Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA. The FDA does not follow the NIH Page Limitation Guidelines or the Enhanced Peer Review Scoring Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.
Components of Participating Organizations	Center for Drug Evaluation and Research (CDER)
Funding Opportunity Title	**Critical Path Public Private Partnerships**
Activity Code	U18 Research Demonstration – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-14-089**
Companion Funding Opportunity	Not Applicable

Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
Funding Opportunity Purpose	As part of its Critical Path Initiative, FDA recognizes the need for collaborations established under the terms and conditions of a cooperative agreement, whereby existing resources and expertise can be used to the fullest extent possible. The Critical Path Institute has developed 8 individual consortia – the Coalition Against Major Disease Consortium (CAMD), the Multiple Sclerosis Outcome Assessment Consortium (MSOAC), the Patient Reported Outcomes Consortium (PRO), the Electronic Patient Reported Outcomes Consortium (ePRO), the Coalition for Accelerating Standards and Therapies (CFAST), the Predictive Safety Testing Consortium (PSTC), the Polycystic Kidney Disease Outcome Consortium (PKD), and the Critical Path to TB Drug Regimens Consortium (CPTR). These consortia have been active in developing biomarkers and Clinical Outcome Assessment Tools for Qualification under the FDA's Drug Development Tool Qualification Program. The goals of this program are to maintain the administrative and scientific infrastructure of these consortia efforts while continuing to support the creation and execution of ongoing and new projects (such as a Neonatal Consortium) under the FDA's Critical Path Initiative.

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	June 24, 2014
Letter of Intent Due Date(s)	Not applicable
Application Due Date(s)	July 25, 2014), by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to

	make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not applicable
Scientific Merit Review	August 2014)
Advisory Council Review	Not applicable
Earliest Start Date	September 2014
Expiration Date	July 28, 2014
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.
Applications that do not comply with these instructions may be delayed or not accepted for review.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background on the FDA Critical Path Initiative: Launched in 2004 with the publication, "Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products." This report stressed the need to "improve the process for getting new and better treatments to patients." In March, 2006, "FDA's Critical Path Opportunities List" was published based on significant public stakeholder input. In 2006, the "Critical Path Opportunities Report" stated, "Many of the Critical Path opportunities described in this report cannot be accomplished by one entity alone. No single company, university, or governmental agency will have sufficient resources, expertise, or information base to undertake the work. We will need to develop new ways to collaborate and share data to accomplish our common goal of a robust Critical Path infrastructure". Public-Private Partnerships convened by neutral non-profit conveners (501c3) are able to bring together stakeholders from government, academia, professional societies, patient advocacy groups, and industry in the pre-competitive space to address these Critical Path needs. Through nationwide collaboration with other Federal, academic, scientific, and industry organizations, the Critical Path Initiative seeks to develop new tools to facilitate innovation in FDA-regulated product development. Examples of tools include novel biomarkers, Clinical Outcome Assessment Tools, laboratory assays, genetic tests, and state-of-the art information technologies, etc. In this initiative, FDA plays the role of a facilitator in the creation of partnerships and collaborations to support specific scientific projects.

As part of its Critical Path Initiative, FDA recognizes the need for collaborations established under the terms and conditions of a cooperative agreement, whereby existing resources and expertise can be used to the fullest extent possible. In 2009, FDA identified the Critical Path Institute (C-Path), a freestanding 501 © (3) non-profit organization as one suitable partner in achieving its goals and awarded them a cooperative agreement to support the direct and indirect costs associated with Critical Path-related projects, mutually identified by FDA and C-Path. As a result of this award, C-Path has developed 8 individual consortia – the Coalition Against Major Disease Consortium (CAMD), the Multiple Sclerosis Outcome Assessment Consortium (MSOAC), the Patient Reported Outcomes Consortium (PRO), the Electronic Patient Reported Outcomes Consortium (ePRO), the Coalition for Accelerating Standards and Therapies (CFAST), the Predictive Safety Testing Consortium (PSTC), the Polycystic Kidney Disease Outcome Consortium (PKD), and the Critical Path to TB Drug Regimens Consortium (CPTR). These consortia have been active in developing biomarkers and Clinical Outcome Assessment Tools for Qualification under the FDA's Drug Development Tool Qualification Program.

The goals of this program are to maintain the administrative and scientific infrastructure of these consortia efforts while continuing to support the creation and execution of ongoing and new projects (such as a Neonatal Consortium) under the FDA's Critical Path Initiative.

