4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1083]

Innovations in Medical Evidence Development and Surveillance-Methods Research Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of Center for Drug Evaluation and Research (CDER). The goal of the CDER is to support the development of appropriate methodologies to conduct medical product safety surveillance in large electronic databases. Innovations in Medical Evidence Development and Surveillance (IMEDS)-Methods is a program within the Reagan-Udall Foundation that supports FDA's scientific mission of serving public health needs by initiating and facilitating research into the methods of safety evaluation in large databases.

DATES:

1. The application due date is June 15, 2015.
2. The anticipated start date is July 15, 2015.
3. The opening date is April 13, 2015.
4. The expiration date is June 16, 2015.

ADDRESSES: Submit the electronic application to: http://www.grants.gov. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT: Patrick Archdeacon, Food and Drug Administration, Bldg. 51 rm.6314, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3952; or Vieda Hubbard, Division of Acquisition Support and Grants (HFA-500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240-402-7588.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at: http://www.grants.gov/

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-15-010

93.103

A. Background

Section 905 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) mandates FDA to develop an enhanced ability to monitor the safety of drugs after these products reach the market. In response to this mandate, FDA launched its Sentinel Initiative, a long-term program designed to build and implement an electronic system for monitoring the safety of medical products in the post market setting. FDA has already created significant infrastructure on which to operate such a system: Through its Mini-Sentinel pilot, a distributed database with access to more than 150 million patient records has been created (the Sentinel Distributed Database). In order to optimally leverage these data, however, new analytic methodologies will be required. IMEDS-Methods is a program within the Reagan-Udall Foundation that supports FDA's scientific mission of serving public health needs by initiating and facilitating research into the methods of safety evaluation in large databases. IMEDS-

Methods aims to improve the tools for conducting post-marketing safety surveillance using automated healthcare data and to foster their adoption.

B. Research Objectives

IMEDS plans to conduct methods research in five core areas: (1) Addressing bias in estimates from observational studies; (2) better understanding uses and limitations of the data; (3) applying lessons learned from earlier IMEDS projects to FDA surveillance activities; (4) expanding the surveillance question to continuous risk/benefit assessment; and (5) continuing to support qualified investigators in industry, government, and academic settings by providing access to de-identified electronic healthcare data and computing resources through the IMEDS Research Laboratory.

C. Eligibility Information

Eligibility is limited to the Reagan-Udall Foundation. The Reagan-Udall Foundation has established the IMEDS-Methods program, which is uniquely positioned to develop the new methodologies required for FDA to conduct effective active post market safety surveillance of medical products using large electronic health care data. The IMEDS organization has developed a network of statisticians, epidemiologists, data scientists, and clinicians who have experience operating in both the IMEDS research laboratory and also familiarity with the Sentinel Distributed Database. In addition, through the Reagan-Udall Foundation public-private partnership, the IMEDS-Methods program has a unique ability to convene FDA, patients, academics, government, and industry so that the findings and tools developed through its research agenda will be promulgated and adopted.

II. Award Information/Funds Available

A. Award Amount

FDA/CDER intends to fund up to $1,000,000 in fiscal year 2015 in support of this program project. It is anticipated that only one award will be made, not to exceed $1,000,000 (direct plus indirect) for total costs.

B. Length of Support

There is a one year period of performance beginning on June 15, 2015 or the date of award.

III. Electronic Application, Registration, and Submission

Only one electronic application will be accepted. To submit an electronic application in response to this FOA, the applicant should first review the full announcement located at http://www.grants.gov/. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

For the electronically submitted application, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit the electronic application to: http://www.grants.gov.

Dated: April 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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