

OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

Distributed Research Partners Selected Research Core Complete

In April 2009, OMOP initiated the Distributed Research Partner Request for Applications (RFA) to solicit proposals from organizations with observational data interested in collaborating with the partnership. One of OMOP's goals is to define processes that can be used to assess the feasibility and utility of using observational data to identify and evaluate associations between drugs and health-related conditions. To facilitate its methodological research, the partnership will conduct a series of studies and evaluate the performance of various analytical methods for identifying drug-outcome associations across multiple disparate observational data sources (administrative claims and electronic health records).

In August, OMOP selected five distributed research partners with observational data to complete the Core Research Team, comprised of a central team of researchers and electronic health record (ambulatory) and claims data resources.

The distributed research partners are:

- i3 Drug Safety
- Indiana University / Regenstrief Institute
- Partners HealthCare System
- SDI Health
- University of Miami-Humana Health Services Research Center

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Distributed Research Partners Selected

Research Core Complete

“In aggregate, the OMOP Research Core with its distributed research partners will represent the diversity of observational data captured throughout the U.S.,” said Thomas Scarnecchia, OMOP executive director. “OMOP is an example of how public and private organizations can work together to benefit drug safety and ultimately public health.”

Over the next 16 months, these data partners will be a critical component of the OMOP Research Core. Each partner will implement the Common Data Model securely within its own research environment and apply multiple methods to its data to evaluate the performance characteristics of each method. The partner will submit the summary results from all studies into the OMOP research lab and will collaborate in the design, review and publication of results from across the OMOP research community. Programs (code) and standardized procedures for executing the studies against the OMOP Common Data Model will be made available to facilitate this process.

While tools are being developed to be applicable for any drug or outcome, OMOP is restricting its study to 11 drug-outcome pairs of interest:

- Angioedema–ACE inhibitors
- Renal failure–Amphotericin B
- Acute liver injury–Antibiotics (erythromycin, sulfonamides, tetracyclines)
- Aplastic anemia–Antiepileptics (carbamazepine, valproic acid, phenytoin)
- Hemorrhage–warfarin
- Hip fracture–benzodiazepines
- GI ulcer hospitalizations–alendronate

- Myocardial infarction–tricyclic antidepressants
- Myocardial infarction–typical antipsychotics
- Reduced hospitalizations–ACE inhibitors
- Lower mortality after MI–beta blockers

The distributed research partners will conduct analyses and generate research results for these test cases to facilitate cross-source comparisons. Analyses of additional drugs and conditions are outside the scope of OMOP and will not be included in any summary reports.

The five distributed research partners were subject to a rigorous selection process that included evaluation by population type and amount of lives. They were found to present a great complement to the existing OMOP Research Core data sets, GE Healthcare’s Medical Quality Improvement Consortium (MQIC) database and Thomson Reuters the MarketScan® Research Databases.

Dr. David Page, University of Wisconsin–Madison Professor, Department of Biostatistics & Medical Informatics and an OMOP Scientific Advisory Board member, who was on the selection committee, commended the effort, saying, “the selection of these five distributed research partners provides an unprecedented opportunity to assess different types of data from across the United States, develop tools and methods to analyze the distributed databases, and evaluate how analyses can contribute to decision-making.”

OMOP Distributed Research Partner Indiana University and The Regenstrief Institute, Inc.

Indiana University and its subcontractor, the Regenstrief Institute, Inc. (<http://www.regenstrief.org>), were awarded OMOP distributed research partner work to collaborate with OMOP in the design of studies, the execution of protocols on the data in its environment, the reporting of structured summary analysis results to OMOP's specifications, and supporting interpretation and publication of results. Shaun Grannis, MD, MS, FAAFP, Research Scientist at the Regenstrief Institute; Assistant Professor of Family Medicine, Indiana University; and Co-Investigator, states, "The OMOP initiative is an ideal opportunity to expand the meaningful use of Regenstrief's sophisticated health IT infrastructure to improve the monitoring of drugs for safety by integrating a variety of clinical sources including claims data, clinical encounter data and medication data."

