

# OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

## Phase 1 Progress Report Research Preparation

The Observational Medical Outcomes Partnership (OMOP) launched Phase 1 of our research plan in February. In Phase 1, we are focused on preparing our research laboratory, staffing the research core and establishing a series of capabilities that will serve as the foundation for the subsequent research phases.

With governance being a key design element of the partnership, the OMOP charter called for establishing two advisory boards to provide scientific and technical oversight of our activities through each phase. In March we launched our Scientific Advisory Board (SAB) and Healthcare Informatics Advisory Board (HIAB). The SAB provides independent review of and expert input into the scientific aspects of OMOP's activities. The HIAB provides independent review of and expert input into OMOP's technology efforts related to privacy and security, terminology and coding, data and data models. The composition of the advisory boards was determined by the OMOP Executive Board and includes representatives from a variety of stakeholder groups including academics, consumer and patient advocacy, health care, government, privacy and industry.

Both advisory boards have been very active in Phase 1, reviewing requests for applications/proposals, reviewing and scoring vendor proposals, and reviewing and providing feedback and advice on design documents.

Work on the OMOP Research Laboratory started in early February with a contract awarded to establish our information technology platform. The Research Lab will provide the computational and data-management resources needed to support our research. The lab provides researchers with access to the data, statistical analysis tools and a methods library. De-identified data have been acquired and loaded onto the platform, providing OMOP with five data sets spanning electronic health records, commercial claims, Medicare and Medicaid supplemental claims and laboratory data.

Work on defining the OMOP Common Data Model (CDM) specification has been completed and reviewed (See page 6 in this newsletter). Information on the CDM is available on the OMOP Web site. Work is underway to configure the data transformation software needed

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to convert the raw data sets to the CDM format and to develop a plan to work with the multitude of vocabulary and terminology standards that we will encounter within the health care data.

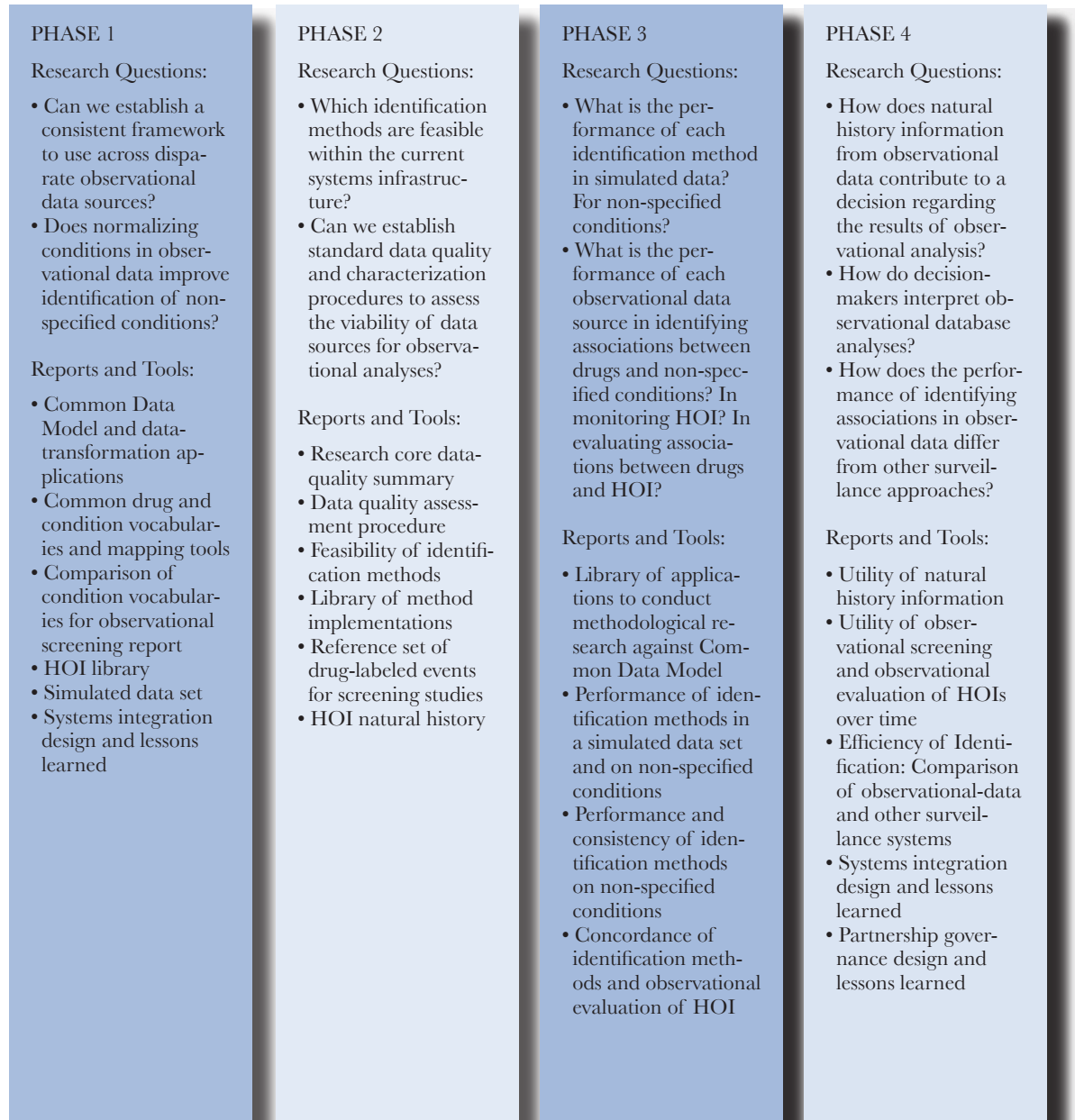
Three major Requests for Applications (RFA) were issued during the first quarter. The first RFA was for the construction of an Observational Medical Data Set Simulator. The project has been awarded and work is underway. The second RFA was for the development of an open-source Health Outcomes of Interest Library. Two research organizations have been engaged to contribute to its establishment. The third RFA was issued to identify potential distributed research partners. It generated a lot of interest and numerous proposals. A panel consisting of representatives from the SAB, HIAB, OMOP PIs, and OMOP Executive Board is in the process of reviewing and scoring the proposals. A recommendation to the full Executive Board is anticipated by the end of June.

