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

Capabilities

Capability	Specifics
OMOP Research Community	• 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	• 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

Research Lab

- 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	• 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	• 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	• 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	• 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

Analysis Problems Under Study

- **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

Leadership Perspective – Key Insights

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

Short Term Objectives

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

Longer Term Objectives

- 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 access 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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