MDIC RECEIVED INITIAL FUNDING FOR NESTcc IN 2016

MDIC is a public-private partnership that facilitates programs and activities to advance the medical device regulatory process for patient benefit. These programs are housed within four core initiatives of MDIC.
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

- Concept
  - 2012: FDA proposed the development of a national system

- Building Capacity
  - 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

- Network Development
  - 2018: NESTcc Strategic and Operational Plan developed
  - Initial NESTcc Data Network formed and testing initiated through Round 1 Test-Cases
  - NESTcc Data Quality and Methods Subcommittees formed

- Utilization & Expansion
  - 2019: Interim and Final Results from Round 1 and Round 2 Test-Cases
  - NESTcc Version 1.0 is operational
  - 2022: NESTcc fully launched and operational

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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
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.
BUILDING NESTcc’S DATA NETWORK

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+*

Patient Records

Common data models

- I2b2
- OMOP
- PCORnet
- Sentinel

Network Collaborators report regular data refreshes

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

Most cited expertise

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

*Does not account for duplicate records

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Numbers reflect data as of February 2018
Utilizing the NESTcc Data Network
PROGRESSIVE EXPANSION OF THE NESTcc CAPABILITIES AND USES

Since 2018, NESTcc has been progressively developing the capabilities of the NESTcc Data Network through Test-Cases with the NESTcc Network Collaborators.

- **2018**: Address retrospective research questions from medical device manufacturers.
- **2019**: Address questions from stakeholders, incorporating patient-generated data (PGD) for prospective research questions.
- **2019**: Utilize the network to address active surveillance safety signal refinement.
- **2020**: Utilize the network's capability to detect safety signals.

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NESTcc Test-Cases Address a Range of Device Questions

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

**Device Classes**
- Class I
- Class II
- Class III

**Regulatory Pathways**
- 510(k)
- PMA

**TPLC Alignment**
- Pre-Market
- Label Expansion
- Post-Market
- Coverage
- Surveillance (Active)

**Disease Area**
- Cardiology
- Dermatology
- Ear, Nose, & Throat
- Mental Health
- Oncology
- Orthopedics
- Respiratory
- Stress Urinary Incontinence
- Surgery
- Vascular

