

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

**REQUEST FOR APPLICATIONS FOR
DISTRIBUTED RESEARCH PARTNERS WITH OBSERVATIONAL DATA
TO COLLABORATE WITH THE OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP**

RELEASED APRIL 15, 2009

PROJECT TITLE: OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP (OMOP)

PROPOSAL DUE DATE:

Wednesday, May 13, 2009 at 5:00 p.m. Eastern time in Washington, D.C.

EXPECTED TIME PERIOD FOR CONTRACT:

July 2009 – December 2010 (Approximately 17 months)

ELIGIBILITY: This procurement is open to those organizations that satisfy the qualifications stated herein and that are available for work.

CONTENTS OF THE REQUEST FOR APPLICATION:

1. Introduction
2. General Information
3. Proposal Contents
4. Evaluation

1. INTRODUCTION

1.1 PURPOSE AND BACKGROUND

Purpose:

The Observational Medical Outcomes Partnership hereafter called "OMOP," is initiating this Request for Applications (RFA) to solicit proposals from organizations interested in collaborating with OMOP on the design of studies, execution of protocols on the respondent's data in their environment, reporting structured summary analysis results to OMOP's specifications, and supporting interpretation and publication of results.

Funding is available and is being administered by the Foundation for the National Institutes of Health (FNIH). The FNIH has committed \$5 million total costs for Calendar Year 2009 - 2010 to fund 3 to 7 contracts in response to this RFA.

Background:

The Observational Medical Outcomes Partnership (OMOP, <http://omop.fnih.org>) is a public-private partnership designed to help improve the monitoring of drugs for safety. The partnership began in Q4-2008 and will conduct a two-year research initiative to determine whether it is feasible and useful to analyze existing healthcare databases to identify and evaluate safety and benefit issues of drugs already on the market.

OMOP draws on the expertise and resources of the pharmaceutical industry, academic institutions, non-profit organizations, the Food and Drug Administration (FDA), and other federal agencies. The OMOP Research Investigators are the lead scientists for the OMOP project and guide and participate in the research across four project phases.

In addition to sponsoring specific research efforts, OMOP will create a set of tools—such as data models, experimental protocols, and database evaluation tools—that will be placed in the public domain to encourage 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. Dissemination efforts will include comprehensive reports on scientific and technical findings, lessons learned, and peer-reviewed articles on the experimental findings by our sponsored investigators.

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 evaluate the performance of various analytical methods for identifying drug-outcome associations across multiple disparate observational data sources (administrative claims and electronic health records). ***OMOP will partner with a number of different organizations with observational data to undertake this research.***

Each partner will implement multiple methods within their data environment. Each partner will then apply all the implemented methods to their observational data within a series of studies to evaluate the performance characteristics of each method. The partner will submit results from all studies into the OMOP research core. Standardized procedures for executing the studies against the common data model will be made available to facilitate this process. The studies include:

- a. Point-performance of Identification Methods on Non-specified Conditions
 - This study assesses the performance of the identification (hypothesis generating) methods across the entirety of each observational data source. Ten drugs have been selected as test cases. For each drug, we define a reference set of ‘true associations’ based on conditions that are specified on the product labels of each product within the target drug class, and classify all other conditions as ‘negative controls’. This experiment measures the degree to which methods applied to screen the entire dataset for potential associations can distinguish between ‘true’ positives and ‘true’ negatives.
- b. Performance over Time of Identification Methods on Non-specified Conditions
 - This study outlines an approach for providing measures of performance for identification methods as data accumulate over time. These analyses will be similar in intent to those described under “Point-performance of Identification Methods on Non-specified Conditions”, but cumulative subsets of each data source will be created to measure time-to-detection, as well as sensitivity and specificity over time for each method. This exercise addresses whether the identified associations change over time.
- c. Concordance of Identification Methods and Observational Evaluation of Health Outcomes of Interest
 - This study will evaluate the performance of identification (hypothesis generating) methods used to monitor specific Health Outcomes of Interest, comparing results to those of evaluation (hypothesis strengthening) studies. It is anticipated that systematic surveillance methods that can be applied to all drugs may not fully capture the specific nuances that are commonly incorporated into a full pharmacoepidemiologic investigation (including issues of study design, inclusion/exclusion criteria, and covariate selection). This study will assess the degree to which the hypothesis-generating results correspond to the hypothesis-strengthening results in light of these analysis differences. Each partner will produce results for the eleven drug-HOI pairs selected for study.

