NEST Coordinating Center
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National Evaluation System for health Technology Coordinating Center (NESTcc)

An Invitation to Submit Concepts for the Second Round of Real-World Evidence Test-Cases

Call for Concepts

The National Evaluation System for health Technology Coordinating Center (NESTcc) is soliciting a second round of recommendations from medical device stakeholders, including manufacturers ("industry partners" or multi-manufacturer initiatives), health system providers and health payers for test-case concepts. These test-cases will generate Real-World Evidence (RWE) in collaboration with NESTcc's Network Collaborators. This round of test-cases will continue to assess the feasibility for key stakeholders to work with the NESTcc Data Network's Real-World Data (RWD) sources to support a range of studies and analyses, as well as address high priority areas of interest for NESTcc, including requirements outlined in MDUFA IV and the U.S. Food and Drug Administration (FDA) Reauthorization Act of 2017 (FDARA).

Background

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 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 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. 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 role;
3. To establish NESTcc's value; and
4. To ensure NESTcc stakeholder engagement.

To begin the development of NESTcc's role, strategic data partnerships have been established with an initial group of Network Collaborators to build the foundation of the NESTcc Data Network. Experts have been selected to form the Data Quality and Methods Subcommittees to develop data quality and methodological standards. NESTcc launched its first round of test-cases to test the capabilities of the NESTcc Data Network in late Fall 2017. More information on NESTcc is available at: http://www.nestcc.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

Request for Test-Case Concepts

NESTcc is soliciting input from medical device manufacturers including medical device associations and multi-manufacturer initiatives, health system providers and health payers on the development and testing of the nascent NESTcc infrastructure—the NESTcc Data Network. To answer the test-case questions, NESTcc's Network Collaborators will be matched to participate in each selected test-case concept to better understand opportunities and barriers of such engagements within the medical device ecosystem. Test-cases are being sought to answer important medical device questions and to explore the Network Collaborators' ability to capture the data needed to support a range of studies and analyses.

After test-case concepts have been reviewed and selected, NESTcc's Network Collaborators will be invited to participate in developing protocols to answer the test-case concept question in collaboration with the entity that has submitted the concept.

Details and Requirements

It is anticipated that these test-cases will explore whether the 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 key stakeholders in the medical device ecosystem to use RWD sources (i.e., electronic health records, public and private claims, registries, and patient-generated health data) offered by NESTcc's Network Collaborators.
(2) Contribute to NESTcc's development of operational processes (e.g., contracting, IRB, data sharing agreements, publication policies).

NESTcc is interested in receiving a wide range of test-case concepts that reflect the diversity of the medical device ecosystem. Areas of interest for the test-cases include:

- Test-cases may support any use case across the Total Product Life Cycle (TPLC), with priority given to pre-market and coverage (payer) decision use-cases. NESTcc describes the TPLC along the following use cases:

  Pre-Market (i.e., PMA, 510(k), De Novo): Using RWE to inform pre-market development of incremental improvement of medical devices.

  Label Expansion: Using RWE in a regulatory submission to support an expanded indication for use of medical devices already on the market.

  Post-Market Approval Studies (PAS): Using generated RWE to track medical device's safety and effectiveness as part of its condition of approval.

  Surveillance: Using generated RWE to track and document medical device safety and effectiveness for products on the market.

  Coverage: Using generated RWE to support coverage and reimbursement decisions by public and private payers, and health systems.

NESTcc is interested in devices subject to approval and clearance pathways, Class II and Class III devices, as well as imaging and diagnostic technologies (IVDs), and technologies used in cancer and should be new

projects that are not currently underway. Please note, test-cases focused on imaging or diagnostic technologies will be considered a high priority for this round of test-cases.

Test-Case Example

The following is a non-exhaustive list of examples of potential test-case concepts:

- 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 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.
- A traditional device technology approved to treat a specific indication is found to be used commonly by physicians for a new indication. A test-case could explore RWD to support the application to the FDA for the expansion of indications for the device.
- A test-case could explore the linking of registry data with EHR data and executing queries to create a validated cohort of a target patient population for a specific indication to evaluate the clinical outcomes over time.

The Role of a Network Collaborator

NESTcc has executed Memoranda of Understanding (MOUs) with twelve organizations to participate as Network Collaborators with NESTcc in the establishment of the NESTcc Data Network. These Network Collaborators include both institutions and consortia and together represent more than 150 hospitals, 3,042 outpatient clinics, and 108 Million patients. The Network Collaborators have access to over 469 million patient records and available data sources include EHRs, pharmacies, public and private claims, registries, and patient-generated health data (PGD). The NESTcc Data Network is being expanded to include new Network Collaborators. As new Network Collaborators are eligible to participate in test-case projects, they will appear as Network Collaborators on the NESTcc website.

The Role of NESTcc

MDIC staff of NESTcc will work collaboratively with the submitting organizations and the Network Collaborators to streamline processes and facilitate efficient discussion and contracting throughout the test-case phases – from solicitation through full project proposal development.

Process

Eligibility
This opportunity is open to medical device, imaging, and diagnostic technology manufacturers, health system providers, and health payers. NESTcc also encourages test-case concepts on behalf of medical device manufacturers who are submitting through an organization or association as a third-party convener i.e., medical device associations and multi-manufacturer initiatives.

Submission
Test-case concepts must be submitted to NESTcc@mdic.org in the required template (available here) by 5p.m. EST on September 19, 2018. The concept submission **must not exceed two (2) pages.**

As part of the application, NESTcc will also request that the submitters describe the availability of in-house data sources that could be used in the study (e.g. device-generated data, list of procedures using the device of interest). Actual data should not be shared with NESTcc at the time of the concept submission.

All submissions will remain confidential among NESTcc staff at MDIC. Information on the test-case submissions will be kept confidential. Submission concepts will not be shared externally unless they are selected as a viable test-case through the review and selection process and an agreement is signed between participating parties.

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. 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 test-cases using criteria of feasibility, timeliness, cost, scalability and generalizability of results. Priority may also be given to concepts addressing high-priority areas of interest. NESTcc will work jointly with medical device manufacturers and Network Collaborators to execute the test-cases in an efficient and equitable manner. NESTcc will also ensure FDA remains informed and engaged with these specific projects.

After preliminary selection takes place in September 2018, NESTcc will facilitate discussions between the organization submitting the test-case concept and the matched Network Collaborator(s). Through those consultation steps, Network Collaborators will determine whether they want to opt-in or opt-out of proposed concepts and will confirm preliminary feasibility to move forward with a collaborative effort to complete preliminary project information forms. Pending approval to move forward, NESTcc may then approve project teams to proceed to submit a full project proposal—including a budget, a list of deliverables, and timeline—which will undergo a formal review by NESTcc to be selected for eligibility to receive NESTcc funding. The slate of recommended projects will then be presented to the NESTcc Selection Team and the MDIC Board for approval.

Timeline

- Posting Date: July 12, 2018
- Public Information Webinar: July 27, 2018
- Due Date: September 19, 2018

Please send proposals or questions to MDIC NESTcc Project Manager, Tiffany Abushaikha,

NESTcc@mdic.org. Deadline for proposals is September 19, 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