For the OMOP research, the Indiana team will be using the Indiana Network for Patient Care (INPC) which stores data for 18 million unique patient registrations representing 10.4 million unique individuals. The system contains clinical data for nearly the entire population of the Indianapolis metropolitan statistical area, which is estimated at 1.7 million. The INPC is a robust health information exchange that has been operational since 1995 and provides population-based, longitudinal, and consistently structured coded and text patient data for citizens of Indiana.

The INPC captures data from many sources including hospitals, physician practices, public health departments, laboratories, radiology centers, pharmacies, pharmacy benefit managers (via

SureScripts) and payors. Sources like hospitals and physician practices provide many types of data including laboratory test results, radiology test results, cardiology diagnostic results, pulmonary-function test results, gastroenterology study results, procedures performed, diagnoses assigned, transcribed reports (admission, operative and discharge) and inpatient, outpatient and emergency department encounters.

The Indiana team has been meeting with the OMOP team and completed a kick-off meeting reviewing project priorities and plans. Subsequently, the team will conduct monthly calls with the OMOP Project Management Office to update it on progress, issues and concerns.

All the distributed research partners have a project plan to maintain and track progress. Team meetings will identify barriers and solutions to ensure adequate progress against the project plan.

Thomas Scarnecchia, OMOP Executive director, stated, "We are looking forward to working with the distributed research partners and could not complete this critical piece of work without each of them."

INPC Characteristics

- A community-wide secure data exchange
- Five major Indianapolis hospital systems:
 - Clarian Health
 - Community Hospitals
 - St. Francis Hospitals and Health Centers
 - St. Vincent Hospitals and Health Services
 - Wishard Health Services
- Other health systems
- Payor claims data
- Over 10 million patients
- INPC created in 1994

OMOP Distributed Research Partner

Research Patient Data Registry at Partners HealthCare System

Partners HealthCare System (PHS) was founded in 1994 by Brigham and Women's Hospital and Massachusetts General Hospital. PHS (<http://www.partners.org>) is a non-profit integrated health care system that offers patients a continuum of coordinated high-quality care. The system includes primary care and specialty physicians, community hospitals, the two founding academic medical centers, specialty facilities, community health centers and other health-related entities.

The Partners Research Patient Data Registry (RPDR) is used within PHS to support clinical research and pharmacovigilance, both locally within PHS, as well as as part of the e-Health Initiative's Collaboration for Drug Safety, which included the eHealth Foundation, pharmaceutical industry representation such as Eli Lilly & Company, Johnson & Johnson and Pfizer, as well as Regenstrief Institute.

In August 2009, PHS started working with OMOP as a distributed research partner. Shawn Murphy, MD, PhD, Medical Director, Research Computing for Partners HealthCare System, is the principal investigator. During the kick-off meeting with the PHS and OMOP team members, Murphy stated, "We are looking forward to using the OMOP-tested methods on our data set which will be transformed into the OMOP Common Data Model and seeing what the results will be. It will be very beneficial to work with the other distributed research partners to hopefully find the methods that work the best on the different data sets that are available via the partners."

The OMOP Research will be performed by PHS within its own data environment, the RPDR, which contains patient demographic, diagnoses,

procedures, medications, inpatient and outpatient encounter information, provider information, microbiology, transfusion services and laboratory data.

Founded in 1999, the RPDR contains most data from the Partners' Clinical Transaction-based Data Repository as well as inpatient and outpatient patient billing feeds. The RPDR is an analytic-structured database. Patients are cross-referenced across institutions and their demographics provided by an Enterprise Master Patient Indexing service. Associated providers, dates, locations of service and other visit-related information accompany the above items as they are fed into the system. The number of patients in the database exceeds 4.1 million. The number of patient-concept pairs, or clinical "facts" about the patients exceeds 900 million, spanning 21 years. The data is refreshed at most once a day and at least once a month. PHS can identify patients that are actively receiving care within the system, and charges that are submitted to the payor. PHS does not have access to payor data at this time for pharmacovigilance.

