

National Evaluation System for health Technology Coordinating Center (NESTcc) Cloud Infrastructure for NESTcc Active Surveillance System

Request for Proposals (RFP)

The National Evaluation System for health Technology Coordinating Center (NESTcc) is seeking a full-service contractor to develop and maintain a cloud platform which can be used to support active surveillance projects.

Eligibility

Private-sector, nonprofit, and for-profit organizations are eligible to submit proposals.

NESTcc Background

In 2016, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) awarded a grant to the Medical Device Innovation Consortium (MDIC) to establish the **National Evaluation System for health Technology Coordinating Center (NESTcc)**. MDIC is a 501(c)(3) nonprofit public-private partnership created with the objective of advancing regulatory science of medical devices for patient benefit. NESTcc's mission is to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research. To support its mission, NESTcc is working across the ecosystem with key stakeholder groups including payers, regulators, health systems, patient groups, industry, and clinicians. NESTcc has developed a strategic approach that focuses on four priority areas, each with its own set of operational milestones:

1. To establish NESTcc governance structure;
2. To develop NESTcc's Data Network;
3. To establish NESTcc's sustainability; and
4. To ensure NESTcc stakeholder engagement.

More information on NESTcc is available at: <http://www.nestcc.org>

More information on MDIC is available at: <http://www.mdic.org>

Project Concept

The timely and accurate detection of safety signals for medical devices is a high priority for the FDA. In order to further this work, the FDA has provided NESTcc with dedicated funding to advance active surveillance activities for medical devices. In November of 2018, the FDA released an update in their [Medical Device Safety Action Plan](#) outlining how NESTcc will be leveraged to more quickly detect emerging safety signals through active surveillance.

Active Surveillance can be defined as the continuous monitoring of large clinical data sources, and once implemented, will be a significant improvement on current efforts that engage in passive surveillance for

identifying safety signals for medical devices. Passive surveillance relies on individuals identifying that a problem has occurred which may be associated with a device and (voluntarily) reporting the problem through an established reporting system. Such reporting is considered important but limited in its ability to quickly identify new risks and changes in frequency of known risks. It is generally agreed that the combination of underreporting, incomplete reporting, and lack of denominator/exposure data is not conducive to the robust and timely detection of safety signals.

To launch NESTcc's active surveillance work, a multi-stakeholder [Active Surveillance Task Force](#) was created. The Task Force is working to develop a Roadmap and operational model for conducting active surveillance work within NESTcc. NESTcc's most important initial active surveillance activities will be the detection of potential safety signals (signal detection). Signal detection will support the identification and analysis of significant adverse events which have not necessarily been pre-specified.

MDIC is seeking a contractor to develop a cloud platform which can be used to support the active surveillance work described above. The platform will be developed in two phases. Phase I will be used to develop an initial platform to intake and store data, conduct analyses, and create dashboards based on the results of each analysis. Phase II will be initiated after the successful launch of the Phase I platform and will include scaling the system across multiple [Network Collaborators](#) and increasing its capabilities, including but not limited to data quality assessments and predictive analytics.

Details and Requirements for the Scope of Work

Key activities under this awarded Scope of Work (SOW) will include:

1. *Phase I: Develop an initial cloud infrastructure for NESTcc's active surveillance work. The initial infrastructure will be developed with the assistance of at least two Network Collaborators that have experience with cloud management and/or have specific knowledge related to active surveillance methodologies. Considerations for the initial cloud system include, but are not limited to:*
 - a) Security of the system including FedRAMP and FISMA compliance.
 - b) Creating different zones or levels of data with different access requirements for each.
 - c) Ingesting and storing data (in compliance with HIPAA regulations) on a continuous basis.
 - d) Conducting analysis on continuously accruing data.
 - e) Executing custom existing R, Python, and SAS code to analyze the data.
 - f) Creating dashboards outlining metrics on data and results of analyses.
2. *Phase II: Scale the system to allow for additional users and more complex pathways and analyses. Considerations include, but are not limited to:*
 - a) Adding additional Network Collaborators into the system quickly and efficiently.
 - b) Conducting data quality assessments.
 - c) Maintaining records (such as inputs, outputs, code for analysis, and logs) and storing data in the system for multiple years after project completion (can be stored in cold storage).
 - d) Plan for incorporating machine learning and predictive analytics into the platform, as necessary.
 - e) Future tailoring for business audiences by creating an easily accessible list of services for organizations across the medical device ecosystem to select.
3. *Phase I and II: System Maintenance*
 - a) Maintaining the system after development in a full-service capacity.
 - b) Providing a recommended staffing plan for NESTcc to take over the maintenance of the system after it is fully developed and operational.

Management of the Project

NESTcc staff will oversee the day-to-day management of the project and will provide approval for each interim and final deliverable. Other NEST stakeholders (e.g., FDA) may be involved during platform creation, as necessary.

Deliverables to be Completed within the Period of Performance

NESTcc staff will approve each of the following deliverables. This list represents a minimum set of required deliverables; additional deliverables can be proposed within the application.

