Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) NOTE: The policies, guidelines, terms, and conditions stated in this Notice of Funding Opportunity (NOFO) may differ from those used by the NIH. Where this NOFO provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this NOFO. The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review 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 Biologics Evaluation & Research (CBER) Center for Devices & Radiological Health (CDRH) Center for Drug Evaluation & Research (CDER) Center for Tobacco Products (CTP) Center for Veterinary Medicine (CVM) Human Foods Program (HFP) Office of the Chief Scientist (OCS) Office of the Commissioner (OC) Office of Inspections & Investigations (OII)
Funding Opportunity Title	Pathways for Regulatory Innovation and Strategic Modernization (PRISM)
Activity Code	U01
Announcement Type	New
Related Notices	None

Funding Opportunity Number (FON)	RFA-FD-26-007
Companion Funding Opportunity	None
Number of Applications	See Part 2, Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.103
Funding Opportunity Purpose	The Pathways for Regulatory Innovation and Strategic Modernization (PRISM) cooperative agreement is intended to advance public health by strengthening the scientific, collaborative, and operational foundations needed to modernize regulatory oversight in an increasingly complex and rapidly evolving public health landscape. As innovation in medical products, diagnostics, foods, and digital health accelerates, our nation must continuously adapt its regulatory science approaches to ensure timely access to safe, effective, and high-quality products for the American public. PRISM is designed to support this modernization by enabling forward-looking, non-regulatory collaborations that align with the Commissioner's strategic priorities and the Administration's broader public health goals. PRISM provides a flexible, scalable approach to patient, consumer, industry, academia, and healthcare workforce engagement to generate applied scientific knowledge, tools, and approaches that enhance regulatory predictability, efficiency, and transparency. By leveraging independent expertise and real-world insights, PRISM bridges gaps between innovation and regulation to optimize uptake of emerging technologies, evolving consumer needs, and new sources of evidence such as real-world data and real-world evidence.
Funding Opportunity Goals	The goals of FDA's Pathways for Regulatory Innovation and Strategic Modernization (PRISM) project are to: 1. Advance the Use of Real-World Data, Real-World Evidence, and Artificial Intelligence to Inform Public Health and Regulatory Science. 2. Strengthen Pathways for Patient Access to Investigational Therapies, Including Expanded Access. 3. Advance Transparency and Public Trust in Regulatory Science.

	4. Support Gold-Standard Science–Based Approaches Across Regulatory Science, Food Safety, and Nutrition.

Key Dates

Posted Date	March 31, 2026
Open Date (Earliest Submission Date)	March 31, 2026
Letter of Intent Due Date(s)	Not Applicable.

Application Due Date(s)

April 30, 2026

All applications are due by 11:59 PM local time of applicant organization.

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.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

AIDS Application Due Date(s)

Not Applicable

Expiration Date	May 01, 2026

Advisory Council Review

Not Applicable

Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

Conformance to all requirements, both in the the Research (R) Instructions How to Apply - Application Guide and in the NOFO, is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide as well as any program-specific instructions noted in Section IV of this NOFO or an applicable related Notice posted to the Guide for Grants and Contracts. When the program-specific instructions deviate from those in the How to Apply - 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. Notice of Funding Opportunity Description

Background

Rapid advances in medical products, diagnostics, foods, nutrition science, and digital health are transforming how public health is protected and promoted in the United States. These innovations increasingly rely on complex data sources, novel technologies, and evolving scientific methodologies that challenge traditional regulatory approaches. To effectively protect public health, we must continuously modernize regulatory science, engagement models, and operational frameworks to ensure timely access to safe, effective, and high-quality FDA-regulated products while maintaining public trust.

Engagement with a regulatory agency such as FDA can be complex for patients, consumers, healthcare professionals, academia, and regulated industry—particularly when collaboration requires shared scientific expertise, financial resources, or data. Transparent, neutral, and trusted mechanisms for engagement are essential to ensure advances in science and technology are translated efficiently into public health benefits. Non-regulatory collaborative approaches play a critical role in enabling cooperation among public- and private-sector stakeholders while preserving FDA's regulatory independence.

The Pathways for Regulatory Innovation and Strategic Modernization (PRISM) project is intended to enable forward-looking collaboration, applied research, and convening activities that strengthen scientific foundations and support the modernization of regulatory oversight to enhance the safety and effectiveness of FDA-regulated products in an increasingly complex and rapidly evolving public health landscape.

Purpose and Research Objectives

The purpose of the PRISM project is to advance public health by strengthening the scientific, collaborative, and operational foundations needed to modernize regulatory oversight across FDA-regulated products. PRISM will support non-regulatory, science-driven activities that align with FDA's public health goals and priorities.

Through applied research, stakeholder engagement, and evidence generation, PRISM seeks to:

- Enhance the use of advanced scientific methods, real-world data, and emerging technologies to improve the development, safety, and/or efficacy of FDA-regulated products.
- Improve pathways for patient access to investigational therapies, including expanded access mechanisms, while preserving appropriate safeguards.
- Increase transparency, predictability, and public understanding of FDA's science-based approaches to enable more effective and efficient product development, evaluation, and oversight.
- Promote gold-standard, evidence-based approaches across regulatory science domains, including food safety, nutrition, and population health.