Dedicated RPDR staff support the research platform at PHS, and an RPDR query tool enables researchers to query the RPDR without technical staff. The user can also request patient data from a HIPAA-compliant, limited-data set or identified patient data (which requires Internal Review Board approval prior to submitting the request). This data is provided in a secure HIPAA-compliant database to the research staff. The RPDR query tool can provide responses and access to the data instantaneously (or can be run as a background query which may take a few hours to complete as needed). Custom research queries (that are study-specific) may require additional technical assistance.

RPDR Characteristics

- Unique tool that clinical research staff can use directly for research needs
- Proven track record of usage with clinical investigators, can also be used for clinical operations
- Many person-years of embedded knowledge about the clinical domain
- Initial mission was to enable a Partners HealthCare research clinician to get a "first cut" of patient cohort to recruit for research studies
- RPDR operational since December 1999

OMOP Distributed Research Partner SDI Health, Inc.

OMOP was excited to award a distributed research partner grant agreement to SDI Health, Inc., (<http://sdihealth.com>) in late July 2009. SDI has been serving the needs of researchers in patient analytics and outcomes since 1982. The company is located in Plymouth Meeting, PA. It participates in a number of collaborative research studies providing data as a common source for methods testing, as well as research in testing various analytical methods.

SDI has compiled the data into a comprehensive data warehouse containing longitudinal patient-level information on over 160 million unique patients.

SDI collects de-identified, encrypted, patient-level data from hospitals, clinics and physician offices, as well as retail and specialty pharmacies. The majority of this information is captured via standard electronic transmission of claims and transactions, including CMS1500, UB-04, Charge Detail Master (both hospital inpatient and hospital outpatient), and NCPDP 5.2 records. SDI has compiled the data into a comprehensive data warehouse containing longitudinal patient-level information on over 160 million unique patients. In addition, SDI has an experienced team of health science professionals with extensive backgrounds in epidemiology and clinical and medical data analysis with doctoral level training; collectively, the team has more than 40 years of experience in advanced medical data analysis.

“SDI can contribute significant experience and expertise in utilizing patient-level data for observational analyses, and is looking forward to working with OMOP,” said Gregory Hess, MD, MBA, SDI Vice President Outcomes Research

and CMO. “Following our first meeting with the core team we are even more excited to be part of this collaborative effort. We are convinced that we will gain a better understanding of the strengths and limitations of the methods and data available for these important analyses, and ultimately be in a better position to meet our clients’ and colleagues’ needs. The challenges are immense in many respects, however, the team and resources assembled are impressive and we are looking

forward to great successes.”

In August 2009, both OMOP and SDI teams met in Pennsylvania and reviewed the overall goals of the distributed research partners and discussed specific project tasks and expected outcomes:

- Receive OMOP Common Data Model specifications
- Complete comparison of OMOP data specifications vs. SDI data files and layouts
- Test the Data Model and QA results and revise as needed
- Complete implementation of the OMOP Common Data Model
- Conduct method feasibility and complete a prioritized number ≤ 20 analyses
- Execute standardized descriptive summary reporting procedures against the Common Data Model
- Work with OMOP and the other distributed research partners on lessons learned, presentations, and publications

OMOP Distributed Research Partner

University of Miami-Humana Health Services Research Center

Humana Inc. (<http://thehsr.org>), headquartered in Louisville, KY, is one of the nation's largest health benefit providers and the second largest administrator of Medicare benefits in the U.S. Its national and regional networks include more than 450,000 physicians, hospitals, pharmacies and ancillary care providers in every state.

With research and innovation as two of its guiding principles, in 2005, Humana Inc. partnered with The University of Miami School of Medicine to form a public-private partnership in health outcomes, pharmaco-epidemiology and health policy research.

This research initiative, known formally as the Miami-Humana Health Services Research Center (HSRC), utilizes Humana's administrative claims database of over 11 million medical members for conducting its various research initiatives. Since its inception, the research center, with a staff of over 25 pharmaco-epidemiologists, physicians, pharmacists, statistical and database analysts and project managers, has successfully completed more than 25 studies and publications in medical peer-reviewed journals.

