RFA (SF424 RR)

Part I Overview Information

Department of Health and Human Services

Issuing Organization
Food and Drug Administration (www.fda.gov)

Participating Organizations
Office of the Commissioner (http://www.fda.gov/oc/)

Components of Participating Organizations
Office of Critical Path Programs (http://www.fda.gov/oc/initiatives/criticalpath/)

Title: Convener of Active Medical Product Surveillance Discussions (U13)

Note: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH.

Announcement Type
New

Request For Applications (RFA) Number: RFA-FD09-012

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See Section IV.

Catalog of Federal Domestic Assistance Number(s): 93.103
Add Information Here

Key Dates
Release/Posted Date: June 23, 2009
Opening Date: June 30, 2009

Letters of Intent Receipt Date(s): Not Applicable
NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).
Application Due Date(s: July 15, 2009
Peer Review Date(s): July 2009
Council Review Date(s): September 2009
Earliest Anticipated Start Date(s): September 2009
Additional Information To Be Available Date (Activation Date): Not Applicable
Expiration Date: July 16, 2009

Due Dates for E.O. 12372
Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** This FOA, issued by the Office of Critical Path Programs (OCPP), Office of the Commissioner, Food and Drug Administration, solicits grant applications from neutral, independent institutions and/or organizations that propose methods for convening a broad range of stakeholders, to include those with relevant expertise, and that would support conferences and meetings to explore and address methodological, data development, technical, and communication issues related to active medical product surveillance and that would synthesize, summarize, and communicate findings from these conferences and meetings to a broad range of organizations and individuals that have the capability to use the information to further develop and create active medical product surveillance methods and systems.
- **Mechanism of Support** This FOA will use the Cooperative Agreement grant mechanism U13.
- **Funds Available and Anticipated Number of Awards.** FDA anticipates providing up to $600,000 (direct costs) during fiscal year (FY) 2009 to support efforts outlined in this FOA. One award will be made.
- **Budget and Project Period.** Subject to the availability of Federal funds and successful performance, an additional 4 years of support up to $600,000 (direct costs) per year may be available.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors (PDs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed activities are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for FDA support.
- **Number of Applications.** Applicants may submit more than one application, provided they are scientifically distinct.
- **Resubmissions.**
  o **Resubmission**. applications are not permitted in response to this FOA.
  o **Renewals**. Renewal applications are not permitted in response to this FOA.
- **Application Materials.** See Section IV.1 for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:

- SF424 (R&R) Application and Electronic Submission Information: http://grants.nih.gov/grants/funding/424/index.htm
- General information on Electronic Submission of Grant Applications: http://era.nih.gov/ElectronicReceipt/

- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The Food and Drug Administration (FDA), Office of the Commissioner (OC) is announcing its intent to solicit grant applications from neutral, independent institutions and/or organizations that propose methods for convening a broad range of stakeholders, to include those with relevant expertise, and that would support conferences and meetings to explore and address methodological, data development, technical, and communication issues related to active medical product surveillance and that would synthesize, summarize, and communicate findings from these conferences and meetings to a broad range of organizations and individuals that have the capability to use the information to further develop and create active medical product surveillance methods and systems.

FDA anticipates providing up to $600,000 (direct cost only) during fiscal year (FY) 2009 to support efforts outlined in this FOA. One award will be made.

Subject to the availability of Federal funds and successful performance, and if the FOA stated objectives are met, an additional 4 years of support up to $600,000 (direct and indirect costs combined) per year may be available.

This Cooperative Agreement ensures substantial FDA involvement in this program and will include, but not be limited to, co-development of the meeting(s) priorities, and agendas and providing feedback on reports and publications related to meeting proceedings on identified topics.

