

**OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP**

OMOP Extended Consortium
Meeting

April 22, 2010

OMOP Extended Consortium

What is it?

- A scientific community around drug-outcome research using large scale observational data (administrative claims, electronic health records)

Who can participate?

- Any stakeholder: industry, government, academia, payers, healthcare organizations, etc.

What can you do?

- Access the OMOP Extended Consortium research community
- Develop new tools and analytical methods
- Contribute to the Health Outcomes of Interest library
- Apply methods to your data and contribute analysis results
- Share learnings and perspectives

How can I get involved?

- This is voluntary participation, there is no funding available
- There are some guidelines to acknowledge before getting started

Today's Agenda – April 22, 2010

- Welcome
- OMOP Overview & Research Goals
- OMOP Extended Consortium Purpose
- OMOP Toolkit
 - Common Data Model
 - Standard Terminologies
 - Data Characteristics
 - Health Outcomes of Interest
 - Analysis Methods
 - Simulated Data
- What's Next?
- Questions

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OMOP Overview
& Research Goals

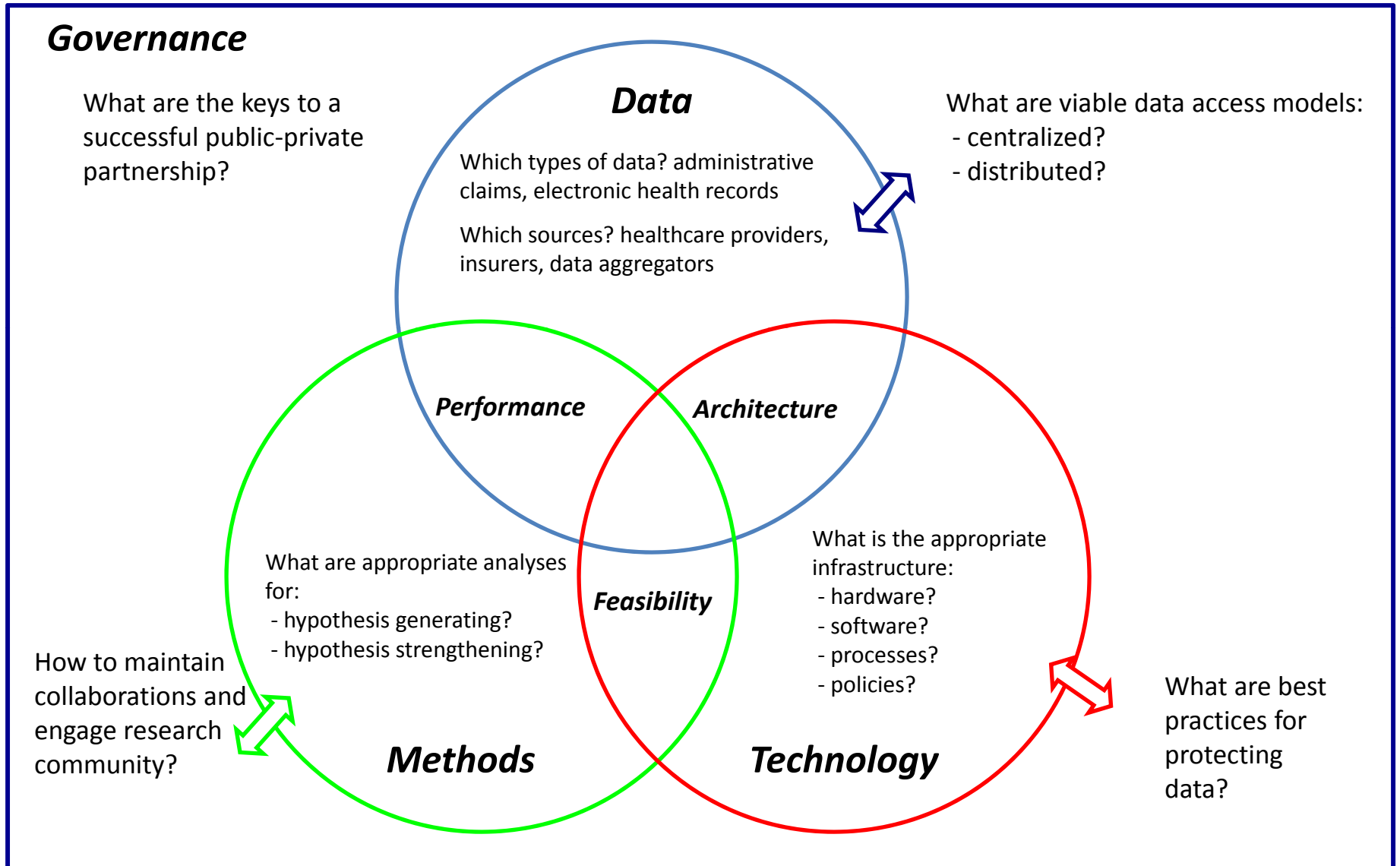
Observational Medical Outcomes Partnership

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.

