



 San Diego 2009

45th Annual Meeting



# Observational Medical Outcomes Partnership

**Patrick Ryan**

Co-Investigator

OMOP

**OBSERVATIONAL  
MEDICAL  
OUTCOMES  
PARTNERSHIP**

**FOUNDATION**  
FOR THE  
National Institutes of Health

# Disclaimer

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# Observational Medical Outcomes Partnership (OMOP)

*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. The design was developed through a Public-Private Partnership among industry, FDA and FNIH.*

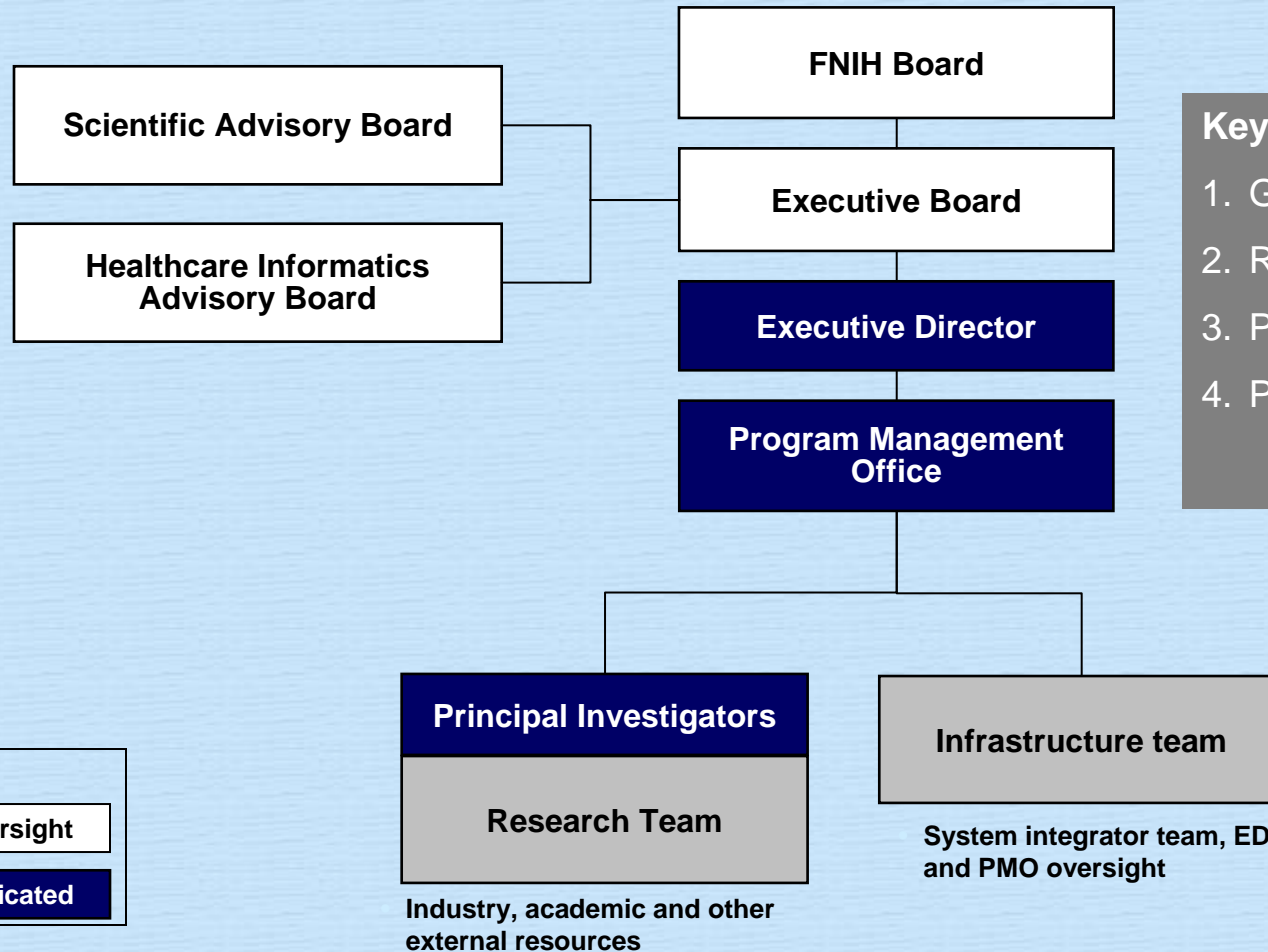
## OMOP Objectives

- To determine the feasibility of assembling the required data into an infrastructure that enables active, systematic monitoring of observational data
- To determine value of using observational data to identify and evaluate the safety and benefits of prescription drugs, as a supplement to currently available tools
- To test required governance structures