Background

The Critical Path Initiative, launched by FDA in 2004, has the objective of helping modernize the development, evaluation, manufacture, and use of FDA-regulated products. Through nationwide collaborations with other Federal, academic, scientific, and industry organizations, the Initiative seeks to develop new tools to facilitate innovation in FDA-regulated product development. Examples of tools include novel biomarkers, laboratory assays, genetic tests, and state-of-the art information technologies. In this initiative, FDA plays the role of a facilitator in the creation of partnerships and collaborations to support specific scientific projects.

In May 2008, the Secretary of Health and Human Services and the FDA Commissioner announced the Sentinel Initiative. The Sentinel Initiative is a long-term effort by the Agency to create a national electronic system for monitoring regulated product safety. The Sentinel Initiative is intended to augment the Agency's existing postmarket (primarily passive) safety surveillance

systems and to allow the Agency to actively gather information about the postmarket safety and performance of its regulated products.

As currently envisioned, the Sentinel Initiative will enable the Agency to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries) to augment the Agency's current surveillance capabilities. The Sentinel Initiative will enable queries of disparate data sources quickly and securely for relevant regulated product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Questions would be sent to appropriate, participating data sources, which in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send results summaries for Agency review.

The Sentinel Initiative is a response to various calls for this type of effort from the Agency. In September 2005, the HHS Secretary asked the Agency to expand its current system for monitoring medical product performance and to explore the possibility of working with multiple automated healthcare data systems to augment the Agency's current capabilities of identifying and evaluating regulated product safety information. The Secretary recommended that the Agency explore creating a public-private collaboration as a framework for such an effort, leveraging large, automated healthcare databases.

In 2006, the Institute of Medicine (IOM) issued a report, entitled The Future of Drug Safety—Promoting and Protecting the Health of the Public. Among other suggestions, this IOM report recommended the Agency identify ways to access other health-related databases and create a public-private partnership to support safety studies.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 905 of this statute calls for the HHS Secretary to develop methods to obtain access to disparate data sources and to establish an active post-market risk identification and analysis system that links and analyzes safety data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires the Agency to work closely with partners from public, academic, and private entities. The Agency views its Sentinel Initiative as a mechanism through which some of the requirements mandated in this legislation can be carried out.

FDA's first step has been to create a broad public forum for discussion of issues related to developing and implementing the Sentinel System. During 2008, FDA sponsored a series of exploratory meetings with a broad variety of stakeholders to identify key issues that will need to be addressed before, during, and after implementation of the Sentinel System. Key questions include, for example what level of collaboration between public and private entities would best ensure the success of the initiative; how a possible governance model could be identified and developed; what kind of methods and tools will be needed to facilitate the development and sharing of highly technical summary results derived from automated healthcare data in disparate systems; and what privacy and security safeguards will be needed and how will they be maintained.

These initial discussions have focused on many of the policy and procedural needs of developing the Sentinel Initiative. To proceed, additional meetings and working groups need to be formed to explore the science of safety needed to support this initiative, as well as methods for communicating about the information learned from the system. This would include specific topics, issues, and questions related to the development of active medical product surveillance methodologies and tools. Subsequently, the information from these meetings and working groups must be described, managed, and made available to the public using a transparent and open approach.

Section II. Award Information

1. Mechanism of Support

This FOA will use the Cooperative Agreement Conference Grant Mechanism (U13). The Project Director (PD) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time information concepts (see SF424 (R&R) Application Guide). It also uses the non-modular budget formats (see http://grants.nih.gov/grants/funding/modular/modular.htm). Applicants must complete and submit budget requests using the Researc & Related Budget component.

This funding opportunity will use a cooperative agreement award mechanism (U13). In the cooperative agreement mechanism, the Project Director (PD) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA staff being substantially involved as a partner with the PD, as described under the Section VI. 2. Administrative Requirements, "Cooperative Agreement Terms and Conditions of Award". Substantive involvement includes, but is not limited to, the following: (1) FDA will work closely with the grantee throughout the lifetime of this program and throughout all phases of planning and conduct of this program and all related projects; (2) FDA will appoint project officer(s) for the task(s) associated with this program and related projects; (3) FDA will identify appropriate staff to provide strategic and scientific input, as needed, throughout the life of this program and related projects.

