

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

**REQUEST FOR PROPOSAL FOR SYSTEMATIC EVALUATION OF HEALTH OUTCOME OF INTEREST
DEFINITIONS IN OBSERVATIONAL STUDIES AND CLINICAL DEFINITIONS FOR THE
OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP**

RELEASED FEBRUARY 23, 2009

PROJECT TITLE: OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP (OMOP)

PROPOSAL DUE DATE:

Monday, March 16, 2009 at 4:30 p.m. Eastern time in Washington, DC.

EXPECTED TIME PERIOD FOR CONTRACT:

April 2009 to July 2009

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 PROPOSAL:

1. Introduction
2. General Information
3. Proposal Contents
4. Evaluation and Contract Award

1. INTRODUCTION

1.1 PURPOSE AND BACKGROUND

The Observational Medical Outcomes Project hereafter called "OMOP," is initiating this Request for Application (RFA) to solicit proposals from organizations interested in participating on a project to:

Purpose

Establish a living, open-source library of Health Outcomes of Interest definitions for general purpose use in observational analyses. Health outcomes of interest (HOI) are a subset of all conditions that are of particular focus due to their historical associations and toxicities with drugs, medical significance, and/or public health implications. There is little consensus for best practice in defining HOIs in observational databases as observational studies for the same outcome often use different definitions. In addition, data sources may vary in available data elements that can be used for definition (e.g., labs) and as such, many outcomes have limited validation work to assess reliability of observational definitions.

These definitions are the critical focus for the central protocols as they bring to the investigators an evidence-based summary of prior observational research definitions and clinical guidelines. These definitions will allow OMOP to compare methods across a number of different data sources using a number of different methods. This RFA provides background, minimum qualifications and describes needed research specific tasks to be accomplished by the contractor.

There are 10 HOIs under study in OMOP:

1. Angioedema
2. Aplastic Anemia
3. Acute Liver Injury
4. Bleeding
5. GI Ulcer Hospitalization
6. Hip Fracture
7. Hospitalization
8. Myocardial Infarction
9. Mortality after Myocardial infarction
10. Renal Failure

Each will require a separate effort to compile the established literature of definitions used in observational database studies and summaries of clinical definitions.

Background

The Foundation for the National Institutes for Health (FNIH) (www.fnih.org) is seeking to hire an experienced researcher to establish a living, open-source library of Health Outcomes of Interest definitions for general purpose use in observational analyses within the OMOP research. The Observational Medical Outcomes Partnership (<http://omop.fnih.org>) is a public-private partnership designed to protect human health by improving the monitoring of drugs for safety and effectiveness. The partnership began in Q4-2008 and will conduct a two-year research initiative to determine the contribution and utility of using existing healthcare databases to identify and evaluate safety 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. It is funded and managed through the Foundation for the National Institutes of Health. 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. These will include comprehensive reports on scientific and technical findings, lessons learned, and peer-reviewed articles on the experimental findings by our sponsored investigators.

1.2 SCOPE OF WORK

The researcher will, under the direction of the OMOP Medical Ontology Manager:

1. Perform systematic literature review for each Health Outcome of Interest
 - Identify clinical diagnostic criteria and coding guidelines
 - Extract operational definitions previously used in observational studies
 - Describe any validation studies that measure case ascertainment performance (including sensitivity, specificity, positive predictive value)
 - Synthesize national estimates of prevalence of disease (if available)

2. Draft HOI design document that characterizes the pool of potential definitions to consider in observational data
 - Submit HOI definition design document for public comment and review by Scientific Advisory Board
 - Elicit feedback from experts in specific clinical domains

1.3 DELIVERABLES

For each Health Outcome of Interest, the researcher will produce the following deliverables:

1. Documentation of search strategy and terms used
2. Archive of all literature reviewed and organized by outcome
3. Completed evidence matrix with explanatory notes as needed for both HOI and clinical definitions
4. List of process steps undertaken and relevant insights

1.4 REQUIRED QUALIFICATIONS

The ideal candidate will be principally responsible for the systematic searching, evaluating and organizing published literature. As such, the qualifications of the organization should include the critical skills and experience of systematic reviews, clinical literature search, and access to electronic publications.