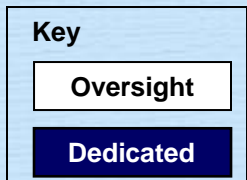


# Governance Provided by an Executive Board

## Scientific and Informatics advisory boards to inform decisions



- Key Design Elements:**
1. Governance and Oversight
  2. Research Leadership
  3. Program Management
  4. Partners & Collaborators



# Executive Board

*Oversees the operation of the Partnership.*

**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**

Director, Center for Biologics Evaluation and Research, 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**

Marion Merrell Dow Chair in Pediatric Pharmacogenomics, Children's Mercy Hospital and Dean Emeritus, Dartmouth Medical School

**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*

**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:** Office of Critical Path Programs, Office of the Commissioner, US Food and Drug Administration

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



# Foundation for the NIH Staff

*The FNIH staff are responsible for managing the day-to-day operations of the Partnership under the direction and guidance of the Partnership's Executive Board and the FNIH Board.*

## **Thomas Scarnecchia, MS**

Executive Director, Observational Medical Outcomes Partnership

## **Emily Welebob, RN, MS**

Senior Program Manager, Research

## **Christian Reich, MD, PhD**

Senior Program Manager, Technology

## **Kay Jenkins**

Executive Assistant



# 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, WHO Monitoring Center; Uppsala, Sweden
- 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, Aetna
- Joy Pritts, Georgetown University
- Rob Thwaites, United BioSource Corporation



