



# Special Emphasis Notice (SEN) Applications to Advance Fast Health Care Interoperability Resources (FHIR®) Capabilities and Identify Data Quality Improvements for USCDI Data Elements Background

Informational Session for SEN Applications under the Leading Edge Acceleration  
Projects (LEAP) in Health Information Technology Notice of Funding Opportunity  
(NOFO)

**April 25, 2023**

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The Office of the National Coordinator for  
Health Information Technology



# Agenda

- Introduction of Speakers
- Reminders
- Special Emphasis Notice for Applications to Advance Fast Health Care Interoperability Resources (FHIR®) Capabilities and Identify Data Quality Improvements for USCDI Data Elements
- Background: Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT)
- Funding, Eligibility, and Application Information
- Application Responsiveness and Merit Review Criteria

# Introduction of Speakers

- **Lolita Kachay**  
Social Science Analyst, ONC Technical Strategy and Analysis Division
- **Alison Kemp**  
Public Health Analyst, ONC Technical Strategy and Analysis Division
- **Yolonda Thompson**  
Grants Management Specialist, ONC Procurement and Grants Division

## Reminders

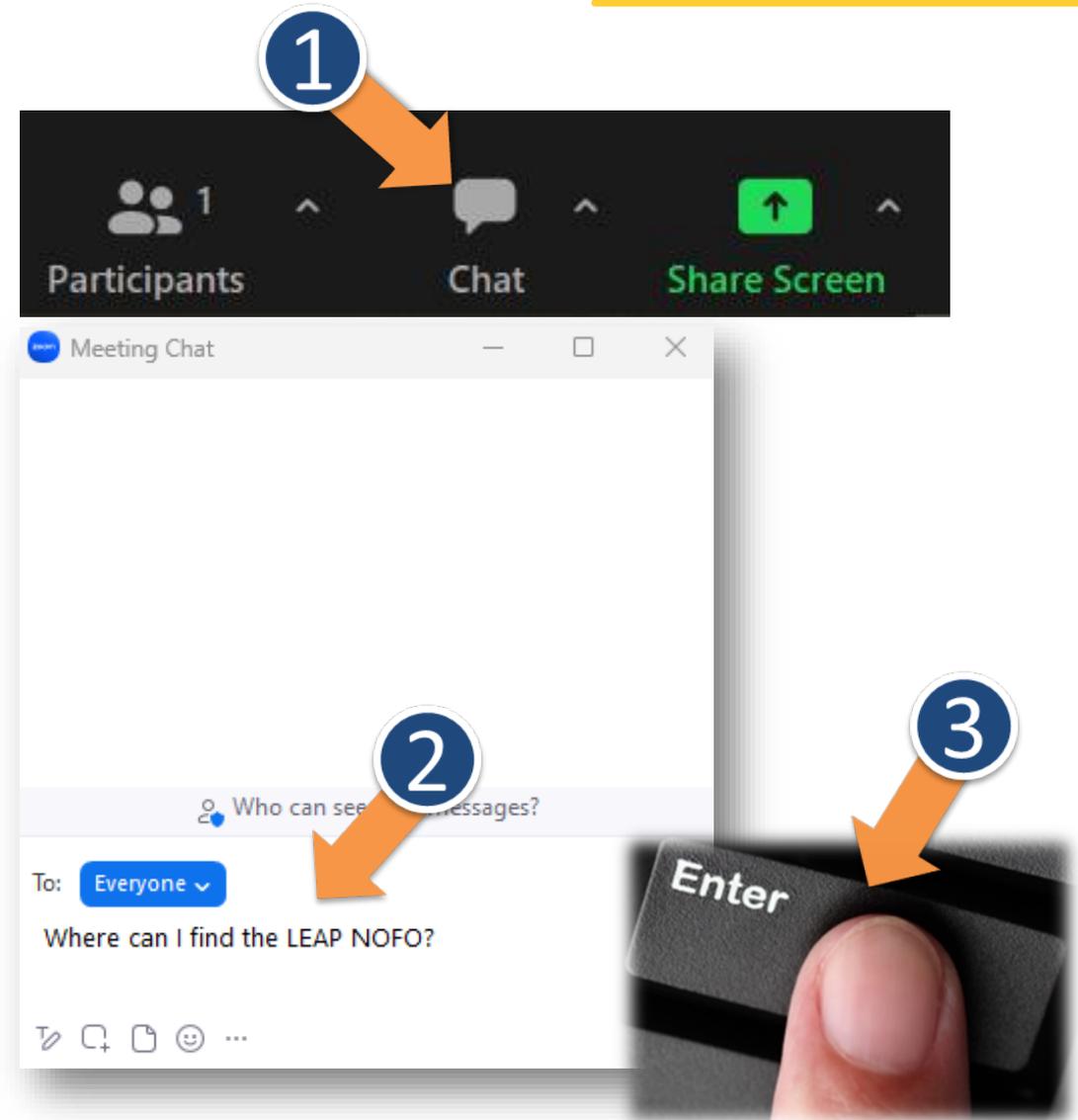
- This webinar is being recorded and will be made publicly available
- All participants will be muted during the presentation
- If you have questions, please enter them into the chat box
  - **Note: All questions will be answered in FAQs made publicly available weekly**
- Webinar and FAQs will be available at <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>

