

2025 Special Emphasis Notice (SEN) Applications to: (1) Demonstrate the Readiness of FHIR®-based Subscriptions Capability as a Foundational Health IT Capability for Improved Interactivity with Third Party Applications, and (2) Identify and Test Innovative Technical Approaches that Would Inform Future Changes to the Trusted Exchange Framework and Common Agreement™ (TEFCA™) Infrastructure to Increase Adoption of Individual Access Services (IAS)

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

March 6, 2025

1. Introduction of Speakers.
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3. Background: LEAP in Health IT.
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5. Application Responsiveness and Merit Review Criteria.

Introduction of Speakers

- **Yolonda Thompson**

ASTP, Office of the Chief Operating Officer, Procurement and Grants Division

- **Alison Kemp**

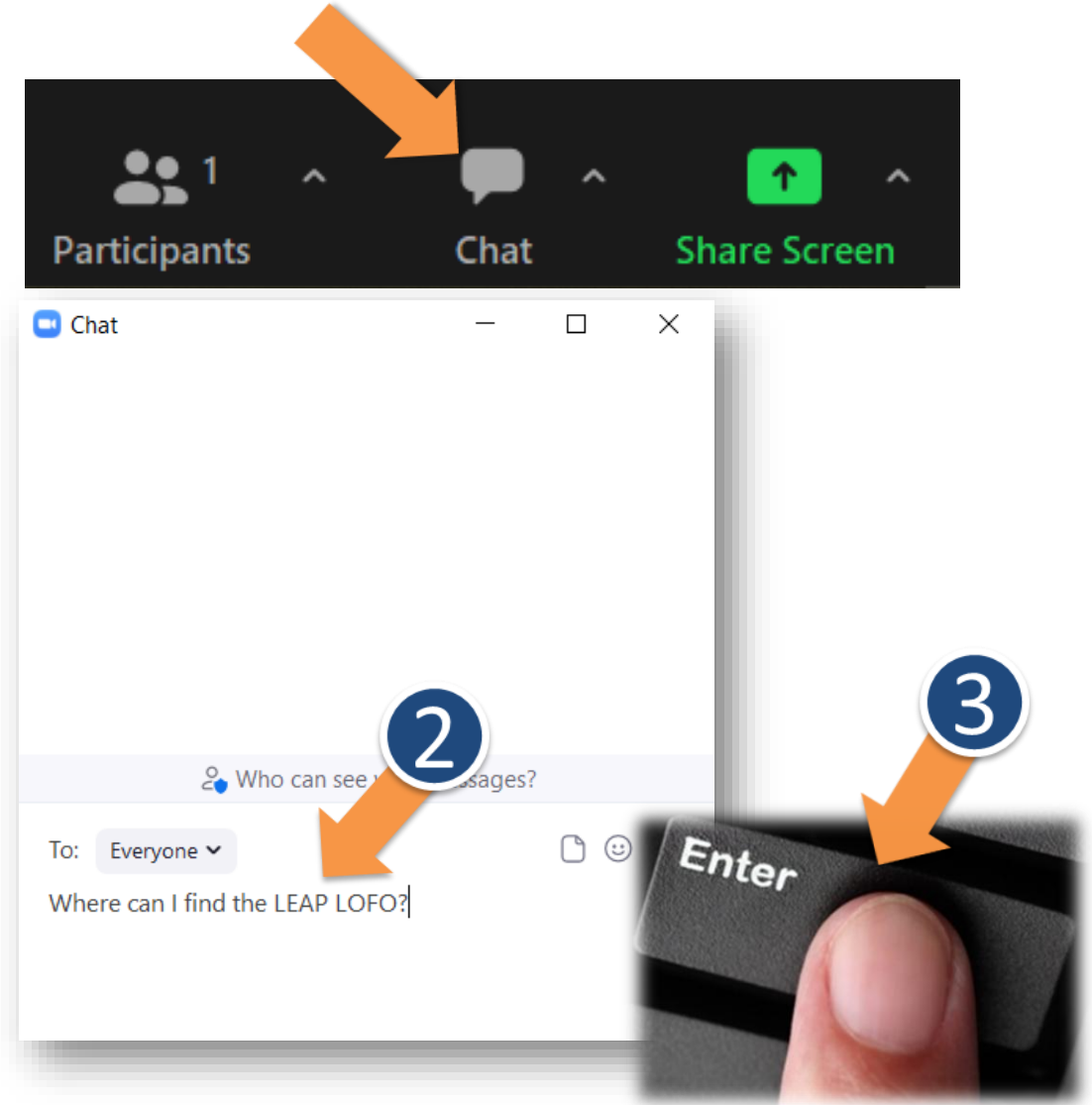
ASTP, Office of Standards, Certification & Analysis, Strategic Initiatives Branch

