NEST Coordinating Center
www.nestcc.org

Posting Date: August 9, 2019
Due Date: October 3, 2019

Opportunity: NESTcc Data Network Expansion

Opportunity Overview

In 2016, the FDA's Center for Devices and Radiological Health (CDRH) awarded a cooperative agreement to the Medical Device Innovation Consortium (MDIC) to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). NESTcc's mission is to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE), and innovative research.

NESTcc is being designed to support evidence generation for use-cases ranging from pre-market approval and clearances to expansion of indications, post-market safety and surveillance studies, and coverage decisions.[1] Both observational and interventional study designs may be appropriate depending on the question at hand. Beginning in 2017, NESTcc has initiated operations, establishing a multi-stakeholder Governing Committee and developing an initial Strategic and Operational Plan to build the foundation for NESTcc through four strategic priority areas:

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

Strategic partnerships have been established with an initial group of Network Collaborators to build the foundation of the NESTcc Data Network and NESTcc launched Test-Cases to assess the capabilities of the NESTcc Data Network in late 2017. More information on NESTcc is available at: http://www.nestcc.org

Opportunity Goal

The intent of the Data Network expansion is to increase the capacity and capabilities by providing the opportunity for additional organizations to apply and become NESTcc Network Collaborators.

Network Collaborator Overview

NESTcc launched the initial Data Network with twelve participating Network Collaborators. These Network Collaborators include both institutions and consortia and together represent more than 195 hospitals, nearly 4,000 outpatient clinics, and approximately 494 Million patient records.[2] The Network Collaborators available data sources within the Data Network include Electronic Health Records (EHR), public and private claims, registries, and patient-generated data.

Network Collaborators are provided opportunities through NESTcc to opt-in to participate in federally and non-federally funded projects, either independently or through collaborations with other Network Collaborators that are matched through NESTcc. The opportunities provided by NESTcc are to conduct

[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
[2] Does not account for duplicate records

observational or interventional studies along the medical device total product lifecycle. In order to participate in projects, Network Collaborators execute a Master Network Participation and Research Agreement and work collaboratively with NESTcc and other ecosystem stakeholders to co-develop future iterations of the agreement. Through the use of the NESTcc templates, standard agreements, and collaborative development of future templates and agreements, NESTcc is striving to create operational efficiencies.

Overall, by joining the distributed Data Network composed of Network Collaborators, organizations have the opportunity to contribute to the identification and development of NESTcc's key functions, services, policies, and procedures to support the sustainable generation and use of timely, reliable, and cost-effective RWE throughout the medical device lifecycle, using Real-World Data (RWD) that meets robust standards.

Funding is allocated to Network Collaborators by projects and activities. There is no baseline funding for becoming a Network Collaborator. Becoming a Network Collaborator provides access to participation in NESTcc opportunities.

Process

Eligibility
This opportunity is open to organizations that have access to high-quality RWD and expertise in research with RWD in order to support improved evidence for medical devices throughout the medical device total product life cycle. RWD sources can include, but are not limited to EHR, public and/or private claims, registry, and/or patient-generated health data.

Review
Each **complete** application will be reviewed internally by NESTcc staff at MDIC and will be reviewed for:

1. Alignment to the NESTcc mission *(Application Narrative)*
2. Ability to contribute to the development of the Data Network and to participate in research activities *(Application Narrative and Data Network Characterization Questionnaire)*
3. Uniqueness, completeness, and accuracy of data assets as well as research capabilities *(Application Narrative and Data Network Characterization Questionnaire)*
4. Prior experience, including with multi-center endeavors, working collaboratively with medical device manufacturers, and using RWE for medical device research *(Application Narrative)*

A complete application includes all required application components. Incomplete applications may not be reviewed. During the application review, applicant Network Collaborators may be interviewed by NESTcc staff.

It is noted in parentheses where reviewers will anticipate finding the relevant information.

Timeline

- Posting Date: Friday, August 9, 2019
- Due Date: Thursday, October 3, 2019
- Notification Date: Late October 2019

NESTcc understands that questions may arise during the application process. Please send questions to NESTcc@mdic.org or to schedule a call with NESTcc staff.

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