# How to Ask a Question

If you have any questions during the presentation, please follow the instructions below.

Use the Chat function to ask a question:

- 1.) Along the bottom of the webinar window, find and click the Chat button.
- 2.) Input your question into the Chat box.
- 3.) Press “Enter” or “Return” to **Send**.



## Additional Questions

If you have additional questions after today's webinar session, please direct them to the following email address:

[ONC-LEAP@hhs.gov](mailto:ONC-LEAP@hhs.gov)



# SEN for Applications under the LEAP in Health IT Notice of Funding Opportunity (NOFO)

# Overview

- Two Areas of Interest
- One award per Area of Interest
- Up to \$1M per award
- Period of Performance: 2 years
- Applicants are encouraged to submit their applications based on a five-year budget period. Additional funding for years three to five may be provided, contingent upon availability of funds, meaningful progress, and ONC priorities.
- Letters of Intent (LOI) due by **April 28, 2023**
- Applications due by **June 12, 2023**



# FY 2023 Areas of Interest

**Area of Interest 1:** Exploring the Use of Advanced Fast Health Care Interoperability Resources (FHIR®) Capabilities

**Area of Interest 2:** Identifying Data Quality Improvements for USCDI Data Elements

**Important Note:** Applicants shall clearly state which Area of Interest the proposed project will address. Application packages addressing more than one Area of Interest will not be considered for award.



# LEAP SEN FY 2023 – Area of Interest 1

## Exploring the Use of Advanced Fast Health Care Interoperability Resources (FHIR) Capabilities (one award up to \$1 million)

### Goal:

Accelerate the adoption readiness of existing, advanced FHIR capabilities developed by the health IT community and demonstrate the value of health IT to solving complex problems in health care. Applicants can achieve this goal by performing a rigorous technical exploration of advanced FHIR capabilities, including identifying use case(s) that will benefit from the use of the advanced feature(s), software development, implementation, testing, and piloting under real-world conditions.

# LEAP SEN FY 2023 – Area of Interest 1

## Key Objectives

Applicants are encouraged to consider the following activities as activities that could achieve the overall goal of Area 1:

- Performing technical exploration of one or more existing advanced FHIR capabilities in at least two use cases.
- Documenting the software requirements and associated artifacts of the advanced FHIR capability or capabilities so that the software source code can be readily used by software developers as an open-source tool and a learning example for independently implementing software in their own development environments.
- Demonstrating the applicability of the advanced FHIR capability or capabilities to meet the goals of the use cases and enhance access, functionality, and user experience in health care interoperability.
- Developing, publishing, and disseminating a report on each advanced FHIR capability and its readiness for industry-wide adoption. For example, the report may include, but is not limited to the following: findings on limitations or challenges in the FHIR capability, recommendations, and next steps to mitigate these limitations and challenges. This report will help health IT implementers to advance FHIR capabilities to improve the exchange of health information and health data management to improve patient care.

