NEST Coordinating Center
www.nestcc.org

Posting Date: May 1, 2018
Questions Due: May 15, 2018
Due Date: May 31, 2018

National Evaluation System for health Technology Coordinating Center (NESTcc)

Planning for the Sustainability of the National Evaluation System for health Technology Coordinating Center (NESTcc)

Key Dates	
Request for Proposal Released	May 1, 2018
Deadline for Questions	May 15, 2018
Responses to Questions	May 21, 2018
Deadline for Proposals	May 31, 2018 (5 p.m. EST)
Projected Notification Date	July 1, 2018
Projected Start Date	August 1, 2018

Request for Proposals (RFP)

The National Evaluation System for health Technology Coordinating Center (NESTcc) is seeking a contractor with a deep understanding of the medical device ecosystem, healthcare research networks, and expertise in business and strategy. This RFP includes two specific scopes of work:

(1) Market Analysis
(2) Business Plan Development

Applicants may choose to submit proposals for one or both scopes of work. MDIC may make up to two awards under this RFP. MDIC expects to make one award per scope of work. The awards may go to the same contractor or distinct contractors.

Eligibility

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

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 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 clinician groups. NESTcc has developed a strategic approach that focuses on four priority areas, each with its own set of operational milestones: establishing NESTcc governance, developing NESTcc's role, establishing NESTcc's value, and ensuring NESTcc stakeholder engagement.

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] NESTcc was envisioned to develop a voluntary data network of collaborators able to efficiently consolidate RWE generated in the routine course of care to inform medical device evaluation and support regulatory decision-making throughout the total product lifecycle (TPLC).

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

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Project Concept

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

MDIC is seeking contractor support to plan for the long-term viability and sustainability of NESTcc after the initial funding from the FDA. Through the MDUFA IV legislation, the FDA is supporting the initial development of NESTcc through a five-year investment. After the initial investment, the goal is that NESTcc is sustainable. The contractor will develop potential business models to support the sustainability of NESTcc for consideration by the NESTcc Executive Director, the NESTcc Governing Committee (GC), the Sustainability Subcommittee of the GC, and the MDIC Board of Directors.

The two scopes of work associated with this project are:

(1) Market Analysis
(2) Business Plan Development

The development of these products will be an iterative process with the NESTcc Executive Director and the NESTcc Deputy Director. The financial model and business model will be interrelated and a feedback loop will connect the two components.

Management of the Project

MDIC staff of NESTcc will oversee the day-to-day management of this project and will provide approval for each interim and final deliverable. NESTcc staff will also provide the selected contractor with a

[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

number of reviews, white papers, and other materials that have been developed in the past by several parties, including NESTcc, the FDA, and other collaborators and organizations.[2,3]

The Sustainability Subcommittee is a subcommittee of the GC and will provide strategic input on the development and implementation of the market analysis and business plan developed through this RFP. The Subcommittee will seek additional input from the GC and other key stakeholders, as needed, to advance the goals of this project.

Details and Requirements for the Scope of Work

The proposal should include a plan for developing and implementing the following one or both scopes of work:

(1) Market Analysis

The contractor will conduct a comprehensive market analysis of the medical device industry. The market analysis must include an analysis of the competitive landscape, key market trends, and industry priorities for all classes of devices. The market analysis must show where NESTcc could fit within this landscape, including the services it could provide and the market share it should expect to capture by doing so. The contractor must solicit and compile an analysis of industry perspectives on the current medical device industry needs for RWE, services, data, etc.; estimates of costs for different types of clinical evidence for device development activities (including per-patient clinical trial costs, variations by therapeutic areas, current data sources and associated costs); and an assessment of the anticipated value of services NESTcc could provide. It is expected that the market analysis be informed by the medical device industry (device developers) and Contract Research Organizations (CROs) providing services for sponsors. The contractor must work with the medical device industry to identify its needs for products and services. This may include outreach to industry through in-depth interviews and/or surveys.

The development of the market analysis must be done in collaboration with the contractor selected to develop the business plan to ensure the plan is in alignment with the findings of the market analysis.

(2) Business Plan Development

The contractor will develop a comprehensive business plan that is inclusive of proposed offerings for NESTcc products and services, an operational model, a proposed organizational structure with staffing model, and a financial model that accounts for the associated costs in the absence of MDUFA funding. The business plan must propose products and services that are strategically designed to meet the evidentiary needs of the medical device industry.

The development of the business plan must be done in collaboration with the contractor developing the market analysis to ensure that the plan is consistent with the analysis findings. During the development of the business plan, it is essential that the contractor solicit industry feedback through current NESTcc stakeholder groups (including the NESTcc Governing

[2] 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)
[3] 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)

Committee and the MDIC Board of Directors) and more broadly (device sponsor companies and CROs as well as data providers such as Health Systems). It will be essential that feedback be solicited at key junctions from these stakeholders in collaboration with the NESTcc team. Before a final structure is developed, multiple business models with advantages and limitations must be developed and feedback provided from the Sustainability Subcommittee for selecting the appropriate model to move forward.

Deliverables to be Completed within the Period of Performance

NESTcc staff, in collaboration with the Sustainability Subcommittee, will approve each of the following deliverables. These lists represent a minimum set of required deliverables. Additional deliverables can be proposed within the application.

(1) Market Analysis
   a. Comprehensive work plan
   b. An approach to soliciting input from the medical device industry (such as interviews and/or a survey)
   c. Report of the findings from medical device industry input (Sponsors and CROs)
   d. A market analysis report approved by the NESTcc Sustainability Subcommittee of the NESTcc Governing Committee

(2) Business Plan Development
   a. A five-year business plan (deliverables must include a draft and final version) for NESTcc that includes goals, objectives, and metrics. The model must include the transition period from the current financial support from the FDA to other sources of revenue. This plan must include:
      i. A near- and long-term financial strategy to ensure sustainability
      ii. Staffing, budgetary, and operating guidance
      iii. Detailed descriptions and pricing of the products and services to be delivered through NESTcc
      iv. A detailed timeline for implementation including the transition period between sources of revenue
   b. A monthly report to the Sustainability Subcommittee of the NESTcc Governing Committee
   c. Collateral and other supplemental materials needed for communication and ongoing implementation, including to be used for presentations with key stakeholders such as the GC and MDIC Board of Directors

Submission Components

To enable NESTcc to evaluate the submission, the responding proposal must include the following <u>for each scope of work</u> using the required template (applicants submitting to complete both scopes of work must submit each required component for each scope of work):

- A project proposal that may not exceed 10 pages
- A timeline for completing the deliverables within the required period of performance

- A budget for a time and materials contract that includes proposed hourly rates for all personnel who will be supporting the project, including all expected costs and expenses
- Curriculum Vitae (CVs) of key personnel with experience with projects of a similar nature (experience with medical device evidence preferred)
- Up to three Letters of Support

Period of Performance

(1) Market Analysis	(2) Business Plan Development
August 1, 2018 – October 31, 2018	August 1, 2018 – December 31, 2018

Review Process

Responses to this RFP will be reviewed by members of the Sustainability Subcommittee of the NESTcc Governing Committee. The Sustainability Subcommittee and NESTcc staff reserve 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 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 August 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: May 1, 2018
- Deadline for Questions: May 15, 2018
- Responses to Questions: May 21, 2018
- Proposals Due to NESTcc: 5 p.m. EST, May 31, 2018
- Notification of Selection by MDIC and Commencement of Contract Negotiations: July 1, 2018
- Projected Start Date: August 1, 2018

Please send proposals or questions to NESTcc, NESTcc@mdic.org. Deadline for proposals is May 31, 2018, 5 p.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