

Observational Medical Outcomes Partnership (OMOP)

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Research Areas



Data-Sharing Enabler

At a Glance

- Status: **Completed Consortium**
- Year Launched: **2007**
- Initiating Organization: **Foundation of the National Institutes of Health**
- Initiator Type: **Nonprofit foundation**
- Location: **North America**

Abstract

The Observational Medical Outcomes Partnership (OMOP) was managed by the Foundation for the National Institutes of Health (FNIH) with the mission to design and implement a pilot project that demonstrates that active observational data, when added to currently used methods, could result in a timely and effective medical product safety surveillance process. Following its original strategy, OMOP was completed in June 2013 and was transferred from FNIH to the Reagan-Udall Foundation for the U.S. Food and Drug Administration (FDA) as the Innovation in Medical Evidence Development and Surveillance (IMEDS) program to support the FDA Sentinel Initiative.

Mission

The goal of OMOP was to demonstrate the feasibility of using observational data — administrative claims and electronic medical records — to supplement the existing use of postmarket medical product safety monitoring systems. OMOP's participants focused on designing a pilot project that tested a common infrastructure, with multiple data sources, using the framework to run a series of experiments and analyses.

OMOP focused on the following objectives:

- Defining and evaluating analytical methods that can be used to identify associations between drugs and health-related conditions
- Developing tools for organizing access to and evaluating the usefulness of multiple observational datasets
- Studying how information from analyses of observational data can be used to inform ongoing pharmacovigilance efforts

Consortium History

In order to achieve its mission, OMOP created the OMOP Research Lab, an informatics infrastructure to manage and analyze the data from more than 100 million patients. The software tools, packaged as the OMOP Web RL Platform, were developed and made available to the public. In addition to these data tools, OMOP discovered methods for using data to reliably identify correlations between individual medical interventions and specific health outcomes. These insights are being used to help inform the FDA Sentinel Initiative as part of the IMEDS program. The achievements of the program included:

- Establishment of a common data model and creation of data characterization tools and vocabulary mappings
- Implementation of “Health Outcome of Interest” definitions, including a program to implement these definitions as part of the Regularized Identification of Cohorts (RICO)
- Release of 14 analysis methods to evaluate the performance of methods and data in identifying drug safety issues

Structure & Governance

FDA, Pharmaceutical Research and Manufacturers of America (PhRMA), and FNIH were the founding partners of OMOP, with FNIH managing the partnership. An Organizing Committee established OMOP's foundations and consisted of one senior representative from each of the three founding partners. This committee was dissolved after formation of the OMOP Executive Board.

OMOP's activities were conducted under the oversight of an OMOP Executive Board, which was composed of 13 members that represented the interests of each of the OMOP major stakeholders.

The Executive Board was supported by several technical advisory boards that were in turn supported by additional technical working groups. Each of these boards and groups were composed of subject-matter experts that represented the broad spectrum of stakeholders. The 14-member Scientific Advisory Board provided independent review of and expert input into the scientific aspects of OMOP's activities. A 6- to 10-member Health Informatics Advisory Board provided independent review and expert input into OMOP's technology governance and project requirements related to privacy and security, terminology and coding, and data and data models.

In general, FDA provided scientific and regulatory expertise to OMOP to further evaluate how observational data can be used to inform regulatory decisions. Industry provided financial, scientific, and technical support to OMOP. An executive director provided day-to-day management of OMOP as an employee of FNIH, reporting to the OMOP Executive Committee and the FNIH Board.

Financing

Biopharmaceutical and other industry members provided financial or in-kind support to OMOP at the beginning of OMOP and/or after the design stage. By providing the majority of the resources needed to fund and run OMOP, contributing members gained the right to nominate a representative to serve on the Executive Board. (During the design stage, the interests of the contributing members were represented by the PhRMA representative on the Organizing Committee.) These organizations also participated in the pilot by providing experts and know-how to the working teams.

Intellectual Property

Certain types of pre-existing data and intellectual property (IP) were contributed or acquired by

participants to achieve OMOP's objectives, including the following:

- Methods or processes for extracting, structuring, or normalizing large databases into a common framework and technical infrastructure for housing data and facilitating analyses
- Databases or other information technology assets
- Analytical methods for screening and evaluating observational data, as well as processes for integrating and interpreting screening and evaluation results

The agreements had the following principles:

- Participants retained full ownership of pre-existing data and IP.
- Non-federal participants were granted a limited, nonexclusive, royalty-free, and remuneration-free license to use relevant pre-existing data and IP for research purposes only in connection with the OMOP.
- To the maximum extent possible, OMOP released all IP to the public domain.
- If necessary, FNIH was responsible for managing any IP not freely accessible to the public.
- Participants had the right to analyze data generated in the course of OMOP in a manner consistent with OMOP's scope using their own methods with the express condition that they would publicly disclose methods and results arising out of their analysis to OMOP within an agreed timeframe.

Patent Engagement

Patients were involved as part of the Executive Board, as well as through an advisory committee.

OMOP continually produced white papers and peer-reviewed journal publications that reflected the

lessons learned during each stage of the project. These are available on the OMOP website, which continues to be maintained after the project transition.

Data Sharing

The source data used by OMOP for its pilot project was contributed in-kind by the owners or purchased from them. Data were aggregated into central databases for use in OMOP that were linked to, queried, or otherwise analyzed by OMOP's participants. Access to OMOP source data was given to specific OMOP working team members, Scientific Advisory Board members, or other analysts and researchers engaged by OMOP for the sole purpose of conducting or providing appropriate oversight of the analyses and experiments required to execute OMOP's mission.

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imeds@reaganudall.org

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