2. Funds Available

It is anticipated that FDA will fund this Cooperative Agreement up to $600,000 (direct cost only). Subject to the availability of Federal funds and successful performance of the FOA stated goals and objectives, four (4) additional years of support may be available depending on annual appropriations.

Appropriated funds will be obligated in fiscal year 2009. Funding beyond the first year will be noncompetitive and will depend on (1) satisfactory performance during the preceding year and, (2) the availability of Federal fiscal year funds.

This award will be funded based on the quality of the applications received and is subject to availability of Federal funds to support the program.

FDA grants policies as described in the DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm will apply to the application submitted and the award made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Non-profit organizations

Foreign institutions are not eligible to apply for conference grant support. An international conference can be supported through the U.S. representative organization of an established international scientific or professional society.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed activities as the Project Director (PD) is invited to work with his/her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current in the DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

3. Other-Special Eligibility Criteria

Number of Applications. Applicants may submit more than one application, provided they are scientifically distinct.

Resubmissions. Resubmission applications are not permitted in response to this FOA.

Renewals. Renewal applications are not permitted in response to this FOA.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, use the "Apply for Grant Electronically" button in this FOA or link to http://www.grants.gov/Apply/ and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

PDs should work with their institutions/organizations to make sure they are registered in the NIH eRA Commons.

Several additional separate actions are required before an applicant can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Registered

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
  Grants.gov Customer Support
  Contact Center Phone: 800-518-4726
  Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
  Email support@grants.gov

2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "List of Grantee Organizations Registered in NIH eRA Commons."
- Direct questions regarding the Commons registration to:
  eRA Commons Help Desk
  Phone: 301-402-7469 or 866-504-9552 (Toll Free)
  TTY: 301-451-5939
  Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time
  Email commons@od.nih.gov

3) Project Director (PD) Registration in the NIH eRA Commons: Refer to the *NIH eRA Commons System (COM) Users Guide*.

- The individual(s) designated as PDs on the application must be registered also in the NIH eRA Commons
- Each PD must hold a PD account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD role; however, if they have both a PD role and an NIH Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- This registration/affiliation must be done by the AOR/SO or his/her designee who is already registered in the Commons.

Both the PDs and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both Grants.gov and the Commons. The FDA will accept electronic applications only from organizations that have completed all necessary registrations.

1. Address to Request Application Information

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

- Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another

FOA); although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo -- Telephone 301-435-0714; Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY: (301) 451-5936

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to FDA. Some fields within the SF424 (R&R) application components, although not marked as mandatory, are required by FDA (*e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD's assigned eRA Commons User ID*). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications."

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

Required Components:

SF424 (R&R) (Cover component)
Research & Related Project/Performance Site Locations
Research & Related Other Project Information
Research & Related Senior/Key Person
PHS398 Cover Page Supplement
PHS398 Research Plan
PHS398 Checklist
PHS 398 Research & Related Non-Modular Budget
Research & Related Subaward Budget Attachment(s) Form as appropriate

(See Section IV.6., "**Special Instructions**," regarding appropriate required budget component.)

Optional Components:

PHS398 Cover Letter File

SPECIAL INSTRUCTIONS

Applications Involving a Single Institution

When all PDs are within a single institution, follow the instructions contained in the SF424 (R&R) Application Guide.

Applications Involving Multiple Institutions

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the subaward budget form.

Information concerning the consortium/subcontract budget is provided in the budget justification.

3. Submission Dates and Times

See (Section IV.3.A) for details.