A call for participation was also issued to identify potential resources, tools and skills to develop and execute analysis code within the OMOP Research Lab. We are looking for individuals and organizations that have existing programming code for an analysis method, are interested in implementing an existing method, or have an idea for a novel approach for identifying non-specified conditions or monitoring of Health Outcomes of Interest (e.g., Aplastic Anemia—find out more about HOIs on the OMOP Web site: <http://omop.fnih.org>).

Staffing of the research core has progressed with the addition of a total of four new programmers and statisticians. In addition to these staff, several academic and industry partners have agreed to provide programming and statistician resources, including David Madigan, Ph.D.; Professor & Chair, Department of Statistics, Columbia University.

**OMOP Project Phases**

1. Feasibility of Data Infrastructure
2. Feasibility of Analyses
3. Performance Measurements
4. Utility of Analyses and Process



# Advisory Boards

## Scientific and Healthcare Informatics Advisory Boards

### Scientific Advisory Board

The Scientific Advisory Board (SAB) provides independent review of and expert input into the scientific aspects of OMOP's activities.

**Elizabeth B. Andrews, M.P.H., Ph.D.**

Vice President, Pharmacoepidemiology and Risk Management, RTI Health Solutions; Adjunct Associate Professor, UNC-CH Schools of Public Health and Pharmacy

**Andrew Bate, Ph.D.**

Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden; Department of Information Systems and Computing Brunel University, London, UK; Research Manager, Visiting Professor

**Dr. Jesse Berlin**

Johnson & Johnson Pharmaceutical R & D, Vice President, Epidemiology

**Robert Lowell Davis, M.D., M.P.H.**

Center for Health Research Southeast; Kaiser Permanente Georgia, Director of Research

**Steven D. Findlay**

Consumers Union, Senior Health Policy Analyst

**Sean Hennessy, Pharm.D., Ph.D.**

Assistant Professor of Epidemiology and of Pharmacology, University of Pennsylvania School of Medicine

**Michael S. Katz**

International Myeloma Foundation; Coalition of Cancer Cooperative Groups, Vice President; Chair, Patient Advisory Board

**Allen A. Mitchell, M.D.**

Professor of Epidemiology & Pediatrics, Boston University Schools of Public Health & Medicine, Director, Slone Epidemiology Center at Boston University

**Dr. David Page**

University of Wisconsin – Madison, Professor, Department of Biostatistics & Medical Informatics

