoring
- Online algorithms
- OMOP Cup (50+ submissions)



OMOP Methods Library

<http://omop.fnih.org/MethodsLibrary>

The screenshot shows the OMOP Methods Library website. The header includes the logo for the Foundation for the National Institutes of Health and the text "Observational Medical Outcomes Partnership". The main content area is titled "OMOP Methods Library - Download Methods" and features a list of available downloads and guidelines. The list includes:

- Disproportionality Analysis Method - OMOP Research Team**
 - Disproportionality Analysis Method specification 7Dec 2009
 - Disproportionality Analysis Method Source Code and Examples 2Feb 2010
 - Disproportionality Analysis Feasibility Test #1 17Jan 2010
 - Disproportionality Analysis Feasibility Test #2 17Jan 2010
- Multi-Set Case-Control Estimation - OMOP Research Team**
 - Multi-set case-control Method specification 7Dec 2009
 - Multi-set case-control Method Source Code and Examples 2Feb 2010
 - Multi-set case-control Feasibility Test #1 17Jan 2010
 - Multi-set case-control Feasibility Test #2 17Jan 2010
- Bayesian Logistic Regression - OMOP Research Team**
 - Bayesian logistic regression specification 2Feb 2010

- 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



Health Outcomes of Interest Library

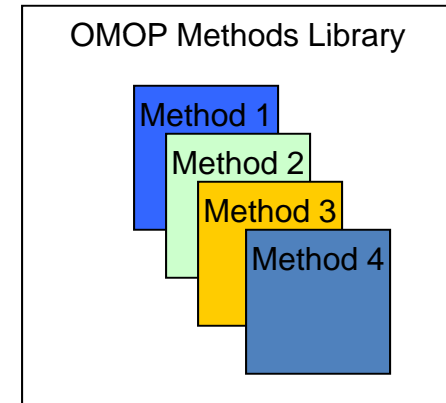
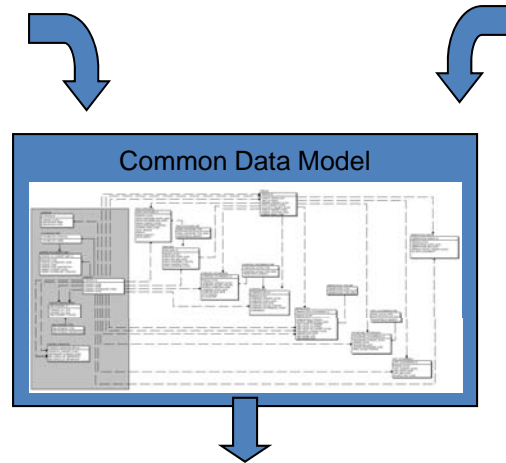
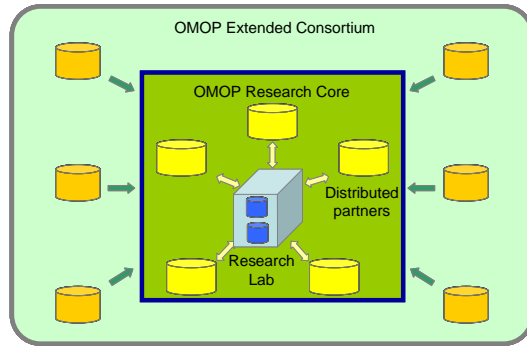
- Identified need for open-source library of definitions:
 - more than 1 per Health Outcomes of Interest (HOI)
 - literature review strategies
 - evidence tables
 - Software code to implement definitions
- OMOP is testing a process for defining HOIs
- Welcome contributions to the library

The screenshot shows the OMOP website interface. At the top, it says 'Observational Medical Outcomes Partnership' and 'Defining Health Outcomes of Interest'. A search bar is visible. The main content area is titled 'Defining Health Outcomes of Interest' and contains introductory text about OMOP's mission. A list of 10 HOIs under study is provided, followed by a section on the implementation process. At the bottom, a table lists resources available for download.

	Not Required	Download
Clinical Guidelines Search Strategy	Not Required	Download
Bibliography Database	Download	Download
Report of Findings	Download	Download

<http://omop.nih.org/HOIDefinitions>

OMOP Research Experiment Workflow



- 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



OMOP Insights

- The establishment of the network of diverse data holding organizations yielded insights into the capabilities needed to be a successful active surveillance site
 - Minimum technology requirements to support analysis of large-scale databases
 - Staff requirements needed to set up and operate an active surveillance site
 - The importance of investigators at each partner site to contribute to the understanding of the variability seen from one data source to another
 - Good governance - the need to balance transparency with participation

OMOP Insights

- Further research is needed to assess variability across databases and identify the minimum common data requirements for active surveillance
 - We are only beginning to understand the complexity of the interaction of the observational data structure and the research methods for active drug surveillance
 - Statistical and systematic analysis approaches to assess data quality and variability show early potential
 - Visualization and summarization techniques are needed to enhance the use of these analyses to extract as much knowledge as possible
 - Having a lot of data does not make it easier to answer drug safety questions

OMOP Insights

- Sustainable processes and community support are required to maintain the mappings between the various medical vocabularies encountered across a network of active surveillance databases
 - OMOP has developed specifications for implementation of standard vocabularies for observational data analysis
 - Since vocabularies are ever changing, frequent updates to mappings are required
 - We feel as if we are breaking new ground in using vocabularies in observational analysis
 - Expertise is very hard to find

OMOP Insights

- Sustainable processes and community support are needed to expand the library of available Health Outcomes of Interest definitions
 - A consensus based approach similar to standards development is the first step
 - Current practice of using literature and manually revisiting source records is not scalable
 - Utilization of automated techniques to create HOI definitions should be explored

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

OBSERVATIONAL
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Thank You!

FOUNDATION
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National Institutes of Health

<http://omop.fnih.org>



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