- (1) In-person kick-off meeting
- (2) Bi-weekly meetings (which could be held as conference calls in the event that the contractor is not in the Washington, DC region) with NESTcc throughout the project
- (3) Phase I Cloud Infrastructure Design plan and demonstration
 - a. Draft plan for implementing a cloud infrastructure that meets the Phase I needs listed above
 - b. Final plan for implementing a cloud infrastructure that meets the Phase I needs listed above
 - c. A demo platform capable of ingesting, storing and analyzing data from a minimum of two Network Collaborators, to be updated with specific needs outlined by NESTcc
 - d. Draft dashboards that outline metrics and data analysis results
 - e. Final dashboards that outline metrics and data analysis results
- (4) Phase II Cloud Infrastructure Design plan
 - a. Draft plan for implementing a cloud infrastructure that meets the Phase II needs listed above
 - b. Final plan for implementing a cloud infrastructure that meets the Phase II needs listed above
 - c. Expansion of the cloud platform built under phase I to be updated with specific needs outlined by NESTcc
- (5) Phase I and Phase II: System Maintenance plan
 - a. Support plan for system maintenance
 - b. Recommended staffing plan for NESTcc to take over maintenance of the system after full development

Submission

Responses must be submitted via [NESTcc's Catch-All Intake Submission Portal](#) through the required template by 5:00 p.m. ET on Tuesday, December 10, 2019. The application must include all of the required components listed below.

To complete the submission, follow these steps:

1. Applicants must complete the Applicant Profile through the [portal link](#). Applicants will need to follow instructions to Sign Up to create an Applicant Profile.
2. After creating an Applicant Profile, click "+ Add Another" to create a new Intake Form.
3. To complete the Intake Form, click "Edit".
4. After completing the edits to the Intake Form, click "Submit" for the First Stage Submission.

Application Components

The following are required application components:

1. [Intake Form](#) Fields (included in the template for reference).
2. [Application Narrative](#) (not to exceed 8 pages) to be uploaded as the first “Proposal Upload” on the Intake Form. The narrative should include:
 - A statement of qualifications including prior experience on similar projects
 - A plan for executing the deliverables described above
 - A timeline for completing each of the deliverables within the required period of performance
 - Statement of past and current approaches to health information security, including any breaches with which you have dealt, and the mitigation plan used to address the issue (this will not disqualify you from being considered)
3. A [budget](#) to be uploaded as the “Budget Upload” for a time and materials contract which includes proposed hourly rates for all personnel who will be supporting the project, including all expected costs and expenses.
4. Curriculum Vitae (CVs) of key personnel with experience on projects of a similar nature (experience with medical device data and support preferred) to be uploaded as the “Personnel Upload” as one file.
 - Please note that key personnel are expected to remain on the project for the duration of the contract or NESTcc reserves the right to end the contract.
5. Up to three Letters of Support to be uploaded as “Letters of Support Upload.”

Period of Performance

The period of performance for Phase I will be March 2020 – June 2020.

The period of performance for Phase II will be July 2020 – December 2020.

Review Process

Responses to this RFP will be reviewed by NESTcc staff members and members of the Active Surveillance Task Force. NESTcc staff reserves the right to contact applicants with additional questions during the review period or conduct an interview. NESTcc staff reserve the right to consult additional external stakeholders to review applications. Any external reviews will be completed in accordance with the MDIC [conflict of interest policy](#). Responses will be reviewed for completeness and appropriateness as they pertain to the required submission components. NESTcc will consider both the programmatic aspects of the proposal for each development phase, as well as the anticipated cost, with the programmatic elements of the proposal receiving greater weight. NESTcc may, for example, choose a costlier proposal if its programmatic offering warrants the premium. However, as potential contractors’ programmatic offerings move toward equivalency, cost the importance of cost will increase.

NESTcc’s selection of a contractor will be contingent upon the parties executing a mutually acceptable contract on or before February 29, 2020. Because this project is funded with support from an FDA Cooperative Agreement, the contract will include all appropriate Federal terms and conditions, including but not limited to those found in 45 C.F.R. Part 75 and the HHS Grants Policy Statement, including any addenda thereto. MDIC reserves the right to terminate contract negotiations at any time and select

another contractor if it determines that it is unlikely that an agreement will be executed in a timely manner.

A complete application includes all required application components. Incomplete applications may not be reviewed.

Timeline

- Posting Date: November 14, 2019
- Deadline for Questions: November 22, 2019
- Responses to Questions will be posted in the form of a FAQ document: November 26, 2019
- Submissions Due: December 10, 2019
- Award Notification Date: January 31, 2019
 - Applicants will be notified by NESTcc if the applicant notification date is extended.

About MDIC

The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created with the sole objective of advancing medical device regulatory science throughout the total product life cycle. MDIC's mission is to promote public health through science and technology and to enhance trust and confidence among stakeholders. We work in the pre-competitive space to facilitate development of methods, tools, and approaches that enhance understanding and improve evaluation of product safety, quality, and effectiveness. Our initiatives improve product safety and patient access to cutting-edge medical technology while reducing cost and time to market.

For more information visit: <http://www.mdic.org>