**Data Sources**
- Claims
- Electronic Health Records (EHR)
- mHealth
- Patient-Generated health Data (PGD)
- Registries
<table>
<thead>
<tr>
<th>TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT</th>
<th>DISEASE AREA</th>
<th>TECHNOLOGY OF INTEREST</th>
<th>DATA SOURCES</th>
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</thead>
<tbody>
<tr>
<td>Pre-market Submission</td>
<td>Dermatology</td>
<td>Wound Closure Devices (topical skin adhesives, staples, sutures)</td>
<td>Claims; Electronic Health Records (EHR)</td>
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<tr>
<td>Label Expansion</td>
<td>Vascular</td>
<td>Endovascular stent</td>
<td>Registry</td>
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<tr>
<td>Label Expansion</td>
<td>Cardiology</td>
<td>Catheters used in Rx of Cardiac Arrhythmias</td>
<td>EHR</td>
</tr>
<tr>
<td>Label Expansion</td>
<td>Cardiology</td>
<td>Mechanical Aortic Heart Valves</td>
<td>EHR; Registry</td>
</tr>
<tr>
<td>Label from General to Specific Indication</td>
<td>Surgery</td>
<td>Microwave Ablation Device</td>
<td>EHR</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>Orthopedics</td>
<td>Total Knee Arthroplasty</td>
<td>Claims; Registry</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>Orthopedics</td>
<td>Craniomaxillofacial Bone Distractors</td>
<td>EHR</td>
</tr>
<tr>
<td>Post-market Surveillance</td>
<td>Orthopedics</td>
<td>Intervertebral Lumbar Body Fusion Devices</td>
<td>Claims; EHR</td>
</tr>
<tr>
<td>TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT</td>
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</tr>
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<td>------------------------------------------</td>
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</tr>
<tr>
<td>Pre-Market Submission</td>
<td>Oncology</td>
<td>Lung Cancer Diagnostic</td>
<td>Electronic Health Records (EHR)</td>
</tr>
<tr>
<td>Pre-Market Submission</td>
<td>Cardiovascular</td>
<td>Electrode Renal Denervation System</td>
<td>EHR</td>
</tr>
<tr>
<td>Pre-Market Submission; Label Expansion</td>
<td>Cardiovascular</td>
<td>Cardiovascular Device</td>
<td>Claims</td>
</tr>
<tr>
<td>Pre-Market Submission; Post-Market</td>
<td>Orthopedics</td>
<td>Annular Closure Device</td>
<td>Claims</td>
</tr>
<tr>
<td>Pre-Market Submission; Label Expansion; Surveillance</td>
<td>Orthopedics</td>
<td>Objective Performance Criteria (OPC) for Knee and Hip Implants</td>
<td>Claims; Registry</td>
</tr>
<tr>
<td>Post-Market; Surveillance; Coverage</td>
<td>Cardiology</td>
<td>Apple Watch Diagnostic + mHealth</td>
<td>EHR; Patient-Generated health Data (PGD)</td>
</tr>
<tr>
<td>Pre-Market Submission</td>
<td>Ear, Nose, and Throat</td>
<td>Ear Tubes</td>
<td>Claims; EHR</td>
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<tr>
<td>Post-Market; Surveillance</td>
<td>Cardiovascular</td>
<td>Cardiac Device Leads</td>
<td>Claims; EHR</td>
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<tr>
<td>Surveillance</td>
<td>Stress Urinary Incontinence</td>
<td>Synthetic Mesh Sling</td>
<td>EHR; Registry</td>
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<tr>
<td>Surveillance</td>
<td>Stress Urinary Incontinence</td>
<td>Urinary Mesh Software mHealth</td>
<td>PGD; Registry</td>
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<tr>
<td>Surveillance; Coverage</td>
<td>Mental Health</td>
<td>mHealth for Insomnia</td>
<td>EHR; PGD</td>
</tr>
<tr>
<td>Coverage</td>
<td>Respiratory</td>
<td>Positive Air Pressure, PAP Therapy</td>
<td>Claims; EHR; PGD</td>
</tr>
</tbody>
</table>
Active Surveillance
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>Evidation Health</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 refinement)
- User experience
- Infrastructure and operations
- Data quality and methodology aspects
- Future directions (future users, products and services)
LAUNCHING NEST 1.0
NEST IS PREPARING FOR A PUBLIC LAUNCH

By the end of 2019, NESTcc will be operationally capable of intaking unsolicited projects from external stakeholders to utilize the capabilities of the NESTcc Data Network.

1. ENGAGE
   Engage with NESTcc to develop a project and gain access to:
   - Data Network Assets
   - Pricing Structures
   - Terms and Conditions

2. LAUNCH
   Launch through collaborations with identified Network Collaborators:
   - Execute required agreements
   - Communicate with the FDA point of contact

3. EXECUTE
   Execute the project through collaboration with the project team of Network Collaborators while engaging with NESTcc to ensure project progress

4. COMPLETE
   Complete the engagement with NESTcc through the receipt of the final report, while participating in:
   - Publications and dissemination opportunities
   - Engaging directly with regulators and coverage providers for product-specific discussions and submissions
Engage with NESTcc
NESTcc QUARTERLY NEWSLETTER

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
Further Reading on NESTcc
NESTcc PUBLICATIONS

NESTcc articles highlighting RWE and RWD in 2019 have been published in JAMA Cardiology, Clinical Pharmacology & Therapeutics, and The Journal of Pediatrics.

Advances in the Use of Real-World Evidence for Medical Devices: An Update From the National Evaluation System for Health Technology

Rachael L. Fleurence* and Jeffrey Shuren*

The National Evaluation System for Health Technology (NEST), a multistakeholder partnership with a mission to accelerate the development and translation of new and safe health technologies leveraging real-world evidence (RWE), was established in 2016. Recent advances in the availability of real-world data (RWD), defined as data generated at the point of care or in the activities of daily life, have increased the potential to generate robust clinical data or real-world evidence. This article describes NEST’s progress.