The Office of the National Coordinator for Health Information Technology (ONC) Announces Special Emphasis Notice (SEN) Interest in 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

NOTICE NUMBER: NAP-AX-18-003

Key Dates
Release Date: February 23, 2021
Expiration Date: May 10, 2021

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 2021 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.

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

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[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

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.

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 2021, ONC is particularly interested in applications whose specific aims address one of the following areas of interest:

- **Area 1:** Referral Management to Address Social Determinants of Health Aligned with Clinical Care
- **Area 2:** Health IT Tools to Make Electronic Health Records (EHR) Data Research – and Artificial Intelligence (AI)-Ready

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 2021. Please note that all applicants must explicitly state the area of interest for which they are applying. Applications that do not clearly state their intended area of interest will **not** be considered. Eligible applicants 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 2021, 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 Notice of Funding Opportunity (NOFO) (NAP-AX-18-003 at https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704) shall apply.

Area 1: Referral Management to Address Social Determinants of Health Aligned with Clinical Care; One Award up to $1M

There is a growing recognition[3] across the health care industry that by capturing and accessing social determinants of health (SDOH) data during the course of patients' care, providers can more easily identify and address non-clinical factors, such as food, housing, and transportation insecurities. These factors and circumstances, often overlooked, can have a major impact on a person's health, well-being, and overall quality of life.

In addition to clinical care, health care providers can play a critical role not only in helping to identify individuals' social determinants of health-related data and social needs, but also to identify and help their patients access available resources within their community. These resources can include Community-Based Organizations (CBOs), community health centers including Federally Qualified Health Centers (FQHCs), and other social and human service settings and organizations. Often, health care providers give patients paper-based or electronic referrals to access specific services as aligned with identified social needs by these available resources; however, the referral may not be integrated within health IT systems. Even when the referrals are included, challenges still persist with individuals accessing services in part due

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3   https://health.gov/healthypeople/objectives-and-data/social-determinants-health
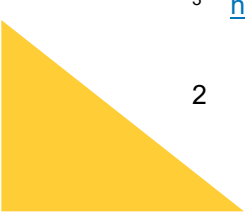
to a lack of interoperability between clinical and community resource systems. This in turn, limits information that can be shared back with a referring provider about the patient from the service provider.

The current challenges in SDOH data use and interoperability warrant investment in piloting health IT standards and non-proprietary approaches for managing care referrals for social services and support, and secure communication tools for non-clinical, health-supporting services. Innovation is needed to ensure care referrals and the bi-directional exchange of electronic information across these organizations are not only possible but done in a manner that keeps patient health records up-to-date and represent longitudinal and person-centered health and care.

ONC is currently working to address these challenges by supporting the collection, access, exchange, and use of SDOH data, to include:
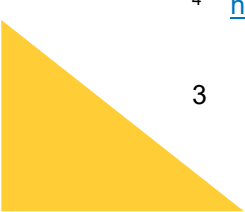
- <u>Standards and Data</u>- Guiding the development, dissemination, and further adoption and use of standard health IT terminologies, definitions, and approaches/methods
- <u>Policy</u>- Identifying and advancing emerging policies to inform overall policy development to overcome SDOH interoperability challenges
- <u>Infrastructure</u>- Supporting states and local governments as they build the infrastructure(s) to support collection, access, exchange, and use of SDOH data
- <u>Implementation</u>- Developing and driving innovative opportunities for integration into clinical care, workflow, and EHRs

Recipients must meet the following goals:

- Demonstrate SDOH data exchange and manage care referrals based on identified individual social needs in a real-world setting, which 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[4]. These domains include housing instability and homelessness, housing inadequacy, transportation insecurity, food insecurity, financial stress, employment, education, Veterans status, social isolation, stress, and interpersonal violence.
- The approach must be piloted 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. This is not limited to an entire county, city, or state, but must include clearly defined communities or participants, and a detailed implementation approach.
- Pilot projects must incorporate a minimum of one of the following existing standards and/or implementation guides (IGs):

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[4]   https://www.hl7.org/gravity/