OMOP will then conduct a study of *Consistency of Identification Methods on Non-specified Conditions*. This study seeks to demonstrate the consistency of results across methods, both across databases and over time. As a descriptive analysis, the similarity in results among methods may support a reduction in the number of alternative methods that are required for further study, while the differences may inform judgments about the robustness of the methods or the data needs for future evaluations of the previously-assessed, or other alternative methods.

For further information regarding methods, please review OMOP’s method documentation found at <http://omop.fnih.org/?q=node/61>.

1.2 SCOPE OF WORK

The solicitation is for several *Distributed Research Partners with Observational Data* to collaborate on the design of studies, execution of protocols on the respondent's data in their environment, reporting structured summary analysis results to OMOP's specifications, and supporting interpretation and publication of results.

The Respondent will be expected to produce and deliver the following products over a 17-month period following award notification:

1. **OMOP Common Data Model:** Implement OMOP's Common Data Model and Terminology Dictionary (initial design found at <http://omop.fnih.org/?q=node/69>)

A Common Data Model and a method for standardizing its content (via a Terminology Dictionary) will ensure methods can be systematically applied to produce meaningfully comparable results across sources.

2. **Method Feasibility:** The OMOP Research Core will produce a catalog of analytical methods and develop implementations of those methods for use against the common data model. Initial efforts to characterize potential methods can be found at: <http://omop.fnih.org/?q=node/61>. OMOP anticipates no more than 20 types of methods, with minor variants within each method type. Our aspiration is that the distributed partner will attempt to run all methods, but we expect the OMOP research core and distributed partner will collaborate to determine the priorities. The Distributed Partner will test and document back to OMOP the feasibility of all implemented methods within their data environment.

All methods determined to be computationally feasible by the Distributed Partner will then be applied within the methodological research studies. A template for the output from these analyses will be determined in a series of meetings and reviewed by the OMOP Scientific Advisory Board.

3. Collaborate with OMOP Research Investigators and other distributed partners on the final protocol design for each study and standardized report.
4. Execute standardized descriptive summary reporting procedures against the common data model within the data environment:
 - a. **Data characteristics report**
OMOP will develop a program for assessing the characteristics of an observational database represented in the common data model to determine its suitability for use in the identification and evaluation. This process will include an inventory of available data elements, a descriptive summary of occurrence of drugs and conditions, and an evaluation of the source's ability to verify clinical observations through medical records or other means.

b. Natural history report

The natural history report is a standardized summary of information about populations of interest. Natural history information is descriptive, with the intent to provide some context and expected rates of drug utilization and condition occurrence to facilitate the interpretation of benefit and risk information. Observational data offers potential value in providing summary information, both about the populations that experience a condition (the disease natural history) as well as the populations that are exposed (natural history of drug utilization). OMOP will develop a program that produces a standardized report to summarize characteristics about the population of interest, including demographic factors (age and gender), co-morbidities and concomitant medications, and health service utilization prior to, during, and after the event onset. The distributed partner will need to execute the natural history procedure for each of the 10 HOIs and 10 drugs under study. Each provider will submit results to the OMOP research core to facilitate cross-source comparisons.

5. Provide source-specific analysis results from each study outlined in 1.1.a-c into the OMOP Research Core for cross-source summary.

For planning purposes, we anticipate 10 methods for monitoring HOIs, which will be run against 10 drug-HOI pairs, for a total of 100 runs of specific method-test case scenarios. For identification of non-specified conditions, we anticipate 5 methods, run against 10 drugs, for 50 total scenarios. If a partner is capable of doing all scenarios across multiple timecuts of their data, then the number of runs could be 2000.

6. Data research partners should assure patient confidentiality and comply with all HIPPA regulations.
7. Collaborate with OMOP Research Investigators and other distributed partners on the final interpretation and publication of results for each study. All distributed partners will be acknowledged in publicly-reported works, and authorship will be determined by established authorship guidelines.
8. Participate in joint meetings with stakeholders to share findings, including the OMOP Executive Board and Advisory Board meetings as appropriate.
9. Prepare and submit quarterly progress reports to the OMOP Program Management Office. A progress report template will be provided, but will include such components as project schedule and budget status, work completed and issues encountered for the reporting period, deliverable tracking and plan for the next quarter. Distributed partners will also be asked to conduct a monthly “check-in” call with the OMOP Program Management Office.