The cooperative agreement will support the generation of applied scientific knowledge, tools, frameworks, and best practices that help bridge gaps between innovation and regulation. The recipient will not participate in regulatory decision-making or provide policy advice to FDA.

Program Scope and Approach

PRISM provides a flexible and scalable platform for engaging a broad range of stakeholders, including patients, consumers, healthcare professionals, industry, academia, and public health experts. Activities supported under this cooperative agreement may include, but are not limited to:

- Convenings, workshops, and public forums to share expertise and identify emerging scientific and operational challenges.
- Applied research and methodological exploration to support modern regulatory science approaches.
- Development and dissemination of tools, frameworks, and best practices that enhance regulatory predictability, efficiency, and transparency.
- Analysis of real-world experiences and data to inform improvements in regulatory science and public health outcomes.

Specific Areas of Research Interest

Research and programmatic activities supported under this project may address a broad range of regulatory science and public health priorities. Appropriate topics include, but are not limited to, the areas described below.

1. Advancing the Use of Real-World Data, Real-World Evidence, and Artificial Intelligence

PRISM will support the development, evaluation, and dissemination of approaches that leverage real-world data (RWD), real-world evidence (RWE), and advanced analytical technologies, including artificial intelligence (AI) and computational modeling, to improve understanding of product performance, safety, and effectiveness across the product lifecycle. Activities may include convenings, applied research, and methodological exploration focused on enhancing post-market surveillance, strengthening causal inference, and improving the use of large-scale and complex data sources to detect safety signals, assess real-world effectiveness, and increase the efficiency and consistency of evidence generation. These efforts will complement FDA's existing data infrastructure and support a transition toward more timely, scalable, and informative approaches to regulatory science that better protect and promote public health.

2. Strengthening Pathways for Patient Access to Investigational Therapies, Including Expanded Access

PRISM will support research and stakeholder engagement aimed at improving pathways for patients with serious or life-threatening conditions to access investigational medical products outside of clinical trials when no comparable alternatives exist. This includes examining barriers, operational challenges, and patient and provider experiences associated with expanded access (compassionate use) mechanisms. By identifying opportunities to streamline processes, improve transparency, and enhance navigation for patients, healthcare providers, and manufacturers, PRISM will contribute to more predictable access to investigational therapies while preserving appropriate safeguards.

3. Advancing Transparency and Public Trust in Regulatory Science

PRISM will support activities that enhance transparency, clarity, and public understanding of FDA's science-based approaches to product evaluation and oversight. Through convenings, research, and evidence-sharing, the project will explore methods to improve communication of regulatory science concepts, data sources, assumptions, and limitations to a variety of audiences, including patients, consumers, healthcare providers, and product developers. By promoting openness and accessibility in how evidence is generated and interpreted—while preserving regulatory independence—PRISM will help strengthen public confidence in FDA-regulated products and enable more effective and efficient product development.

4. Supporting Gold-Standard Science–Based Approaches Across Regulatory Science, Food Safety, and Nutrition

PRISM will support applied research and stakeholder engagement grounded in gold-standard scientific methods to advance modern, evidence-based approaches across FDA's regulatory science portfolio, including food safety, nutrition, and dietary exposures that affect population health. Activities may include rigorous examination of emerging and large-scale data sources, real-world use and consumption patterns, and validated analytical, computational, and causal inference methods to strengthen understanding of the relationships among regulated products, exposures, and health outcomes. By fostering collaboration across public health, regulatory science, epidemiology, nutrition science, and data analytics communities, PRISM will contribute to the generation of high-quality, reproducible evidence that supports proactive, prevention-oriented strategies, enhances product safety and effectiveness, and promotes healthier outcomes, particularly for children and other vulnerable populations.

5. Advancing Competition and Domestic Innovation

PRISM will support proposals for innovative research and implementation projects that will advance a faster, more efficient early-stage clinical ecosystem and promote domestic medical innovation. Proposed activities should address the preclinical and first phase of clinical trials, and will target 1) chemistry, manufacturing, and controls requirements, 2) toxicology expectations, and 3) streamlining data standards for investigator-initiated trials. Successful projects will foster collaboration between IRBs, CROs, and institutions while generating evidence and validating expedited approaches for advancing regulatory reform and onshoring clinical development in the U.S.

Relationship to Other Funding Opportunities

This cooperative agreement is distinct from investigator-initiated or product-specific research programs in that it emphasizes non-regulatory collaboration, convening, and applied regulatory science across multiple FDA-regulated domains. PRISM focuses on cross-cutting scientific and operational challenges that affect regulatory modernization broadly, rather than on individual product approvals or policy development.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A financial assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. See Section VI.2 for additional information about the substantial involvement for this NOFO.