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- o Social Determinants of Health Clinical Care IG (Project Gravity)[45] – Identify coded data elements and associated value sets to represent SDOH documented in EHRs across four (4) clinical activities: (1) screening; (2) diagnosis; (3) planning; and (4) interventions that could reasonably overcome challenges or barriers relative to the overall benefits and impact of SDOH data elements.
  - o 360X[6, 7] - Advance interoperable health care data exchange for closed loop referrals from within health IT workflow, enable improved care coordination between providers and other entities utilizing disparate health IT systems, enhancing the efficiency and value of patient care while decreasing provider burden, transcription errors and the cost of care.
  - o Long-Term Services and Support (eLTSS[8]) - Support exchange of data generated during the planning and provision of long-term services and support currently scoped to data commonly found on LTSS service plans
  - o Other emerging nationally relevant, recognized, and available health IT standards, including those specified in the Interoperability Standards Advisory (ISA)[9].
- The development and/or use of any non-proprietary tools necessary for the successful completion of a pilot project must be clearly defined.
- Engage with the current efforts (i.e., Gravity, 360X, and eLTSS) to inform future implementation efforts and further existing standards development activities including testing and update of standards used in the pilot.
- Work with existing CBOs to ensure alignment with the needs of community health centers such as FQHCs, 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 organizations to send/receive referrals and associated clinical information (as necessary) using the proposed standards and documenting levels of readiness and/or feedback from implementation. This must also include any additional implementation challenges that would inhibit large scale adoption of the selected standards, if applicable. Work with the appropriate standards development organizations (SDOs) to update relevant standards and/or propose additional needs or opportunities for interoperability between clinical care and social services that have yet to be identified.

To be considered for an award in this area of interest, applicants' proposals must include a coalition of key stakeholders, along with letters of commitment(s), who will be directly involved in the project, such as health

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5   https://confluence.hl7.org/display/GRAV/The+Gravity+Project
6   https://www.healthit.gov/techlab/ipg/node/4/submission/276
7   https://oncprojecttracking.healthit.gov/wiki/display/TechLab360X/360X+Home
8   http://hl7.org/fhir/us/eltss/2019May/
9   https://www.healthit.gov/isa/

care providers across care settings, CBOs, social service organizations, health information exchanges (HIEs), health IT developers or vendors, and state/local agencies.

An applicant's proposal shall not rely on a single vendor or proprietary technology.

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

- Content, vocabulary, and transport standards to support the exchange of SDOH data
- Stakeholder coordination with clinical care providers, CBOs, HIEs, community information exchanges (CIEs)
- Workflow and technical architecture that supports referral management

Area 2: Health IT Tools to Make EHR Data Research- and AI-Ready; One Award up to $1M

The ability to aggregate and compare EHR data across diverse health care settings is necessary to ensure research findings are valid and generalizable [10,11]. Development of health IT tools to facilitate the standardized gathering and assessment of high-quality data needed for research, including development and testing of artificial intelligence (AI) applications [12,13], in research remains an outstanding need. This is particularly true when dealing with clinical data generated by different health care organizations and captured in varying EHR systems. Development and dissemination of such tools would benefit the research community broadly but is particularly important to increasing participation of under-resourced settings in research. ONC has recently prioritized the development of tools and functions that better support research, as well as increase participation of under-resourced settings and diversify its research populations in its National Health IT Priorities for Research: A Policy and Development Agenda [14,15]. Furthermore, the 2020-

[10] Casey JA, Schwartz BS, Stewart WF, Adler NE. Using Electronic Health Records for Population Health Research: A Review of Methods and Applications. Annu Rev Public Health. 2016;37:61-81. doi:10.1146/annurev-publhealth-032315-021353

[11] U.S. Food & Drug Administration. Executive Summary for the Patient Engagement Advisory Committee Meeting: Artificial Intelligence (AI) and Machine Learning (ML) in Medical Devices. https://www.fda.gov/media/142998/download. Accessed December 15, 2020.

[12] JASON. Artificial Intelligence for Health and Health Care. Washington, DC: Office of the National Coordinator for Health Information Technology; 2017. https://healthit.gov/jason. Accessed December 15, 2020.

[13] Matheny, M., S. Thadaney Israni, M. Ahmed, and D. Whicher, Editors. 2019. Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril. NAM Special Publication. Washington, DC: National Academy of Medicine. https://nam.edu/wp-content/uploads/2019/12/AI-in-Health-Care-PREPUB-FINAL.pdf. Accessed December 15, 2020.

[14] Office of the National Coordinator for Health Information Technology. National Health IT Priorities for Research: A Policy and Development Agenda. 2020. https://www.healthit.gov/research-agenda. Accessed December 15, 2020.

[15] Zayas-Cabán T, Chaney KJ, Rucker DW. National Health Information Technology Priorities for research: A Policy and Development Agenda. J Am Med Inform Assoc. 2020;27(4):652-657. doi:10.1093/jamia/ocaa008

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2025 Federal IT Strategic Plan, has prioritized conducting research that "reflects the diversity of the U.S. so that findings can be applied across populations"[16].

In particular, the development of transparent AI applications requires that the data used to train and develop them are auditable with regard to provenance, appropriateness, and quality[9]. AI training data must be appropriately selected to avoid bias[17]. Tools that allow researchers to systematically assess information about a data set, including additional features, are vital for mitigating unintended biases. Knowing whether data reflect the diversity of the U.S. and can produce findings that serve relevant patient populations will be key for clinical validity.

