# OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

## OMOP Overview and Insights

**Abraham G. Hartzema PharmD, MSPH, PhD, FISPE for OMOP**

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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

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# 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

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# 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***

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# 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

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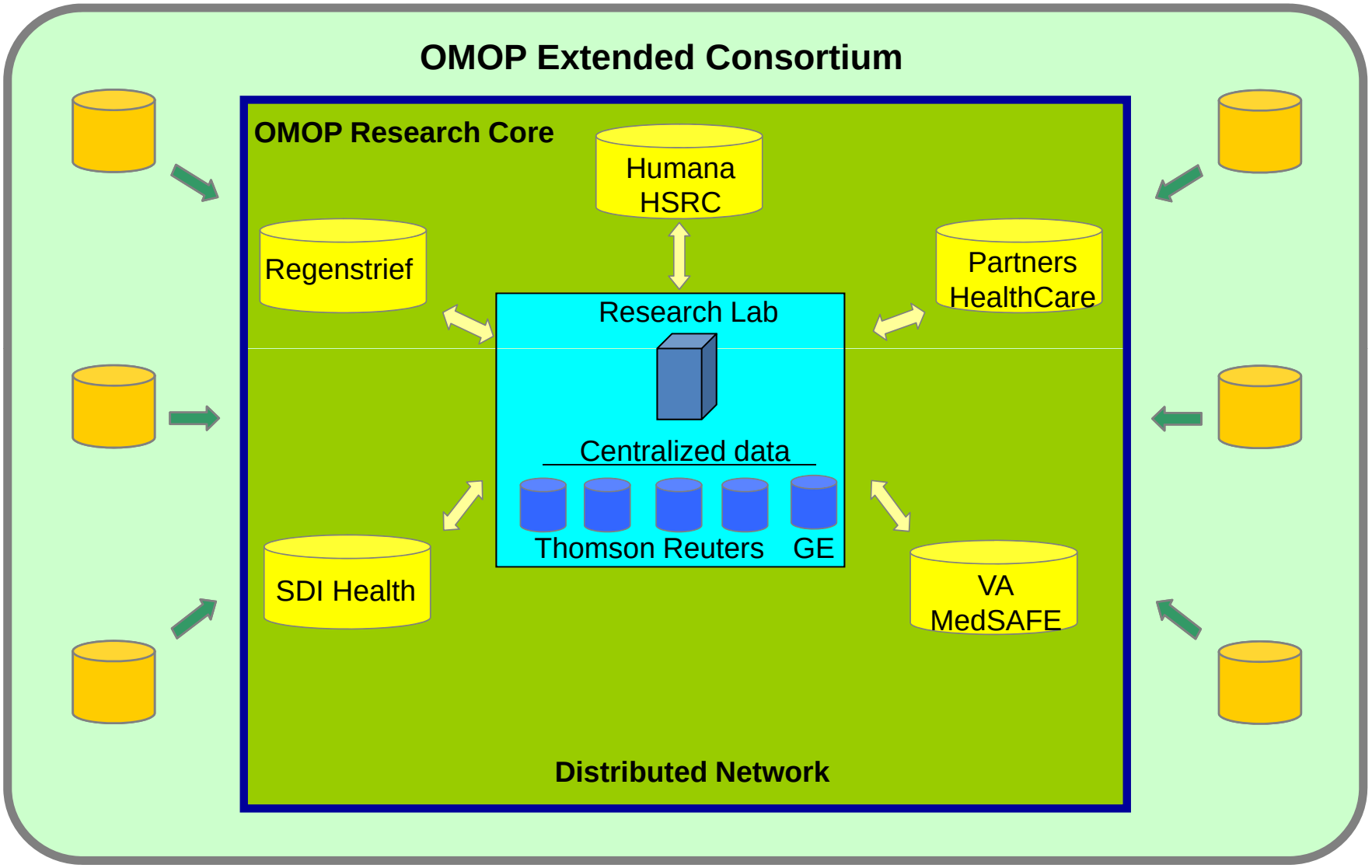
# OMOP Data Community



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# OMOP's Methods Landscape

## *Disproportionality Analysis*

| | *AE j = Yes* | *AE j = No* |
|---|---|---|
| **Drug *i* = Yes** | *a*=20 | *b*=100 |
| **Drug *i* = No** | *c*=100 | *d*=1080 |

- Distinct Patients
- SRS
- Modified SRS

X

MGPS
BCPNN
PRR
Chi
etc.

