

Special Emphasis Notice (SEN) for Applicants to Advance Health IT Standards and Tools to Improve Social Determinants of Health Data Exchange, and to Develop Tools for Making Electronic Health Records Data Research and Artificial-Intelligence Ready

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

Informational Session

Tuesday, March 9, 2021; 2:00 p.m. – 3:00 p.m. ET

The Office of the National Coordinator for Health Information Technology



Agenda

- Introduction of Speakers
- Reminders and Housekeeping
- Special Emphasis Notice for Applications to Advance Health IT Standards and Tools to Improve Social Determinants of Health Data Exchange, and to Develop Tools for Making Electronic Health Records Data Research and Artificial-Intelligence Ready
- 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

- **Tevon Taylor**
Grants Management Specialist
ONC Procurement and Grants Division
- **Kevin Chaney**
Senior Program Manager
ONC Chief Scientist Division
- **Sherilyn Pruitt**
Innovation and Engagement Branch Chief
ONC Standards Division
- **Derrick Ware**
Moderator
ONC Procurement and Grants Division (Contractor)

Housekeeping

- This Webinar is being recorded and will be made publicly available
- All phone lines 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 each week
- Webinar and FAQs will be available at <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-notice-funding-opportunity>

How to Ask a Question

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

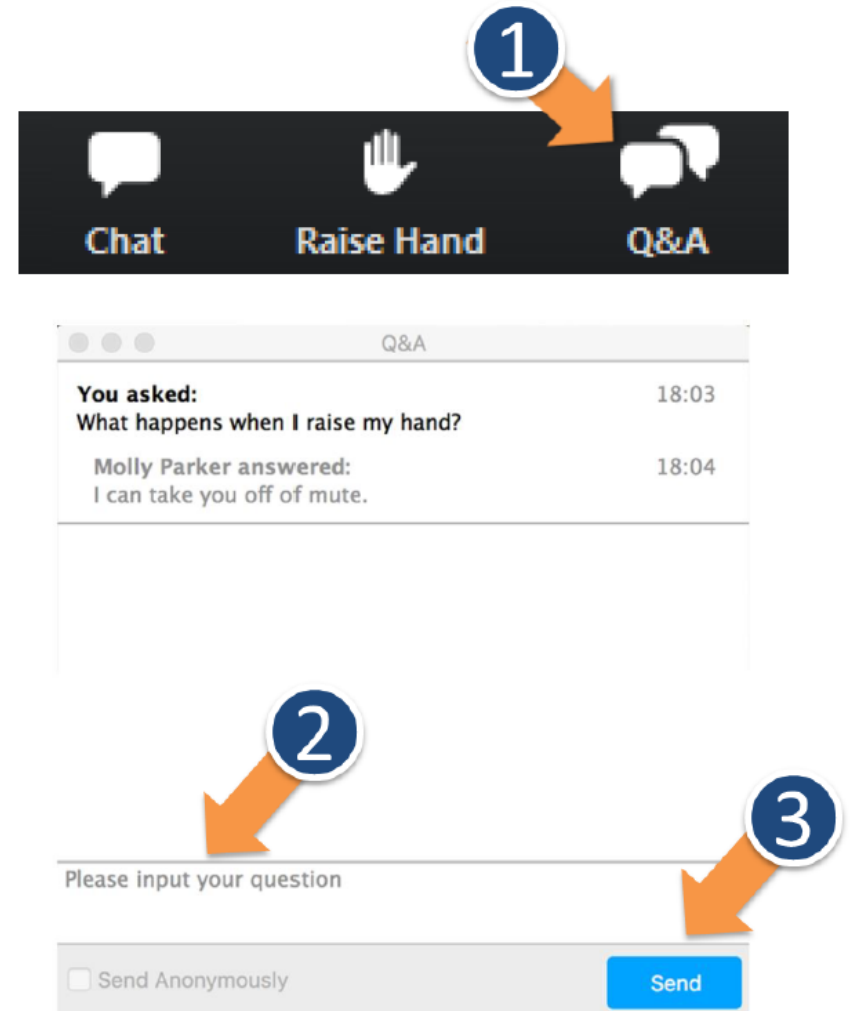
Use the Q&A function to ask a question:

1.) Along the bottom of the webinar window, find and click the Q&A button. The Q&A panel will then expand on your screen.

2.) Input your question into the Q&A box.

