Advances in the Use of Real-World Evidence for Medical Devices: The National Evaluation System for health Technology (NEST)

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Executive Director, NESTcc

May 7, 2019
NESTcc’s MISSION & VISION

Mission

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

Vision

To be the leading organization within the health technology and medical device ecosystem for conducting efficient and timely high-quality Real-World Evidence (RWE) studies throughout the Total Product Life Cycle (TPLC).
NESTcc DEVELOPMENT BEGAN IN 2012

- 2012: FDA proposed the development of a national system
- 2015: NESTcc envisioned as a voluntary data network of collaborators by Planning Board
- 2016: FDA awarded funding for NESTcc to Medical Device Innovation Consortium (MDIC)
- 2017: NESTcc Executive Director named and Governing Committee selected
- 2018: NESTcc Strategic and Operational Plan developed
- 2018: Initial NESTcc Data Network formed and testing initiated through Round 1 Test-Cases
- 2019: NESTcc Data Quality and Methods Subcommittees formed
- 2019: Interim and Final Results from Round 1 and Round 2 Test-Cases
- 2022: NESTcc Version 1.0 is operational
- 2022: NESTcc fully launched and operational

@NESTccMedTech  www.nestcc.org
MULTI-STAKEHOLDER GOVERNING COMMITTEE ADVISES NESTcc

NAOMI ARONSON
Blue Cross Blue Shield Association (BCBSA)

KATHLEEN BLAKE
American Medical Association (AMA)

MARK DEEM – MDMA Nominee
The Foundry, LLC

PAMELA GOLDBERG
Medical Device Innovation Consortium (MDIC)

BILL HANLON – ACLA Nominee
LabCorp/Covance

ADRIAN HERNANDEZ
Governing Committee Vice Chair
Duke Clinical Research Institute (DCRI)

HARLAN KRUMHOLZ
Yale University

JENNIFER LURAY
Research!America

MICHELLE MCMURRY-HEATH – AdvaMed Nominee
Governing Committee Chair
Johnson & Johnson Medical Devices

VANCE MOORE
Governing Committee Treasurer
Mercy Health

JEFFREY SHUREN
CDRH, FDA

SHARON TERRY
Genetic Alliance

DIANE WURZBURGER – MITA Nominee
GE Healthcare

MARC BOUTIN
National Health Council

TAMARA SYREK JENSEN
Center for Clinical Standards and Quality, CMS

Trade Association Nominees
To achieve success, NESTcc will focus on four strategic priority areas in 2019:

1. Establish NESTcc Governance
2. Develop NESTcc’s Data Network
3. Establish NESTcc’s Sustainability
4. Ensure NESTcc Stakeholder Engagement
Establishing the NESTcc Data Network
NESTcc has established relationships with 12 Network Collaborators to advance evaluation and use of high-quality Real-World Data (RWD) from various sources. Profiles of each Network Collaborator can be found on NESTcc’s website.
NESTcc surveyed its Network Collaborators to determine current capabilities, gaps, and priority areas.

**12 Network Collaborators**

- Duke University Health System
- HealthCore
- Lahey Clinic
- Mayo Clinic
- MDEpiNet
- Mercy
- NYC-CDRN
- OneFlorida
- PEDSnet
- STAR
- Vanderbilt University
- Yale New Haven Health System

Network Collaborators represent:

- **195 Hospitals**
- **3,942+ Outpatient Clinics**

**Patient data represents**

- **494M+**

*Does not account for duplicate records*

**Common data models**

- ✓ I2b2
- ✓ OMOP
- ✓ PCORnet
- ✓ Sentinel

**Network Collaborators report regular data refreshes**

- 2 Daily
- 3 Monthly
- 4 Quarterly
- 3 Mixed Rates

**Most cited expertise**

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

Numbers reflect data as of February 2018
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)
Utilizing the NESTcc Data Network
Since 2018, NESTcc has progressively tested the capabilities of the NESTcc Data Network, through Test-Cases with the NESTcc Network Collaborators.
SELECTED TEST-CASES SUPPORT THE TOTAL PRODUCT LIFE CYCLE

NESTcc Test-Cases are intended to explore the Network Collaborators’ ability to capture the data needed to support a range of studies and analyses.

NESTcc Test-Cases Advance Across the Medical Device Total Product Life Cycle (TPLC)

- Pre-Market
- Label Expansion
- Post-Market Approval
- Surveillance
- Coverage
NESTcc TEST-CASES ADDRESS A RANGE OF DEVICE QUESTIONS

NESTcc’s Round 1 Test-Cases span a wide range of devices classes, regulatory pathways, TPLC stages, data sources, and disease areas.