X

Stratified

- Temporal Pattern Discovery (WHO)

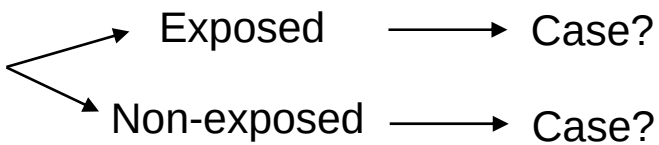
## *Sequential Methods*

| | *AE j = Yes* | *AE j = No* |
|---|---|---|
| **Drug *i* = Yes** | *a*=20 | |
| **Drug *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

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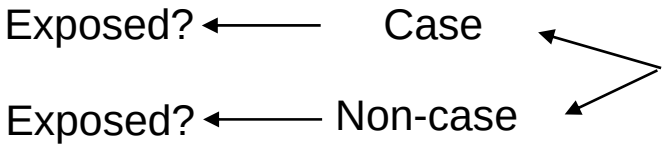
# OMOP's Methods Landscape

## *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)

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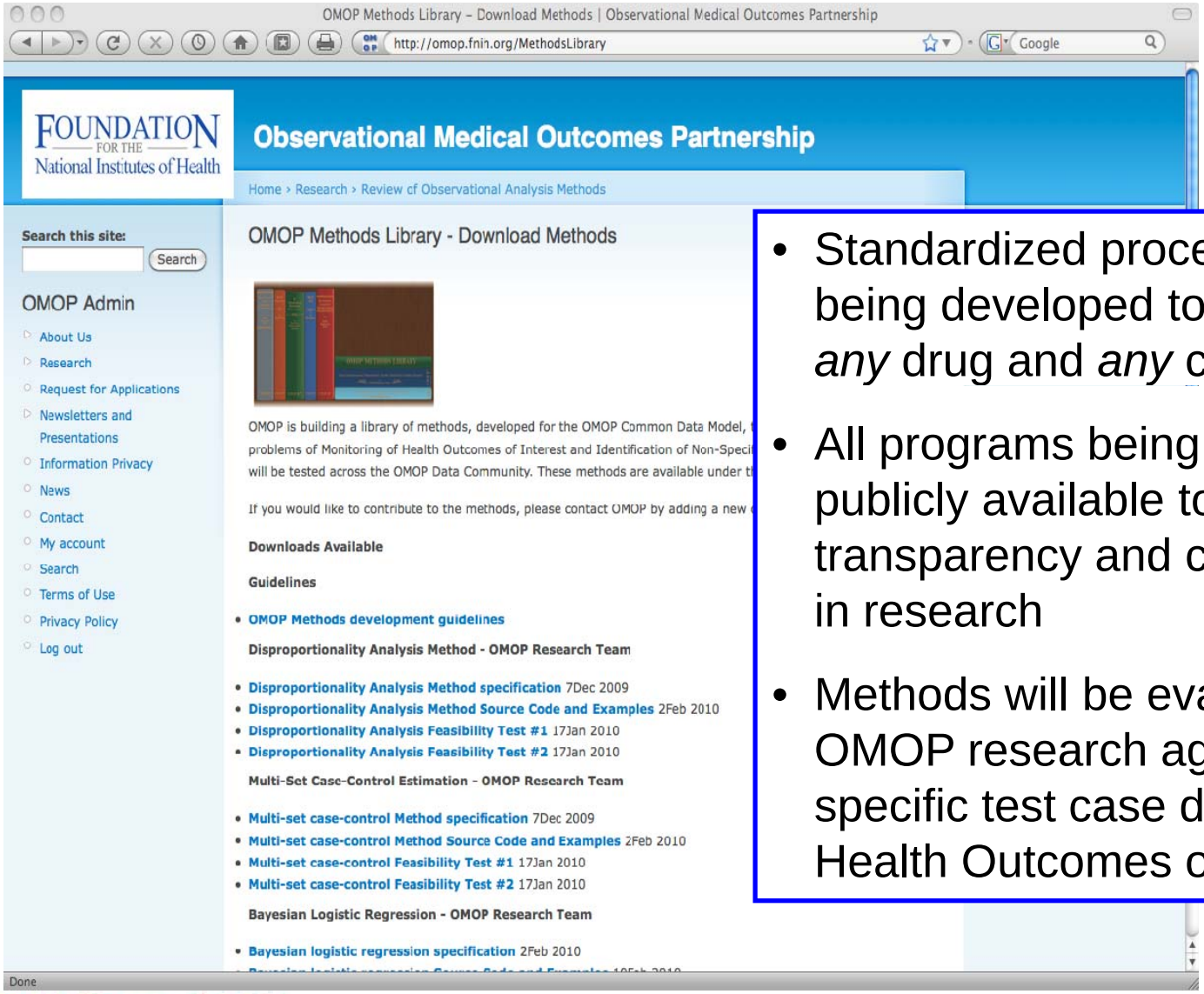
# OMOP Methods Library