Note: Check 'Send Anonymously' if you do not want your name attached to your question in the Q&A

3.) Click **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



SEN for Applications under the LEAP in Health IT NOFO

SEN for Applications to Advance Health IT Standards and Tools to Improve Social Determinants of Health Data Exchange, and to Develop Tools for Making Electronic Health Records Data Research and Artificial-Intelligence Ready

- Two Areas of Interest
- One award per Area of Interest
- \$1M per award
- Period of Performance: 2 years
- May propose additional 3 years (up to 5 years total), subject to availability of funds and meaningful progress
- Letters of Intent (LOI) due by March 23, 2021
- Applications due by May 10, 2021



SEN Areas of Interest

Area 1: Referral Management to Address Social Determinants of Health (SDOH) Aligned with Clinical Care

Area 2: Health IT Tools to Make Electronic Health Record (EHR) Data Research and Artificial Intelligence (AI)-Ready

Important Note: Applicants must indicate which area of interest they are applying for. Application packages addressing more than one area of interest will not be considered for award.



LEAP SEN FY 2021 – Area 1

Referral Management to Address Social Determinants of Health Aligned with Clinical Care (One Award up to \$1M)

GOAL: Pilot health IT standards and non-proprietary, innovative approaches for managing care referrals for social services and support, and secure communication tools for non-clinical, health-supporting services needed to ensure care referrals and the bi-directional exchange of electronic information across these organizations to keep patient health records up-to-date and represent longitudinal and person-centered health and care.

LEAP SEN FY 2021 – Area 1

Associated Objectives

Area 1 Recipient must:

- Demonstrate SDOH data exchange and manage care referrals based on identified individual social needs in a real-world setting, that constitutes “closing of the loop” between clinicians and community-based stakeholders through pilot projects that demonstrate the exchange of one or more SDOH domain(s) identified by the Gravity Project.
- Pilot this approach in at least two (2) jurisdictions to ensure the approach is scalable and replicable to one or more of the SDOH domains, regardless of locality.
- Proposed projects must incorporate a minimum of one (1) of the following existing standards and/or implementation guides (IGs):
 - SDOH Clinical Care IG (Project Gravity);
 - 360X;
 - Electronic Long-Term Services and Support (eLTSS); or
 - Other emerging, nationally relevant, recognized, and available health IT standards, including those specified in the Interoperability Standards Advisory (ISA)

LEAP SEN FY 2021 – Area 1

Associated Objectives - Continued

Area 1 Recipient must:

- Develop and/or use any non-proprietary tools necessary to successfully complete the project
- Engage with current efforts to inform future implementation efforts and further existing standards development activities including testing and update of standards used in the project, as necessary
- Work with existing community-based organizations (CBOs) to ensure alignment with the needs of community health centers and other existing local or community resources
- Identify gaps in coding and terminology standards to support the advancement of the use cases and standardized SDOH data
- Document technical requirements for social/community service organization to send and receive referrals and associated clinical information using the proposed standards and document the levels of readiness and/or feedback from implementation.

LEAP SEN FY 2021 – Area 1

Applicant Required Expertise

- Content, vocabulary, and transport standards to support the exchange of SDOH data
- Stakeholder coordination with clinical care providers, CBOs, Health Information Exchanges (HIEs), and/or Community Information Exchanges (CIEs)
- Workflow and technical architecture that supports referral management

Other Requirements:

- Applicants must also include a coalition of key stakeholders, along with letter(s) of commitment, who will be directly involved in the project
- Applicants must not rely on a single vendor or proprietary technology

LEAP SEN FY 2021 – Area 2

Health IT Tools to Make EHR Data Research- and AI-Ready (One Award up to \$1M)

GOAL: To develop tools for making EHR data research- and AI-ready by systematically measuring completeness and quality; improving interoperability; and automating assessment of data, their features, and provenance through the standardization of open-source health IT tools that can be enhanced or expanded to improve the cross-institutional sharing and use of high-quality data for computation to provide universal solutions to problems faced by researchers.

LEAP SEN FY 2021 – Area 2

Associated Objectives

Area 2 Recipient must:

- Implement a phased approach for the enhancement and/or development of open, scalable, health IT-based tools to boost high quality data for training, learning, modeling, and analysis in coordination with relevant stakeholders, including but not limited to federal health research funders, researchers (i.e., potential tool end-users), and health IT developers, to advance their use in at least two of the health research needs identified above.
- Provide specific examples of the types of research and AI algorithms and/or applications that would benefit from these data.