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 Frequently Asked Questions (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:

ASTP-LEAP@hhs.gov



Background: LEAP in HEALTH IT Notice of Funding Opportunity (NOFO)

Background: LEAP in Health IT NOFO

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 Notice of Funding Opportunity (NOFO) (NAP-AX-22-001).
- Aside from the 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, with the exception of the applicant capabilities.**

Eligible Applicants

- This is a competitive funding opportunity open to public or nonprofit private institutions—such as a university, college, or faith-based or community-based organization—units of local or State government, eligible agencies of the Federal Government, and 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 subrecipient 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 subrecipient 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.

Eligible Applicants (Continued)

- U.S. Department of Health and Human Services (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.

Special Emphasis Notice (SEN) for Applications Under the LEAP in Health IT 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 5-year budget period. Additional funding for Years 3 to 5 may be provided, contingent upon availability of funds, meaningful progress, and ASTP priorities.
- Letters of Intent (LOI) due by **March 27, 2025**.
- Applications due by **April 25, 2025**.

FY2025 Areas of Interest

- **Area of Interest 1:** Demonstrate readiness of FHIR®-based Subscriptions capability as a foundational health IT capability for improved interactivity with third-party applications.
- **Area of Interest 2:** Identify and test innovative technical approaches that would inform future changes to the TEFCA™ infrastructure to increase adoption of IAS.
- **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 FY2025 – Area of Interest 1

Demonstrate readiness of FHIR®-based Subscriptions capability as a foundational health IT capability for improved interactivity with third-party applications (one award up to \$1 million)

Goal: The goals of this area of interest are first, to demonstrate that HL7® FHIR® -based Subscriptions is a foundational capability that supports a broad array of essential health information interoperability needs via HL7® FHIR® -based application programming interfaces (APIs). Projects should, through their implementation, demonstrate whether the implementation specifications developed by the standards community, for HL7® FHIR® -based Subscriptions capabilities are ready to be widely implemented by health IT developers, and to be made available to third-party client applications.

LEAP SEN FY2025 – Area of Interest 1

Applicant Required Expertise

Applicants shall demonstrate familiarity with and understanding of the following:

- Experience with developing applications using HL7® FHIR® Release 4.0.1.
- Familiarity with HL7® FHIR® Subscriptions capability.
- Experience with engaging health IT standards community.
- Experience with developing patient-facing apps using HL7® FHIR®.

Other requirements:

- The technical solution must be based on the HL7® FHIR® Release 4.0.1 standard.
- The technical solution must demonstrate and pilot HL7® FHIR® based Subscriptions specification using a server and an unaffiliated third-party application acting as the Subscriptions client.
- The technical solution must include at least one use case that demonstrates beneficial interactive exchange with third-party client applications over query-based exchange.

LEAP SEN FY2025 – Area of Interest 1

Key Objectives

- Advance and mature existing HL7[®] FHIR[®]-based Subscriptions capability for readiness to be widely adopted by health IT developers.
- Demonstrate how use of Subscriptions capability can lead to beneficial interactive data exchange between EHRs and third-party client applications.
- Demonstrate how a HL7[®] FHIR[®]-based Subscriptions specification can be a foundational health IT capability to support a modern API-based digital health care system in the United States.