Objectives:

- 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



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 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 and 21 Advisory Board members - <http://omop.fnih.org/governance>
- Led by 6 research investigators
- Program Management Office & Statistical / Programming Teams

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!

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

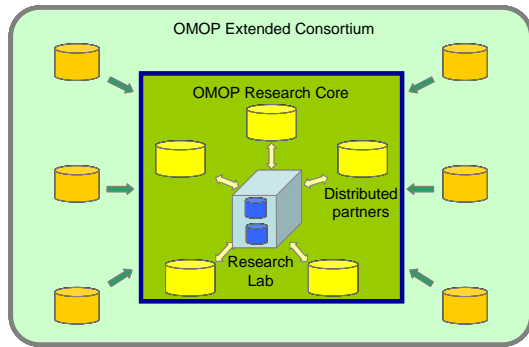
Research Collaborators: Data and Infrastructure

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
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

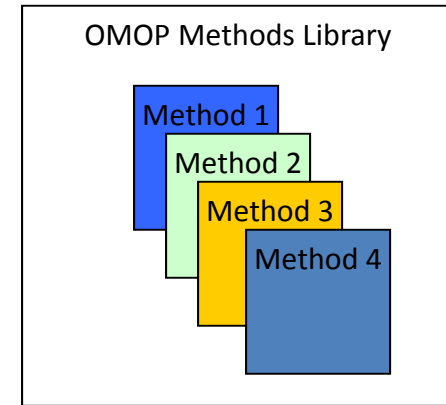
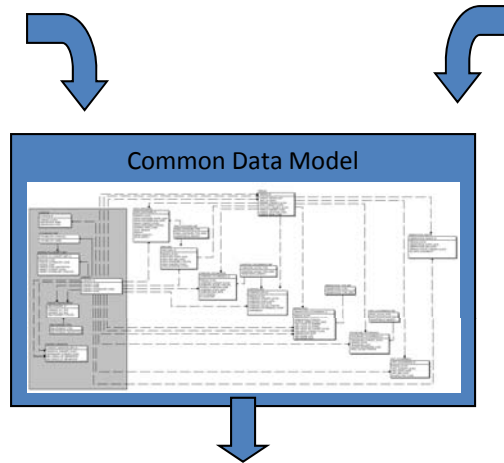
Research Collaborators: Methods

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
Slone Epidemiology Center at Boston University	David Kaufman, ScD	Methods Partner
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

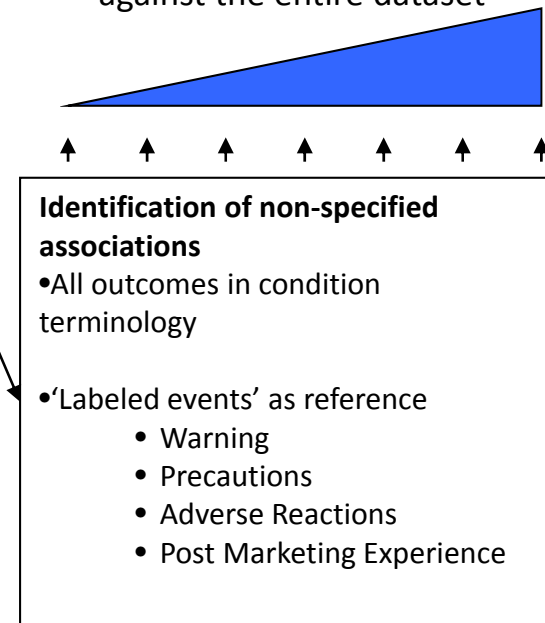
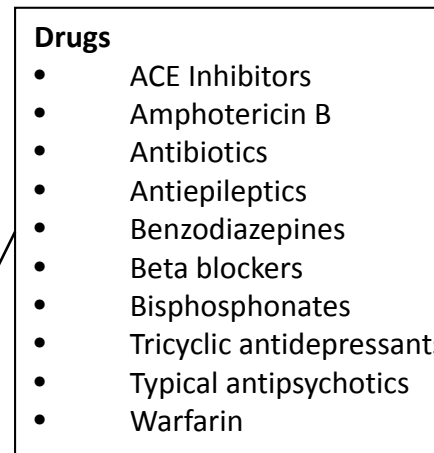
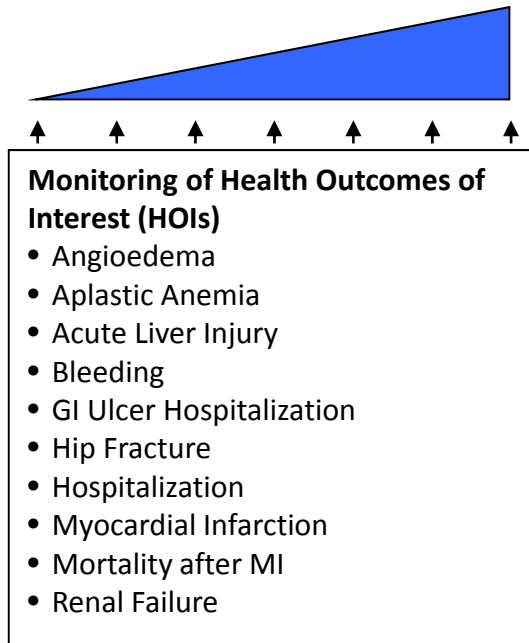
OMOP research experiment workflow