LEAP SEN FY 2021 – Area 2

Associated Objectives – Continued

Area 2 Recipient must:

- Demonstrate their tools for preparing research- and AI-ready EHR data in partnership with at least two other institutions. It is desirable that institutions use differing health IT systems from different health IT developers. Partnerships should be formed to demonstrate generalizability and provide external validity of research findings. Involvement with FQHCs and small-sized health care providers is strongly encouraged to demonstrate tool scalability with providers typically unable to participate in research.
- Develop and implement a comprehensive dissemination plan to scale and spread their awarded project's findings and outputs to be used by other relevant stakeholders.

LEAP SEN FY 2021 – Area 2

Applicant Required Expertise

- Issues with quality and completeness of EHR data and their suitability for use in research and for AI development and testing
- Health informatics and the use of health IT and electronic health data for research
- Common data models used in research (e.g., i2b2, PCORnet, OMOP, FDA's Sentinel Initiative)
- Use and understanding of open data standards, including FHIR, research tools, and EHRs
- Research tool development, implementation, and use, including user-centered design and testing
- Research enterprise and research processes such as:
 - Patient identification, data sharing, consent, and privacy considerations for sharing clinical data for research and AI development and testing
 - Patient consent and consent management
 - EHR data aggregation and curation
 - Assessing and addressing EHR data quality issues relevant to research and AI development and testing
 - AI training data set development



Background: LEAP in Health IT NOFO

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LEAP in Health IT seeks to address well-documented and fast emerging challenges inhibiting the development, use, and/or advancement of well-designed, interoperable health IT, which is scalable across the health care industry.



Background: LEAP in Health IT NOFO

- Applications submitted under this SEN will be funded under the LEAP in Health IT NOFO (NAP-AX-18-003)
- Aside from areas of interest, required expertise, and deadlines listed in the Special Emphasis Notice **all other requirements, application instructions, and terms and conditions of NOFO NAP-AX-18-003 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 program is to improve health care in the United States, foreign institutions may participate in projects as members of a consortia or as a sub-recipient only
 - 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 or program activity and not merely serve as a conduit of funds to another party or parties
 - Applicant organizations may submit more than one application, provided that each application is scientifically distinct

Deliverables

- For each area of interest applicants shall submit a draft project plan, as an appendix to the application, with corresponding table of key dates and milestones to ensure objectives are met within the self-contained two-year period
- Recipients will also conduct virtual mid-point demonstrations/update of any proposed approaches, prototype(s), and/or enhancements to illustrate their progress on the selected area of interest
- For each area of interest applicants shall provide a deliverable table that consists of expected deliverables which will be produced in support of execution of the cooperative agreement and the due dates

Deliverable Table

No.	Deliverable	Due Date
1	Draft Project Plan and Timeline <i>The recipient will submit a detailed draft project plan, that should include (but is not limited to), key milestones, identified risks and risk mitigation strategies, stakeholder coordination (as applicable), and timeline.</i>	NLT 1 month after award date
2	Mid-point demonstration/update of proposed approach, prototype(s), and/or enhancements <i>The recipient will provide ONC with a live, virtual demonstration of their project progress to-date</i>	NLT 13 months after award date
3	Mid-point specification revisions revised project plan and timeline (as applicable) <i>Based on milestone and project progress up to the mid-point, in addition to feedback from ONC from the mid-point demonstration, the recipient will submit a revised project plan and timeline and initiate any specification revisions as applicable.</i>	NLT 1 month after completion of deliverable 2
4	Draft legal and policy landscape assessment <i>The recipient will submit a draft assessment that addresses the impact of legal and policy factors on project goals</i>	NLT 20 months after award date
5	Final legal and policy landscape assessment <i>The recipient will submit a final assessment that addresses impact of legal and policy factors on project goals</i>	NLT 22 months after award date
6	Submission of final approach and if applicable, prototype(s) (i.e., computer software, including all associated code and tools), and/or enhancements, as well as making prototypes publically accessible for approval by ONC.	NLT 23 months after award date

Key Milestones

- Developing an initial two-year project plan, delineating components that will complete in two years, as well as longer term components if proposed;
- Establishing a technical expert panel to review research methods, results, and provide guidance;
- Implementing the plan to translate project outcomes into broader uptake;
- Scheduling and conducting (as appropriate) and participating in expert panel meetings, team meetings and stakeholder meetings;
- Conducting and managing project to conclusion in two years;
- Conducting and managing the long-term projects to significant, demonstrable progress in out years, if awarded; and
- Communicating findings through appropriate mechanisms and making available as they are generated.