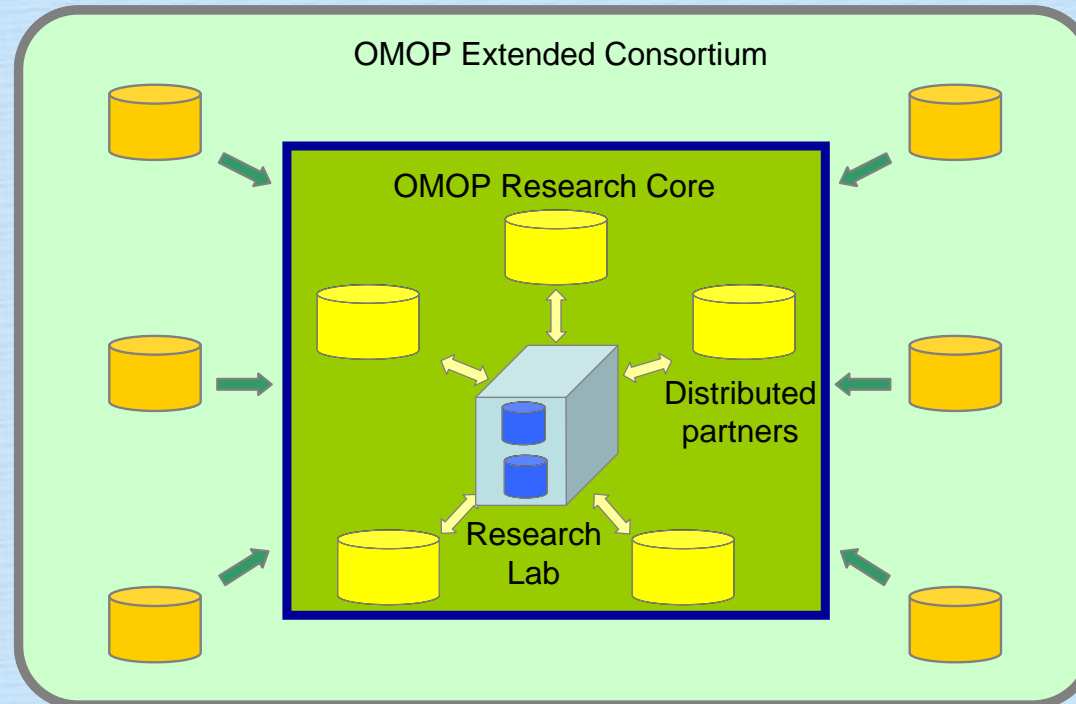


# OMOP Research Plan

## Overview



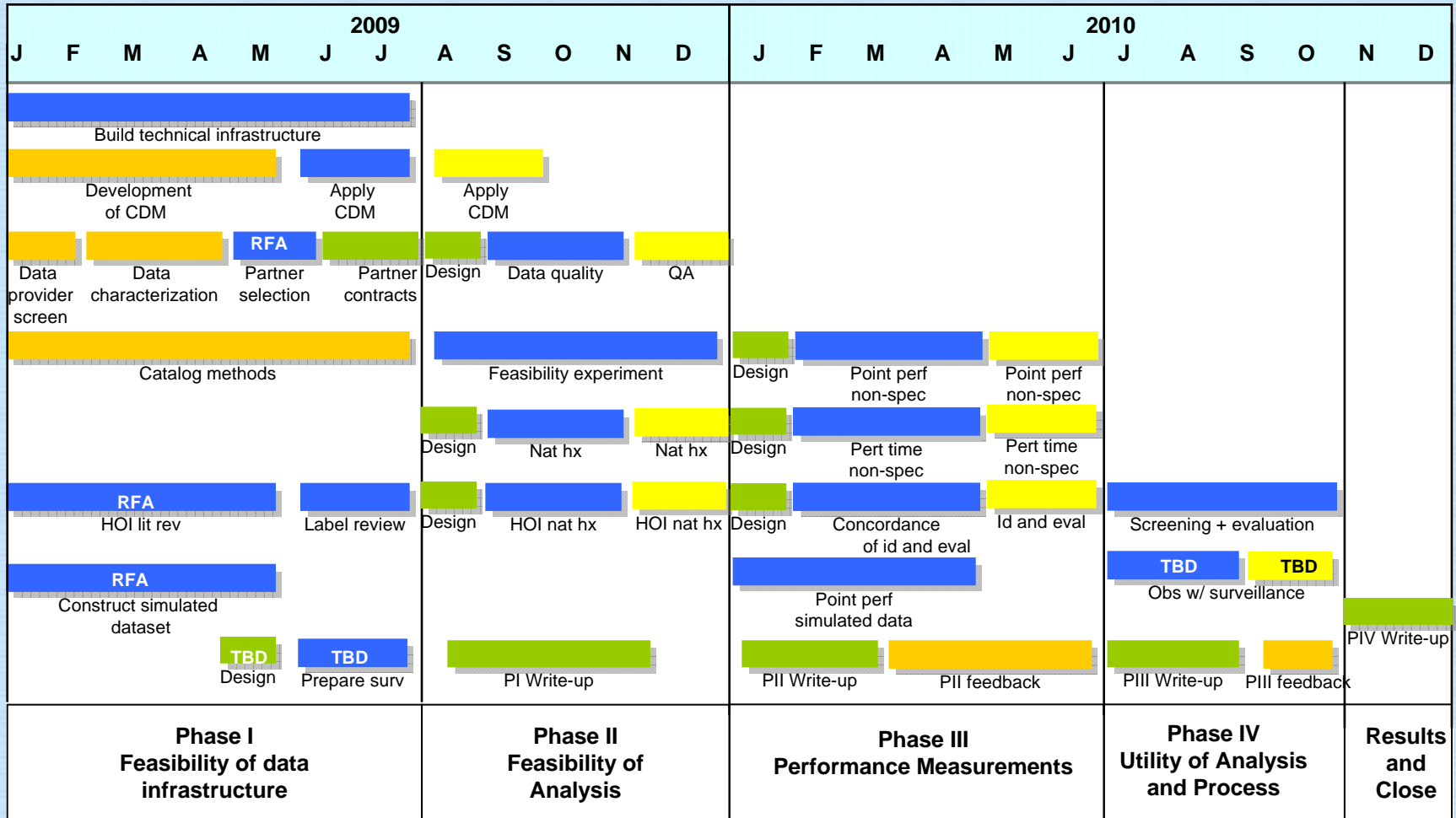
# Overview of Partnership Design



- **OMOP Research Core** is responsible for designing, developing and managing the execution of the approved research proposals.
- **OMOP Research Lab** will be used to manage analysis process across all data sources within the Research Core.
- **Distributed Research Partners** implement the OMOP Common Data Model and execute protocols within their data environment
- The broader scientific community can participate in the **OMOP Extended Consortium**



# OMOP Timeline



Central Research Core

Distributed Research Core only

Central and Distributed Research Core

Extended Consortium



# OMOP Phases and Deliverables

## Phase 1

*Feasibility of Data Infrastructure*

**February 2009-July 2009**

**Research Questions:**

- Can we establish a consistent framework to use across disparate observational data sources?
- Does normalizing conditions in observational data improve identification of non-specified conditions?