<table>
<thead>
<tr>
<th>TPLC Alignment</th>
<th>Regulatory Pathway</th>
<th>Device Classes</th>
<th>Disease Area</th>
<th>Data Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Market</td>
<td>501(k)</td>
<td>Class I</td>
<td>Cardiology</td>
<td>Claims</td>
</tr>
<tr>
<td>Label Expansion</td>
<td>PMA</td>
<td>Class II</td>
<td>Dermatology</td>
<td>Electronic Health Records (EHRs)</td>
</tr>
<tr>
<td>Post-Market</td>
<td></td>
<td>Class III</td>
<td>Orthopedics</td>
<td>Registries</td>
</tr>
<tr>
<td>Active Surveillance</td>
<td></td>
<td></td>
<td>Surgery</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vascular</td>
<td></td>
</tr>
</tbody>
</table>
Eight **Test-Cases** were selected in the initial round of test-cases:

<table>
<thead>
<tr>
<th>TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT</th>
<th>REGULATORY PATHWAY</th>
<th>PRODUCT(S)</th>
<th>PARTICIPATING NETWORK COLLABORATORS (n)</th>
<th>DISEASE AREA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-market Submission</td>
<td>510(k)</td>
<td>Wound Closure Devices (topical skin adhesives, staples, sutures)</td>
<td>2</td>
<td>Dermatology</td>
</tr>
<tr>
<td>Label Expansion</td>
<td>PMA</td>
<td>Endovascular stent</td>
<td>3</td>
<td>Vascular</td>
</tr>
<tr>
<td>Label Expansion</td>
<td>PMA</td>
<td>Catheters used in Rx of Cardiac Arrhythmias</td>
<td>3</td>
<td>Cardiology</td>
</tr>
<tr>
<td>Label Expansion</td>
<td>PMA</td>
<td>Mechanical Aortic Heart Valves</td>
<td>2</td>
<td>Cardiology</td>
</tr>
<tr>
<td>Label from General to Specific Indication</td>
<td>510(k)</td>
<td>Microwave Ablation Device</td>
<td>4</td>
<td>Surgery</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>510(k)</td>
<td>Total Knee Arthroplasty</td>
<td>2</td>
<td>Orthopedics</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>510(k)</td>
<td>Craniomaxillofacial Bone Distractors</td>
<td>1</td>
<td>Orthopedics</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>510(k)</td>
<td>Intervertebral Lumbar Body Fusion Devices</td>
<td>2</td>
<td>Orthopedics</td>
</tr>
</tbody>
</table>
Advancing Active Surveillance
LAUNCHING ACTIVE SURVEILLANCE ACTIVITIES

NESTcc received $3m in targeted funding from FDA and formed a Task Force which will establish a Roadmap for advancing NESTcc’s active surveillance work.

- Roadmap under development and issued for public commitment in Fall 2019.

### Task Force Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Perspective</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kathy Blake</td>
<td>NESTcc Governing Committee/Providers</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>Owen Faris</td>
<td>FDA</td>
<td>FDA</td>
</tr>
<tr>
<td>Kevin Haynes</td>
<td>Network Collaborators/Payers</td>
<td>HealthCore</td>
</tr>
<tr>
<td>Harlan Krumholz</td>
<td>NESTcc Governing Committee/Network Collaborators</td>
<td>Yale</td>
</tr>
<tr>
<td>Brad Malin</td>
<td>Network Collaborators/Privacy</td>
<td>Vanderbilt</td>
</tr>
<tr>
<td>Michelle McMurry-Heath</td>
<td>NESTcc Governing Committee/Industry</td>
<td>Johnson &amp; Johnson</td>
</tr>
<tr>
<td>Bray Patrick-Lake</td>
<td>Patients</td>
<td>DCRI</td>
</tr>
<tr>
<td>Fred Resnic</td>
<td>Network Collaborators/Integrated Health System</td>
<td>Lahey</td>
</tr>
</tbody>
</table>
The NESTcc Active Surveillance Roadmap will be developed to lay out the high-level foundation for Version 1.0 of Active Surveillance activities. Items will include:

- Initial users (FDA and medical device manufacturers)
- Products and services (signal detection and signal discernment)
- User experience
- Infrastructure and operations
- Data quality and methodology aspects
- Future directions (future users, products and services)
Ensuring Data Quality & Methods
ADVANCING DATA QUALITY & METHODS

In 2018, NESTcc established multi-stakeholder subcommittees to support its efforts to conduct real-world evidence studies for medical devices, leveraging ongoing initiatives including expertise from MDEpiNet, PCORnet, and Sentinel.

DATA QUALITY SUBCOMMITTEE

• Chaired by Lesley Curtis, Duke University School of Medicine
• 12-person subcommittee includes representation from:
  • 6 health systems, including Network Collaborators
  • 3 medical device manufacturers
  • FDA

METHODS SUBCOMMITTEE

• Chaired by Sharon-Lise Normand, Harvard Medical School
• 9-person subcommittee includes representation from:
  • 3 health systems, including Network Collaborators
  • 4 medical device manufacturers
  • FDA
NESTcc Data Quality & Methods Subcommittee framework development will include a public comment period before the first iterations are released.

**NESTcc Data Quality & Methods Frameworks Timeline**

- **May 2019**: Public Comment Period Opens
- **June 2019**: Public Comment Period Closes
- **July 2019**: Version 1 of NESTcc Frameworks Released
- **Implementation**: NESTcc Frameworks Utilized to Inform Test-Cases & Active Surveillance
Engaging with NESTcc
The NESTcc Quarterly Newsletter is distributed on the first Tuesday of each quarter.

- The Newsletter is in response to feedback from NESTcc stakeholders for a high-level update on NESTcc activities.
- The Newsletter contains upcoming dates and links to news items and publications from the previous quarter.
- The newsletter is available to the public and can be subscribed to here.
Explore opportunities to connect with NESTcc online with the following resources:

- Contact us to develop a partnership: NESTcc@mdic.org
- Connect with us on Twitter: @NESTccMedTech
- Check out our updates on the website: www.nestcc.org
- Explore open opportunities for engagement: nestcc.org/opportunities
- Initiate a request to use the NESTcc Data Network: nestcc.org/consultation