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



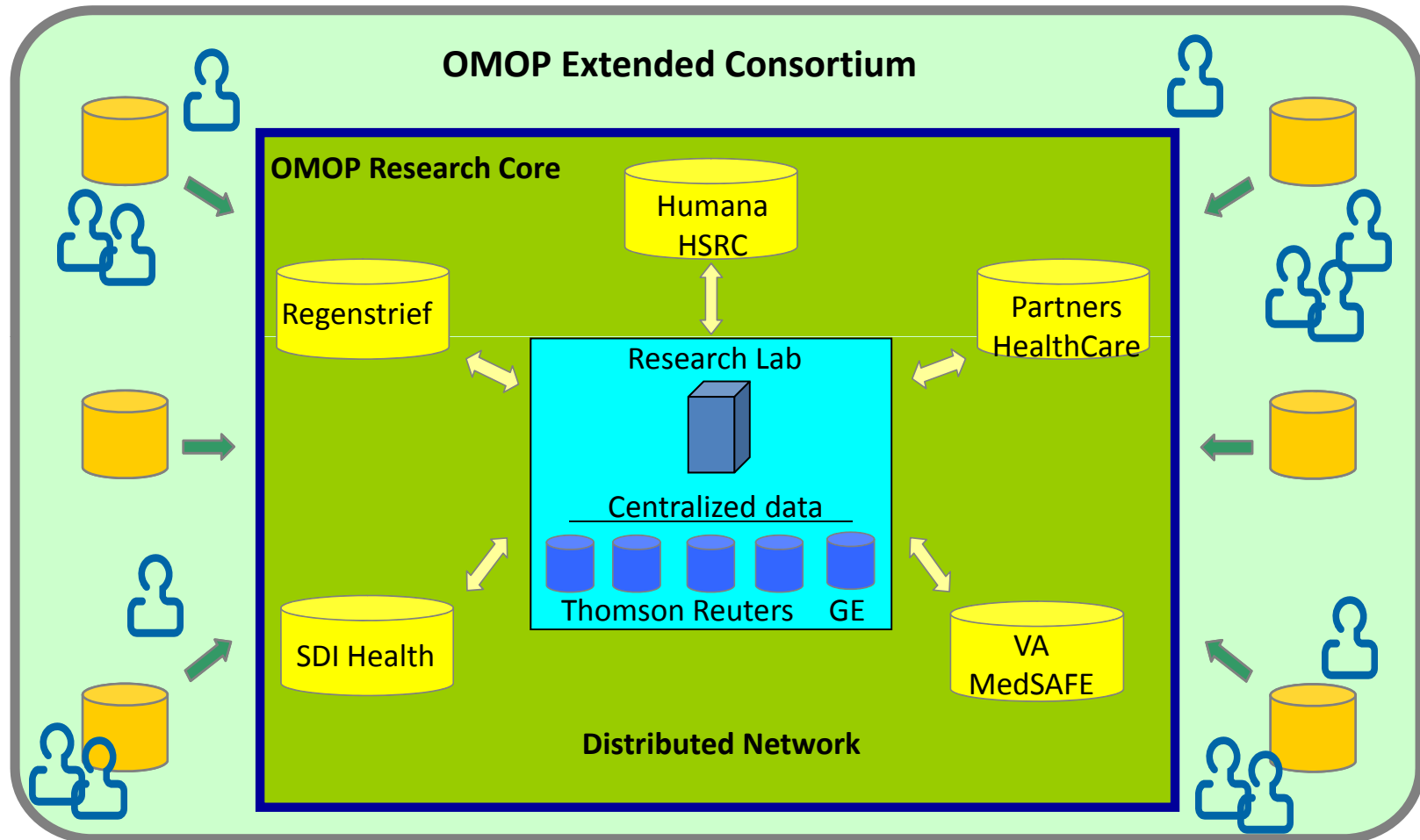
Testing in each source:
-accumulating over time
-against the entire dataset



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OMOP Extended Consortium
Purpose

Building A Community to use OMOP Tools



OMOP Extended Consortium: Purpose

- To facilitate a virtual research community with participation from various types of stakeholders
- To share the tools and findings from OMOP's current research
- To collaborate and learn from each other:
 - Apply methods to your data and contribute analysis results
 - Define Health Outcomes of Interest
 - Develop new tools and methods
 - Share learnings and perspectives
- Participation is voluntarily and will be recognized as part of the OMOP research community.