**Reports and Tools:**

- Common data model, and data transformation applications
- Common drug and condition vocabularies, and mapping tools
- Report: Comparison of condition vocabularies for observational screening
- Health Outcomes of Interest library
- Simulated dataset
- Systems integration design and lessons learned

## Phase 2

*Feasibility of Analyses*

**August 2009-December 2009**

**Research Questions:**

- Which identification methods are feasible within the current systems infrastructure?
- Can we establish standard data quality and characterization procedures to assess the viability of data sources for observational analyses?

**Reports and Tools:**

- Research Core Data quality summary
- Data quality assessment procedure
- Feasibility of Identification methods
- Library of method implementations
- Reference set of drug labeled events for screening studies
- Health Outcomes of Interest natural history

## Phase 3

*Performance Measurements*

**January 2010-June 2010**

**Research Questions:**

- What is the performance of each identification method in simulated data? For non-specified conditions?
- What is the performance of each observational data source in identifying associations between drugs and non-specified conditions? In monitoring Health Outcomes of Interest (HOI)? In evaluating associations between drugs and HOI?

**Reports and Tools:**

- Library of applications to conduct methodological research against common data model
- Performance of identification methods in a simulated dataset and on non-specified conditions
- Performance and consistency of identification methods on non-specified conditions
- Concordance of identification methods and observational evaluation of HOI

## Phase 4

*Utility of Analyses and Process*

**July 2010-December 2010**

**Research Questions:**

- How does natural history information from observational data contribute to a decision regarding the results of observational analysis?
- How do decision-makers interpret observational database analyses?
- How does the performance of identifying associations in observational data differ from other surveillance approaches?

