NEST Coordinating Center
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Posting Date: December 4, 2017
Indication of Interest: December 15, 2017
Due Date: January 17, 2018

National Evaluation System for health Technology Coordinating Center (NESTcc)

Assessment of Appropriate Use of Real-World Evidence for Medical Devices

Request for Proposals (RFP)

The National Evaluation System for health Technology (NESTcc) is seeking a contractor to complete an assessment consistent with the Medical Device User Fee Amendments ("MDUFA IV") of 2017 and the FDA Reauthorization Act of 2017 ("FDARA"),[1] which will "evaluate the strengths, limitations, and appropriate use of real-world evidence for regulatory and coverage decisions, and determine whether current methods, systems, and programs for real-world evidence can generate reliable and timely evidence about the effectiveness or safety surveillance of devices."

Background

The current fragmented health care ecosystem does not support the seamless, near real-time, and cost-effective use of electronic health data to generate high-quality evidence for regulatory, coverage and clinical decision-making for medical technologies. The medical device ecosystem includes a broad range of technologies, from high-risk implants (e.g., cardio defibrillators) to lower-risk technologies (e.g., infusion pumps), to imaging and diagnostic technologies. With increasing technological advances, software is increasingly being used as a medical device.

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) public-private partnership created with the objective of advancing regulatory science of medical devices for patient benefit. NESTcc's mission is to establish clear pathways within the ecosystem to support the timely, reliable, and cost-effective development of evidence using Real-World Data sources for key stakeholders, including the medical device industry, regulators, payers, patients, clinicians, and health systems. NESTcc will support evidence generation—both observational and interventional—for use-cases ranging from pre-market approval, label expansions, post-market safety and surveillance studies, and coverage decisions.[1]

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

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[1] Shuren J, Califf RM. Need for a National Evaluation System for Health Technology. JAMA. 2016 Sep 20;316(11):1153-4. doi: 10.1001/jama.2016.8708

Project Concept

The goal of this RFP is to identify a contractor to conduct an assessment of the strengths, limitations, and appropriate use of Real-World Evidence for informing pre-market and post-market decision-making for multiple device types and to determine whether current methods, systems, and programs for Real-World Evidence can generate reliable and timely evidence about the effectiveness or safety surveillance of devices.

NESTcc's Role

MDIC staff of NESTcc will oversee the management of this project and provide approval for each interim and final deliverable.

Details and Requirements

Both MDUFA IV and FDARA require assessment of the progress and outcomes of the usability of Real-World Evidence.[2]

Proposals should specify a plan for developing and implementing an assessment framework. The plan should address the following:

(1) An assessment of the strengths, limitations, and appropriate use of Real-World Evidence for:
    a. Informing pre-market and post-market decision-making (e.g., clearances, approvals, expansion of indication, post-market safety and surveillance studies, coverage decisions)
    b. Multiple device types, including Class II and Class III devices and imaging and diagnostic technologies

(2) An assessment of whether current sources of data, methods, systems, and programs for Real-World Evidence can generate reliable and timely evidence that is fit-for-purpose and that evaluates the effectiveness or safety surveillance of devices for regulatory, coverage, and other types of decision-making.

(3) The assessment should consider the status of devices that are not subject to a registry. Examples of high-quality registries with device information include the American College of Cardiology's suite of NCDR registries and the Vascular Quality Initiative.

The proposal should include:

(1) An approach to designing and implementing the assessment framework
(2) An approach to identifying the appropriate proposed metrics, milestones, and case-studies
(3) A plan for data collection and analysis
(4) A draft outline of the final report

The proposal **must not exceed 10 pages.**

NESTcc staff will work closely with the selected contractor to share previously-collected background information. It is anticipated that the data required to complete the analysis may be collected through

[2] https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf; https://www.congress.gov/bill/115th-congress/house-bill/2430/text#toc-H5688D4BD25CB40D2B09AAB4D50A17033

the surveys, observations, stakeholder interview outputs, and other information provided by NESTcc. Additional data sources will be mutually agreed upon by the contractor and NESTcc.

Submission Components

To enable NESTcc to evaluate the submission, the responding proposal must include the following:

- A plan for developing an assessment framework. The plan must comply with the guidelines outlined above and **not exceed 10 pages.**
- A timeline for completing the required deliverables within the period of performance
- A proposed budget that includes proposed hourly rates for all personnel who will be supporting the project, as well as expected costs and expenses
- Curriculum Vitae (CVs) of potential investigators and prior experience conducting similar engagements (experience with medical device evidence preferred)
- Up to 3 Letters of Support

MDIC encourages interested parties to arrange a teleconference with leaders from NESTcc to discuss potential submissions.

Responses should be completed using the provided submission form template.

Period of Performance

March 1, 2018 – September 30, 2020

Deliverables to be completed within the period of performance

NESTcc staff will approve each of the following deliverables and interim deliverables. These deliverables represent a minimum set of required deliverables. Additional deliverables can be proposed within the application.

Deliverable	**Associated Interim Deliverables**
1. Assessment Framework	a. Draft Framework b. Final Framework
2. Identification of Data Sources	a. Draft Proposed Sources b. Final Sources
3. Quarterly Alignment Meetings and Associated Project Status Report	a. Meeting Materials (including meeting agenda and post-meeting summary) b. Project Status Report (in template provided by NESTcc)
4. Annual Interim Report (in template provided by NESTcc)	N/A
5. Analysis Report, including analysis framework and recommendations	a. Draft Analysis Report b. Final Analysis Report

Indication of Interest

As a preliminary step in the application submission process, please indicate your interest in submitting a proposal by contacting NESTcc@mdic.org by 5p.m. EST on December 15, 2017. NESTcc will provide interested parties with supplemental material on December 18, 2017 to prepare the proposals.

Review Process

Responses to this RFP will be reviewed by NESTcc staff. NESTcc staff reserve the right to contact applicants with additional questions during the review period. NESTcc staff reserve the right to consult 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 of the responses as they pertain to the required submission components. NESTcc will consider both the programmatic aspects of the proposal, 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 will gain in importance.

NESTcc's selection a contractor will be contingent on the parties executing a mutually acceptable contract on or before March 1, 2018. 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. NESTcc 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.

Timeline

- Posting Date: December 4, 2017
- Indication of Interest: December 15, 2017
- NESTcc Distribution of Supplemental Material: December 18, 2017
- Proposals Due to NESTcc: January 17, 2018
- Notification of Selection by MDIC and Commencement of Contract Negotiations: January 26, 2018
- Work Initiated: March 1, 2018
- Work Completed: July 1, 2020 in anticipation of a public meeting that will be held no later than October 1, 2020 and a report due no later than January 31, 2021

Please send completed submission form or questions to MDIC NESTcc Project Manager Hither Jembere, NESTcc@mdic.org. Deadline for proposals is January 17, 2018, 5p.m. EST.

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