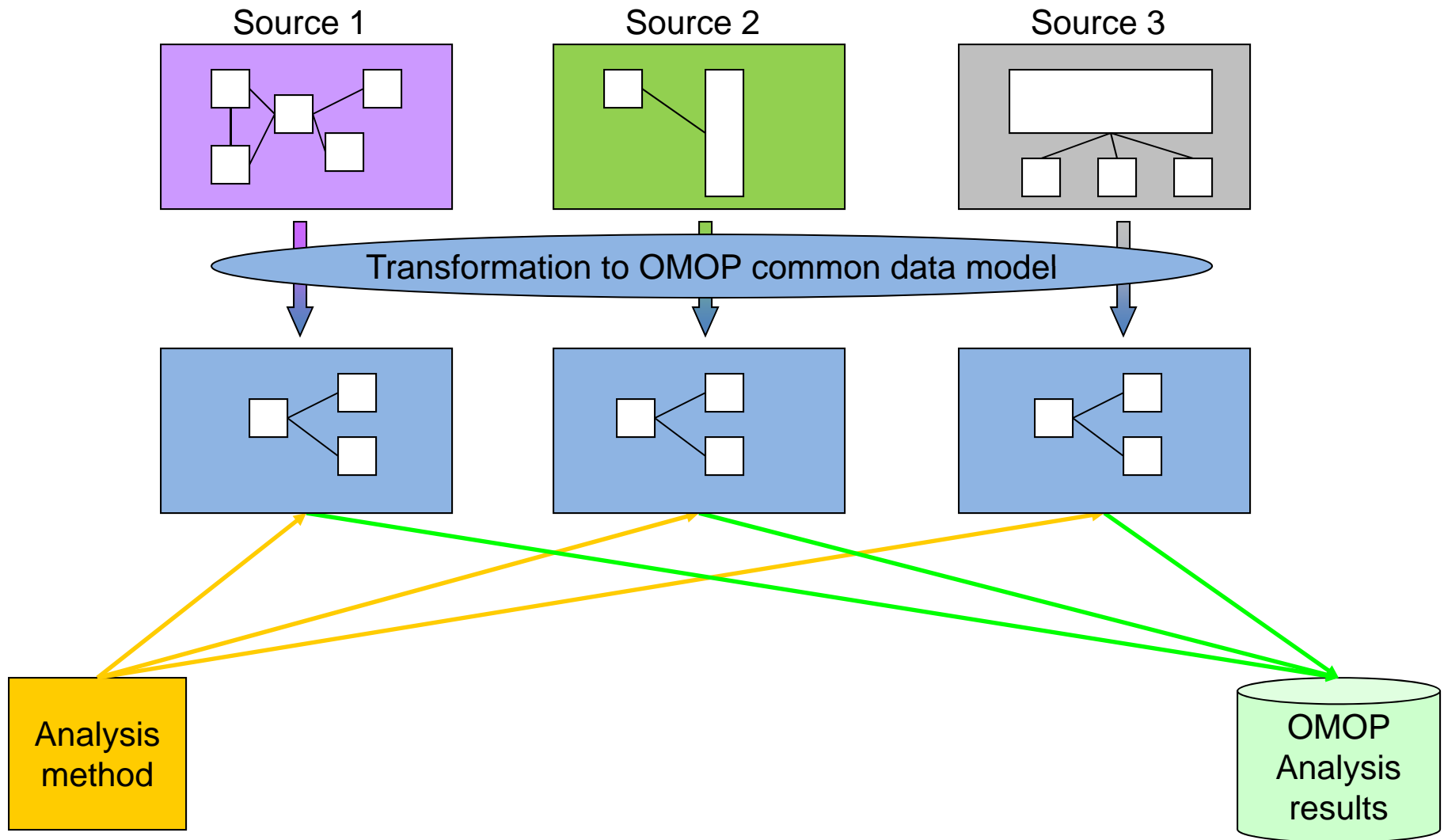
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OMOP Toolkit

