



National Evaluation System for health Technology Coordinating Center (NESTcc) An Invitation to Submit Concepts for Real-World Evidence Test-Cases to the NEST Coordinating Center (NESTcc)

Call for Concepts

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)**. NESTcc's mission is to establish clear and efficient pathways for manufacturers and other stakeholders to generate timely, reliable, and cost-effective evidence using Real-World Data sources.

NESTcc is being designed to support evidence generation for use-cases ranging from pre-market approval and clearances to expansion of indication, 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. During 2017, NESTcc has initiated operations, established a multi-stakeholder Governing Committee, developed initial strategic and operational plans, established strategic data partnerships, and identified an initial 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>

Request for Test-Case Suggestions

NESTcc is soliciting input from medical device manufacturers on the development and testing of the nascent NESTcc infrastructure. As a first step, NESTcc is interested in receiving recommendations from industry for test-cases using Real-World Evidence (RWE) that could be implemented with NESTcc's early data partners. Test-cases are being sought to assess feasibility and are intended to explore the data partners' ability to capture the data needed to support a range of studies and analyses. It is expected that a number of these test-cases could develop into targeted NESTcc projects demonstrating the value of RWE for pre-market needs, such as label or indication expansions, or the development of objective performance criteria.

NESTcc has executed Memoranda of Understanding (MOUs) with nine organizations to participate as initial data partners with NESTcc. These organizations include both institutions and

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

consortia. Approximately 108 Million patients are represented by these health partners. A number of these institutions and consortia have advanced linkages with public and private claims data. Discussions are underway to explore their ability to support medical device studies.

It is anticipated that these early test-cases will explore whether relevant, reliable data are available and whether further studies to support regulatory or coverage decisions are possible (see examples below).

The goals of the test-cases are to:

- (1) Explore the feasibility for industry to use Real-World Data sources offered by NESTcc's initial set of partners. Other sources of Real-World Data could be explored if needed (e.g., registries, de-identified claims data, patient-generated data).
- (2) Identify areas where NESTcc could play a role in reducing transaction costs (e.g., contracting, IRB, data sharing agreements, publication policies).

NESTcc is interested in receiving a broad range of test-cases:

- Test-cases may support any domain across the Total Product Life Cycle with priority given to pre-market use-cases (i.e., first-time approvals, expanded indications for use, supporting case to move from general to specific indications, development of a control group, or development of objective performance criteria and performance goals).
- NESTcc is interested in devices under both approval and clearance pathways, Class II and Class III devices, as well imaging and diagnostic technologies.
- Test-cases should be for projects not yet underway.
- In particular, NESTcc is interested in submissions from small and/or start-up companies.

Non-Exhaustive Examples of Test-Cases:

- A diagnostic technology approved for adults is widely used in practice in the pediatric population. A test-case could explore the feasibility of using high-quality EHR data from pediatric hospitals to support a label expansion.
- A manufacturer has in-house device-generated data. A test-case could involve exploring the feasibility of linking this data with corresponding EHR data in health systems to generate a dataset with clinically-meaningful efficacy and safety outcomes.
- A manufacturer has an in-house registry mandated for high-risk Class III implants. A test-case would involve feasibility of linking this data to health system data to enrich it with long term clinical data.

Process

Eligibility

This opportunity is open to medical device, imaging, and diagnostic technology manufacturers.

Submission

Recommendations for test-case concepts should be submitted to NESTcc@mdic.org by completing the provided submission form template by 5p.m. EST on January 17, 2018. The submission must not exceed two pages.

Submissions will remain confidential among NESTcc staff and contractors at MDIC. De-identified Concept Proposals may be shared with the NESTcc data partners to assess test-case feasibility during the review process. Submitting medical device manufacturers will not be disclosed during the review process. Full submissions will not be shared externally unless they are selected as viable test-cases through the review and preliminary selection process and agreements are signed by the submitting organization and NESTcc data partners to begin collaboration discussions.

Please contact NESTcc (NESTcc@mdic.org) if you have any questions or would like to discuss ideas prior to submitting.

Review

Each concept will be reviewed by two to four reviewers from MDIC and the FDA through objective evaluation criteria. As needed, NESTcc data partners may be consulted to assess the feasibility of test-cases using the de-identified Concept Proposals. Comments will be used by the NESTcc Executive Director to recommend a slate of test-cases to a Selection Team (a subset of the NESTcc Governing Committee). The Selection Team will complete conflict of interest disclosures in accordance with the [MDIC conflict of interest policy](#).

Preliminary Selection

NESTcc will select up to 10 viable test-cases based on test-case alignment to NESTcc's strategic priorities and need for collaboration with NESTcc. After preliminary selection takes place in February 2018, NESTcc will initiate discussions between the organization submitting the test-case concept and NESTcc data partners, upon consent from the submitting organization. If the organization does not consent to begin discussions with the data partners, the test-case may be removed from the portfolio of viable test-cases. After preliminary selection, NESTcc may request additional information such as a full project proposal—including a budget—that may be subject to additional review and approval prior to moving forward.

NESTcc will work collaboratively with medical device manufacturers and health data partners to execute the test-case.

Funding

NESTcc may provide funding for selected test-cases to be implemented with health data partners.

To the extent that any selected test cases are funded, they will be supported by an FDA Cooperative Agreement and will be considered sub-awards. All funding decisions will be contingent on FDA approval of the sub-awardee and the parties reaching agreement on a contract that includes 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.

Timeline

- Solicitation Date: December 4, 2017
- Response Date: January 17, 2018
- Preliminary Selection Date: February 2018
- Initiate Conversations with NESTcc Data Partners: February 2018
- Execution Date: April 2018
- Reporting Date: November 2018

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>