**Kenneth J. Rothman, Dr.PH.**

RTI Health Solutions, RTI International, Research Triangle Park, NC, Distinguished Fellow and Vice President, Epidemiology Research; Boston University, Boston, MA, Professor of Epidemiology and Medicine

**Judy A. Staffa, Ph.D., R.Ph.**

FDA/CDER/OSE, Associate Director for Regulatory Research

**Alexander M. Walker, M.D., Dr.PH.**

World Health Information Science Consultants, LLC, Wellesley, MA, Principal; Department of Epidemiology Harvard School of Public Health, Boston, MA, Adjunct Professor

### Healthcare Informatics Advisory Board

The Healthcare Informatics Advisory Board (HIAB) provides independent review and expert input into the OMOP's technology efforts related to privacy and security, terminology and coding, data, and data models.

**Col. Kevin Abbott, M.D., M.P.H.**

Staff Nephrologist, Washington, DC

**Jeffrey S. Brown, Ph.D.**

Harvard Medical School; Harvard Pilgrim Health Care; Department of Ambulatory Care and Prevention, Lecturer; Director of the HMORN CERT Data Coordinating Center; Research Director, Therapeutics Research and Infectious Disease Epidemiology

**Stanley M. Huff, M.D.**

Intermountain Healthcare; University of Utah School of Medicine, Chief Medical Informatics Officer; Professor (clinical)

**Diane T. MacKinnon**

FDA Patient Representative Program, Patient Consultant

**Dr. Clement J. McDonald**

Director, Lister Hill Center for Biomedical Communications

**David S. Memel, M.D., M.S., M.B.A.**

Aetna, Head of Aetna Informatics

**Joy Pritts**

Research Associate Professor, Health Policy Institute, Georgetown University; Senior Scholar, O'Neill Institute for National and Global Health Law, Georgetown University

**Robert Thwaites**

United BioSource Corporation, Senior Executive Director - Europe

#### Advisory Boards

Two advisory boards provide technical oversight to the Partnership:

1. Scientific Advisory Board (SAB)
2. Healthcare Informatics Advisory Board (HIAB)

Composition of these boards is defined in the OMOP charter, determined by the Executive Board and approved by the foundation Board

# One-on-One

## Q&A with SAB member Robert L. Davis, M.D., M.P.H.



*In April 2009, Emily Welebob, OMOP Research Program Manager, interviewed Robert L. Davis, M.D., M.P.H., Director of the Center for Health Research Southeast (CHR/SE), Kaiser Permanente of Georgia, and member of the OMOP Scientific Advisory Board. What follows are Dr. Davis' thoughts on the challenges of using claims and health care data for research and the opportunities that lie ahead.*

*Dr. Davis, a pediatrician, has an extensive career in research and academic medicine. The Center for Health Research is a non-profit research institution dedicated to advancing knowledge to improve health.*

**Q: In your role as director of research, what are the challenges you face in using either claims or health care data for research?**

**RD:** One challenge in using either claims or clinical data is that often you do not know how believable the data is. Are the codes indicative of a new occurrence of a disease or condition? Or do they indicate something else—for example, the history of a condition or a visit to rule out some disease, or maybe it's just a mis-coded diagnosis. Even when you get a handle on how to use your own data, you find that it is always changing and shifting. With multiple priorities today, it is hard to find the resources and the time to do a complete medical review on every person in every study, and with study populations frequently ranging into the millions, it's simply not feasible.

In addition, it is always important to remember that the data in the electronic medical record (or paper charts) was collected for medical purposes and not research purposes—so even when you do a medical-record review, often times the quality or quantity of information that you are hoping for simply is not recorded. It is humbling but important to acknowledge these challenges when we do research.

We are getting better as more research is being

done in drug-safety surveillance—we have gotten better about validating the data we use, and paying more attention to identifying those areas where automated data can be used—and understanding those areas where more data quality work is needed before we can rely on automated data sources.

Another challenge, which is under-appreciated, is that it is critical to work with people who know the data intimately. Local data has quirks in it and may not always be generalizable. Researchers need to be in the team of people who are closest to the data. Not only can it take a lot of time for data analysts and programmers to gain experience in understanding the data and how it is stored and can be interpreted, but I have found that what you need to know is not always written down about the data.

