ONC Announces Special Emphasis Notice (SEN) Interest in Applications to Address the Development and Testing for Data Sharing Functionalities to Support Clinical Care, Research, and Improved Health Care Outcomes

Notice Number: NAP-AX-18-003

Key Dates
Release Date: April 6, 2020
Expiration Date: June 8, 2020

Issued by
Office of the National Coordinator for Health Information Technology (ONC)

Purpose

This Notice announces ONC's interest in funding projects under the Leading Edge Acceleration Projects (LEAP) in Health Information Technology (IT) funding opportunity (see NAP-AX-18-003 at https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704) in fiscal year 2020 to address the Development and Testing for Data Sharing Functionalities to Support Clinical Care, Research, and Improved Health Care Outcomes.

Areas of Interest

The Office of the National Coordinator for Health Information Technology (ONC) is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology (IT) and the electronic exchange of health information. Created in 2004, through Executive Order 13335[1] and legislatively authorized in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009,[2] ONC is at the forefront of the federal government's health IT efforts and is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide health information exchange to improve health care.

The goal of the LEAP in Health IT funding opportunity is 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. Solutions are expected to further a new generation of health IT research and inform the development, implementation, and refinement of standards, methods, and techniques for overcoming major barriers and challenges in an innovative fashion as they are identified.

---

[1] https://www.govinfo.gov/content/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf
[2] https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf

It is critical that the field of health care innovate and leverage the latest technological advancements and breakthroughs far quicker than it currently does to optimize real-time solutions, especially in areas which are ripe for acceleration.

In fiscal year 2020, ONC is particularly interested in applications whose specific aims address one of the following areas of interest:

- **Area 1:** Advancing Registry Infrastructure for a Modern API-based Health IT Ecosystem
- **Area 2:** Cutting Edge Health IT Tools for Scaling Health Research
- **Area 3:** Integrating Health Care and Human Services Data to Support Improved Outcomes

ONC anticipates issuing one award for area of interest 1 and one award for area of interest 2 (for a total of 2 awards), up to $1 million per award (for a total of up to $2 million in funding in fiscal year 2020), and one award for area of interest 3, up to $500,000 in fiscal year 2020. Please note that all applicants must explicitly state the area of interest for which they are applying. Applications that do not state their intended area of interest will **not** be considered. You may apply for more than one area of interest; however, a separate application is required for each area. Outside of the specific areas of interest as listed above and described below for fiscal year 2020, and the required expertise noted for each area of interest described below, all other requirements and evaluation criteria as described in the LEAP in Health IT NOFO (NAP-AX-18-003 at https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704) shall apply.

Area 1: Advancing Registry Infrastructure for a Modern API-based Health IT Ecosystem; One Award up to $1M

A clinical registry[3] is a collection of health information about individuals, usually focused around a specific diagnosis or condition. Many registries collect information from participating providers' electronic health record (EHR) systems. Clinical registries can provide health care professionals and researchers with first-hand information about people with certain conditions, both individually and as group over time, to increase understanding of that condition. These registries are also used to achieve objectives such as discovering new therapies and finding new techniques to diagnose diseases.

Within the context of accountable care, registries sometimes include both clinical and financial information. These can be used by participating provider organizations to identify gaps in care, such as screening services that have not been provided but may be appropriate for a given population, or monitoring of a clinical condition that should occur and where a patient has yet to come in for care. Registries also provide vital source of data that can be used by researchers to address health management for whole populations, including those with chronic diseases and those at high risk of complications.

Registries face following challenges:

---

[3] https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries

- Data submission by providers is often time- and cost-intensive, requiring the development of "Extract-Transform-Load" (ETL) processes that are unique across registries.
- Data obtained from multiple sources are often non-standard, and require time-consuming data normalization processes. Additionally, each time a registry connects with a new data source, the mapping process has to be done before the data can be integrated into the registry platform.
- Lack of timely availability of registry information within the workflow of providers, in the form and manner that is most useful to the providers.