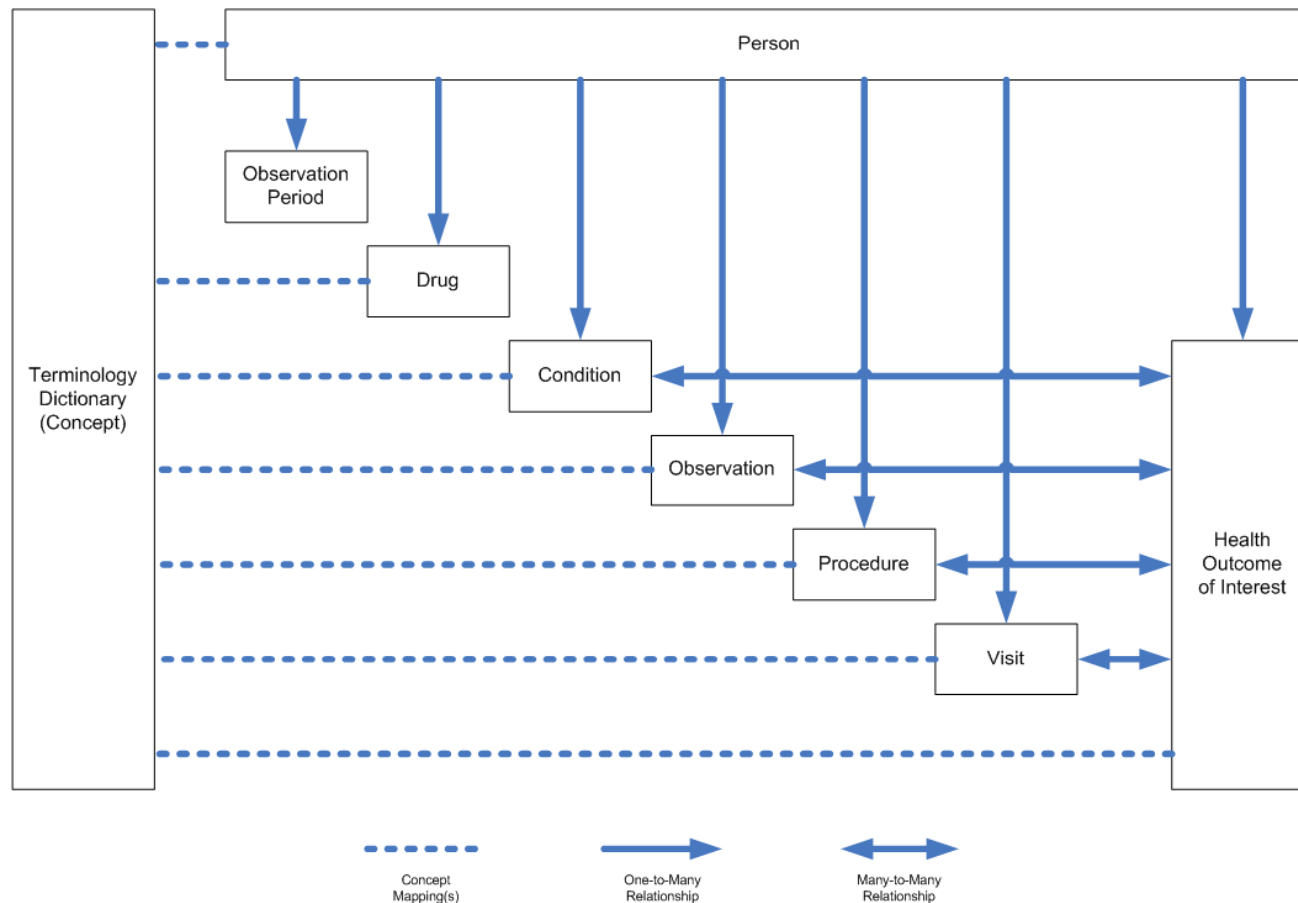
Tools Available to You

- Common Data Model
 - <http://omop.fnih.org/CDMandTerminologies>
- Standardized Terminology
 - <http://omop.fnih.org/Vocabularies>
- Data Characteristics Tools
 - OSCAR - <http://omop.fnih.org/OSCAR>
 - NATHAN - <http://omop.fnih.org/NATHAN>
- Health Outcomes of Interest Library
 - <http://omop.fnih.org/HOI>
- Methods Library
 - <http://omop.fnih.org/MethodsLibrary>
- Simulated Data
 - <http://omop.fnih.org/OSIM>

OMOP Analysis Process



Establishing a common data model

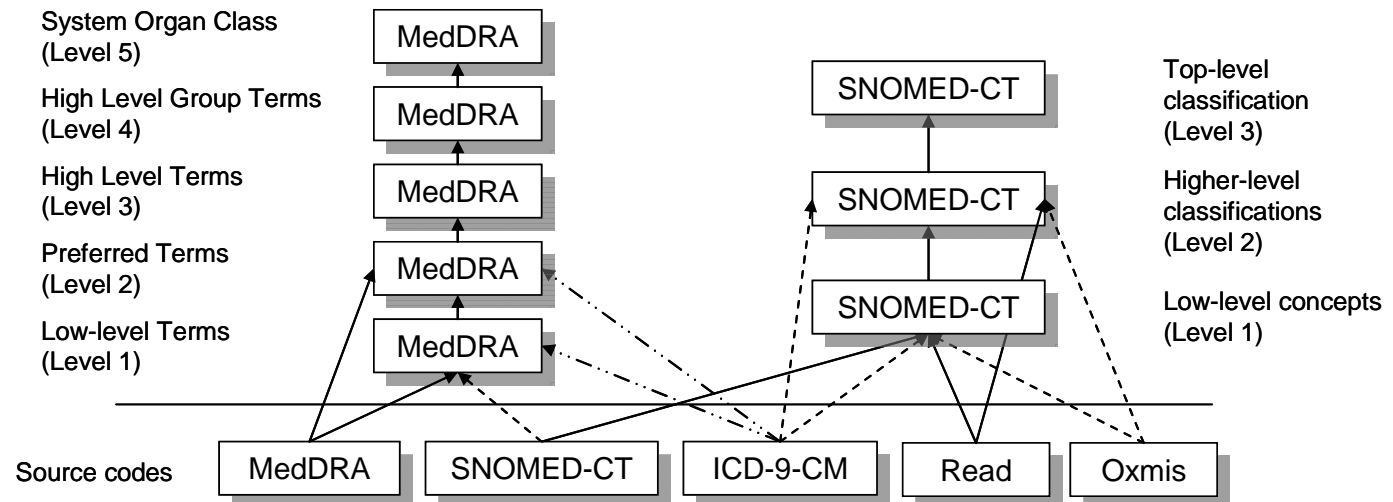


- Developed with broad stakeholder input
- Designed to accommodate disparate types of data (claims and EHRs)
- Applied successfully across OMOP data community