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**Q: How do you see drug safety getting more attention in research institutions, outside of clinical trials?**

**RD:** With all the recent attention to high-profile medication issues and problems over the past decade, drug safety has moved to center stage. This attention in turn is highlighting the need for a larger and more efficient infrastructure to monitor drug-safety issues. Clinical-trial data are critical, and often have excellent quality characteristics, but they ultimately have

# One-on-One

## with Dr. Robert L. Davis

limited ability to inform us about the safety of drugs when used in people who are excluded from the trials (e.g., people with polypharmacy or chronic diseases). We do not know enough about Adverse Drug Events (ADEs) that may occur due to long-term drug usage, or about ADEs that are very rare, but serious, or about ADEs when used in those people who are excluded from trials. Clinical trials are very valuable, but only part of the story.

The OMOP project is going to give needed attention to drug safety outside of clinical trials. OMOP is part of an overdue move toward standardizing how to create and/or capture this drug-safety information.

It is good that OMOP is convening discussions among researchers and is looking to explore new ways of collecting and analyzing data.

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lot of progress in terms of how we extract study data from these different resources, how we ensure high-quality data, and how we standardize the various study data elements. In addition, it is not too early to be thinking about the data sets of the future. For example, how do we begin to capture pharmacogenetic data in the local data sets, with an eye toward standardizing quality and quantity, while also ensuring that we maintain patient privacy?

Secondly, it is important to improve upon the granularity of the data that we collect right now. For example, it would be great for drug-safety research to have access to coded EKG readings, not just a scanned report that is ultimately not coded and only accessible by medical-record review. Too much of what happens to the patient is still not accessible for efficient use in large, population-based research.

**Q: How important are validation studies?**

**RD:** Validation of data and results is essential. We need to be stringent on requiring external sources by which to validate one's findings. In many of these studies, we look at many different drug exposures and many different outcomes—and so it is to be expected that we will come up with a number of statistically significant findings—some of which may be true while others are false. The question, then, is where we should turn to validate the information? We need to build in an explicit approach to do these sorts of validation studies, so that, if and when action is necessary with regards to drug safety, we are moving forward based on multiple data points, from different populations or from different areas.

**Q: There is no perfect data set to perform research on. What is needed to make the data sets friendlier?**

**RD:** This requires a significant investment of money and infrastructure. Right now, many of the data sets used around the country bear some general relationship to one another, but are a long way from being interchangeable. It is not realistic to expect all the different types of administrative data sets used by the different parts of the U.S. health care system to be interchangeable. But nevertheless, we can still make a

**Q: What are your thoughts on using a common data model across disparate data sources?**

**RD:** A design for a common data model needs to be done to move to the next generation of large safety-surveillance research. This is going to take a substantial monetary investment to develop. However, we do not have to build the perfect Common Data Model today, but it is important to have an iterative approach. OMOP is a process for research and development; it is not a resource yet. I am hopeful that through the OMOP Common Data Model work, we can gain experience, and have some early success with the foundational issues, and later expand upon these successes.

**Q: Within the OMOP research plan, what interests you the most?**

**RD:** I am most interested in the methods. We have to develop and employ better statistical methods to allow for efficient, reliable and effective combining of data across health care organizations in order to end up with something that is useful and helpful for researchers, regulatory agencies and the public. There is a lot of work being done in this area, and it is an exciting time to be involved.

# Common Data Model

## Phase I Progress Report

Because OMOP’s methodological research will be conducted across multiple disparate observational databases (administrative claims and electronic health records), it is necessary to develop a common structure and framework for organizing and standardizing observational data so that consistent analyses across disparate data sources can be made. To this end, the OMOP system integrator is designing and implementing a Common Data Model (CDM). All analysis methods and codes used to execute OMOP research protocols will adhere to the CDM, enabling portability of research methods and semantic interoperability. A terminology dictionary containing standard terminologies for data transformation will be utilized within the OMOP Research Lab and by all participating distributed research partners. The developmental, iterative approach to the CDM

implementation lays the groundwork for support of broader pharmacovigilance activities.

On March 26, members from the Scientific and Healthcare Informatics advisory boards met to offer feedback and recommendations for the next steps in implementing the CDM. The advisers unanimously agreed to move forward with testing the initial CDM design on the OMOP research core. Immediate next steps include the application of the CDM to the Central Research Core databases within the core IT platform and the reporting of lessons learned, implementation code, and suggestions for model refinement. OMOP Web site subscribers can find materials from the Common Data Model meeting at <http://omop.fnih.org/?q=node/84>.

For CDM updates and new document releases go to <http://omop.fnih.org>.