# LEAP SEN FY 2023 – Area of Interest 1

## Applicant Required Expertise

Applicants shall demonstrate familiarity with:

- API standards adopted for the ONC Health IT Certification Program
- Advanced FHIR capability or capabilities they propose in their use cases

### Other Requirements:

- To be considered for an award in this Area of Interest, an applicant's proposal shall include:
  - Propose at least one advanced FHIR capability, including but not limited to those explicitly listed in this SEN, so long as they provide evidence that the selected advanced capability or capabilities were previously developed by the FHIR community and are openly available for implementation. This is to ensure that applicant focuses on existing advanced FHIR capabilities in need of maturity rather than developing a brand-new capability as part of this LEAP award. Applicants can propose a single advanced FHIR capability to meet two separate use cases if each use case is independently tested as specified further below.
  - Identify at least two use cases and provide detailed explanation on how the applicant plans to test the advanced FHIR capability or capabilities to solve the problem associated with the use case effectively compared to existing solutions.
  - Provide a detailed project plan for performing, at a minimum, all aspects of technical exploration described in this SEN.

# LEAP SEN FY 2023 – Area of Interest 2

## Identifying Data Quality Improvements for USCDI Data Elements

(one award up to \$1 million)

**Goal:** Identify, understand, and assess the quality of USCDI data elements that are collected, exchanged, and used by various health IT systems (e.g., EHRs, health information networks, laboratory information systems, etc.) and implement non-proprietary solutions to improve data quality. Applicants can achieve this goal by performing a 360-degree evaluation, in real world clinical settings, of data quality of the selected data elements collected (e.g., identify and assess any missing), the degree of conformance to data standards (e.g., use of mature standards and vocabulary codes) and the ability (or lack thereof) to successfully match patient records, perform aggregation of the data, and compare data obtained from disparate sources.

# LEAP SEN FY 2023 – Area of Interest 2

## Key Objectives

Applicants are encouraged to consider the following activities as activities that could achieve the overall goal of Area 2:

- Identifying at least two data elements in USCDI (v1 through v3) and assess the data quality of these data elements collected in real world clinical settings.
- Developing one or more measures to assess data quality of the identified data elements across selected health IT system actors or within a health care system. The assessments of data quality and detailed “root cause” analysis of data quality issues must be based on large production data sets aggregated from disparate practice settings and health IT systems to clearly surface variations that exist in real world settings.
- Based on the assessment of the current state of data quality, piloting at least one non-proprietary solution to assess and improve the quality of data that can be scaled across other health care settings and health IT systems. The solution may include a focus on policies and workflows.

# LEAP SEN FY 2023 – Area of Interest 2

## Key Objectives (continued)

- Developing a comprehensive dissemination plan so that project findings may be used by other interested parties.
- Developing, publishing, and disseminating a report on each identified data element, with information on root causes of data quality issues (where possible) and readiness for industry-wide adoption of the solution.

# LEAP SEN FY 2023 – Area of Interest 2

## Applicant Required Expertise

### **Applicants shall demonstrate familiarity with:**

- USCDI, applicable vocabulary standards and the appropriate content and exchange standards and implementation specifications used in the access, exchange, and use of these data elements.
- Ability to perform data quality assessment and standards conformance on real-world demographic and clinical data in real world settings (e.g., hospitals, integrated delivery networks, academic medical centers, HINs, etc.)
- Ability to develop scalable measures that can provide clear and transparent assessment of the quality of identified data elements.

# LEAP SEN FY 2023 – Area of Interest 2

## Applicant Required Expertise Continued

### Other Requirements:

- To be considered for an award in this Area of Interest, an applicant's proposal shall:
  - Provide detailed explanation on their ability to conduct a pilot(s) of any identified solution(s).
  - Provide a detailed project plan for performing, at a minimum, all aspects of the SEN for this area of interest.