3.A. Receipt, Review and Anticipated Start Dates

Release/Posted Date: June 23, 2009
Opening Date: June 30, 2009
Letters of Intent Receipt Date(s): Not Applicable
NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).
Application Due Date(s): July 15, 2009
Peer Review Date(s): July 2009
Council Review Date(s): September 2009
Earliest Anticipated Start Date(s): September 2009
Additional Information To Be Available Date (Activation Date): Not Applicable
Expiration Date: July 16, 2009

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

3.B. Sending an Application to the FDA

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow Steps 1-4. Note: Applications must only be submitted electronically**. PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application due date(s). (See Section IV.3.A. for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD and the Authorized Organization Representative/Signing Official (AOR/SO) have two

weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the FDA Grants Management Team for processing.
- Prior to the submission deadline, the AOR/SO can "Reject" the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process. The AOR/SO will have the option to "Reject" the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications. The "Reject" feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.
- If the two-day window falls after the submission deadline, the AOR/SO will have the option to "Reject" the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn't transfer correctly during the submission process). The AOR/SO should first contact the eRA Commons Helpdesk to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to "Reject" the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the NIH late policy guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Upon receipt, applications will be evaluated for completeness and responsiveness by the FDA Office of the Commissioner, Critical Path Initiative program Project Officer and the grants management contact. Incomplete and non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the Commons. The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PD receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.

The FDA will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review (see http://www.whitehouse.gov/omb/grants/spoc.html

5. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the DHHS Grants Policy Statement. The Grants Policy Statement can be found at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

Pre-award costs are allowable. A grantee may, at its own risk and without FDA prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the grant, if awarded, without FDA prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain FDA approval before incurring the cost. FDA prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on FDA either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. FDA expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project (see DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm).

6. Other Submission Requirements and Information

Awardees must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI.2.A "Award Administration Information."

The following instructions are to be used in conjunction with the SF424 (R&R) Application Guide accompanying the SF424 (R&R) application forms:

SF424 (R&R) Cover Component. Enter “Convener of Active Medical Product Surveillance Discussions” on line item 11.

Research and Related Project/Performance Site Locations. If identified, enter the site of the conference or meeting as the Performance Site. If this is yet to be determined, enter the site where the planning and support related to this project will take place.

Research and Related Senior/Key Person: Personnel are defined as the PD and those responsible for the scientific planning and organization of the meeting. Attach a biographical sketch for the PD, key personnel, and any proposed key speakers that have confirmed their willingness to participate in this project.

Research and Related Budget: Enter the direct costs requested. Provide a narrative justification for each proposed personnel position, including role and proposed level of effort.

Allowable Costs: Salary (in proportion to the time or effort spent directly on the conference/meeting); rental of necessary equipment; travel and per diem or subsistence allowances; supplies needed for conduct of the meeting (only if received for use during the budget period); conference services; publication costs; registration fees; speakers’ fees.

Non-allowable costs: Purchase of equipment; transportation costs exceeding U.S. carrier coach class fares; visas; passports; entertainment; tips; bar charges; personal telephone calls; laundry charges; dues; honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem or admiration; patient care; alterations or renovations; facilities and administrative costs/indirect costs. Please also refer to the DHHS Grants Policy Statement for additional information regarding costs.

PHS 398 Research Plan Component: Submit one attachment, which may not exceed 10 pages, under the Research Design and Methods section (line item 5). Note that this section will be called "Conference Plan" in the system-generated Table of Contents. Letters of agreement from key speakers and participants should be attached at line item 13. Do not complete Sections 2 – 4 and the Human Subjects Sections (Items 6-10) of the PHS 398 Research Plan.

In the "Conference Plan" section of the application (uploaded as attachment #5), describe the objectives, proposed topics, and proposed logistical arrangements (if available) for the meeting. Describe the anticipated format and agenda, including the principal topics to be covered, problems to be addressed, and developments or contributions the meeting might stimulate. Provide a detailed background for the meeting(s), including the scientific need, timeliness, and usefulness of the meeting(s) to the scientific community. Describe the composition and role of the organizing committee, and provide the names and credentials of key participants in the meeting, including the basis for their selection and documentation of their agreement to participate.

