

Observational Medical Outcomes Partnership

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OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP



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Public-Private Research Partnership established to inform the appropriate use of observational healthcare databases for active surveillance by:

- **Conducting methodological research** to empirically evaluate the performance of alternative methods on their ability to identify true drug safety issues
- **Developing tools and capabilities** for transforming, characterizing, and analyzing disparate data sources
- **Establishing a shared resource** so that the broader research community can collaboratively advance the science

Capability	Specifics
OMOP Research Community	<ul style="list-style-type: none">• OMOP Research Lab with five data sets• Distributed network of five active Data Partners• Extended Consortium• OMOP Methods Collaborators (17)• Online community website with 1300+ users• Annual Symposium (Jan 11, 2011)
OMOP Common Framework	<ul style="list-style-type: none">• Framework to use across disparate observational data sources• Common Data Model (CDM)• Standardized terminology specifications• CDM reference tables that contain the standardized terminologies and mappings from source vocabularies• ETL specifications for all data partners• GE Centricity & Thomson ETL source code

- Computational resources
 - Up to 250 Linux processors available
 - Access to high performance GPU-based servers
- Data
 - 1 EHR & 5 Claims Datasets
 - OMOP Common Framework
 - OSIM I and OSIM II Simulated
- Tools
 - Oracle, R, SAS, C++, perl, Python, Java, Prolog
 - OMOP Methods Library
 - OMOP HOI Library
 - Spotfire
- Available to OMOP participants
 - To pursue OMOP's research agenda
 - Restricted to methodological research
 - Research activities fall under OMOP governance
 - Work product goes into the public domain

Capabilities



Capability	Specifics
Methods Library and Development Framework	<ul style="list-style-type: none">• White papers on methods (methods points-to-consider and inventory matrix)• 12+ methods specifications & source code• Observational Medical Dataset Simulator (OSIM) - specification, source code, and datasets• OSIM II
Standard data characterization & ability to make comparisons across databases	<ul style="list-style-type: none">• Observational Source Characteristics Analysis Report (OSCAR) Specification and Source Code• Natural History Analysis (NATHAN) Specification and Source Code• Generalized Review of OSCAR Unified Checking for data quality and validation analysis

Capabilities



Capability	Specifics
Health Outcome of Interest definitions	<ul style="list-style-type: none">• HOI definition process (literature review strategy & evidence table)• HOI Library with 35 definitions for 10 HOIs• Regularized Identification of Cohorts (RICO)- program to implement HOI definitions within CDM
Public-private partnership governance model	<ul style="list-style-type: none">• 12 Executive Board members, chaired by FDA and managed by Foundation for NIH• 20 Advisory Board members• 6 research investigators and FNIH Program Management Office

- **Monitoring of Health Outcomes of Interest (HOIs):**
 - Estimate the strength of the association between drug exposure and specific events (e.g. acute liver failure, bleeding, MI)
 - Modest in number so can customize analytic approach
 - Expert assessment of drug-HOI causal associations based on literature search
- **Identification of non-specified associations (NSA):**
 - More exploratory in nature
 - Same goal: estimate the strength of the association between drug exposure and conditions
 - Necessarily more generic analyses (e.g., adjust for age and sex)
 - Causality assessment relies on the product labels
- **Performance against simulated data**
 - Complement ‘real world’ experiments
 - Ground truth explicitly defined

We have gained important insights into:

- the establishment of the network of diverse data holding organizations
- the capabilities needed to be a successful active surveillance site
- software development and deployment practices for analytical methods
- the process of defining adverse events in observational data
- the complexity of using observational data for adverse event detection
- the interplay between data, methods, and the health outcome of interest definition
- the processes and resources needed to assess data quality

OMOP is pursuing the continuation of its mission to improve our ability for drug safety (and benefit) monitoring:

- **Advance methodological research** to explore the performance of methods over time, within populations of interest, and across a broader array of medical products and health outcomes
- **Refine and enhance OMOP's tools and capabilities** to translate research into practice
- **Sustain the shared resource (research lab)** so the research community maintains an open forum for collaborative research

Build a sustainable business model for OMOP:

- **Diversify the funding base** from a broader array of stakeholder communities, including federal, healthcare, insurance, biopharmaceutical, information technology, and nonprofit sources

- Expand OMOP's methods program
 - Other types of medical products such as devices and biologics
 - Analytical methods for comparative effectiveness
 - Data characterization methods for healthcare quality measures
- Evaluate alternative data resources including registry data

In Summary



- Established public-private partnership and diverse research community
- Robust governance model with broad stakeholder representation across two advisory boards and an executive board
- Secure research computing laboratory and network of data partners with access to observational data representing over 200 million patients
- Successful framework for organizing, characterizing, and analyzing disparate data sources across a network of healthcare and insurance providers
- Process and expertise to define health outcomes of interest
- Process and technology to assess the quality of a data source for use in an active safety surveillance system
- Growing portfolio (12+) of tested and deployed analysis methods within the OMOP Research Lab and other data environments
- Open and transparent research culture
- Building open source community around the OMOP Common Framework, technology, and methods

Thank you



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