	Administrative Claims	Electronic Health Records
<b>Data Source</b>	<ul style="list-style-type: none"> <li>• Prescriptions from pharmacy claims</li> <li>• Diagnoses from procedures/medical billing claims</li> </ul>	<ul style="list-style-type: none"> <li>• All data (medications, prescriptions, symptoms, diagnoses, labs) from point-of-care</li> </ul>
<b>Advantages</b>	<ul style="list-style-type: none"> <li>• Very large sample size</li> <li>• Long exposure</li> <li>• Comprehensive summary of health-related activities during enrollment</li> </ul>	<ul style="list-style-type: none"> <li>• Large sample size</li> <li>• More rich and granular data relevant to provider</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Part of medical history beyond enrollment may be missing</li> <li>• Few symptoms</li> <li>• Misclassification, since data is recorded for billing, not for research purposes</li> <li>• Bias: population with private insurance</li> </ul>	<ul style="list-style-type: none"> <li>• Data only from participating health care professionals (patient data incomplete for portion of care received outside EHR system)</li> </ul>

**OMOP Project Phases**

1. Feasibility of Data Infrastructure
2. Feasibility of Analyses
3. Performance Measurements
4. Utility of Analyses and Process

Common Data Model Scope Foundational Approach	
<b>What OMOP is Doing</b>	
<ul style="list-style-type: none"> <li>• Creating one common data model that could accommodate any type of data</li> <li>• Facilitating comparison of analyses’ results across sources</li> <li>• Providing a conceptual model to allow researchers to develop analyses that can be portable across data sources</li> </ul>	
<b>What OMOP is Not Doing</b>	
<ul style="list-style-type: none"> <li>• Combining multiple data sets into one centralized database</li> <li>• Forcing claims data into a EHR mode</li> <li>• Forcing EHR data into a claims mode</li> <li>• Developing a graphical user interface to automatically create structured queries</li> </ul>	

# Why a Simulated Data Set?

## In Search of the “True Association”

In February, OMOP released a Request for Application for the development of an automated procedure to construct simulated patient data sets. The goal of the data sets is to assist the evaluation of analytic methods in identifying potential drug-outcome records in observational databases. By March, several vendors had provided proposals describing approaches for the design and development of a simulation program. OMOP awarded the Simulated Data Set work to Prosanos Corporation ([www.prosanos.com](http://www.prosanos.com)). Why the need for simulated tool and data sets?

Methodological research typically requires some benchmark or gold standard to measure performance. A desired gold standard would be a true causal relationship between a drug and a health outcome of known parameters. Unfortunately, most observational data sources are poorly characterized, clinical observations may be insufficiently recorded or poorly validated and are unknown to the researcher; thus the truth may not be determined. True relationships between drugs and outcomes may be difficult to ascertain as these “known associations” may be affected by issues, including too small a sample size, inadequacy of data capture, and measured and unmeasured confounding variables.

The simulation procedure allows for the construction of data sets of hypothetical patients and fictitious drugs and outcomes. The data sets are as similar as possible to real-patient observations. Having simulated claims or electronic health record data sets with known characteristics will facilitate methodological research by creating an environment in which to evaluate the performance of various analytical methods.

The simulated data structure, including table names, field names and data types, will conform to the OMOP’s Common Data Model. The simulated populations may include at least 100 million hypothetical persons.

OMOP’s advisory boards and research investigators will identify and define the dimensions, categories and associated probability distributions required to characterize the types of scenarios to be

included within the simulated data set.

The data sets will be constructed so that the relationships between the fictional drugs and fictional outcomes are characterized as “true” or “false” associations. That is, hypothetical persons will be created and assigned varying drug exposure lengths and incidences of health outcomes based on random sampling from probability distributions that define the relationships between the fictional drugs and outcomes. These relationships will be simulated, but will be representative of the types of relationships expected to be observed within real observational data sources.

The use of the simulated data sets will be limited to perform statistical evaluations of the analytical methods used to identify drug-outcome associations. The performance characteristics (sensitivity, specificity, positive and negative predictive value) of the analytical methods can then be empirically measured in terms of the known characteristics of the data; will enable the classification of the drug-outcome relationships as “true” or “false,” and will allow classification of the drug-outcome pairs as positives or negatives. As the simulated data will represent hypothetical patients fictional drug classes and artificial outcomes types,

there can be no clinical interpretations drawn from the data.