Currently Health Level Seven International (HL7®) standards, including the Fast Healthcare Interoperability Resources ® standard, and the United States Core Data for Interoperability's (USCDI) standardized set of health data classes, provide guidance on how clinical data should be structured. However, there is still variability in how content is captured within that structure. Individual clinicians or health care organizations may interpret and use EHR fields incongruously[18, 19]. These differences may only come to light when it comes time to aggregate data across institutions. Pragmatic and scalable tools are needed to provide straightforward and standardized assessments of data quality. When data conform to expected values and outputs, are complete, and are plausible they are considered high-quality[20]. Frameworks have been described to systematically assess the quality of EHR data as it is captured by in common data models [21, 22].

The goal of this area of interest is 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. To meet this goal, recipients will develop standardized open-source health IT tools that can be enhanced or expanded to improve the cross-institutional sharing

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[16] Office of the National Coordinator for Health Information Technology. 2020-2025 Federal Health IT Strategic Plan. https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf. Accessed December 15, 2020.

[17] U.S. Government Accountability Office. Technology Assessment Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care. https://www.gao.gov/assets/720/710920.pdf. Accessed December 15, 2020.

[18] Cohen GR, Friedman CP, Ryan AM, Richardson CR, Adler-Milstein J. Variation in Physicians' Electronic Health Record Documentation and Potential Patient Harm from That Variation. J Gen Intern Med. 2019;34(11):2355-2367. doi:10.1007/s11606-019-05025-3

[19] Council of State and Territorial Epidemiologists. Improving the Quality and Completeness of Electronic Health Record Data Used in Syndromic Surveillance: Final Report. www.cste.org/resource/resmgr/nssp/Improving_the_Quality_and_Co.pdf. Accessed December 15, 2020.

[20] Kahn MG, Callahan TJ, Barnard J, et al. A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data. EGEMS (Wash DC). 2016;4(1):1244. Published 2016 Sep 11. doi:10.13063/2327-9214.1244

[21] Data Quality Assessment. https://data.ohdsi.org/DataQualityDashboard/. Accessed December 15, 2020.

[22] Sentinel. Sentinel Data Quality Review and Characterization Programs. https://dev.sentinelsystem.org/projects/QA/repos/qa_package/browse. Accessed December 15, 2020.

and use of high-quality data for computation. Such tools should provide universal solutions to problems faced by researchers such as:

- Automating mapping of EHR data to common data models (e.g., Informatics for Integrating Biology & the Bedside [i2b2]'s data model[23, 24], Patient-Centered Outcomes Research Network [PCORnet]'s common data model[25], Observational Medical Outcomes Partnership [OMOP][26], FDA's Sentinel Initiative common data model[27])
- Enhancing semantic interoperability (i.e., fluent machine-to-machine communications) of multi-institution generated data
- Assessing and documenting data quality using standardized terms such as conformance, completeness, and plausibility[18]
- Synthesizing metadata (e.g., patient demographic or provider characteristic metrics) in a standardized way to assess and mitigate downstream bias, including representation bias, measurement bias, aggregation bias, and historical bias

More specifically, to meet this goal, the 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.
- 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.

[23] i2b2. About Us: Overview. https://www.i2b2.org/about/. Accessed December 15, 2020.
[24] Visweswaran S, Becich MJ, D'Itri VS, et al. Accrual to Clinical Trials (ACT): A Clinical and Translational Science Award Consortium Network. JAMIA Open. 2018;1(2):147-152. doi:10.1093/jamiaopen/ooy033
[25] The National Patient-Centered Clinical Research Network. Data-Driven. https://pcornet.org/data-driven-common-model/. Accessed December 15, 2020.
[26] OHDSI. OMOP Common Data Model. https://www.ohdsi.org/data-standardization/the-common-data-model/. Accessed December 15, 2020.
[27] Sentinel. Sentinel Common Data Model. https://www.sentinelinitiative.org/methods-data-tools/sentinel-common-data-model. Accessed December 15, 2020.

- 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.

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

- 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[22,23,], PCORnet[24], OMOP[25], FDA's Sentinel Initiative[26])
- 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:
  - o Patient identification, data sharing, consent, and privacy considerations for sharing clinical data for research and AI development and testing
  - o Patient consent and consent management
  - o EHR data aggregation and curation
  - o Assessing and addressing EHR data quality issues relevant to research and AI development and testing
  - o AI training data set development

Further Guidance

Unless otherwise indicated in this Notice, all requirements, instructions, and terms and conditions of 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) will apply to applications submitted and awards made in response to this Notice.

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.

An Informational Session will be held on March 9, 2021. 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 March 23, 2021 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, the intended area(s) of interest, 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 May 10, 2021. This Notice will expire on May 11, 2021.**

Inquiries

Please direct all program related inquiries to:

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