Vinit Nair, BS Pharm, MS RPh, who leads and directs the HSRC's Drug Safety and Pharmacovigilance Research will serve as the principal investigator for the OMOP initiative. "The OMOP work can enhance drug safety research and further the understanding of observational data and its abilities to make reliable inference of the results," he said. "Being selected an OMOP distributed research partner is a very timely initiative in support of and to contribute to

lessons learned for the FDA's Sentinel Initiative and the national discussion on drug safety."

Currently the Humana research database contains health care information for approximately 6.5 million members, including those in Medicare Advantage, Medicare Part D and commercial (PPO & HMO) plans. The source contains medical (inpatient, outpatient and ER), pharmacy and laboratory data (including test results) available back to the year 2002. The distribution of members and total membership varies through time and the



The OMOP research team visited HSRC in August 2009 to conduct various project initiation activities.

database is linkable at the patient level. Medical claims data usually has a lag of three months for all claims to be adjudicated. Pharmacy data is updated daily. There is a time lag for laboratory services but it rarely exceeds three months. Complete medical, pharmacy, laboratory, eligibility and

special data (as described above) going back to three years from the current month is stored in SAS® format and is instantaneously accessible. Data going beyond three years is typically stored in archival format and is accessible via advanced IT support in four to six weeks from the date of the specific request.

To begin the distributed research partner scope of work, HSRC, similar to the other distributed research partners, will be utilizing the guidance and process documents provided by OMOP to implement the codes and processes to create the OMOP Common Data Model and Terminology which will be housed in HSRC's computational environment. This activity sets the foundation for the forthcoming methods and study implementations.

Progress Report

The Observational Medical Outcomes Partnership (OMOP) has wrapped up Phase 1 of our research plan with the launch of the Research Lab and the awarding of grants to our Distributed Data Partners and Methods Development Partners. Five distributed data partners and 16 methods collaborators have joined the OMOP research core.

Work on the OMOP Research Lab (data and computational resources) concluded in August. The final platform consists of five data sets which have been transformed into the OMOP common data model. These include:

- Thomson MedStat- Commercial (Claims)
- Thomson MedStat- Medicare
- Thomson MedStat- Medicaid
- Thomson MedStat- Lab
- GE Centricity (EHR)

The OMOP statistics team gained access to the the lab in late August. In addition to the data listed above, the team has been provided a series of software development tools including SAS and R analysis systems.

The development of an Observational

Medical Dataset Simulator (OSIM) has been completed. OMOP has released the toolset and supporting documentation into the public domain via the OMOP Web site. A 10 million patient simulated data set has been generated and is in use within the Research Lab. This data set is also being used to support the OMOP Methods Competition.

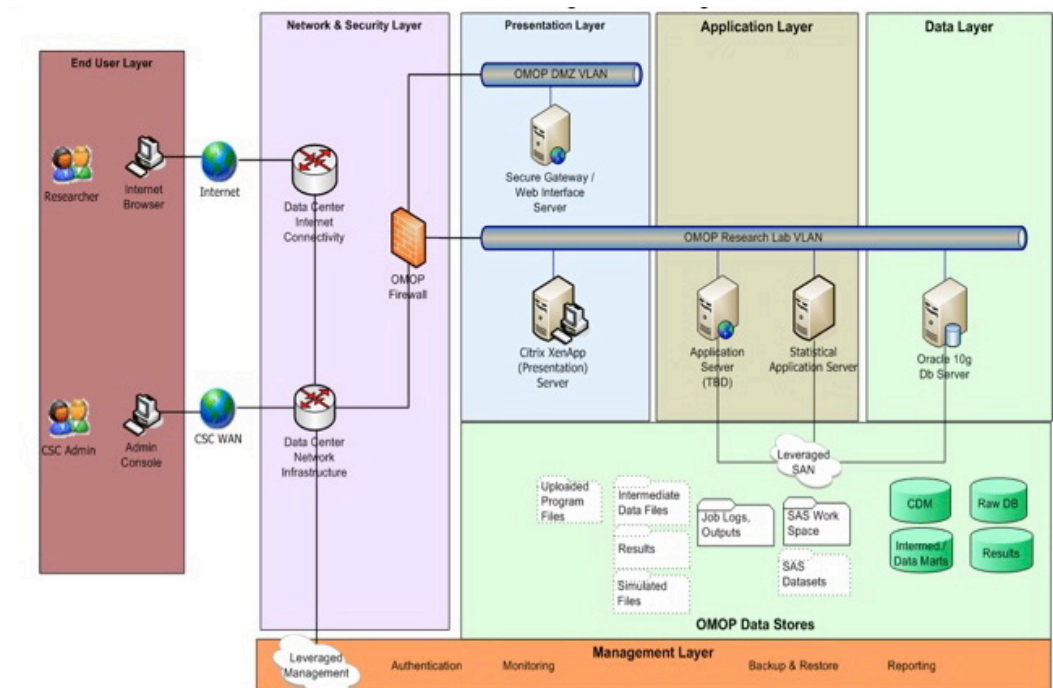
The Health Outcomes of Interest systematic literature reviews were submitted by our collaborators for review. The results are now being used to determine coding requirements for methods development.