Application Programming Interfaces (APIs) to Enhance Providers' Access and Use of Clinical Registries

There has been rapid progress made over the last several years in the adoption and implementation of modern Health Level Seven International's (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard[4] in health IT. FHIR provides a secure standards-based API that enables authorized users to access, exchange, and use health information easily.

Recent analysis from ONC shows that almost 87% of hospitals and 69% of clinicians that participate in the Centers for Medicare & Medicaid Services' (CMS) Promoting Interoperability (PI) program use products from health IT developers that support the FHIR standard.[5]

FHIR provides a large set of industry curated data elements via FHIR "resources," which group together different data that have a common theme. Additionally, HL7 has published the U.S. Core Implementation Guide (IG)[6] that provides further specificity of data elements that are commonly exchanged by health IT systems in the U.S.

The FHIR standard has been extended via the development of the Bulk Data Access IG[7], which provides a standardized, FHIR-based approach for efficient export of large volumes of information on groups of individual to authorized users.

The use of FHIR standard, and the associated implementation specifications, provide an excellent opportunity to both the registry organizations and the users of the registry information, to make substantial improvements in all aspects of the registry ecosystem, including the following:

- Using FHIR APIs for a single patient and at the population level to submit data efficiently into registries.
- Using FHIR APIs to access data from the registry for patient care and research.
- Using the FHIR standard and associated IGs as a common registry data model.

---

[4] http://hl7.org/fhir/
[5] https://www.healthit.gov/buzz-blog/interoperability/heat-wave-the-u-s-is-poised-to-catch-fhir-in-2019
[6] http://hl7.org/fhir/us/core/
[7] http://hl7.org/fhir/us/bulkdata/2019May/index.html

- Performing modern analytics and clinical decision support (CDS) using advanced capabilities including CDS Hooks.[8]

Knowing the potential for the FHIR standard to improve registry performance, the U.S. Department of Health and Human Services (HHS) under the Assistant Secretary for Planning and Evaluation (ASPE) funded the Coordinated Registry Network (CRN) for Women's Health Technologies (WHT) project.[9] The CRN project developed the Women's Health Technologies Coordinated Registry Network IG (CRN IG),[10] which uses the FHIR standard, and successfully piloted the use of the CRN IG for submitting standardized data to the registry. One of the lessons learned from the pilot, was that the FHIR standard and its associated IGs could be easily adopted by registries and provide similar benefits as seen by the adoption of FHIR APIs for patient access.

Currently, providers are required to manually submit their data into a registry in order for a registry to collect and organize data in a form that make it easily usable by providers. The primary focus of this area of interest is targeted at improving the ability for providers to submit and use data through a registry, including collaboration for both providers and registries.

Specifically, the goal of this area of interest is to advance the use of FHIR-based APIs for all aspects of registry data submission and use of data from registries, with the goal of decreasing data acquisition burden for all participating entities, reducing data normalization and standardization efforts, and ultimately providing providers with timely access to data for analytics and actionable knowledge.

More specifically, the recipient must:

- Identify the clinical registries that will be used by the project
  - Applicants selecting this area of interest must include a letter of commitment from the clinical registry(ies) they intend to partner with for purposes of this project in their application
- Utilize an HL7 FHIR standards-based approach based on the prior CRN IG to support submitting and accessing registry data
- Identify and implement FHIR "resources" that are suitable for exchanging with the identified registries
- Use the Bulk Data Access IG to perform efficient data submission and access for groups of individuals
- Ensure that the APIs used for accessing data for a single patient and for a population, are secured using appropriate security standards, such as the SMART App Launch Guide,[11] Backend Services Authorization,[12] and OpenID Connect Core 1.0 incorporating errata set 1[13]

[8] https://cds-hooks.org/
[9] https://aspe.hhs.gov/developing-strategically-coordinated-registry-network-crn-womens-health-technology
[10] http://hl7.org/fhir/us/womens-health-registries/2018Sep/
[11] http://hl7.org/fhir/smart-app-launch/
[12] http://hl7.org/fhir/us/bulkdata/2019May/authorization/index.html
[13] https://openid.net/specs/openid-connect-core-1_0.html