LEAP SEN FY2025 – Area of Interest 2

Identify and test innovative technical approaches that would inform future changes to the TEFCA™ infrastructure to IAS funding, eligibility, and application information (one award up to \$1 million)

Goal: The goal of this area of interest is to explore and test innovative technical approaches that could be applied to the technical infrastructure used for IAS exchange in TEFCA. These approaches would ideally lead to increased participation of IAS Providers, improved responses for IAS requests from responding nodes, and markedly increase the number of individuals using TEFCA to access their EHI. We expect that TEFCA partners, including Qualified Health Information Networks (QHINs), Participants, and Subparticipants may also be informed by the technical approaches identified through this area of interest.

LEAP SEN FY2025 – Area of Interest 2

Applicant Required Expertise

Applicants shall demonstrate familiarity with and understanding of the following:

- TEFCA, including its technical and policy components.
- Understanding of IAS in TEFCA.
- Understanding of health IT networks.
- Developing patient-facing apps using HL7[®] FHIR[®].

LEAP SEN FY2025 – Area of Interest 2

Other Requirements

The application shall also include, at a minimum:

- Describe in detail one or more technical barriers currently impeding entities that could be IAS Providers from participating in TEFCA; or that impede QHINs, Participants, or Subparticipants from becoming IAS Providers and offering IAS services to individuals; or both.
- Describe in detail a technical solution to the technical barrier(s), including:
 - Provide sufficient details on the technical solution to demonstrate it is based on non-proprietary technologies.
 - Provide a detailed plan on how the applicant intends to test the solution.
 - Provide a detailed plan describing how the solution will be demonstrated in a manner that would be informative to future changes to technical infrastructure used for IAS exchange in TEFCA.
- Identify an approach to improve IAS exchange while adhering to data security and privacy standards, including ensuring consistency for covered entities' compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule where applicable, its implementing regulations, and other relevant regulations.
- Provide details of any changes that the applicant believes might be needed to TEFCA Standard Operating Procedures (SOPs) related to IAS exchange to implement the technical solution.

LEAP SEN FY2025 – Area of Interest 2

Key Objectives

As described in the Background Section, TEFCA is currently operational and actively facilitating exchange of electronic health information (EHI) among QHINs, Participants, and Subparticipants using established technical infrastructure and Standard Operating Procedures that define the contours of IAS exchange. Any changes to the technical infrastructure in TEFCA would need to be well-tested in a sandbox environment, demonstrated to meaningfully add value over existing approaches, and be likely to be embraced by partners currently participating in TEFCA.

Based on these considerations, there are three key objectives in this area of interest, as follows:

- Identify technical barriers that impede entities that could be IAS Providers from participating in TEFCA and offering services to individuals.
- Develop and test non-proprietary innovative technical solutions to the identified technical barriers.
- Demonstrate the technical solutions to the identified barriers that can be made to the technical infrastructure used for IAS exchange in TEFCA.

LEAP SEN FY2025 – Area of Interest 2

Additional Objectives

Applicants have flexibility to propose activities that achieve the goals and objectives of Area 2, which could include (not required), for example:

- Improvements to the technical requirements for IAS Providers and any related standard operating procedures that would increase utilization of patient facing applications under TEFCA.
- Implementing new ways to perform identity proofing, verification, resolution, and overall identity management of individuals in the context of TEFCA exchange that could simplify the process for individuals to use IAS Provider services.
- Identifying a method of replacing demographics-based patient matches with non-proprietary deterministic approaches that could be broadly adopted within TEFCA.