The call of participation for Methods Partners yielded over two dozen proposals. Sixteen proposals were accepted and work has begun to establish the OMOP Methods Library.

Five Distributed Data Partners have started the process of transforming their data environments into the OMOP Common Data Model and preparing their analytical environments to support Phase 3 activities.

Visit the <http://omop.fnih.org> for current updates on our progress, recent presentations, and posted deliverables.

The OMOP Research Lab



What is OMOP?

A Public-private Research Partnership of the Foundation for NIH

OMOP is a two-year research effort that will develop and evaluate analytical methods and assess the value of their application to large observational health care data sets, chiefly focusing on health care claims and electronic medical records. OMOP draws on the expertise and resources of the Food and Drug Administration, other federal agencies, academic institutions, the pharmaceutical industry and non-profit organizations. The two-year project is funded through, and managed by, the Foundation for NIH.

In addition to sponsoring specific research efforts, OMOP will create a set of

tools—such as data models, experimental protocols, and database evaluation software—to be placed in the public domain to encourage parallel research by a broad community of scientific investigators. All project results will be made public in accordance with the public health mission of the partnership. These will include comprehensive reports on scientific and technical findings, lessons learned, and peer-reviewed articles on the experimental findings by our sponsored investigators. The goal is to provide significant insights for other efforts to improve the nation's drug safety.

Participate in OMOP

Here are some ways you can get involved:

- Review and comment on draft documents on the OMOP Web site
- Enter the OMOP Methods Competition (more information at <http://omop.fnih.org>)
- Attend the Fall 2009 OMOP Symposium
- Become an OMOP Extended Consortium participant

OMOP Newsletter

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Mark your calendar for the

OMOP 2009 Symposium

Hyatt Regency
Bethesda

One Bethesda
Metro Center (7400
Wisconsin Avenue)
Bethesda, MD
20815

[http://bethesda.
hyatt.com/hyatt/
hotels/index.jsp](http://bethesda.hyatt.com/hyatt/hotels/index.jsp)

November 12th:
Open to the public
via on-site and Web
conferencing

Registration
information will be
posted at [http://
omop.fnih.org](http://omop.fnih.org)

Follow OMOP

OMOP will be presenting at the following events:

M2009 Data Mining Conference

October 26-27, 2009
Las Vegas, NV

(AMIA) American Medical Informatics Association

Panel: Informatics
Opportunities and Challenges
for Improving Drug Safety
November 2009

American Medical Informatics Association (AMIA) Annual Symposium

Panel: Informatics
Opportunities and Challenges
for Improving Drug Safety
November 14-18, 2009
San Francisco, CA

2nd DIA Conference on Signal Detection and Data Mining

International Perspectives on
Spontaneous Reports and
Other Healthcare Data Sets
November 17-18, 2009
New York

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