Application Types Allowed	New The OER Glossary and the How to Apply - Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Need help determining whether you are doing a clinical trial?
Funds Available and Anticipated Number of Awards	FDA intends to commit $1,300,000 for fiscal year 2026. The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for FOUR (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. It is anticipated that up to one (1) award will be made, not to exceed $1,300,000 in total costs (direct plus indirect).
Award Budget	Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $1,300,000 YR 02: $1,300,000 YR 03: $1,300,000 YR 04: $1,300,000 YR 05: $1,300,000
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is 5 (five) years.

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

Section III. Eligibility Information

Eligible Organizations

Only the following applicant is eligible to apply for this single source funding: Reagan-Udall Foundation for the Food and Drug Administration.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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 How to Apply - 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference the HHS Grants Policy Statement for additional information

- System for Award Management (SAM) 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.
    - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. 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 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 their organization to develop an application for 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 How to Apply - Application Guide.

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required.

2. Cost Sharing

This NOFO does not require cost sharing.

3. Additional Information on Eligibility

Number of Applications

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

The FDA will not accept duplicate or highly overlapping applications under review at the same time.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

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

Page Limitations

All page limitations described in the How to Apply - Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the How to Apply - Application Guide must be followed.

R&R Budget

All instructions in the How to Apply - Application Guide must be followed.

R&R Subaward Budget

All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Research Plan

All instructions in the How to Apply - 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 as provided in the How to Apply - Application Guide.

Other Plan(s): Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:

All applicants planning research (funded or conducted in whole or in part by the FDA) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply - Application Guide.

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or FDA-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply - Application Guide, with the following additional instructions:

If you answered "Yes" to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply - Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the How to Apply - Application Guide must be followed.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. 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. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

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. FDA 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 and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the FDA Policy on Late Application Submission.

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 How to Apply - Application Guide.

6. 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.

- Recipients must comply with all applicable federal anti-discrimination laws material to the government's payment decisions for purposes of 31 U.S.C. § 3729(b)(4).
- Discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate:
    - racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation.
    - denial by the recipient of the sex binary in humans or the notion that sex is a chosen or mutable characteristic.
    - harm reduction
    - illegal immigration; or
    - any other initiatives that compromise public safety or promote anti-American values.

All activities proposed in your application and budget narrative must align with the current Executive Orders, and where applicable, demonstrably advance the President's policy priorities. If an application does not align, the application will not receive funding.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - 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 How to Apply - Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. 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 to the FDA. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the assigned FDA Grants Management Specialist and responsiveness by components of participating organizations. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Not applicable.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the FDA in support of the FDA mission are evaluated for scientific and technical merit through the FDA objective review system.

Overall Impact

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. 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.

Significance	**Maximum Points: 10**
Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? 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?	
Investigator(s)	**Maximum Points: 10**
Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those 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?	
Innovation	**Maximum Points: 30**
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?	

Approach	Maximum Points: 25
Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? 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? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? If the project involves human subjects and/or FDA-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 individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?	

Environment	Maximum Points: 25
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 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 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.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals 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.

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.

Applications from Foreign Organizations

Not Applicable.

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 Resource Sharing Plan(s) (i.e., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

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.

Applications will be evaluated for scientific and technical merit by (an) appropriate Objective Review Committee convened by the FDA, using the stated review criteria. Assignment to an Objective Review Committee will be shown in eRA Commons.

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 NOFO.

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

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

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

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the HHS Grants Policy Statement.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in FDA-funded studies, the recipient must provide FDA copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through FDA:

- The rules listed at 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All FDA grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in the HHS Grants Policy Statement.

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. FDA may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination and HHS Grants Policy Statement.

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data. Please refer to HHS Grants Policy Statement for additional information.

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 (HHS) grant administration regulations at 2 CFR Part 200, 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 recipients 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 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 recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the FDA as defined below.

To assist recipients in achieving the purpose of this award, FDA will conduct the following activities above and beyond normal programmatic oversight, monitoring, and stewardship of awards:

- FDA staff from Components of Participating Organizations will collaborate with recipients in the planning, execution, and evaluation of project activities to ensure alignment with goals and priorities of this NOFO.

3. Data Management and Sharing

Consistent with the FDA Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the HHS Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the HHS Grants Policy Statement.

A final RPPR, 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. . FDA NOFOs outline intended research goals and objectives. Post award, the FDA will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients 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 the threshold. See the HHS Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (Responsibility/Qualification in SAM.gov, formerly FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

Enter text here.

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 Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Scientific/Research Contact(s)

Luke Hall

Office of the Commissioner (OC)
Email: Luke.hall@fda.hhs.gov

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Patrick Johnson

Office of Acquisitions and Grants Services (OAGS)
Email: patrick.johnson@fda.hhs.gov

Section VIII. Other Information

Recently issued policy notices may affect your application submission. A full list of policy notices is provided in the Guide for Grants and Contracts. 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 Sections 301 of the Public Health Service Act as amended (42 USC 241) and subject to 2 CFR Parts 200 and 300.