- In the case that gaps are identified and/or improvements or modifications are made to the WHT CRN IG, Bulk Data Access IG, the applicant is required to document these actions and other implementation specifications to support the chosen use cases
- Document best practices in implementing the standards and IGs in support of the chosen use cases
- Coordinate with the appropriate standards development organization(s) to ballot and adopt new and/or updated standards and/or IGs that result from this project

To be considered for an award in this area of interest, applicants must also demonstrate expertise in the following:

- Registry data submission and use of data from registries
- Familiarity with data acquisition burden for providers using registries
- HL7 FHIR standard and balloting of standards in HL7
- Implementation Guides, including the CRN IG and Bulk Data Access IG
- SMART App Launch Guide

Applicants must also be utilizing a FHIR-enabled product. If an applicant is not currently FHIR-enabled, they will be required to become upgrade their software to become FHIR-enabled within six (6) months of the project award date

Area 2: Cutting Edge Health IT Tools for Scaling Health Research; One Award up to $1M

The increased adoption and use of electronic health record (EHR) systems,[14,15] coupled with the growth of personal connected devices[16] has led to an exponential growth of electronic health data available for research. Unfortunately, capitalizing on the value of these data for the purposes of biomedical and health services research remains slow to due to difficulties with both the data and the health IT infrastructure. To overcome these challenges, ONC led the development of the National Health IT Priorities for Research: A Policy and Development Agenda[17] (the Agenda) establishing nine priorities and associated actions and supporting strategies intended to address relevant data, tools, and infrastructure needs.[18] ONC, along with the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and Veteran's Health Administration (VHA) recognize the importance of advancing the Agenda[19] to better align the clinical and research ecosystems so researchers can pursue more complex research questions and make faster, more reliable discoveries for a 21st century health system.

In particular, the Agenda identified the need to develop tools and functions that leverage the health IT infrastructure to better support research. Additional tools and functions are needed to support research that could be embedded within the health IT infrastructure. In particular, tools are needed to more effectively index, search, and query systems to identify and recruit possible

---

14 https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php
[15] https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php
[16] https://www.thieme-connect.com/products/ejournals/html/10.15265/IY-2017-016
[17] https://www.healthit.gov/sites/default/files/page/2020-01/PolicyandDevelopmentAgenda.pdf
[18] https://doi.org/10.1093/jamia/ocaa008
[19] https://doi.org/10.1093/jamia/ocaa011

patient cohorts for a given study as well as easily extract data about participants. Such tools should facilitate not only participant recruitment for research studies, but enrollment and randomization as well. While such tools may exist, challenges and barriers (e.g., difficulties in tool identification, lack of clarity of tool purpose, poor usability/usefulness, lack of use of open standards, etc.) can limit their use and uptake.

- Accordingly, the goal of this area of interest is to (1) identify open health IT-based tools that leverage open standards as appropriate and could be enhanced or expanded for broader support and uptake and/or (2) identify needs for new health IT-based tools for research that require development. Based on an understanding of challenges and barriers for why some health IT-based tools for research have had limited use and uptake, the applicant must identify in its application where innovative tools are needed for development or identify enhancement needed of existing tools, describe how they intend to seek out approaches for building and scaling identified tools, and describe how they intend to build upon any relevant, existing health IT-based tools, technologies, platforms, and applications for supporting research, as appropriate.

More specifically, to better inform the work under this award, the recipient must:

- Conduct a landscape analysis to explore, identify and describe current open health IT-based tools for research that could be enhanced and/or disseminated more broadly and/or identify two or more research needs that would benefit from health IT-based tool development from the ones listed below:
  - Linking and aggregating research-relevant data sources with EHR data
  - Improving the ability to match individuals to different data sources
  - Developing tools to efficiently manage data use agreements (DUAs) across organizations
  - Developing functionalities needed to manage data across distributed sources, including to identify redundancy; account for updates to data and metadata; and analyzing data in different formats
  - Supporting robust de-identification and use of de-identified data sets to increase confidence in security and manage risk
  - Searching, indexing, and querying systems to identify patient cohorts or extracting data about research participants
  - Exploring consent tools that allow patients to control and update their data-sharing preferences if embedded into the health IT infrastructure that could facilitate research participation and data sharing
- Work with ONC on a phased approach for the enhancement and/or development of open, scalable, health IT-based tools to support research in coordination with relevant stakeholders, including but not limited to federal health research funders, users, developers, and the ONC Health IT Certification Program, to advance their use in at least two of the health research needs identified above.