## Background: LEAP in Health IT NOFO

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LEAP in Health IT seeks to address well-documented and fast emerging challenges that inhibit the development, use, and/or advancement of well-designed, interoperable health IT.



## Background: LEAP in Health IT NOFO

- Applications submitted under this SEN will be funded under the LEAP in Health IT NOFO (NAP-AX-22-001)
- Aside from Areas of Interest, required expertise, and deadlines listed in the SEN, **all other requirements, application instructions, and terms and conditions of NOFO NAP-AX-22-001 apply.**

# Eligible Applicants

- This is a competitive funding opportunity open to public or non-profit private institutions, such as a university, college, or a faith-based or community-based organization; units of local or state government, eligible agencies of the federal government, Indian/Native American Tribal Governments (federally recognized, other than federally recognized, and tribally designated organizations).
- For-profit organizations may participate in projects as members of a consortia or as a sub-recipient only. Because the purpose of this NOFO is to improve healthcare in the United States, foreign institutions may participate in projects as members of a consortia or as a sub-recipient only. Applications submitted by for-profit organizations or foreign institutions will not be reviewed.
  - Organizations described in section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities are not eligible.
- HHS grants policy requires that the grant recipient perform a substantive role in the conduct of the planned project activity and not merely serve as a conduit of funds to another party or parties. If consortium/contractual activities represent a significant portion of the overall project, the applicant shall justify why the applicant organization, rather than the party(s) performing this portion of the overall project, should be the recipient and what substantive role the applicant organization will play.
  - Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

# Project Activities

- Define a project plan that will include all key objectives.
- Document and report progress throughout the project timeframe.
- Publish (e.g., manuscript, report, blog post, and white paper) and disseminate project findings in a way that translates project outcomes into useable knowledge and insights for federal partners, health IT industry, SDOs, CBOs, developers, healthcare systems, and providers to maximize the accessibility of this knowledge to the entire health IT community.
- Select measurable outcomes that are specific to the project's Area of Interest and key objectives.
- Conduct virtual mid-point demonstrations and provide an update regarding any proposed approaches, prototype(s), and/or revisions to the project plan to illustrate their progress on the Area of Interest.

A large, abstract graphic on the left side of the slide, composed of numerous overlapping triangles and polygons in various shades of blue, green, yellow, and orange, creating a complex, multi-dimensional geometric pattern.

# Funding, Eligibility, and Application Information

# Summary of Key Details

## SEN FOR APPLICATIONS UNDER LEAP IN HEALTH IT NOFO

<b>Type of Award</b>	Cooperative Agreement
<b>Available Funding</b>	Up to \$2,000,000
<b>Number of Awards</b>	2 awards
<b>Application Due Date</b>	June 12, 2023
<b><u>Anticipated Award Date</u></b>	August 1, 2023
<b>Performance Period</b>	2 years
<b><u>Anticipated Start Date</u></b>	August 1, 2023
<b>No. of Awards and Available Funding by Project Topic</b>	Area of Interest 1: One award, up to \$1 million Area of Interest 2: One award, up to \$1 million

# Letter of Intent (LOI)

- Applicants are strongly encouraged to submit a non-binding e-mail letter of intent to apply for this funding opportunity.
- Submit by April 28, 2023, 11:59 p.m. ET
- Send to: [ONC-LEAP@hhs.gov](mailto:ONC-LEAP@hhs.gov)
- Identify:
  - Title: LEAP Special Emphasis Notice (SEN) Applications to Advance Fast Health Care Interoperability Resources (FHIR®) Capabilities and Identify Data Quality Improvements for USCDI Data Elements
  - Area of Interest (1 or 2)
  - Name of applicant organization
  - City and state of applicant organization
  - NOFO No. NAP-AX-22-001