Two simulated data sets will be made available to the public. The first simulated data set and documentation outlining the expected relationships will be used to encourage methods development from the research community, and enable researchers to evaluate the performance of their methods. The second simulated data set will be made available without publication of the expected associations, and will be used to enable independent replication and validation of methods findings. Researchers will be encouraged to provide the methods implementation and summary results to the OMOP research core, so they can be compared to the true relationships in assessing methods performance.

OMOP Web site subscribers can find further detail on OMOP’s Simulated Data Set at <http://omop.fnih.org/?q=node/70>.

*OMOP’s advisory boards and research investigators will identify and define the dimensions, categories and associated probability distributions required to characterize the types of scenarios to be included within the simulated data set.*

# The OMOP Research Laboratory

## Computing Platform

The Observational Medical Outcomes Partnership researchers are developing and testing various analytical methods for their ability to detect and evaluate drug-safety issues and benefits over time. They do this by utilizing databases of de-identified patient medical records and health insurance claims. The OMOP Research Laboratory is providing a secure computing environment to facilitate these activities.

Design of the Research Lab began early in the planning phases of OMOP, with the formation of a work group comprised of technology experts from academia, government, information technology, health care and pharmaceutical research organizations. The work group focused on defining the core technology requirements needed to enable the software development activities, data management, data security, methods testing and analysis, and results management activities of OMOP. It also assessed available technology options and potential technology partners.

Foundation for the National Institutes of Health staff and OMOP research investigators assumed responsibility for completing the design work and selecting a technology partner in late 2008. Computer Sciences Corporation (CSC) was engaged to provide systems integration services to complete the detailed design work, build the computing environment (known as the OMOP Research Laboratory), and operate it for the foundation.

The initial task facing the OMOP team and CSC was gaining access to a suitable interim secure computing facility to house five large health care databases within weeks of the formal launch of the partnership. Early access to these databases was needed to support OMOP's research preparation plans and to complete the design of the Research Lab.

The primary activity on this temporary platform was the creation of a common data model, or CDM, and addressing the complex challenge of mapping a wide variety of medical coding terminologies and health care vocabularies into the model (see related article on page 6). CSC established the interim platform in one of its Boston-area data centers and had it available to OMOP within two months.

After loading the raw, de-identified data into the interim research lab, the OMOP technology team started developing and implementing the CDM. In July of 2009, the development of the CDM will be complete and all data will be moved to the more powerful permanent research lab, which is designed to support OMOP's computationally intensive research activities.

Health care databases consisting of electronic medical records and insurance claims data are very large, containing tens to hundreds of millions of records, differ greatly in their content and format, and present a significant challenge to anyone attempting to analyze them with a common set of methods. There are two schools of thought with respect to addressing this challenge; either modify each method to run within each targeted database environment or create a common data model (CDM), transform each of the targeted databases to the CDM, and run a common set of methods against the data in the CDM format. OMOP elected to take the CDM route and will not only apply it to the five acquired data sets, but also require our research partners to do the same.

The core features and capabilities of this new Research Lab include:

- a large database system for the health care data and the CDM implementation
- sufficient computing power to develop and run methods that can be very computationally demanding
- work-flow services to enable batch scheduling of tens of thousands of method runs
- activity logging and audit to monitor data usage
- remote access for a geographically dispersed team of programmers, statisticians, research investigators and collaborators
- strong security mechanisms to protect data

The computing technology utilized in the Research Lab consists of:

- Oracle Database Server: Sun M5000 server with 16 processors (8 x dual-core CPUs), 64GB memory, redundant power, network, and storage, dual-port FibreChannel (FC) host bus adapters (HBA) for Storage Area Network (SAN) connectivity
- SAN with 10TB of total usable storage
- Statistical Application Server (SAS, R): Sun M5000 server with 12 processors (6x dual-core CPUs), 32GB memory, redundant power, network, and storage, dual-port FibreChannel (FC) host bus adapter (HBA)s for Storage Area Network (SAN) connectivity

*(continued)*

# The OMOP Research Laboratory Computing Platform

- Oracle Life Science Hub Server: Sun M5000 server with 12 processors (6 x dual-core CPUs), 32GB memory, redundant power, network, and storage, dual-port FC HBAs for SAN connectivity
- Virtual Citrix Secure Gateway/Web Interface and Virtual Citrix XenApp/Presentation remote access servers
- Windows Interactive Development Server with two processors, 4GB memory and 50GB local storage

