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NESTcc Deputy Director

NESTcc Call For Concepts Public Webinar:
Second Round of Real-World Evidence Test-Cases

July 27, 2018
Welcome

NESTcc Overview and Current Activities

Review Call for Concepts for Broad Test-Cases

**Resources:**

*Open Opportunity for Second Round of Real-World Evidence Test-Case announcement and submission form*

**TERMINOLOGY DEFINITIONS**

**NESTcc Data Network:** A network of organizations to help determine current capabilities, gaps, and priority areas of Real-World Data (RWD) and Real-World Evidence (RWE) for the medical device landscape.

**NESTcc Network Collaborator:** A range of organizations, companies, and collaborators that will be a resource of high-quality Real-World Data that include but are not limited to: Health Systems, Health Payers, Registries, Patient- or Device-Generated Data, Analytics Offerings, etc. These partnerships will help set data quality and methods standards for clinical studies due to their access to EHR and private claims data as well as linkage data with coverage information.
NESTcc IN A SNAPSHOT

NESTcc Mission Statement

To accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research.

History of NESTcc

2015
NEST envisioned as a voluntary data network of collaborators by Brookings Planning Board and Medical Device Registry Task Force

2016
FDA awarded grant for NESTcc to Medical Device Innovation Consortium (MDIC)

2017
NESTcc multi-stakeholder Governing Committee selected

2018
Initial NESTcc Data Network formed and testing initiated

NESTcc Data Quality and Methods Committees formed

NESTcc announces Second Round of RWE Test-Case Call for Concepts, and a targeted call for Patient-Generated health Data (PGD)

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Establish initial **NESTcc Data Network** with 11 Network Collaborators

**Implement test-cases** with manufacturers and NESTcc Network Collaborators

Establish **Data Quality** and **Methods standards** as well as initial **NESTcc operating processes**

Identify **optimal uses of NESTcc Data Network and gaps** (e.g. UDI) that need addressing

**Expand NESTcc Data Network** to include additional Network Collaborators
CURRENT DATA NETWORK ACTIVITIES
BUILDING NESTcc’S DATA NETWORK

NESTcc has established relationships with Network Collaborators to advance evaluation and use of high-quality RWD from various sources.

TO DATE, MEMORANDA OF UNDERSTANDING (MOUs) HAVE BEEN SIGNED WITH 12 NETWORK COLLABORATORS:

Duke Health, HealthCore, Lahey Hospital & Medical Center, Mayo Clinic, MDEpiNet PP, Mercy, Mid-South Clinical Data Research Network, OneFlorida Clinical Research Consortium, PEDSnet, Vanderbilt University Medical Center, Weill Cornell Medicine, Yale
BUILDING NESTcc’S DATA NETWORK

NESTcc surveyed its Data Network to determine current capabilities, gaps, and priority areas.

Survey respondents represent:

Completed Capabilities Surveys

Duke University Health System • HealthCore • Lahey Clinic • Kaiser Permanente • Mayo Clinic • MDEpiNet • Mercy • OneFlorida • PEDSnet • Vanderbilt University • Weill-Cornell Medical Center • Yale New Haven Health System

Patient data represents:

- **469M+** Patient Records

Common data models:

- ✔ I2b2
- ✔ OMOP
- ✔ PCORnet
- ✔ Sentinel

Network Collaborators report regular data refreshes:

- 150 Hospitals
- 3,042+ Outpatient Clinics

Most cited expertise:

- ✔ Cardiovascular and Cardiac Surgery
- ✔ Women’s Health
- ✔ Neurosurgery
- ✔ Gastroenterology
- ✔ Orthopedic

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CLOSER LOOK AT NESTcc’S DATA SOURCES

The collaborators comprising the NESTcc Data Network have access to a range of available data sources, including those listed below.

**AVAILABLE DATA SOURCES**

- EHR
- Pharmacies
- Public Claims
- Private Claims
- Registries*
- Patient-Generated Data

**UDI IMPLEMENTATION**

- UDI

*Registries Include (but are not limited to):
- Anesthesia Quality Institute’s National Anesthesia Clinical Outcomes
- Cardiac Catheterization
- Cardiogenic Shock
- Immunization
- Implant registries
- Integrated tumor
- International Consortium Lower-GI
- American College of Surgeons National Surgical Quality Improvement Program
- Oncology
- Pediatric Cardiomyopathy
- Prostate Ablation-Related Energy Devices
- Robotic Surgery
- Society of Thoracic Surgeons National Database
- Society for Vascular Surgery
- Thalassemia Clinical Research Network - Thalassemia Registry
- Vital Records (Birth and Death)
High-level concepts of each test-case currently in development are summarized below:

<table>
<thead>
<tr>
<th>TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT</th>
<th>PRODUCT(S)</th>
<th>AREA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label Expansion</td>
<td>Stent graft component product</td>
<td>Vascular</td>
</tr>
<tr>
<td>Pre-market Submission</td>
<td>Topical Skin Adhesive</td>
<td>Dermatology</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>Knee replacement</td>
<td>Orthopedics</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>Bone Distractor</td>
<td>Orthopedics</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>Spinal decompression device</td>
<td>Orthopedics</td>
</tr>
<tr>
<td>Move from General to Specific Indication</td>
<td>Device used for soft tissue ablation</td>
<td>Surgery (Oncology)</td>
</tr>
<tr>
<td>Label Expansion</td>
<td>Catheters used in Rx of Atrial Fibrillation</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Patient Management Clinical Guidelines</td>
<td>Anti-coagulation dosage post mechanical heart valve (MHV) replacement</td>
<td>Cardiovascular</td>
</tr>
</tbody>
</table>
BROAD RWE TEST-CASE
CALL FOR CONCEPTS
CONCEPTS FOR BROAD RWE TEST-CASE ANNOUNCEMENT

NESTcc is interested in receiving recommendations from industry, health system providers, and health payers for test-cases using RWE that could be executed with NESTcc’s Network Collaborators.