To be considered for an award in this area of interest, applicants must also be able to demonstrate expertise in the following:

- Health informatics and the use of health IT and electronic health data for research
- Common data models used in research (e.g., PCORnet's common data model, Observational Medical Outcomes Partnership (OMOP) common data model)
- Use of open data standards, research tools, and EHRs
- Research tool development, implementation, and use, including user-centered design and testing
- Research enterprise and research processes such as:
    - DUAs and data sharing
    - Patient matching and linkage
    - Patient and data de-identification
    - Patient consent and consent management
    - Data aggregation
    - Identifying patients and participant research cohorts

Applicants must also include a dissemination plan to address the scalability of their awarded project's findings and outputs.

Area 3: Integrating Health Care and Human Services Data to Support Improved Outcomes; One Award up to $500,000

In recent years, HHS has emphasized the need for improved coordination and appropriate integration across health care and human service providers to improve the delivery of services and supports, health care, outcomes and to support value-based payment goals. Indeed, lack of effective coordination across health care and human services providers comes at great cost to patients and caregivers, providers, and the health care system, and is a significant problem.

The Draft Federal Health IT Strategic Plan 2020-2025[20] includes an objective to integrate health care and human services information which is necessary for "providing person-centered health care and human services" that address social determinants of health (SDOH) at the individual and population level. In this context, it is important to understand the importance of adopting and using the United States Core Data for Interoperability (USCDI) and additional, relevant Interoperability Standards Advisory (ISA)[21] health IT standards to advance nationwide interoperability.

Medicaid serves as the primary payer across the nation for long-term services and supports (LTSS), including home and community-based services (HCBS). HCBS includes transportation, diet and nutrition services and assistance with self-care, such as bathing and dressing, and household activities, such as preparing meals and managing medication that enable older Americans, people with disabilities and/or mental illness to live independently in their home or community rather than an institutional setting.[22] In 2016, 57% of all Medicaid LTSS spending was on HCBS, totaling $94 billion.[23]

---

[20] https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan
[21] https://www.healthit.gov/isa/
[22] https://www.kff.org/report-section/medicaid-home-and-community-based-services-enrollment-and-spending-issue-brief/
[23] https://www.medicaid.gov/sites/default/files/2019-12/ltssexpenditures2016.pdf

Medicaid requires that home and community-based services (HCBS) are provided pursuant to person centered plans. For example, the HCBS regulation at 42 CFR 441.301(c)(2)(ix)[24] specifies that, for HCBS provided under a section 1915(c) waiver, the person centered service plan must be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation. Fundamental to improving the delivery of community-based services for individuals is the ability to capture, document, and share the person-centered care plan across providers in the care continuum. To achieve this, ONC seeks solutions with replicable IT system architectures to more efficiently collect and use data (e.g., assessment data used in level of care determination and as part of the person-centered plan development), including functional and cognitive status and other related data sources, as a way to improve outcomes and increase efficiencies. Solutions under this award must demonstrate the use of health IT that leverages the electronic Long-Term Services and Supports (e-LTSS) plan of care standard.[25]

Specifically, the goal of this area of interest is to:

- Improve electronic data sharing between health care providers and human service providers (e.g., USCDI, assessments such as Functional Assessment Standardized Items[26], and e-LTSS plan of care)
- Advance the role of the USCDI beyond health care settings to include human services programs
- Supporting real-world implementation of the e-LTSS standard as part of federal programs with person-centered planning requirements (e.g., section 1915(c) Medicaid waivers)
  - Document any improvements or modifications to the e-LTSS plan of care and any associated implementation specifications to support the integration of health care and human services data, as applicable
- More efficiently share care plans from both health and human service providers to improve outcomes as measured by the HCBS quality framework[27]
- Document best practices in implementing the required technology in support of providing person-centered health care and human services