1.3 REQUIRED QUALIFICATIONS

The ideal distributed partner will be responsible for the execution of scientific methods that have been previously executed on the OMOP research lab infrastructure.

1. Distributed Partner Qualifications:

- a. The lead or principal researcher should have demonstrated experience in managing healthcare claims or electronic healthcare data and experience with patient data research.
- b. The research team should have demonstrated experience in drug safety assessment and longitudinal evaluation of quantitative and qualitative data.
- c. Expertise in creating datasets for relational database management systems.
- d. Proven ability to meet deadlines and produce quality work in this area.
- e. Ability to interact and communicate verbally with groups of managers, clients, customers, and the general public.
- f. Ability to review and coordinate the preparation of reports, papers, and presentations for the OMOP Research Core and Advisory Boards.
- g. Knowledge and experience with institutional requirements (e.g., IRB review) for meeting HIPAA requirements.

2. Data Qualifications:

- a. If not previously completed, the candidate partner must complete OMOP's Data Profile <http://www.zoomerang.com/Survey/?p=WEB228TGEVHEKK>. The profile will be used to evaluate the appropriateness of the setting for the methodological research and to understand the data characteristics including whether the data contains required elements of drug exposure and outcome occurrence.
- b. The candidate distributed partner must provide a description of prior use of its data in research. Bibliographic citations from the group are encouraged.
- c. Provide a brief description of the structure of data.

1.4 PERIOD OF PERFORMANCE

The period of performance of any contract resulting from this RFA is tentatively scheduled to begin in July 2009 and to end on December 31, 2010. Amendments extending or reducing the period of performance or reducing the scope of work, if any, shall be at the sole discretion of OMOP.

As part of any grant agreement, OMOP and its partners will agree on timelines and milestones for performance. As adherence to these benchmarks is vital to the achievement of the project's overall goals, FNIH and OMOP must reserve the right to terminate any non-performing grant.

2. GENERAL INFORMATION

2.1 RFA COORDINATOR

The RFA Coordinator is the sole point of contact for this procurement. All communication between the Applicant and FNIH upon receipt of this RFA shall be with the RFA Coordinator, as follows:

Name	Emily Welebob
Address	818 Connecticut Avenue, N.W., Suite 500
City, State, Zip Code	Washington, D.C. 20006
Phone Number	703-508-6225
E-Mail Address	ewelebob@fnihi.org

Communication directed to parties other than the RFP Coordinator may result in disqualification of the Consultant.

2.2 ESTIMATED SCHEDULE OF PROCUREMENT ACTIVITIES

FNIH reserves the right to revise the schedule.

Issue Request for Application on OMOP Website	April 15, 2009
Question and answer period	April 16 to April 23, 2009
Bidders conference	April 24, 2009 1:00 p.m. – 2:00 p.m. Eastern
Proposals due	May 13, 2009
Evaluate proposals	May 2009
Determine awards	June 2009
Negotiate contract & begin work	July 2009

2.3 SUBMISSION OF PROPOSALS

Proposals shall be sent electronically in either Microsoft Word or Adobe Acrobat. Proposals must be received by OMOP no later than 5:00 p.m. Eastern Time, on May 13, 2009. The proposal is to be sent to the RFA Coordinator at the email noted in Section 2.1.

Late proposals will not be accepted and will be automatically disqualified from further consideration. The proposals must respond to the procurement requirements. Do not respond by referring to material presented elsewhere. The proposal must be complete and must stand on its own merits.

Failure to respond to any portion of the procurement document may result in rejection of the proposal as non-responsive. All proposals and any accompanying documentation become the property of OMOP and will not be returned.

2.4 PROPRIETARY INFORMATION/PUBLIC DISCLOSURE

Materials submitted in response to this competitive procurement shall become the property of FNIH.

2.5 COSTS TO PROPOSE

FNIH will not be liable for any costs incurred by the Applicant in preparation of a proposal submitted in response to this RFA, in conduct of a presentation, or any other activities related to responding to this RFA.

2.6 REJECTION OF PROPOSALS

FNIH reserves the right at its sole discretion to reject any and all proposals received without penalty and not to issue a contract as a result of this RFA.

3. PROPOSAL CONTENTS

The major sections of the proposal are to be submitted in the order noted below. Supporting materials should also be provided electronically.