# Application Process

- Applicants must:
  - Submit all material electronically through [Grants.gov](https://www.grants.gov); this process is outlined in the NOFO.
  - For assistance with submitting applications on [Grants.gov](https://www.grants.gov), please contact the [Grants.gov](https://www.grants.gov) Helpdesk at [support@grants.gov](mailto:support@grants.gov) or call at (800) 518-4726.
  - Have a Unique Entity Identifier (UEI). UEI can be obtained via registering at <https://sam.gov/content/entity-registration> and typically takes 7 to 10 business days. Please plan accordingly.
  - Register in the System for Award Management (SAM) at [www.sam.gov](http://www.sam.gov) and use their UEI. The SAM registration process takes 7 to 10 business days so please plan accordingly. If you have already registered with the SAM but have not renewed your registration in the last 12 months, you will need to renew your registration.
  - Ensure the application meets application requirements and page limits.

# Application Components

COMPONENT	LIMIT
Project Abstract	< 500 words
Project Narrative	35 pages
Form SF-424, Application for Federal Assistance	No limit
Form SF-424 A, Budget Information for Non-construction Programs	No limit
Form SF-424 B, Assurances for Non-construction Programs	No limit
Form SF-LLL, Disclosure of Lobbying Activities	No limit
Budget Narrative	No limit
Letter of Commitment	No limit

# Project Abstract

- The abstract represents a high-level summary of the project that can be understood without reference to other parts of the application and that provides a description of the proposed project, including the project's goal(s), objectives, overall approach, anticipated outcomes, products, and duration.
- Format:
  - No more than 500 words
  - Project title
  - Applicant name
  - Physical address
  - Contact name
  - Contact phone numbers (voice, fax)
  - Email address
  - Website address, if applicable

# Project Narrative

- The project narrative should address the elements articulated in the Areas of Interest section of the SEN.
- The project narrative should also align with the Performance Goals and Objectives and Merit Review criteria presented in the NOFO.
- Applications that do not follow the outlined format must be reviewed by an ONC Designated Official.
- Format:
  - Double-spaced and no more than 35 pages.
  - Formatted to 8 ½" x 11" (letter size) plain white pages.
  - Either Cambria or Times New Roman font.
  - 1" or larger margins and font size 11 or greater.

## Project Narrative - Continued

Your project narrative should include the following components. These components will be counted as part of the page limit. The suggested lengths of the components, given below, are guidelines to help applicants create a balanced document. They are not mandatory restrictions:

1. Understanding of Project Purpose (2-3 pages)
2. Proposed Approach and Activities (10-14 pages)
3. Applicant Capabilities (9-15 pages)
4. Budget Narrative (2-3 Pages)

# 1. Understanding of Project Purpose

- This section should offer the applicant's conceptualization of the selected Area of Interest.
- This should include, from the applicant's perspective, a **specific delineation of the objectives and research challenges** the proposed project will address, specifically distinguishing between challenges that can be addressed in the self-contained project period (two years) and challenges requiring a longer period (three to five years).
- Applicants shall clearly state which Area of Interest the proposed project will address.

## 2. Proposed Approach and Activities

- Provide a **clear and concise description** of the approach the applicant is proposing to use to conduct the research and development work, including **identifying the major challenges and proposed activities** used in the approach.
- Organized so that **each element of the project plan is clear and aligns to the project's key objectives and project goals.**
- The applicant should include the usage of novel concepts, approaches, methodologies, tools, and/or technologies and provide insight as to how their usage will inform the field of health IT.
- The approach should also include proposed strategies on how the results of the project may be disseminated and transitioned to field at large.