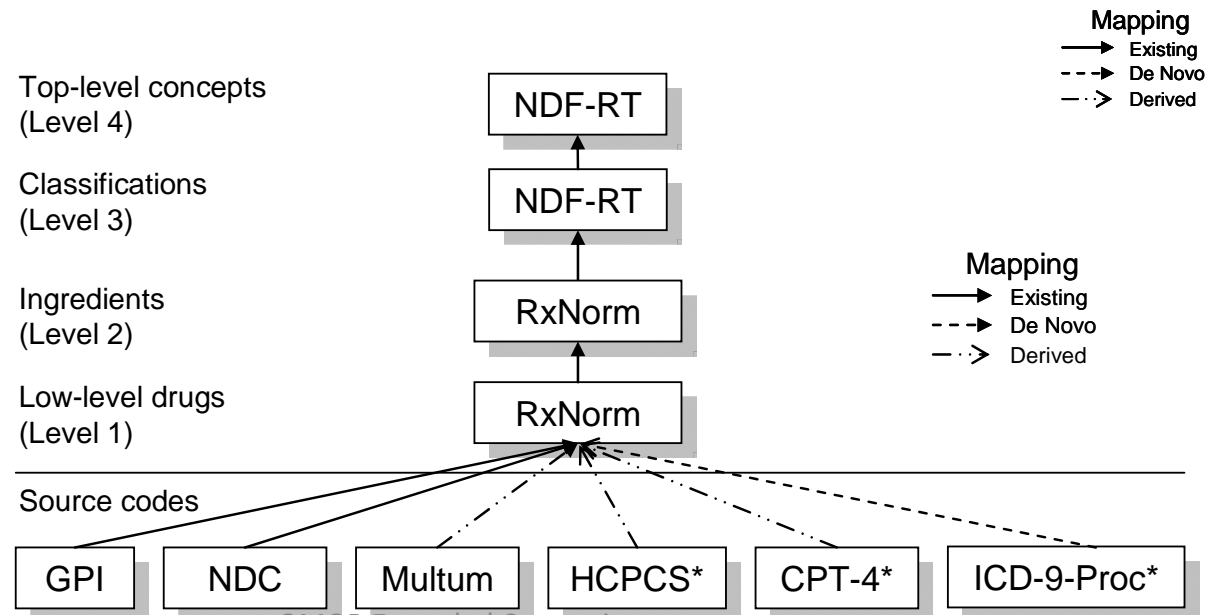
<http://omop.fnih.org/CDMandTerminologies>

Standardizing terminologies to accommodate disparate observational data sources

Standardizing conditions:



Standardizing drugs:



Observational Source Characteristics Analysis Report (OSCAR)

- Provides a systematic approach for summarizing observational healthcare data stored in the OMOP common data model.
- Uses
 - Validation of transformation from raw data to OMOP common data model
 - Comparisons between data sources
 - Comparison of overall database to specific subpopulations of interest (such as people exposed to a particular drug or people with a specific condition)
 - Providing context for interpreting and analyzing findings of drug safety studies