Funding, Eligibility, and Application Information

Summary of Key Details

SEN FOR APPLICATIONS UNDER LEAP IN HEALTH IT NOFO	
Type of Award	Cooperative Agreement
Available Funding	Up to \$2,000,000
Number of Awards	2 awards
Application Due Date	April 25, 2025
<u>Anticipated</u> Award Date	June 05, 2025
Performance Period	2 years
<u>Anticipated</u> Start Date	June 05, 2025
No. of Awards and Available Funding by Project Topic	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 email LOI to apply for this funding opportunity.
- Submit by **March 27, 2025, 11:59 p.m. ET.**
- Send to ASTP-LEAP@hhs.gov.
- Identify:
 - Title: LEAP Special Emphasis Notice (SEN) Applications to Demonstrate the readiness of FHIR®-based Subscriptions Capability as a Foundational Health IT Capability for Improved Interactivity with Third Party Applications, and Identify and Test Innovative Technical Approaches that Would Inform Future Changes to the TEFCA™ Infrastructure to Increase Adoption of Individual Access Services (IAS) Funding, Eligibility, and Application Information.
 - Area of Interest (1 or 2).
 - Name of applicant organization.
 - City and State of applicant organization.
 - NOFO No. NAP-AX-22-001.

Application Process

- Submit all material electronically through [Grants.gov](https://grants.gov); this process is outlined in the NOFO.
- Contact the [Grants.gov](https://grants.gov) Helpdesk at Support@grants.gov or call at (800) 518-4726 for assistance with submitting applications on [Grants.gov](https://grants.gov).
- Have a Unique Entity Identifier (UEI). UEIs can be obtained via registering at <https://sam.gov/content/entity-registration> and typically takes 7 to 10 business days. 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 that the application meets application requirements and page limits by the deadline.

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 this NOFO.
- The project narrative should also align with the Performance Goals and Objectives and Merit Review criteria presented in this NOFO.
- Applications that did not follow the outlined format must be reviewed by an ASTP 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 pt. 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.

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

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 (2 years) and challenges requiring a longer period (3 to 5 years).
- Applicants shall clearly state which Area of Interest the proposed project will address.

Proposed Approach and Activities

- This section should 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.
- This should be 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 the field at large.

Proposed Approach and Activities (Continued)

- The approach should include as much details as possible given the page limitation.
- The plan for each activity, at a minimum, shall state the following:
 - 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.

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 composed of, but 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.**

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 ASTP, illustrating how the prototype will be made and maintained in a publicly available and acceptable domain at no cost to the general public.

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.

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 ongoing progress, preparation of reports, and communications with other collaborating organizations and ASTP.
 - Recipients will be required to maintain information relevant to executing the proposed project plan and performance-based outcomes.

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 the following:
 - A detailed project timeline as an appendix that incorporates those objectives.
 - An organizational chart as an appendix that reflects roles and responsibilities.

Organizational Capability Statement

- This section 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.
- The statement should 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 toward the 35-page limit.

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 NOFO:
 - 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://grants.gov).
- [Grants.gov](https://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, ASTP may make an award.
- ASTP is not obligated to make an award if none of the applications meets 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 **Friday, April 25, 2025, at 12:00 p.m. ET** through <https://grants.gov/>.
 - The application contains all required components (e.g., Project 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 reviews 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
Total	100

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 NOFO.
- 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 NOFO.
- 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 2-year timeframe **(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?

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://grants.gov) or to apply, go to <https://grants.gov/search-results-detail/341131>.
- For assistance with submitting applications in [Grants.gov](https://grants.gov), please contact the Grants.gov Helpdesk at Support@grants.gov or call (800) 518-4726.

Questions

- All questions must be submitted in writing either via the Chat during this Webinar or emailed to ASTP-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 made publicly available each Monday at <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>.

LEAP SEN FY 2025

Dates to Remember:

- Release Date: January 15, 2025.
- Informational Session: March 6, 2025.
- Letter of Intent (LOI): March 27, 2025.
- Application Deadline: April 25, 2025.
- Anticipated Award Date: June 05, 2025