## 2. Proposed Approach (continued)

- The approach should include as much details as possible given the page limitation.
- The plan for each activity, at a minimum, shall state
  - Specific aims
  - Previous work of the investigative team on which the proposed research is directly based
  - The methods that will be applied, the anticipated outcomes of the work, and their potential significance in addressing the challenges of the selected Area of Interest
  - The key personnel who will be involved

## 3. Applicant Capabilities

- This section should describe the applicant's project team, personnel qualifications, and past performance demonstrating experience consistent with successfully meeting the goals of the cooperative agreement. It is recommended that the project team be comprised of, but is not limited to, the following roles:
  - Project Director/Principal Investigator (PD/PI)
  - At least one person on the proposed team shall possess health IT expertise
  - For Area of Interest 1, the proposed research team must have expertise **in the areas outlined in the SEN**
  - For Area of Interest 2, the proposed research team must have expertise **in the areas outlined in the SEN**

## 3a. Plan for Disseminating and Transitioning Appropriate Research Results into Practice

- This section should include a plan for engaging industry stakeholders to adopt, disseminate, and transition findings from the project into data standards, data infrastructures, health IT products, tools, and best practices.
- Collaborative arrangements with industry and other groups outside of the applicant institution should be accompanied by appropriate letters of support.
- In the event an applicant's solution includes the development of a prototype, the applicant should also submit a plan for approval by ONC, illustrating how the prototype will be made and maintained in a publicly available and acceptable domain at no cost to the general public.

## 3b. Stakeholder Coordination

- This section should describe plans to establish and operate a technical expert panel of relevant and appropriate stakeholders, including names of members who have committed to join or proposed to join to help inform the work to be conducted on the relevant Area of Interest.

## 3c. Project Management

- This section should include a clear delineation of the roles and responsibilities of the principal investigator, participating researchers, project staff, consultants, and collaborating organizations, and how they will contribute to achieving the research objectives and outcomes.
  - If the application includes subcontractors, plans for coordinating activities across multiple organizations should be described.
  - This section should specify who would have day-to-day responsibilities for key tasks such as: leadership of project, monitoring the project's on-going progress, preparation of reports, and communications with other collaborating organizations and ONC.
  - Recipients will be required to maintain information relevant to executing the proposed project plan and performance-based outcomes.

## 3c. Project Management - Continued

- The application should describe the approach that will be used to assess project performance and monitor and track progress toward meeting key objectives.
- The application should include:
  - A detailed project timeline as an appendix that incorporates those objectives.
  - An organizational chart as an appendix that reflects roles and responsibilities.

## 3d. Organizational Capability Statement

- Should describe the organization's capabilities, qualifications, and approach to address the work to be completed.
  - The statement should highlight potential strategies the organization may employ in an effort to sustain research efforts beyond the scope of the project timeframe.
  - Include the relevant organizational resources available to perform the proposed project (e.g., facilities, equipment, and other resources).
  - Applicants who are working with project counterparts as part of a consortia shall also provide letters of commitment from them.
    - The letters of commitment shall be included with the appendices and will not count towards the 35-page limit.

## 4. Budget Narrative

- This section should include a detailed breakdown of how the applicant plans to spend the allotted resources to complete the activities detailed in the SEN:
  - Budget Narrative on how the proposed budget, as articulated in the SF-424A, aligns with the applicant's project narrative.
  - Application for Federal Assistance, Form SF-424
  - Budget Information for Non-Construction Programs, Form SF-424A
  - Assurances for Non-Construction Programs, Form SF-424B
  - Disclosure of Lobbying Activities, Form SF-LLL
- Detailed budget instructions are provided in the NOFO.



# Application Responsiveness and Merit Review Criteria

# Application Review Process

- Submit all application materials electronically through [Grants.gov](https://www.Grants.gov)
- [Grants.gov](https://www.Grants.gov) issues an email receipt upon successful submission
- Applications are reviewed for responsiveness and categorized as pass/fail
- All applications that pass the review for responsiveness are forwarded for merit review
- Once the merit review is complete, ONC may make an award
- ONC is not obligated to make an award if none of the applications meet the intent of program requirements or if there is a change in funding levels or availability of funds

# Application Responsiveness Criteria

- All applicants **must** meet the following completeness criteria or they will be administratively eliminated and not sent forward for merit review:
  - The applicant meets the eligibility criteria
  - The application is received by the deadline of Monday, June 12, 2023, at 12:00 noon ET through <http://www.grants.gov>
  - The application contains all required components (e.g., Program Narrative, SF-424, etc.)
  - The application meets all formatting and length requirements
  - Appendices and attachments are not used as a mechanism to exceed page limits of the Project Narrative