MISSION OF TEST-CASES

Test-cases are being sought to assess feasibility and explore the Network Collaborators’ ability to capture the data needed to support a range of studies and analyses.

- Explore the feasibility for industry to use Real-World Data sources (EHR, public and private claims, registries, etc.) offered by NESTcc’s Network Collaborators.
- Identify areas where NESTcc could play a role in reducing transaction costs (e.g., contracting, IRB, data sharing, and publication policies).

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CONCEPT DETAILS AND REQUIREMENTS

NESTcc is interested in receiving a broad range of test-cases. The following eligibility criteria and priority areas listed were informed by the first round of test-cases submitted.

<table>
<thead>
<tr>
<th>ELIGIBILITY CRITERIA</th>
<th>PRIORITY AREAS</th>
</tr>
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<tbody>
<tr>
<td>• Concepts may be submitted by:</td>
<td>• Test-cases addressing FDARA and MDUFA IV requirements, especially evidence supporting a <strong>new clearance or approval</strong></td>
</tr>
<tr>
<td>o Medical device, imaging, and diagnostics technology manufacturers</td>
<td>• Test-cases intended for pre-market (new clearance or approval) and coverage (payer) decision purposes</td>
</tr>
<tr>
<td>o Multi-industry collaborations (submitting through an organization or association as a third-party convener)</td>
<td>• Imaging or diagnostic technologies</td>
</tr>
<tr>
<td>o Health system providers and health payer groups</td>
<td>• Technologies to diagnose and treat cancer</td>
</tr>
<tr>
<td>• Projects that are not currently underway</td>
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</tbody>
</table>
TEST-CASE EXAMPLES

The following are two examples of test-case concepts, supplementing information available in the Call for Concepts.

**ORTHOPEDIC TEST-CASE**

- Explore the feasibility of using Real-World Data (RWD) for proactive post-market surveillance.
- Assess the availability of data for regulatory obligations (necessary data elements, estimation of sample size, and representativeness of the sample for purposes of generalizability to the patient population of users) for one orthopedic device.
- The population of interest is pediatric patients undergoing craniofacial reconstruction.
- Develop capacity to coordinate data access through data use agreements, common data models or interoperability of data elements for analysis, linkage opportunities and decreased risk to patient privacy.

**TOPICAL SKIN ADHESIVE (TSA) TEST-CASE**

- Develop the value proposition for a new device to bring to the US market that is currently approved in the EU and not in the US.
- The population of interest is patients treated for wound closure with at least six months of data available.
- Explore the feasibility of using Real-World Data (RWD) for a retrospective analysis to evaluate the outcomes of alternative approaches for skin closure methods (TSA, staples, sutures, and combinations) for skin wounds.
- Assessing outcomes of interest such as the type of surgery, the type of wound or surgical laceration, and adverse events or complications, as well as efficacy and cost-effectiveness.
SUBMISSION, REVIEW AND SELECTION PROCESS

Submission Process

Phase I
September

• Organization submits a test-case concept to NESTcc.
• Test-case information will be kept confidential.

Review Process

Phase II
September – January

• Each concept will be reviewed by two to four reviewers from MDIC staff and the FDA.
• Network Collaborators will assess feasibility and interest through an opt-in/opt-out process.
• NESTcc staff will use responses to match concepts and Network Collaborators for feasible projects.
• Full proposals and budgets will be developed through a collaborative process between the submitting group and the matched Network Collaborators.

Selection Process

Phase III
February (Anticipated)

• NESTcc will select up to 10 test-case concepts.
• The recommended projects will be presented to the NESTcc Selection Team and the MDIC Board for approval.
ADDITIONAL CONSIDERATIONS

- NESTcc may request additional information from submitters to facilitate its matching process.

- Funds from NESTcc will be available to support the selected test-cases. Funding will go to Network Collaborators participating in the projects.

- NESTcc will request full project proposals and budgets at later date.

- NESTcc anticipates providing $250-550k per project, depending on the award structure and number of participating Network Collaborators participating in each project.
KEY DATES AND REMINDERS

SUBMISSION REMINDERS

• Submissions for test-case concepts should be submitted to NESTcc Project Manager, Tiffany Abushaikha, at NESTcc@mdic.org.

• The deadline for submitting concepts is 5p.m. EDT on September 19, 2018.

• A required submission template is available here, and can also be found at https://nestcc.org/opportunities/.

• The concept submission must not exceed two (2) pages.

• Please direct all questions to the NESTcc team at NESTcc@mdic.org.

OPPORTUNITY TIMELINE

July 12, 2018
Call for Concepts publicly announced

July 27, 2018
Public Information Webinar

September 19, 2018
Submission deadline for test-cases

February
Anticipated selection date for test-cases