http://omop.fnih.org/MethodsLibrary




- 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

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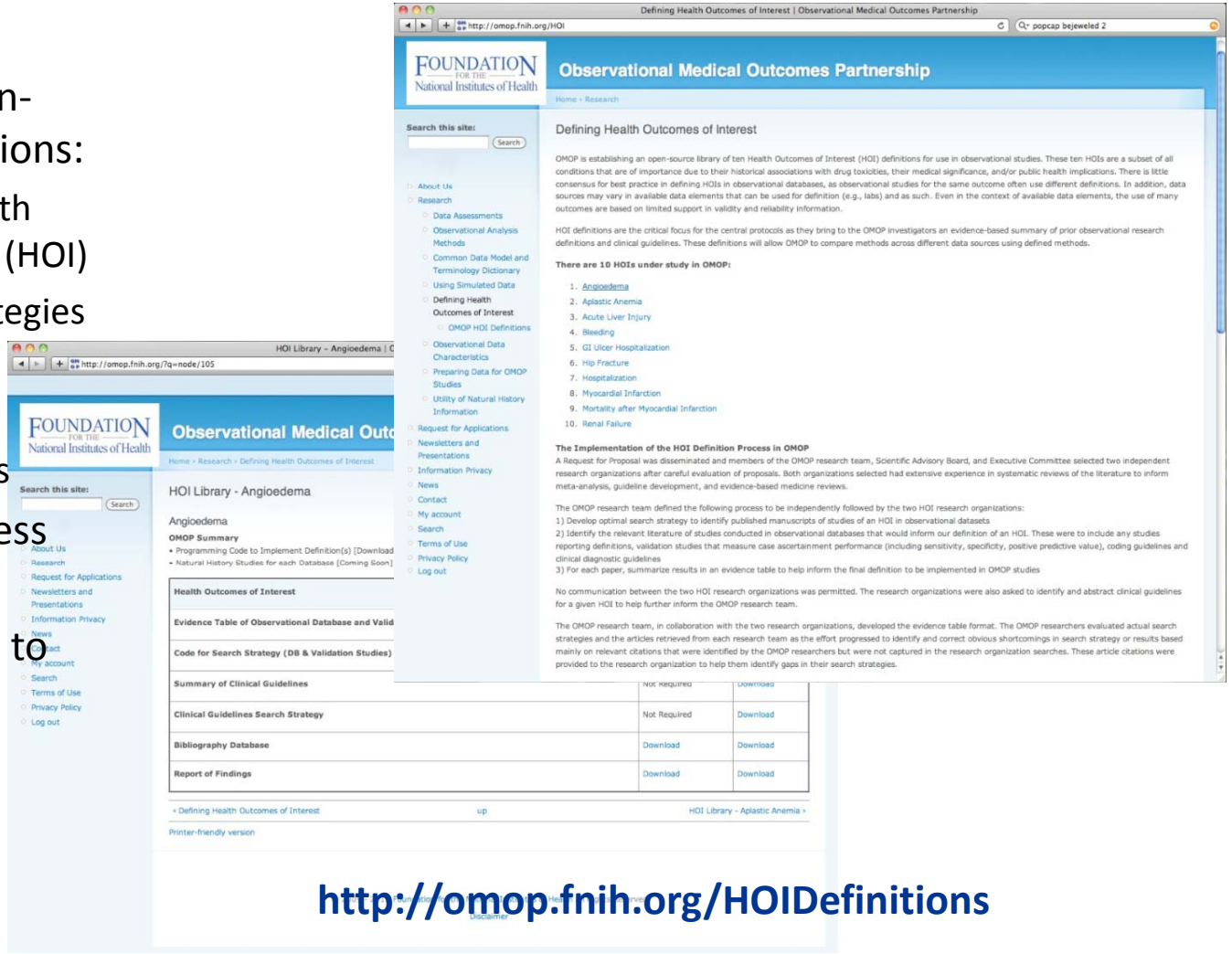
# Health Outcomes of Interest Library

- 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/HOIDefinitions**

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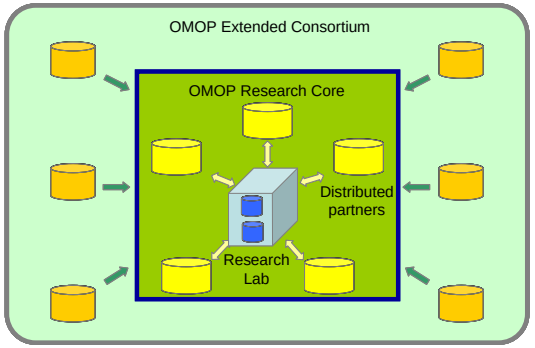
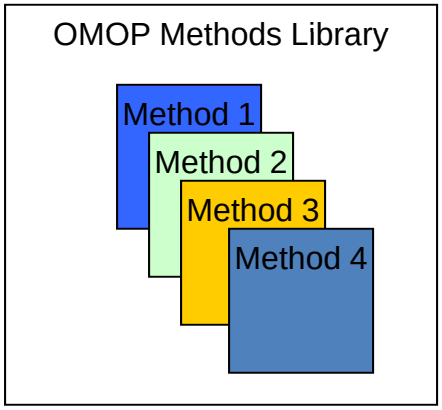
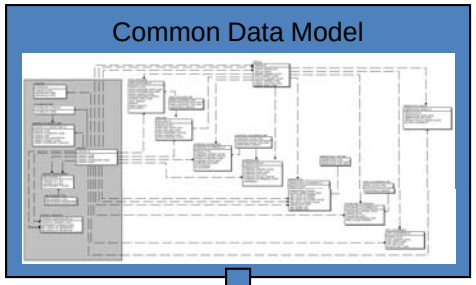
# OMOP Research Experiment Workflow




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

**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

**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

# Thank You!

FOUNDATION FOR THE National Institutes of Health

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