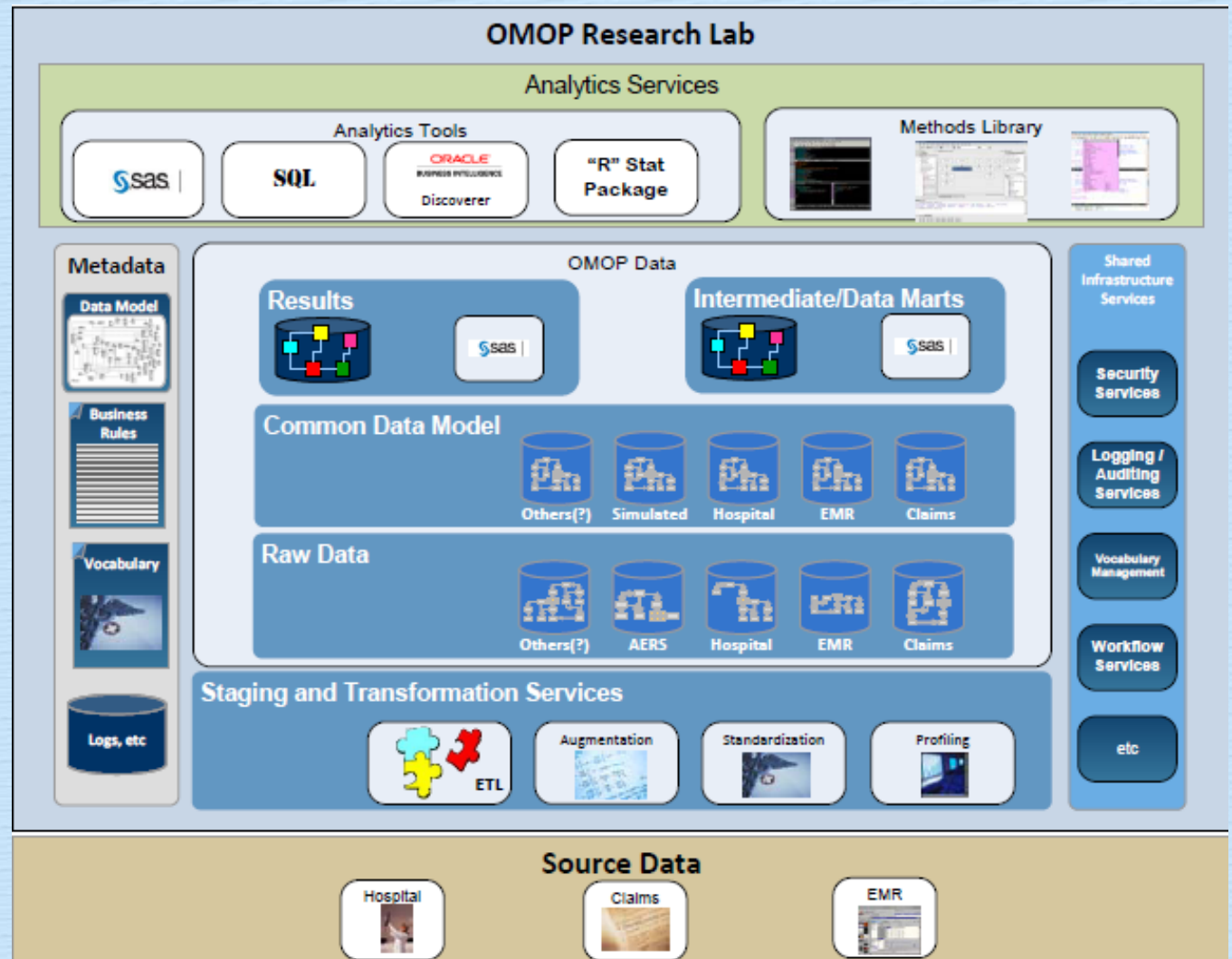
**Reports and Tools:**

- Utility of Natural History information
- Utility of observational screening and observational evaluation of Health Outcomes of Interest over time
- Efficiency of Identification: Comparison of observational data and other surveillance systems
- Systems integration design and lessons learned
- Partnership governance design and lessons learned



# OMOP Research Lab

- Provides the core IT needed to support research conducted using OMOP licensed data.
- Provides the OMOP researcher with access to the data, statistical analysis tools, and method library.



The OMOP Research Lab is implemented and managed by CSC.



# Phase 1 Progress

Common Data Model  
Data Assessments and Distributed  
Research Partners  
Health Outcomes of Interest  
Simulated Dataset



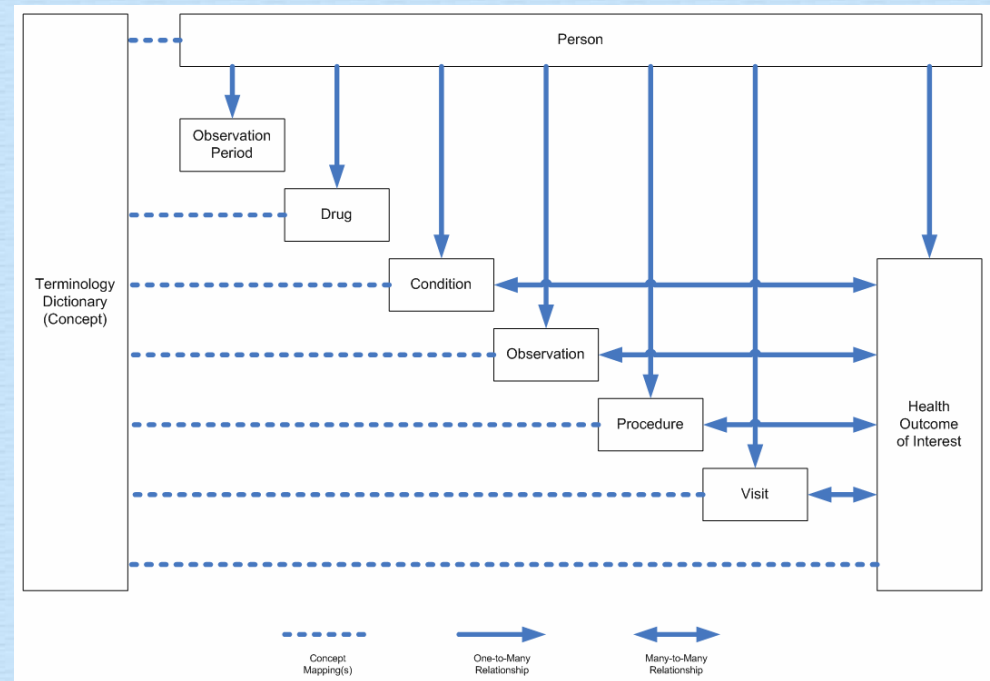
# Common Data Model

## What we are doing

- Creating one model that could accommodate any relevant type of observational data
- Facilitating comparison of analysis results across sources
- Providing a conceptual model to allow researchers to develop analysis methods that are portable across data sources

