Sentinel Innovation Center

Request for Proposal

Questions and Answers

Enhancing the validity of pharmacoepidemiology studies through the inclusion of semi-structured and unstructured electronic health record (EHR) data in confounding adjustment and outcome ascertainment

Department of Population Medicine
Harvard Medical School / Harvard Pilgrim Health Care Institute

Version 3.0

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History of Modifications

Version	Date	Modification	Author
1.0	03/30/2022	Original Version	Sentinel Operations Center
2.0	04/19/2022	Additional Material Included	Sentinel Operations Center
3.0	04/26/2022	Additional Material Included	Sentinel Operations Center

1 Start and End Dates

1.1 Proposed activities should not exceed 24-months but what is the expected start date for the period of performance?

The precise start date will depend on duration of the contracting process between Harvard Pilgrim Health Care Institute and the subcontractor selected for the award; however, we anticipate that the project would start in late Summer or very early Fall 2022.

1.2 Should projects be set to begin on July 1, 2022, or later?

Upon selection of the bidder to be awarded, Sentinel Operations Center (SOC)/Harvard Pilgrim Health Care (HPHC) Institute will engage with the awarded entity using a standard SOC process to initiate work and contracting. This will involve development of a Work Order, which requires review and approval by the U.S. Food and Drug Administration (FDA), prior to the direct subcontracting process between HPHC and the awarded bidder. These processes typically take 6-10 weeks; thus we anticipate that the project would start in the late Summer or very early Fall 2022. Please use a date estimate for your proposal with the expectation that this may be modified as applicable during the contracting process. The project will be operationalized as a Sentinel Innovation Center Workgroup, with membership from the awarded entity (and any other organizations/vendors that the proposal includes), the Innovation Center, and the SOC.

2 Data Access

2.1 While I have access to electronic health record (EHR) data, I'm currently looking for the best option to access claims data. Do you have any recommendations in this regard?

Please identify a claims data source that provides sufficient overlap with the patient population for which EHR data are available. Please indicate whether you would plan to utilize awarded funding to perform linkage as part of the proposal/study if you do not have current access to a linked claims-EHR data source. Please note that if you plan to conduct linkage as a proposed study activity, this could impact the competitive nature of your proposal, relative to other proposals that may have current access to linked data.

2.2 Will Sentinel provide all data (EHR) needed for this project? Or will the awardee need to provide various datasets?

The requirement for the proposal is for the bidder/awardee to either have current access to a linked claims-EHR dataset, or to propose to use funds from the award to establish a linked claims-EHR/dataset to be used for the proposed study and feature development. Sentinel will not be providing any data for this project.

3 Formatting

3.1 Is there a document template for this Request for Proposal (RFP)? Do you have a recommended structure?

We do not have specific formatting requirements, though for optimal readability, we suggest a 1.25 or 1.5 line spacing and at least size 11pt font in Georgia, Arial, or Helvetica font. Please feel free to use the National Institutes of Health (NIH) grants format requirements if this is helpful.

We also do not have specific proposal structure requirements, though we encourage you to use a structure that allows you to best present the information that is required per the RFP (Section 2.2). The structure denoted (Activity Background, Activity Details (which contains Aims or Objectives), Activity Timeline, Roles and Responsibilities, Other Budget Items) would be reasonable.

4 Finance

4.1 Is this opportunity intended to be a fixed fee or labor and hour contract?

The pricing/contracting model is to-be-determined and is under discussion with Sentinel finance at this time. We expect that this will be negotiated directly with the awardee upon proposal selection. The required budget template should be completed with staff hourly rates, by role.

4.2 Can our organization re-use a Harvard Pilgrim Health Care Institutional Commitment Form we have used previously for this proposal requirement?

Generally, we will only need the Institutional Commitment form if your group is awarded; this is not needed for the proposal itself.

5 Reporting and Deliverables

5.1 Beyond the source code and the report are there any additional deliverables to be expected?

The RFP requires that the awarded subcontractor/lead investigator will conduct a full-scale pharmacoepidemiologic study, and then evaluate how the use of unstructured EHR data adds value to the study, above claims data alone. We encourage bidders to develop deliverables that may be typically commensurate with such a large project. This could include such deliverables as a study protocol, presentations to the Workgroup/FDA on output and results, an interim report and a final report, or manuscript(s) that describe the study findings at the project's conclusion.

5.2 Can you please clarify whether this is a single report or if you require draft and final versions? If multiple versions of the report are necessary: How many versions of the draft report should we budget for? Who are the reviewers of the report? What is the anticipated timeline for report review comments?

For a report, we encourage budgeting for at least two versions of the report (draft and final).

The project will be operationalized as a Sentinel Workgroup project, which will include members of the awarded entity, Innovation Center, Sentinel Operations Center, and FDA. Typically, these projects require routine meetings with the larger Workgroup, during which the lead organization would report out on progress. We anticipate that reports and/or manuscripts would be reviewed by the Workgroup and would require clearance by FDA for public posting and/or publication. Federal agency manuscript clearance processes can take from 4-8 weeks.