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	\$2,000,000
Number of Awards	2 awards
Application Due Date	May 10, 2021
<u>Anticipated Award Date</u>	July 1, 2021
Performance Period	2 years
<u>Anticipated Start Date</u>	July 1, 2021
No. of Awards and Available Funding by Area of Interest	Area of Interest 1: One award, up to \$1M Area of Interest 2: One award, up to \$1M

Letter of Intent (LOI)

- Applicants are strongly encouraged but not required, to submit a nonbinding email Letter of Intent (LOI) to apply
- Submit by March 23, 2021 11:59 p.m. ET
- Identify:
 - Name of applicant organization
 - Organization type
 - City and State
 - NOFO No. NAP-AX-18-003
 - Title: LEAP Special Emphasis Notice (Applications to Advance Health IT Standards and Tools to Improve Social Determinants of Health Data Exchange, and to Develop Tools for Electronic Health Record Data Research and Artificial Intelligence-Ready)
 - Area of Interest
- Send to: ONC-LEAP@hhs.gov

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](mailto:support@grants.gov) Helpdesk at support@grants.gov or call at (800) 518-4726.
 - Have a Dun & Bradstreet (D&B) Universal Numbering System (DUNS) number.
 - Register in the System for Award Management (SAM) at www.sam.gov; allow a minimum of 5 days to complete the registration. If you are already registered in SAM and have not renewed your registration in the last 12 months, you must 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:
 - Not more than 500 words double-spaced
 - 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 Funding Opportunity Description (Section A) and adhere to Application and Submission Information (Section D) in the NOFO.
- Align with the Performance Goals and Milestones with Merit Review Evaluation criteria presented in the NOFO.
- Applications that did 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

- The project narrative should include the following components. These components will be counted as part of the page limit. The suggested lengths of the sections, given below, are recommended guidelines to help applicants create a balanced document and not mandatory restrictions.
 1. Area of Interest, Vision Statement, and Key Challenges (2–3 pages)
 2. Proposed Approach (10–14 pages)
 3. Project Team (2–3 pages, exclusive of biosketches)
 4. Plan for Disseminating and Transitioning Appropriate Research Results into Practice (2–3 pages)
 5. Stakeholder Coordination (2–3 pages)
 6. Project Management (3–5 pages, exclusive of project timeline and organizational chart)
 7. Organizational Capability (2–4 pages)

1. Area of Interest, Vision Statement, and Key Challenges

- This section should offer the applicant's conceptualization of the selected area of interest.
- This should also 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 a self-contained project period (2 years) and future challenges requiring a longer period (3–5 years).
- Applicants **must clearly state** which **area of interest from the Special Emphasis Notice** the proposed project will address.

2. Proposed Approach

- 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** in the focus area and **how to advance the field** via proposed activities to meet the objectives of that specific research area.
- Organized so that **the relationship of each element of the plan to each of the area's objectives and associated activities** are completely clear.
- The development or employment of novel concepts, approaches, methodologies, tools, or technologies; or combination of common research elements in an innovative fashion should be described, as well as how it will generate much-needed insight to inform the field of health IT.
- Proposed strategies on how the results of the project may be disseminated and transitioned to the field at large.

2. Proposed Approach (continued)

- The approach should include as much detail as possible given the page limitation.
- The plan for each activity, at a minimum, **must 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 focus area being addressed.
 - The key personnel who will be involved.

3. Project Team

- The section must describe the proposed research team's expertise and experience to include the following:
 - Project Director/Principal Investigator
 - At least one person on the proposed research team must possess health IT expertise
 - For Area of Interest 1, the proposed research team must have expertise **in the areas outline in the SEN (see slide 11 of this presentation)**
 - For Area of Interest 2, the proposed research team must have expertise **in the areas outline in the SEN (see slide 16 of this presentation)**
 - The application should include a biosketch for key project personnel

4. Plan for Disseminating and Transitioning Appropriate Research Results Into Practice

- This section should describe a plan for engaging health IT stakeholders and interested groups in promoting the dissemination and transition of appropriate research activities and results into data standards, data infrastructures, health IT products, tools, and best practices.
- The plan should be specific in proposing activities that will disseminate and transition the results of the proposed self-contained (2-year) projects in products and best practices.
- Collaborative arrangements with industry and other groups outside the applicant institution should be accompanied by appropriate letters of support.