# Merit Review Criteria

- Responsive applications are forwarded for merit review
- Merit review will be conducted by a review panel of at least three experts in their field from academic institutions, nonprofits, and local and federal government agencies
- Applications can receive a maximum of 100 points, using the following scale:

MERIT REVIEW CRITERIA	POINTS
Understanding of Project Purpose	10
Proposed Approach and Activities	40
Applicant Capabilities	30
Budget Narrative	20
<b>Total</b>	<b>100</b>

# Merit Review Criteria:

## Understanding of Project Purpose - 10 points

- The extent to which the application addresses the objectives and project goals of this NOFO.
- The extent to which the application identifies a project plan and activities that align with one of the two identified Areas of Interest within the SEN.
- The extent to which the application identifies barriers and ways to mitigate those barriers with one of the two identified Areas of Interest within the SEN.
- The extent to which the applicant describes how the project, expected outcomes, and results will inform future health IT development, research, and implementation.

## Merit Review Criteria: Approach and Activities - 40 points

- The extent to which the approach, design, methods, and analyses are specifically stated, adequately developed, well-integrated, well-reasoned, and appropriate to the project goals/key objectives of the Area of Interest. **(20 points)**
- The extent to which the applicant proposes a clear and detailed plan for disseminating and transitioning appropriate research results into practice. This section of the application should include a plan for engaging industry stakeholders to adopt, disseminate, and transition findings from the project to stakeholders who will continue to advance the work. **(15 points)**
- The extent to which the plan describes a project management approach for ensuring project success. **(5 points)**

## Merit Review Criteria: Applicant Capabilities - 30 points

- The extent to which the applicant identifies all the resources necessary to perform the proposed work and outline strategies to complete this work within a two-year time frame. **(5 points)**
- The extent to which the scientific environment(s) in which the work will be done contributes to the probability of success, employs useful collaborative arrangements, and has evidence of institutional support. **(5 points)**
- The extent to which the project proposal integrates and provides an appropriate level of research and technical knowledge and subject matter expertise. **(20 points)**

## Merit Review Criteria: Budget Narrative - 20 points

- Does the application provide the proposed levels of effort of the project team and consultants (if needed) and describe how they are adequate and appropriate to advance the project in accordance with the project plan?
- Does the application include an explanation of how the proposed budget supports the project and is cost-efficient and reasonable for meeting the project activities?

# LEAP SEN FY 2023

## Dates to remember:

- Release Date: April 10, 2023
- Informational Session: April 25, 2023
- Letter of Intent (LOI): April 28, 2023
- Application Deadline: June 12, 2023
- Anticipated Award Date: August 1, 2023



## Questions

- All questions must be submitted in writing either via the Chat during this Webinar or emailed to [ONC-LEAP@hhs.gov](mailto:ONC-LEAP@hhs.gov)
  - Questions submitted today in the Chat will not be answered today
- All questions will be answered in the form of an FAQ and be made publicly available each Monday at <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>

## Q&As

- Thank you for attending!
- We will remain online for 5 minutes – please submit any remaining questions via the Chat on this webinar page
- To see the NOFO on [Grants.gov](https://www.grants.gov) or to apply, go to <https://www.grants.gov/web/grants/search-grants.html?keywords=nap-ax-22-001>
- For assistance with submitting applications in [Grants.gov](https://www.grants.gov), please contact the [Grants.gov](https://www.grants.gov) Helpdesk at [support@grants.gov](mailto:support@grants.gov) or call (800) 518-4726

**Please submit your questions.**

**5 Minutes Remaining**

**Please submit your questions.**

**3 Minutes Remaining**

**Please submit your questions.**

**1 Minute Remaining**

**The moderator will now  
end this session.**

**Thank you for attending.**