It is ONC's intention that successful completion of the above listed goals will better enable others to implement health IT solutions that perform functions such as:

- Providing data, reporting, and analytics that inform beneficiaries, payers, and health care professionals
- Providing data, reporting, and analytics that support research around the benefits – clinical, social and financial - of incorporating health care and human services data into a person-centered plan

---

[24] https://www.federalregister.gov/documents/2014/01/16/2014-00487/medicaid-program-state-plan-home-and-community-based-services-5-year-period-for-waivers-provider
[25] http://hl7.org/fhir/us/eltss/ and https://oncprojecttracking.healthit.gov/wiki/display/TechLabSC/eLTSS+Home
[26] https://del.cms.gov/DELWeb/pubHome
[27] https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/measuring-and-improving-quality-home-and-community-based-services-hcbs/index.html

- Advancing value-based purchasing (VBP) arrangements in Medicaid funded home- and community- based services programs
- Informing the IT infrastructure and data sharing requirements necessary to create a VBP model in an HCBS programs by relevant payers and providers (e.g., states and health systems)

To be considered for an award in this area of interest, applicants must also be able to demonstrate expertise in applying principles of value-based purchasing to HCBS programs. This includes expertise in:

- Person-centered planning requirements in the context of HCBS;[28]
- The role of health IT standards in data sharing (e.g. e-LTSS plan of care standard, USCDI);[29]
- Experience in using the e-LTSS plan of care standard;[30]
- Balloting of standards in HL7; and
- Principles of value-based payment programs (e.g. Health Care Payment Learning & Action Network Category 1-4).[31]

Further Guidance

Use of Funding Mechanism. ONC will use the existing Leading Edge Acceleration Projects (LEAP) in Health Information Technology Notice of Funding Opportunity (NOFO) to support applications submitted in response to this Notice. This NOFO, NAP-AX-18-003 can be found at https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information or https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704. Outside of the Areas of Interest and updated dates described in this Special Emphasis Notice, all other requirements, application instructions, and terms and conditions of NOFO NAP-AX-18-003 apply.

Limitations on Timelines and Funds. ONC currently limits the total (direct plus indirect) costs for these applications to no more than $1,000,000 for the entire project period for Areas of Interest 1 and 2 and no more than $500,000 for the entire project period for Area of Interest 3. The project period can be up to two years.

Application Submission and Special Application Receipt Date. Information about the application process can be found at https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information or https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704.

---

[28] https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-training-series/index.html - see section on Person-Centered Service Planning

[29] https://www.healthit.gov/isa/

[30] http://hl7.org/fhir/us/eltss/ and https://oncprojecttracking.healthit.gov/wiki/display/TechLabSC/eLTSS+Home

[31] http://hcp-lan.org/workproducts/apm-framework-onepager.pdf

An Informational Session will be held on April 15, 2020. Further details about the informational session – including the date, time, and instructions for joining – are available at: https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information.

Although not required, applicants are strongly encouraged to submit a non-binding e-mail letter of intent to apply for this funding opportunity. This letter of intent will assist ONC in planning for the application review process. When submitting your letter of intent, please identify which area of interest your organization plans to apply for. The letter of intent is requested by 11:59 P.M. Eastern Standard Time on April 27, 2020, and should be sent to ONC-LEAP@hhs.gov. The letter should identify the name of the applicant organization, the city and state in which the applicant organization is located, and the Notice of Funding Opportunity title and number.

Applications focused on the areas of interest identified in this Notice must be submitted by **11:59 P.M. Eastern Standard Time on June 8, 2020. This Notice will expire on June 9, 2020.**

Inquiries

Please direct all program related inquiries to:

Tracy H. Okubo, CSM, PMP
Senior Program Analyst
Office of the National Coordinator for Health Information Technology (ONC)
Email: ONC-LEAP@hhs.gov

Please direct all grant related inquiries to:

Carmel Halloun
Grants Branch Chief
Office of the National Coordinator for Health Information Technology (ONC)
Email: oncgrants@hhs.gov