The following activities will be supported by this cooperative agreement. The applicant must demonstrate the ability to: (1) establish an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort;(2) identify and/or hire sufficient number of qualified personnel to conduct the necessary research and project-manage all related activities, including review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, all for approval by FDA, and for subsequent distribution in the public domain; (3) in conjunction with FDA, develop plans for the conduct of identified research projects (4) identify and/or build, and effectively leverage databases and other facilities and/or resources for the conduct of identified projects; and (5) upon completion of a given project, propose related studies/projects, if needed, to build on the findings of the project and continue to leverage established resources and personnel.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities.
Application Types Allowed	New The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	CDER intends to commit $2.1M in FY 2014 to fund 1 award.
Award Budget	Subject to the availability of Federal funds and successful performance, an additional 5 years of support up to $2.1M (direct and indirect costs combined) per year may be available.
Award Project Period	5 years

FDA grants policies as described in the HHS Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for FDA support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement*, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her 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 NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement.*

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

FDA will not accept any application that is essentially the same as one already reviewed within the past twelve months (as described in the HHS Grants Policy Statement), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:

- For this specific FOA, the Research Strategy section is limited to 30 pages.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, required and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover (Required)

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations (Required)

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information (Required)
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile (Required)
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Budget (Required)
All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report
When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report
When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

3. Submission Dates and Times
Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration. eRA Commons and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to

Grants.gov on or before the application due date. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Pre-award costs are allowable only as described in the HHS Grants Policy Statement.

Additional funding restrictions may be part of the Notice of Award.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. PAPER APPLICATIONS WILL NOT BE ACCEPTED.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

Important reminders:
All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application toFDA. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Grants Office and responsiveness by components of participating organizations, FDA. Applications that are incomplete and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

1. Criteria

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

The FDA Critical Path Initiative was launched in 2004 with the publication, "Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products." This report stressed the need to "improve the process for getting new and better treatments to patients." In March, 2006, "FDA's Critical Path Opportunities List" was published based on significant public stakeholder input. In 2006, the "Critical Path Opportunities Report" stated, "Many of the Critical Path opportunities described in this report cannot be accomplished by one entity alone. No single company, university, or governmental agency will have sufficient resources, expertise, or information base to undertake the work. We will need to develop new ways to collaborate and share data to accomplish our common goal of a robust Critical Path infrastructure". Public-Private Partnerships convened by neutral non-profit conveners (501c3) are able to bring together stakeholders from government, academia, professional societies, patient advocacy groups, and industry in the pre-competitive space to address these Critical Path needs. Through nationwide collaboration with other Federal, academic, scientific, and industry organizations, the Critical Path Initiative seeks to develop new tools to facilitate innovation in FDA-regulated product development. Examples of tools include novel biomarkers, Clinical Outcome Assessment Tools, laboratory assays, genetic tests, and state-of-the art information technologies, etc. In this initiative, FDA plays the role of a facilitator in the creation of partnerships and collaborations to support specific scientific projects.

As part of its Critical Path Initiative, FDA recognizes the need for collaborations established under the terms and conditions of a cooperative agreement, whereby existing resources and expertise can be used to the fullest extent possible. In 2009, FDA identified the Critical Path Institute (C-Path), a freestanding 501c(3) non-profit organization as one suitable partner in achieving its goals and awarded them a cooperative agreement to support the direct and indirect costs associated with Critical Path-related projects, mutually identified by FDA and C-Path. As a result of this award, C-Path has developed 8 individual consortia – the Coalition Against Major Disease Consortium (CAMD), the Multiple Sclerosis Outcome Assessment Consortium (MSOAC), the Patient Reported Outcomes Consortium (PRO), the Electronic Patient Reported Outcomes Consortium (ePRO), the Coalition for Accelerating Standards and Therapies (CFAST), the Predictive Safety Testing Consortium (PSTC), the Polycystic Kidney Disease Outcome Consortium (PKD), and the Critical Path to TB Drug Regimens Consortium (CPTR). These consortia have been active in developing biomarkers and Clinical Outcome Assessment Tools for Qualification under the FDA's Drug Development Tool Qualification Program.

The goals of this program are to maintain the administrative and scientific infrastructure of these consortia efforts while continuing to support the creation and execution of ongoing and new projects (such as a Neonatal Consortium) under the FDA's Critical Path Initiative.