## What we are not doing

- Combining multiple datasets into one common data model
- Trying to force claims data into a EHR model or vice versa
- Developing a graphical user interface to automatically create structured queries



# Data Assessments

## OMOP Data Screen and Profile

- Data Screening
  - To gather information on available data and potential research partners for further assessment
  - To begin to develop relationships with these potential partners
  - Data Screen responses: 39/70 (56%)
- Data Profile
  - OMOP Distributed Research Partners must have completed the Data Profile
  - 22 Data Profile responses, reflecting diversity in available data
  - OMOP will publish report with de-identified analyses about characteristics of data sources





# Health Outcomes of Interest

- Goals
  - To identify and organize definitions used to date for Health Outcomes of Interest (HOIs) as reflected in literature (from observational studies)
  - To test the process for identifying and organizing this information
  - To identify clinical criteria for the HOI
- Consistent with these goals, we are testing the process as well as assure quality of final deliverable
  - Engaged two groups to perform systematic literature reviews for 10 HOIs to ensure at least one report for each HOI is completed and provide independent replication of review process
- Outcomes
  - Standard evidence table and HOI reporting structure
  - HOI Library, with 10 HOI reports



# Drug-HOI Pairs

Drug/class	Health Outcome of Interest
ACE inhibitors	Angioedema
ACE inhibitors	Hospitalization (including readmission and mortality)
Amphotericin B	Renal failure
Antibiotics: erythromycins, sulfonamides, and tetracyclines	Acute liver injury (symptomatic hepatitis)
Antiepileptics: carbamazepine, valproic acid, and phenytoin	Aplastic anemia
Benzodiazepines	Hip fracture
Beta blockers	Mortality after MI
Bisphosphonates: alendronate	GI ulcer hospitalizations
Tricyclic antidepressants	Myocardial infarction
Typical antipsychotics	Myocardial infarction
Warfarin	Bleeding



# Simulated Dataset

- OMOP will test a modest number of real observational data sources
- Observational data is poorly characterized
- Methodological research typically requires some benchmark to measure performance
- Simulated datasets, comprised of hypothetical persons with fictitious drug exposure and condition incidence, can be created with known characteristics that represent the types of scenarios expected in real observational sources



# Observational Medical Dataset Simulator: OSIM

- Capable of generating 1 to 100,000,000+ persons
- Two types of output files:
  - **Simulated Drug & Condition Files:** including attributes used to model confounding (provides “answer key” for analytic research)
  - **Hypothetical Person Files:** longitudinal record of drug exposures and condition occurrences
- **Data characteristics and confounding controlled by input probability distributions**
  - Confounding variables age, gender, race, indication introduced as risk factors for select drugs & conditions
  - Default distributions produced from analysis of real observational data; can be modified by user
- **Format of Hypothetical Person Files conforms to OMOP Common Data Model**

Implementation by ProSanos Corporation



# Opportunities to Engage

- Review and comment on draft documents and participate in online discussions of key topics as registered users on the OMOP website: <http://omop.fnih.org>
- We are harvesting brains, ideas, and time!
  - Distributed Research Partners (RFA process in review)
    - Run the protocols in your own data and report it back to OMOP
  - Call for Participation: Implementing Observational Analysis Methods
    - If you have existing programming code for an analysis method, are interested in implementing an existing method, or have an idea for a novel approach
  - OMOP Extended Consortium
  - Coming Soon:
    - Methods Competition
    - OMOP Symposium (Fall 2009)



# OMOP Extended Consortium

- Within Your Own Data Environment:
  - Implement OMOP's Common Data Model and Terminology Dictionary
  - Apply methods from the OMOP catalog of analytical methods against the common data model
  - Collaborate with OMOP Research Investigators, OMOP Distributed Research Partners and other Extended Consortium individuals and organizations
  - Participate in joint meetings with various stakeholders to share findings and lessons learned



<http://omop.fnih.org>