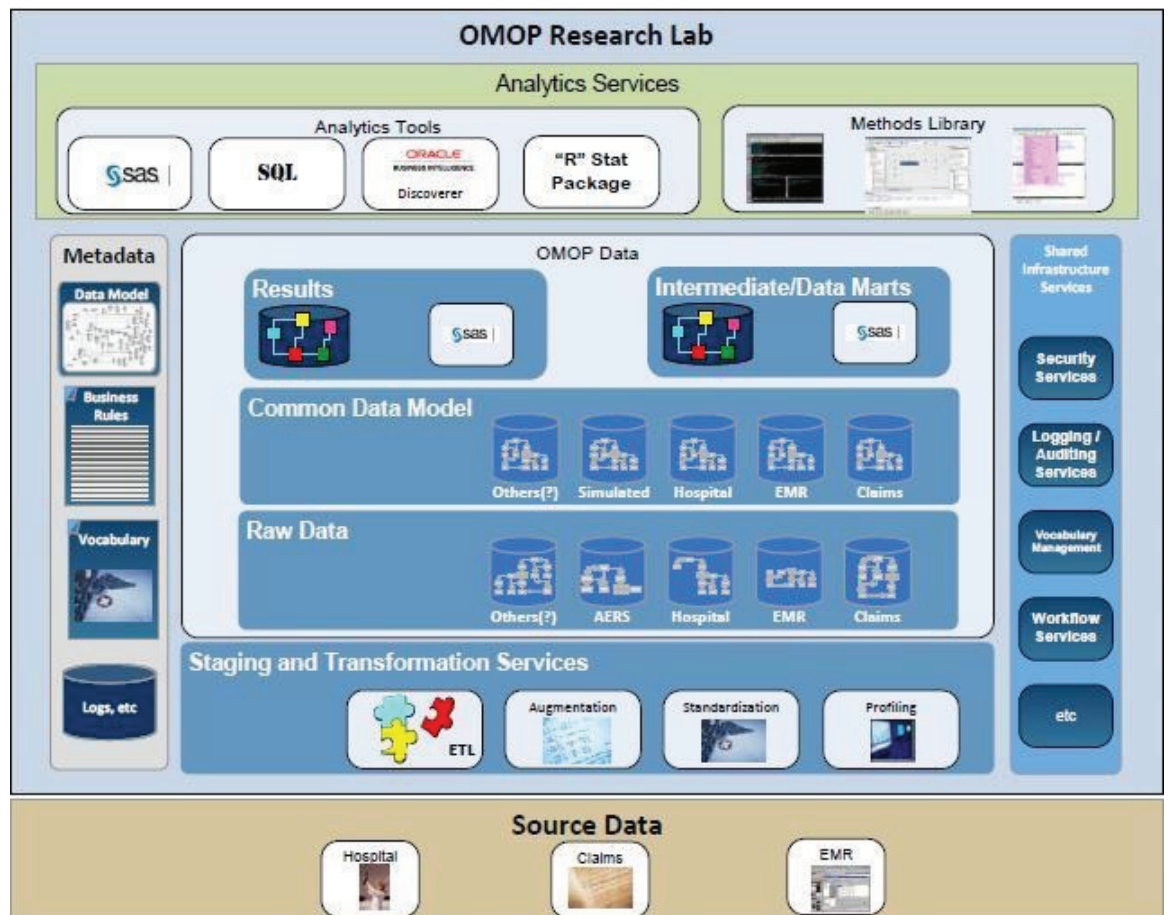
Since the OMOP research team, partners and collaborators are located throughout the United States, the Research Lab is accessible to them via the Internet through the secure Virtual Citrix Gateway. This allows the research team and partners to participate in methods development while ensuring that no data leaves the research lab. The Citrix Gateway provides remote access to integrated software development environments, which are primarily the SAS and R statistical analysis tools.

When software for each method is complete, it will be transferred to the Oracle Life Science Hub (LSH). LSH is used to manage the methods software library, analysis of the work-flow process, auditing and reporting, and scheduling of production applications on the Statistical Application Server.

The Statistical Application Server is configured to handle the complex computational analysis activities that the library of methods will generate. These analyses will be scheduled to run in batch mode rather than in the interactive environments the software developers will utilize.

The Research Laboratory provides a secure interactive environment needed to support the programming and management of a large library of analytical methods, a robust database environment to query and transform very large data sets for analysis, and a computational environment to test and analyze the performance of these methods.