The following activities will be supported by this cooperative agreement. The applicant must demonstrate the ability to: (1) establish and/or maintain an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort;(2) employ and/or hire a sufficient number of qualified personnel to conduct the necessary research and project-manage all related activities, including review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, all for approval by FDA, and for subsequent distribution in the public domain; (3) in conjunction with FDA, develop plans for the conduct of identified projects (4) maintain and/or build, and effectively leverage databases and other facilities and/or resources for the conduct of identified projects; and (5) upon completion of a given project, propose related studies/projects, if needed, to build on the findings of the project and continue to leverage established resources and personnel.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) expects the applicant for the award of the Cooperative Agreement to be able to maintain the current Critical Path Institute (C-Path) consortia groups (Coalition Against Major Diseases (CAMD), Coalition for Accelerating Standards and Therapies (CFAST), Critical Path to TB Drug Regimens (CPTR), Multiple Sclerosis Outcome Assessments Consortium (MSOAC), Polycystic Kidney Disease Outcome Consortium (PKD), Patient Reported Outcome Consortium (PRO), Electronic Patient Reported Outcome Consortium

(ePRO), and the Predictive Safety Testing Consortium (PSTC). In addition, the applicant will work with the FDA to support the creation and execution of new consortia (such as the Neonatal Consortium) under FDA's Critical Path Initiative.

To be successful, an applicant must satisfy the criteria set out in Section 566 of the Federal Food, Drug, and Cosmetic Act:

The entity must have experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

It must demonstrate that it is capable of developing and critically evaluating tools, methods, and processes to increase efficiency, predictability, and productivity of medical product development and to more accurately identify the benefits and risks of new and existing medical products, of establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and of securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

The applicant must also provide an assurance that it will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the it provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Please cite specific examples from the current consortia (Coalition Against Major Diseases (CAMD), Coalition for Accelerating Standards and Therapies (CFAST), Critical Path to TB Drug Regimens (CPTR), Multiple Sclerosis Outcome Assessments Consortium (MSOAC), Polycystic Kidney Disease Outcome Consortium (PKD), Patient Reported Outcome Consortium (PRO), Electronic Patient Reported Outcome Consortium (ePRO), and the Predictive Safety Testing Consortium (PSTC)) as well as any planned future consortia efforts.

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Have they demonstrated an ongoing record of accomplishment in developing and maintaining the consortia efforts including CAMD, CFAST, CPTR, MSOAC, PKD, PRO, ePRO, and PSTC?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Please cite examples of potential areas of innovation stemming from consortia efforts related to CAMD, CFAST, CPTR, MSOAC, PKD, PRO, ePRO, and PSTC, as well as any planned future consortia efforts.

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Are potential problems, alternative strategies, and benchmarks for success of the continued efforts of the consortia presented? If any future consortia efforts are in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the

committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable.

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Renewals

Not Applicable.

Revisions

Not Applicable.

Additional Review Considerations

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

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an objective review panel, using the stated review criteria.

As part of the objective review, all applications:

- Will receive a written critique.

Appeals of objective review will not be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement*.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, FDA will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. 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.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA.

Additional terms and conditions regarding FDA/CDER regulatory and Programmatic requirements may be part of the Notice of Award.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) 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, 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.

The PD(s)/PI(s) will have the primary responsibility for:

- 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 DHHS, PHS, and FDA policies.

FDA staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

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

Areas of Joint Responsibility include:

- None; all responsibilities are divided between awardees and FDA staff as described above.

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)
Finding Help Online: http://grants.nih.gov/support/index.html
Email: commons@od.nih.gov

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact CenterTelephone: 800-518-4726

Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

Dr. Chekesha Clingman
Office of Translational Sciences/CDER/FDA
10903 New Hampshire Ave.
Silver Spring, MD 20993 301/796-8531
chekesha.clingman@fda.hhs.gov

Objective Review Contact(s)

Daniel Lukash
Office of Acquisition & Grants Services (OAGS)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857
Telephone: 240/402-7596
Email: daniel.lukash@fda.hhs.gov

Financial/Grants Management Contact(s)

Daniel Lukash
Office of Acquisition & Grants Services (OAGS)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857
Telephone: 240/402-7596
Email: daniel.lukash@fda.hhs.gov

Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360bbb-5), Sections 301 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.