



NEST Coordinating Center

www.nestcc.org

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) Establishing the Value of Using Real-World Evidence for Regulatory and Coverage Decisions: Case-Studies in Medical Technologies

Request for Proposals (RFP)

The National Evaluation System for health Technology Coordinating Center (NESTcc) is seeking a contractor to complete a review and analysis of the value for industry stakeholders of using Real-World Evidence (RWE) for regulatory and coverage decisions through a series of case-studies.

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. In addition, with significant 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 is being developed to support evidence generation—using observational or interventional study designs as appropriate—for use-cases ranging from pre-market approval to label expansions, post-market safety and surveillance studies, and coverage decisions.¹

During 2017, NESTcc has initiated operations, established a multi-stakeholder Governing Committee, developed initial strategic and operational plans, established strategic data partnerships, and identified a set of designated NESTcc Demonstration Projects.

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

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

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

NESTcc was conceived as an opportunity to address the lack of high-quality, near real-time, and low-cost evidence to support RWE generation for medical devices for key stakeholders. NESTcc's goal is to establish clear pathways for stakeholders to implement such studies.

An important step in the development of a national system such as NEST is to identify and communicate the value to industry stakeholders and other key stakeholders of using new data sources and methods for evidence generation for regulatory and coverage purposes. A number of successful regulatory submissions to the FDA from industry have taken place over the past few years across a range of use-cases (e.g., expanded indications for use, post-market surveillance studies, post-approval device surveillance as condition of approval, control group, and objective performance criteria and performance goals).² NESTcc has an important role in describing these case-studies, evaluating their returns on investment, and making these exemplar cases known across the medical device ecosystem.

The goal of this RFP is to identify a contractor to conduct a review of up to 10 case-studies with analyses of the returns on investment, uses of Real-World Data for regulatory decisions, and, if available, coverage decisions.

NESTcc's Role

MDIC staff of NESTcc will oversee the management of this project and will provide approval for each interim and final deliverable. NESTcc staff will also provide the selected contractor with a number of reviews, white papers, and other materials that have been developed in the past by a number of parties, including NESTcc, the FDA, and other collaborators and organizations.^{3,4}

Details and Requirements

The proposal should include a plan for developing and implementing the following:

1. Identification and Selection of Case-Studies

- a. The proposal should describe a process for identifying and selecting significant examples of successful use of Real-World Data for regulatory and coverage purposes to the FDA and/or payers.
- b. Additionally, the proposal should include plans to select unsuccessful cases in order to identify barriers and learn from these examples.
- c. The following sources of information may be considered:
 - i. Publicly-available data (e.g., data from the FDA website and other public sources)
 - ii. Data shared by medical device manufacturers
 - iii. Developing a Request for Information (RFI) from industry manufacturers willing to share information and present a case-study
 - iv. NESTcc staff and the NESTcc Governing Committee will assist with outreach to manufacturers where appropriate.

² Reference FDA Guidance on RWE, August 31, 2017

³ Duke Margolis Center for Health Policy, A FRAMEWORK FOR REGULATORY USE OF REAL-WORLD EVIDENCE, September 13, 2017, https://healthpolicy.duke.edu/sites/default/files/atoms/files/rwe_white_paper_2017.09.06.pdf (accessed November 4, 2017)

⁴ Duke Margolis Center for Health Policy, Opportunities and Gaps in Real-World Evidence for Medical Devices April 26 2017 (all day meeting) <https://healthpolicy.duke.edu/events/opportunities-and-gaps-real-world-evidence-medical-devices> (accessed November 4, 2017)

- d. NESTcc staff will share previously-collected information, including a completed 2016 landscape review.
- e. The proposal should describe a process for prioritizing and selecting case-studies. Considerations should include a range of:
 - i. Types of devices (Class II, Class III, imaging and diagnostic technologies)
 - ii. Types of regulatory decisions (e.g., approvals, clearances, expanded indications for use, post-market safety studies, development of objective performance criteria or goals, surveillance studies)
 - iii. Study designs (observational and interventional)
 - iv. Small and large manufacturers, including venture-capital funded companies that have developed products that have gained market approval
 - v. Consumer-facing technologies that have received FDA approval
- f. The proposal should outline how the case-studies will be described in the report, including, but not limited to, the following aspects:
 - i. Regulatory or coverage use-case, including the relationship between regulatory and coverage approvals. The proposal should include a strategy to review the logical possibilities of various decisions:
 - a. Positive regulatory approval and positive coverage approval
 - b. Positive regulatory approval and lack of coverage approval
 - c. Lack of regulatory approval and lack of coverage approval
 - ii. Data source and data quality processes
 - iii. Methodological approach
 - iv. Timing of evidence generation and regulatory or coverage decision-making
 - v. Unique lessons learned

2. Analysis of the Return on Investment

The proposal should describe an approach to evaluating the financial return on investment (ROI) to industry of generating evidence for regulatory or coverage purposes using Real-World Data.

- a. The proposal should recommend appropriate metrics to evaluate ROI (e.g., cost savings, days saved, information generated that could not have been generated otherwise)
- b. NESTcc staff will share current examples of ROI evaluation that have been undertaken by CDRH staff in collaboration with academic partners and that could be used as frameworks for other case-studies.

3. Future Directions and the Role of NESTcc

- a. The proposal should include an outline for a final section that will review the current state-of-play, lessons learned from the case-studies, challenges and gaps, and the role of NESTcc in accelerating adoption.

4. Dissemination of Findings

- a. The proposal should also recommend ways to disseminate learnings from the project to industry stakeholders, including materials, blogs, meetings, and journal submissions.

Final deliverables for this project will include:

- 1) A final report and corresponding slide deck to be posted publicly on the NESTcc website
- 2) A presentation to the NESTcc Governing Committee

Submission Components

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

- A response to the requirements detailed above **(not to exceed 10 pages)**
- A timeline for completing the required deliverables within the period of performance
 - This proposal must also include a process for addressing any anticipated or actual delays with the project execution, as the timeline for the project is critical for the NESTcc to meet its operational objectives for 2018.
- 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 with experience with projects of a similar nature (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 – August 1, 2018

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. Work Plan Outlining Project Approach	a. Draft Work Plan b. Final Work Plan
2. Request for Information (RFI)	a. Draft RFI b. Final RFI c. Public RFI Posting d. Compilation of All RFI Responses e. Process for Reviewing RFI Responses
3. Targeted Collection of Case-Studies for Analysis	a. Approach to Identify Case-Studies b. Process for Selecting Case-Studies c. Selection of Case-Studies
4. Analysis of Case-Studies	a. Draft Framework for Analysis, including ROI b. Final Framework for Analysis, including ROI
5. Data Analysis	N/A
6. Synthesis Presentation	a. Draft Presentation

	b. Final Presentation
7. Final Report	a. Draft Report b. Final Report
8. Presentation to the NESTcc Governing Committee	a. Draft Presentation b. Preliminary Presentation to NESTcc staff c. Presentation to the NESTcc Governing Committee

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 of 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 MDIC NESTcc: January 17, 2018
- Notification of Selection by MDIC and Commencement of Contract Negotiations: February 9, 2018
- Contract Executed: February 28, 2018
- Work Initiated: March 1, 2018
- Work Completed: August 1, 2018

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>