Describe plans for the appropriate involvement of women, minorities, and persons with disabilities in the planning and implementation of the proposed meeting. A critical part of the application for FDA support of conferences is documentation of appropriate representation of women, racial/ethnic minorities, persons with disabilities, and other individuals who have been traditionally underrepresented in science. These individuals must be included in all aspects of planning, organization, and implementation of FDA sponsored and/or supported meetings. "Appropriate representation" means representation based on the availability of these scientists from these groups known to be working in a particular field of biomedical or behavioral research.

Estimate the expected size and composition of the audience, as well as the method of selection. Describe plans for publicizing the meeting and publication of the proceedings. Identify related meetings held on the subject during the past three years.

Applications requesting multiple years of support must provide the following additional information for each future year requested, in as much detail as possible: meeting topic(s); tentative dates, locations, and participants; and contingency plans for future meetings dependent upon, for example, the outcome of the first year's meeting or developments in the field.

Appendix: The appendix is limited to announcements and reports of previous meetings under the same sponsorship. No other information or material should be submitted as appendices.

PHS 398 Checklist Component: The checklist is required; however, no information regarding F&A should be included as this is not an allowable cost for this mechanism.

PD Credential (e.g., Agency Login)

The FDA requires the PD(s) to fill in his/her Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see "Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications."

PHS398 Research Plan Component Sections

Page limitations of the PHS398 Research Plan component must be followed as outlined in the SF424 (R&R) Application Guide. While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF

attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to FDA in PDF format; filenames must be included with no spaces or special characters, and a .pdf extension must be used.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See http://grants.nih.gov/grants/funding/424/index.htm).

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not comply with the required page limitations may be delayed in the review process.

Resource Sharing Plan(s) Not applicable.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by FDA's Office of Critical Path Programs in accordance with FDA peer review procedures and to the extent applicable, the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), and the DHHS Awarding Agency Grants Administration Manual shall govern the establishment and operation of peer review groups, using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by the National Cancer Institute, National Advisory Board

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of the proposed project to program priorities

Scientific/Technical Review Criteria

1. The application clearly demonstrates an understanding of the purpose and objectives of the Cooperative Agreement.
2. The application clearly describes the steps involved in a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the Cooperative Agreement.
3. The application establishes the applicant's ability to perform the responsibilities under the Cooperative Agreement including the availability of appropriate staff and sufficient funding.
4. The application describes the awardees ability to act as a neutral, independent third party to convene a wide group of diverse stakeholders with relevant expertise related to selected topics on active medical product surveillance methods and systems.
5. The application specifies the manner in which interaction with FDA will be maintained throughout the lifetime of the project.
6. The application specifies how the awardee will monitor progress of the work under the Cooperative Agreement and how progress will be reported to FDA.
7. The application shall include a detailed budget that shows: (1) anticipated costs for personnel, travel, communications and postage, and supplies; and (2) the sources of funds to meet those needs, if other than FDA.

FDA's mission is to protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. As part of this mission, applications submitted to FDA for grants or cooperative agreements to support the protection and promotion of public health are evaluated for scientific and technical merit through the FDA peer review process.

Overall Impact. Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the topics involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Core Review Criteria. Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Personnel. Are the PDs, collaborators, and other personnel well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative, do the proposed personnel have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Does the PD(s) demonstrate an ability to act as a neutral convener, able to convene a wide range of stakeholders on various topics related to active medical product surveillance? Does the PD(s) have relevant experience related to health policy?

Approach. Are the overall strategy and methodology well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented?

Environment. Will the environment in which the work will be done contribute to the probability of success? Does the applicant organization have the ability to contribute to the probability of success? Will the project benefit from unique features of the scientific environment or collaborative arrangements?

Innovation. Does the proposed plan employ novel approaches or methods to fulfill its purpose?