Proposal Sections:

1. Data Description and Quality
2. Computational Environment
3. Work Plan and Schedule
4. Staff and Organizational Qualifications / Experience
5. Cost Proposal

3.1 PROPOSAL CONTENTS

The Technical Proposal must contain a comprehensive description of services that address the scope of work described in Section 1.2. The proposal should including the following elements:

A. Data Description and Quality

Using information from the OMOP data profile, provide a description of the data that you would use to perform the analyses. If there is additional information that OMOP should be aware of concerning your data source, please use this section to further describe. Please describe a rationale for how the candidate partner's data source would be appropriate and robust enough to fulfill OMOP's research objectives.

B. Computational Environment

Please provide a detailed description of the research computing environment where the studies will executed.

C. Work Plan and Schedule

Include all project requirements and the proposed tasks, services, activities, etc., necessary to accomplish the scope and timeline of the project defined in this RFA. This section of the proposal must contain sufficient detail to convey to members of the evaluation team the Applicant's ability to follow the OMOP schedule:

- a. Complete implementation of the OMOP Common Data Model by September 2009.
- b. Implement a determined number of methods (See Section 1.2.2 - determined by the feasibility step) prior to the end of the year 2009.
- c. Over the next 8 months (2010) conduct the studies outlined in Section 1.1 and submit results to OMOP.
 - i. Point-performance of Identification Methods on Non-specified Conditions
 - ii. Performance over Time of Identification Methods on Non-specified Conditions
 - iii. Concordance of Identification Methods and Observational Evaluation of Health Outcomes of Interest
- d. During the last 4 months of 2010, work with OMOP and the other Distributed Partners on lessons learned, presentations, and publications

D. Staff and Organizational Qualifications / Experience

Identify staff who will be assigned to the potential contract, indicating the responsibilities and qualifications of such personnel, and include the amount of time each will be assigned to the project. Provide résumés for the named staff, which include information on the individual's particular skills related to this project, education, experience, significant accomplishments and any other pertinent information.

The Applicant must commit that staff identified in its proposal will actually perform the assigned work. Any staff substitution must have the prior approval of OMOP. Based upon OMOP's work in the research lab with method execution, it is anticipated that dedicated FTE requirements for the implementation of the common data model and executing approximately twenty methods may include: (1) full-time database analyst; (1) full-time programmer; and a part-time Principal Investigator over the 17-month period. Methods and code to implement the methods will be provided in SAS, SQL, and / or R to awardees.

E. Cost Proposal

Identify all costs including expenses to be charged for performing the services necessary to accomplish the scope of work of the contract. The Applicant is to submit a fully detailed budget including staff costs, administrative costs, travel costs, and any other expenses necessary to accomplish the tasks and to produce the deliverables under the contract. Costs for subcontractors are to be broken out separately.

Note: FNIH allows the grantee institution to claim indirect costs of up to 15% of your direct costs, LESS any costs for sub-grantees and/or equipment. In addition, the grantee institution may claim indirect costs of \$5,000 per sub-grantee or 1% of the sub-grant amount, whichever is less. Sub-grantees also are limited to indirect costs of 15% of direct costs minus equipment.

For purposes of indirect cost calculation, equipment is defined as items costing more than \$5,000 each (including multiple parts for one piece of equipment that cumulatively cost more than \$5,000). Equipment costing \$5,000 or less is defined as supplies.

While the formulas above state allowable maximums, one factor in our grant making decisions is the financial efficiency with which an organization can achieve its goals. Therefore we encourage applicants to be thoughtful about the level of indirect costs necessary to complete the proposed project.

4. EVALUATION

4.1 EVALUATION PROCEDURE

Responsive proposals will be evaluated strictly in accordance with the requirements stated in this solicitation and any addenda issued. The evaluation of proposals shall be accomplished by an evaluation team, to be designated by OMOP, which will determine the ranking of the proposals.

4.2 CLARIFICATION OF PROPOSAL

The RFA Coordinator may contact the Applicant for clarification of any portion of the proposal.

4.3 EVALUATION WEIGHTING AND SCORING

The following weighting and points will be assigned to the proposal for evaluation purposes:

Proposal Section	Totals
a. Data Description and Quality	25
b. Computational Environment	15
c. Work Plan and Schedule	10
d. Staff Qualifications/Experience	25
e. Costs	25
GRAND TOTAL FOR WRITTEN PROPOSAL	100 points