5. 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.

6. 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 subrecipients with contractual relationships, plans for coordinating research activities across multiple organizations should be described.
 - This section should specify who would have day-to-day responsibility for key tasks such as leadership of project, monitoring the project's ongoing progress, preparation of reports, and communications with other collaborating organizations and ONC.
- Recipients will be required to maintain information relevant to proposed milestones and performance-based outcomes.

6. 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 milestones.
- The application should include:
 - A detailed project timeline as an appendix that incorporates those milestones.
 - An organizational chart as an appendix that reflects roles and responsibilities.

7. Organizational Capability Statement

- Should outline the established research program relevant to the research focus area and highlight established collaborative relationships with healthcare stakeholders.
 - 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).
 - The statement should also highlight capabilities of the applicant not included in the program narrative.
 - Applicants who are working with partners as part of a consortia must also provide letters of commitment from their proposed project partners.
 - Letters of commitment shall be included with the appendixes and do not count towards the 35-page limit.

Budget Narrative and Budget Forms

- Complete the following budget forms to document costs of proposed project activities:
 - Budget Narrative on how the proposed budget 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, May 10, 2021 at 11:59 p.m. 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 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
Approach and Activities	40
Applicant Capabilities	30
Budget, Level of Effort, and Justification	20
Total	100

Merit Review Criteria: Understanding of Project Purpose— 10 points

- How well does the application address the purpose and objectives of this SEN and identify a specific research area of interest? To what extent is the proposed project and activities parallel SEN goals and objectives associated with one of the two identified areas of interest?
- The extent to which the applicant has identified an important, coherent, and parsimonious set of challenges and associated research questions within one of the two identified areas of interest that are—or, if not addressed, will be—clear barriers to advancing interoperability and/or advancing clinical knowledge at the point of care.
- The extent to which the applicant describe how the project and expected outcomes and results will inform the field and future health IT development, research, and implementation, as appropriate.

Merit Review Criteria: Approach and Activities - 40 points

- The extent to which the proposed research methods promise to address the challenges with breakthrough findings on a proposed timeline within the parameters of a self-contained two-year project period and potentially longer project period, if funded **(20 points)**
- The extent to which the applicant proposes a clear and detailed transition/dissemination plan. The extent to which the plan to transition/disseminate results to products and best practices is complete and feasible; and envisions the release of the outcomes of their research into open-source communities **(15 points)**
- The extent to which the plan describes a project management approach for ensuring project success within and across collaborators **(5 points)**

Merit Review Criteria: Applicant Capabilities - 30 points

- Strength of evidence that the project brings an appropriate level of research and technical knowledge and expertise, for the chosen focus area and strength of evidence that the project will integrate the efforts of those team members **(20 points)**
- Extent to which the proposed activities bring all the resources necessary to perform the proposed work and the identification of proposed strategies to complete activities within a two year time frame and sustain research efforts beyond the project time frame **(5 points)**
- 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)**

Merit Review Criteria: Budget, Level of Effort, and Justification - 20 points

- Is the use of consultants and/or sub-recipients appropriate and adequate to advance the project in accordance with the timelines? **(10 points)**
- Extent to which the budget is justified with respect to the adequacy and reasonableness of resources requested, and the amount of the budget allocated to administration is minimized while still allowing coherent management of an integrated project **(10 points)**

Questions

- All questions must be submitted in writing either via the Q&A function during this Webinar or emailed to ONC-LEAP@hhs.gov
 - Questions submitted today in the Q&A function 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-notice-funding-opportunity>

Q&As

- Thank you for attending!
- We will remain online for 5 minutes – please submit any remaining questions via the Q&A function on this webinar page
- To see the SEN on [Grants.gov](https://www.grants.gov) or to apply, go to <http://www.grants.gov/web/grants/view-opportunity.html?oppld=306704>
- 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 or call at (800) 518-4726

Please submit your questions.

5 Minutes Remaining

Please submit your questions.

3 Minutes Remaining

Please submit your questions.

1 Minute Remaining

LEAP SEN FY 2021

Dates to remember:

- Release Date: February 23, 2021
- Informational Session: March 9, 2021
- Letter of Intent (LOI): March 23, 2021
- Application Deadline: May 10, 2021
- Target Award Date: July 1, 2021



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

Thank you for attending.