Additional Review Considerations. As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Budget and Period Support. The reasonableness of the proposed budget and the requested period of support in relation to the proposed plan. The priority score should not be affected by the evaluation of the budget.

Previous Experience. Is there previous experience with the organization in similar undertakings? If so, what?

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed activity.

Resource Sharing Plans. Not Applicable

3. Anticipated Announcement and Award Dates

Notice of Award will follow within two weeks of the scheduled second level review by the National Cancer Institute, National Advisory Board.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD will be able to access his or her Summary Statement (written critique) via the NIH eRA Commons.

If the application is under consideration for funding, FDA will request "just-in-time" information from the applicant. For details, applicants may refer to the DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the Grants Management Officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Section IV.5. "Funding Restrictions."

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the FDA Grants Policy Statement as part of the Notice of Award. For these terms of award, see the DHHS Grants Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Project Director as well as to the appropriate institutional official, on the Notice of Grant award.

2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement (U13), an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the FDA as defined below.

2. A.1. Project Director Rights and Responsibilities

Project Director will have the primary responsibility for directing and overseeing the project and ensuring its completion in accordance with this cooperative agreement. The awardee will be responsible for all logistical planning and overseeing the payment of meeting expenses related to meetings convened and all related follow-up activities under this FOA. The awardee will provide project management support to coordinate and convene the activities described. In addition, the awardee will facilitate drafting and finalizing documents for public posting related to all discussions convened under this cooperative agreement, these may include, but not limited to, transcripts and meeting summaries. All documents will need to be 508 Compliant.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and FDA policies.

2. A.2. FDA Responsibilities

An FDA Project Coordinator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below under collaborative responsibilities.

Additionally, an agency program official or OC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

2.A.3. Collaborative Responsibilities

The awardee and the FDA will work together to identify program priorities, topics, and agendas for meetings.

3. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Peer Review Contacts:

Melissa Robb
Office of Critical Path Programs
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14B-45
Rockville, MD 20857
Telephone: (301) 827-1516
FAX:
Email: melissa.robb@fda.hhs.gov

2. Financial or Grants Management Contacts:

Staff Contact Name Gladys M. Bohler
Division: Office of Grant and Contracts
Organization: Food and Drug Administration
Building Number, Room Number: 5630 Fishers Lane; Rm 2105

Bethesda, MD 20857
Telephone: (301) 827-7168
FAX: 301-827-7101
Email: gmbohler@fda.hhs.gov

Section VIII. Other Information

Required Federal Citations

Sharing Research Data: If the final data/resources are not amenable to sharing, this must be explained in Resource Sharing section of the application.

Access to Research Data through the Freedom of Information Act:
The Freedom of Information Act, U.S.C. 552, provides individuals with a right to access certain records in the possession of the Federal government. The government may withhold information pursuant to the exemptions and exclusions contained in the act. The exact language of the exemptions can be found in the act. Additional guidance on the exemptions and how they apply to certain documents can be found in the HHS regulations implementing the FOIA (45 CFR Part 5). Also see the HHS Web site http://www.hhs.gov/foia/

Data included in the application may be considered trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552) and FDA's statute and implementing regulations. FDA will protect trade secret or confidential commercial information to the extent allowed under applicable law. See http://www.fda.gov/foi/default.htm for additional information.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity.

URLs in FDA Grant Applications or Appendices:
All applications and proposals for FDA funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, internet addresses (URLs) **must** be used for **publicly** accessible on-line journal articles. Unless otherwise specified in **this** solicitation, Internet addresses (URLs) should **not** be used to provide any **other** information necessary for the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372. FDA's authority to enter into grants and cooperative agreements is detailed under title XVII of the Public Health Service Act (42 U.S.C. 300u-1). Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the DHHS Grants Policy Statement. The DHHS Grants Policy Statement can be found at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm.

Smoke – Free Workforce: The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.