Qualifications: The Applicant must:

- Have 5 years experience in systematic reviews in healthcare with particular experience in identifying and summarizing observational and/or health care database research publications
- Knowledge of systematic review process and outputs
- Knowledge of creating evidence tables for summarizing findings
- Proficient use of standard office computer software, clinical research publication searching taxonomy and software
- Proven ability to meet deadlines and produce quality work in this area
- Ability to interact and verbally communicate with groups of managers, clients, customers, and the general public
- Review and coordinate the preparation of reports, papers, and presentations for the OMOP Research Core, Executive Board, and Advisory Boards

1.5 PERIOD OF PERFORMANCE

The period of performance of any contract resulting from this RFA is tentatively scheduled to begin in April 2009 and to end July 2009. Amendments extending the period of performance, if any, shall be at the sole discretion of OMOP.

2. GENERAL INFORMATION FOR APPLICANTS

2.1 RFA COORDINATOR

The RFA Coordinator is the sole point of contact for this procurement. All communication between the Applicant and OMOP 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@fnih.org

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

2.2 ESTIMATED SCHEDULE OF PROCUREMENT ACTIVITIES

OMOP reserves the right to revise the schedule.

Issue Request for Application on OMOP Website	February 23, 2009
Question and answer period	February 23, 2009 to March 02, 2009
Proposals due	March 16, 2009
Evaluate proposals	March 16 – 27, 2009
Announce “Apparent Successful Applicant” and send notification via e-mail to unsuccessful proposers	March 31, 2009
Negotiate contract & begin work	April

2.3 SUBMISSION OF PROPOSALS

Proposals shall be submitted in hard copy (1 original) and sent electronically. Proposals must be received by OMOP no later than 4:30 p.m. Eastern, on March 16, 2009. The proposal is to be sent to the RFA Coordinator at the address and 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 Foundation for the National Institutes of Health and will not be returned.

2.4 PROPRIETARY INFORMATION/PUBLIC DISCLOSURE

Materials submitted in response to this competitive procurement shall become the property of Foundation for the National Institutes of Health

2.5 COSTS TO PROPOSE

Foundation for the National Institutes of Health will not be liable for any costs incurred by the Consultant 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

Foundation for the National Institutes of Health 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

Proposals must be submitted as Microsoft Word documents or Excel documents (for the Cost Proposal). Supporting materials should also be provided electronically. Proposals must provide information in the same order as presented in this document with the same headings. The major sections of the proposal are to be submitted in the order noted below:

1. Project Approach / Methodology
2. Work Plan and Schedule
3. Deliverables
4. Staff 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 the Objective Section 1.2. The proposal should include the following elements:

- A. Project Approach / Methodology** – Include a complete description of the Applicant’s proposed approach and methodology for the project as explained in the Scope of Work Section 1.2. This section should convey Applicant’s understanding of the proposed project, as well as describe any experience on similar projects.
- B. Work Plan and Schedule**– Include all project requirements and the proposed tasks, services, activities, etc. necessary to accomplish the scope of the project defined in this RFA. This section of the technical proposal must contain sufficient detail to convey to members of the OMOP evaluation team the Applicant’s knowledge of the subjects and skills necessary to successfully complete the project. Include a project schedule indicating when the elements of the work will be completed and when deliverables will be provided.
- C. Deliverables** – Fully describe deliverables to be submitted under the proposed contract.
- D. Staff 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.
- 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, if needed, are to be broken out separately.

4. EVALUATION AND CONTRACT AWARD

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. Project Approach/Methodology	40
b. Work Plan and Schedule	10
c. Project Deliverables	05
d. Staff Qualifications/Experience	30
e. Costs	15
GRAND TOTAL FOR WRITTEN PROPOSAL	100 points

4.4 NOTIFICATION TO PROPOSERS

Applicants whose proposals have not been selected for further negotiation or award will be notified via e-mail.