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

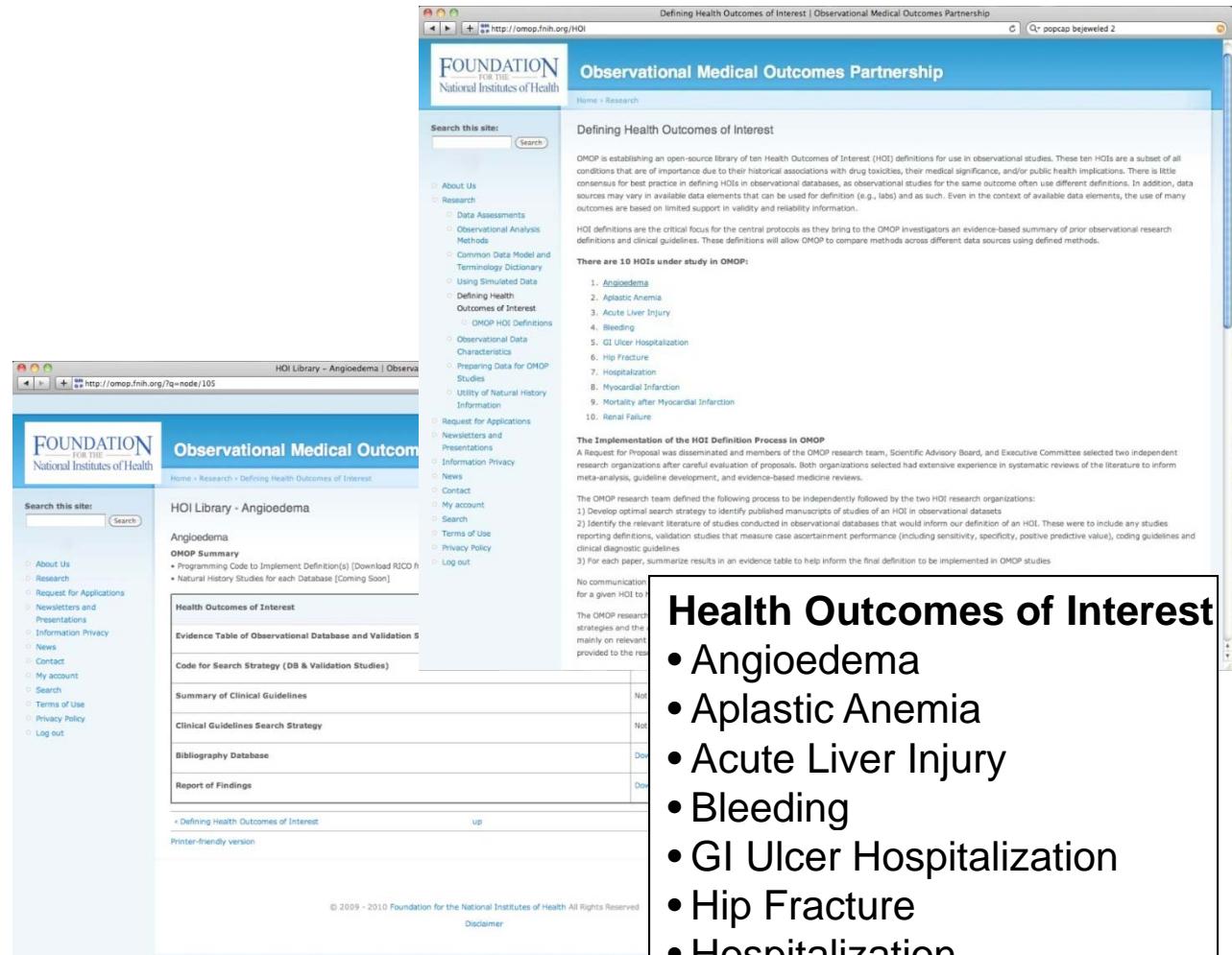
Natural History Analysis (NATHAN)

- OSCAR provides a systematic approach for summarizing all data within the OMOP common data model.
- Natural History Analysis (NATHAN) is an extension of OSCAR, where data characteristics can be produced for a particular subpopulation of interest
 - Exposed population (e.g. patients taking antibiotics)
 - Cases (e.g. patients with acute liver injury)
 - Exposed cases (e.g. patients taking antibiotics with acute liver injury)
- Uses:
 - Evaluate alternative cohort definitions (HOIs)
 - Comparisons between data sources
 - Providing context for interpreting and analyzing findings of drug safety studies