More details on the Research Laboratory will be posted on the OMOP Web site in July.



The OMOP Research Lab is implemented and managed by CSC

# FAQs

## General Information

**Q: What is the Observational Medical Outcomes Partnership?**

**A:** The Observational Medical Outcomes Partnership (OMOP) is a public-private partnership aimed at improving the monitoring of drugs for safety, as well as evaluating benefits.

**Q: What will the partnership do?**

**A:** The partnership will conduct research to determine the feasibility and value of using health care databases to study the effects of medicines on the market. The series of studies will include assessing different types of data from across the United States, developing tools and methods to analyze the databases, and evaluating how analyses can contribute to decision-making. Together, these studies should provide the objective evidence needed to inform best practices for using such data.

**Q: Where will the research data come from?**

**A:** Data for the project will come from commonly available commercial health-research databases, health care providers' patient records, and insurers' claims records. OMOP will ensure strict privacy and security safeguards while conducting research on these data.

**Q: How will patient data privacy be assured?**

**A:** Organizations providing data to OMOP will de-identify all patient records and ensure HIPAA compliance. Research using patient-identifiable information will be conducted only by partner institutions within their secure computing facilities. In addition, patient advocates and data-privacy experts from the OMOP Executive Board, Scientific Advisory Board, and Health Care Informatics Advisory Board will provide oversight of the research.

**Q: What does the partnership mean for patients?**

**A:** Enhancing the ability to identify and evaluate the safety and benefits of medicines has clear benefit for the entire health care system, including patients. The partnership hopes that its research will benefit patients in the long term by helping improve the nation's drug-safety system.

**Q: Who is involved in the partnership?**

**A:** OMOP is a collaborative public-private partnership involving the pharmaceutical industry, academic institutions, non-profit organizations, the Food and Drug Administration and other federal agencies. It is managed by the Foundation for the National Institutes of Health.

**Q: How is the partnership funded?**

**A:** OMOP is funded by the Foundation for the National Institutes of Health, with contributions from 16 corporate and non-profit donors. For a full

listing of current donors, visit the "About Us" section of the OMOP Web site: <http://omop.fnih.org>

**Q: Will findings be released to the public?**

**A:** OMOP intends to promote transparency by placing all information of interest in the public domain as quickly as possible. A publicly accessible Web site will communicate the research and maintain awareness for consumers, patients and providers.

**Q: Is the partnership studying only drug safety?**

**A:** The partnership will utilize methodological research to identify and evaluate all effects of medicines. The primary focus is on potential safety issues, but studies will be conducted to explore beneficial outcomes as well.

**Q: Are there unique challenges to studying benefits? Isn't there evidence that observational data aren't useful in understanding benefits?**

**A:** It is true that current observational methods are unsatisfactory for studying health benefits of therapy. But this project will create a new research infrastructure that may prove useful in exploring questions beyond safety. The collaborators therefore will ask a few initial questions to determine how and whether methods can be developed to appropriately study benefit using these kinds of data.

**Q: Does the research include medical devices?**

**A:** The partnership core will focus on drugs only. However, an observer from the medical-device industry will sit on the Executive Board to ensure its activities can translate to the medical-device world.

**Q: When will the partnership complete its research?**

**A:** The current plan calls for the partnership to complete its work by the end of 2010.

**Q: How is the partnership being managed?**

**A:** An Executive Director provides overall executive management under direction from the partnership's Executive Board and the Foundation for NIH Board. Three principal investigators, one each from the pharmaceutical industry, the non-profit sector and the FDA are leading the research program.

**Q: How is the partnership governed?**

**A:** An Executive Board consisting of consumer, patient, academic, health care provider, data provider, FDA and pharmaceutical-industry representatives sets the direction and provides oversight for the partnership. It will be assisted by a Scientific Advisory Board and a Health Care Informatics Advisory Board, which will provide additional expertise and perspective on key scientific and information-technology issues.

**Q: Where can I learn more about the partnership?**

**A:** Visit the OMOP Web site at <http://omop.fnih.org>

### FAQs

Check the OMOP Web site for updates

# What is OMOP?

## A Public-private Research Partnership of the Foundation for the 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 the 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 and participate in online discussions on the OMOP Web site
- Answer the Call for Participation: Implementing Observational Analysis Methods
- Enter the OMOP Data Mining Competition (more information coming in July)
- Attend the Fall 2009 OMOP Symposium

### OMOP Newsletter

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partnerships

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