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

Health Outcomes of Interest (HOI) Library

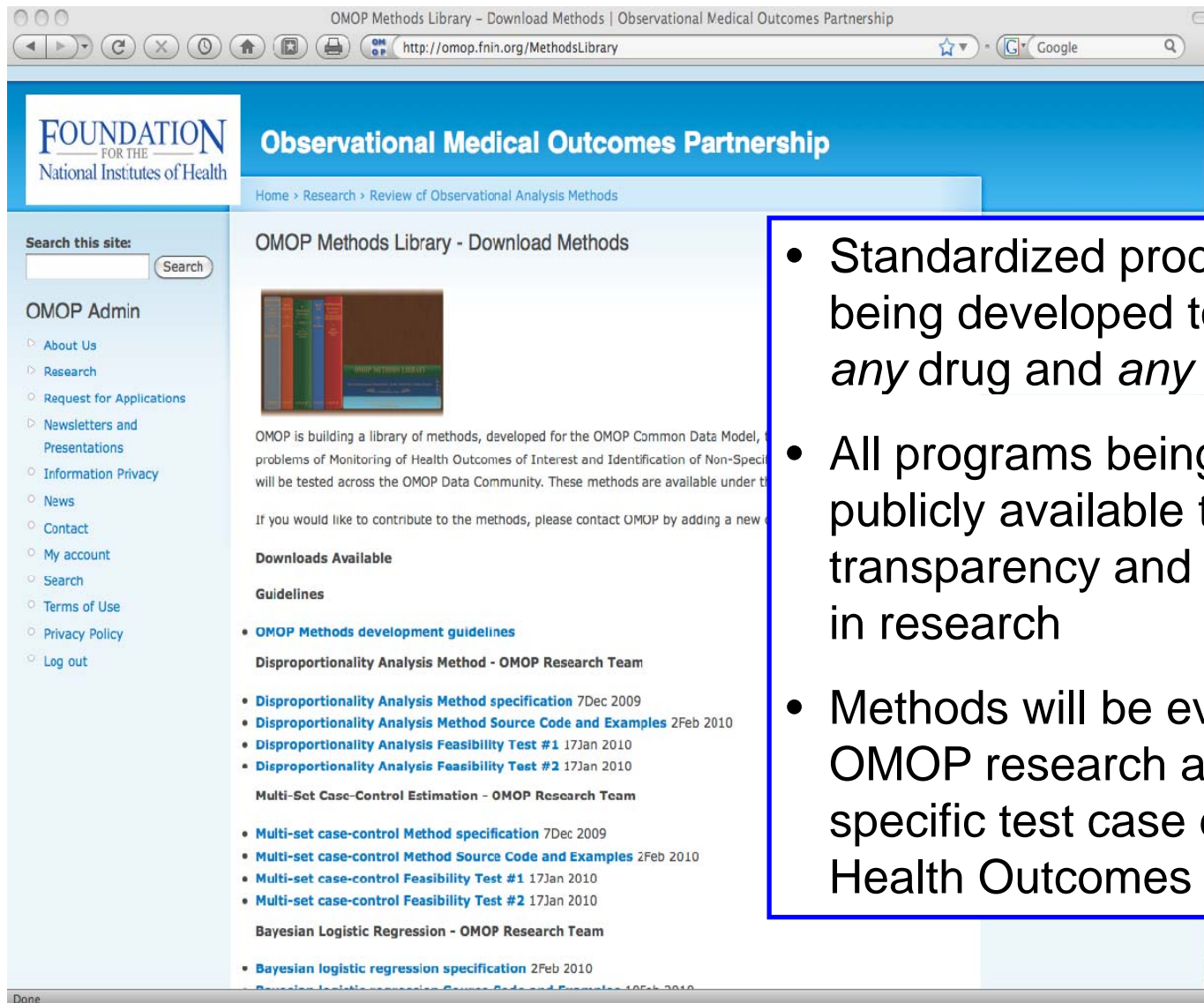
- Identified need for open-source library of HOI definitions:
 - 1 or more per HOI
 - literature review strategies
 - evidence tables
 - Software code to implement definitions
- OMOP is testing a process for studying HOIs
- Welcome contributions to the library



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

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

OMOP Methods Library



The screenshot shows a web browser window displaying the OMOP Methods Library page. The page 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 methods. A search bar is visible on the left side of the page.

OMOP Methods Library - Download Methods

OMOP is building a library of methods, developed for the OMOP Common Data Model, to address the problems of Monitoring of Health Outcomes of Interest and Identification of Non-Specific Health Outcomes. These methods will be tested across the OMOP Data Community. These methods are available under the following terms and conditions:

If you would like to contribute to the methods, please contact OMOP by adding a new method.

Downloads Available

Guidelines

- **OMOP Methods development guidelines**
- **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

OMOP's Methods Landscape

Disproportionality Analysis

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

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

- Temporal Pattern Discovery (WHO)

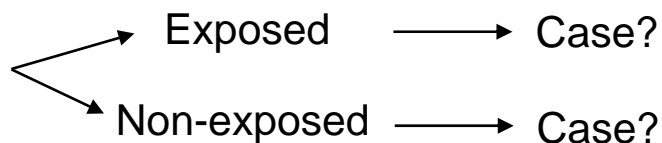
Sequential Methods

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

Compare to baseline Poisson

- Maximized Sequential Probability Ratio Test (maxSPRT)
- Condition Sequential Sampling Procedure (CSSP)

Exposure Based Methods

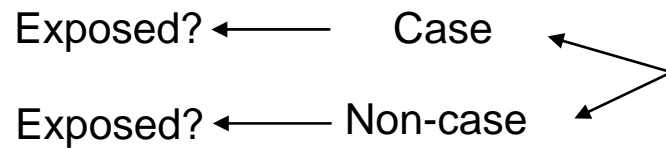


- Observational screening
- HSIU
- Incident User Designs
- High-Dimensional Propensity Scoring

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

OMOP's Methods Landscape

Case Based Methods



- Case control surveillance
- Multiset case control estimation
- 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 (60+ submissions)

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

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Participate in the OMOP
Extended Consortium

What can you do as an Extended Consortium Participant?

- Download and use the OMOP toolkit components
- Contribute analysis results, methods, and definitions
- Share comments, ask questions and give feedback to your community
- Receive public acknowledgement on the OMOP website
- Be part of building a research community

Next Steps

- Go to <http://omop.fnih.org/ExtendedConsortium>
 - Download and review the EC guidelines and procedures so you can access the community dialogue and share your thoughts on the EC forums
- OMOP is planning the next OMOP Extended Consortium quarterly call for August 2010

Questions – Contacts

- Contact Us via the OMOP Website:

<http://omop.fnih.org>

- Email :

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