ESTABLISHMENT OF NESTcc

The National Evaluation System for health Technology Coordinating Center (NESTcc) was established in 2016 through funding from the FDA.

› CHALLENGE

There is a lack of high-quality, near real-time, and low-cost evidence to support evidence generation for medical devices for key stakeholders including industry, FDA, payers, patients, clinicians, and health systems.

› SOLUTION

To change the current ecosystem, NESTcc will establish functional and efficient pathways for key stakeholders to generate lower-cost, nearer real-time evidence of sufficient quality for regulatory, coverage, patient, and clinical decision-making.
NESTcc GOALS

By end of December 2017

- Establish functional governance
- Engage with key stakeholders to develop NESTcc strategy and goals
- Issue strategic and operational plans
- Issue draft data strategy for standing up NESTcc data network
- Designate first NESTcc Demonstration Projects
- Initiate planning for sustainability

By end of December 2018

- Ensure functional governance given MDIC leadership changes
- Make the case for use of RWE to key stakeholders
- Provide information on how to do RWE studies
- Establish NESTcc data network and reduce transaction costs
- Outline viable sustainability plan
- Ensure buy-in for NESTcc from key stakeholders

By end of December 2019

- NESTcc is operational
- Ensure governance is consistent with NESTcc structure and strategy
- Establish mature data network with data quality and methods standards
- Become the go-to resource for industry and other stakeholders for RWE studies
- Deploy viable financial sustainability plan
- Establish NESTcc as go-to front-door to conduct RWE studies

By end of December 2022

- NESTcc is fully operational and sustainable
- Offer a range of compensated services to stakeholders, including access to a data network and reduced transaction costs
- NESTcc is a recognized partner for conducting RWE studies with the medical device ecosystem
To achieve success, NESTcc will focus on four strategic priority areas:

1. Establish NESTcc Governance
2. Develop NESTcc’s Role
3. Establish NESTcc’s Value
4. Ensure NESTcc Stakeholder Engagement
### Governance
- Established Governing Committee and approved Governing Committee charter
- Hosted six Governing Committee meetings
- Launched RFP for assessment of RWE activities
- Hired five NESTcc staff

### Role
- Developed NESTcc Strategic & Operational Plan
- Executed MOUs with nine data network partners
- Selected initial three rounds of Demonstration Projects (3-10 projects)*
- Launched call for test-cases from industry
- Launched RFP for value of RWE Case Studies

### Value
- Launched sustainability planning
- Began identifying models for valuable products and services

### Engagement
- Identified and prioritized key stakeholders
- Launched NESTcc communications channels, including Twitter, LinkedIn, and nestcc.org
- Held speaking roles at 20+ conferences and events

* Activities are still underway and are on-track to be completed by the end of December 2017.
1 ESTABLISH NESTcc GOVERNANCE

To achieve success for establishing NESTcc governance, NESTcc will:

2018 OPERATIONAL MILESTONES

1.1 Report regularly to the MDIC Board (ongoing)

1.2 Work collaboratively with the FDA to meet FDA requirements (ongoing)

1.3 Initiate an assessment of RWE activities (issue RFP for contractor)

STRATEGIC PRIORITIES

Execution of Operational Milestones will enable NESTcc to achieve the following Strategic Priorities by the end of each year noted:

2017

- Established functional and efficient NESTcc Governing Committee

2018

- Ensure NESTcc’s optimal functioning during MDIC’s leadership transition
- Ensure optimal governance for NESTcc across all stakeholders

2019

- Ensure NESTcc governance is consistent with sustainability plans and adapt accordingly if needed
2 DEVELOP NESTcc’S ROLE

To achieve success for developing NESTcc’s role, NESTcc will:

2.1 Establish NESTcc data network and launch initial test-cases elicited from industry

2.2 Make the case for the use of RWE to industry and other stakeholders through a case-study report (issue RFP for contractor)

2.3 Provide information ("living playbook") for conducting RWE studies across use-cases and device types, including methodological standards (collaborate with MDEpiNet)

2.4 Identify priority areas for reducing transaction costs for conducting studies and provide resources to address

2018 OPERATIONAL MILESTONES

2019

• Establish mature data network with data quality and methods standards
• Become the go-to resource for industry and other stakeholders for RWE studies

STRATEGIC PRIORITIES

Execution of Operational Milestones will enable NESTcc to achieve the following Strategic Priorities by the end of each year noted:

2017
• Developed strategic plan for NESTcc
• Designated first NESTcc Demonstration Projects

2018
• Make the case for use of RWE to key stakeholders
• Provide information on how to do RWE studies
• Establish NESTcc data network and reduce transaction costs

2019

• Establish mature data network with data quality and methods standards
• Become the go-to resource for industry and other stakeholders for RWE studies

Version 2
**NESTcc USE CASES**

NESTcc’s role will be established through use cases that span the Total Product Life Cycle (TPLC) and include interventional and observational study designs.

<table>
<thead>
<tr>
<th>PRIORITY USE CASES</th>
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<tbody>
<tr>
<td><strong>Pre-Market: PMA, 510(k), De Novo</strong></td>
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<tr>
<td>Using RWE to inform pre-market development or incremental improvement of medical devices</td>
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<tr>
<td><strong>Label Expansion</strong></td>
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<tr>
<td>Using RWE in a regulatory submission to support an expanded indication for use of medical devices already on the market</td>
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<tr>
<td><strong>Post-Market Approval Studies (PAS)</strong></td>
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<tr>
<td>Using generated RWE to track medical device’s safety and effectiveness as part of its condition of approval</td>
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<tr>
<td><strong>Surveillance</strong></td>
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<tr>
<td>Using generated RWE to track and document medical device safety and effectiveness for products on the market</td>
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<tr>
<td><strong>Coverage</strong></td>
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<tr>
<td>Using generated RWE to support coverage and reimbursement decisions by public and private payers</td>
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</tbody>
</table>
To achieve success for establishing the value of NESTcc, NESTcc will:

### 2018 OPERATIONAL MILESTONES

3.1 Establish pricing models for NESTcc functions and services

3.2 Solicit stakeholder feedback to ensure the value of NESTcc products and services to customers

### STRATEGIC PRIORITIES

Execution of Operational Milestones will enable NESTcc to achieve the following Strategic Priorities by the end of each year noted:

- **2017**
  - Initiated planning for sustainability

- **2018**
  - Outline viable sustainability plan
  - Define NESTcc services and pricing

- **2019**
  - Deploy viable sustainability plan
ENSURE NESTcc STAKEHOLDER ENGAGEMENT

To successfully engage stakeholders from across the ecosystem, NESTcc will:

2018 OPERATIONAL MILESTONES

4.1 Develop and launch a strategic communications plan
4.2 Establish forums to integrate feedback from key stakeholders and enlist their collaboration in building out NESTcc
4.3 Establish the NESTcc brand and increase awareness (ongoing)
4.4 Identify collaboration opportunities with MDEpiNet (ongoing)

STRATEGIC PRIORITIES

Execution of Operational Milestones will enable NESTcc to achieve the following Strategic Priorities by the end of each year noted:

- 2017
  - Engaged with key stakeholders to develop NESTcc strategy and goals and obtain feedback on strategy and operations

- 2018
  - Ensure buy-in for NESTcc from key stakeholders
  - Ensure feedback from a range of stakeholders is integrated as NESTcc develops

- 2019
  - Establish NESTcc as go-to front-door to conduct RWE studies
## SIX-MONTH SELECT KEY MILESTONES FOR THE FUTURE

<table>
<thead>
<tr>
<th>2018:</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN</th>
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</thead>
<tbody>
<tr>
<td><strong>Governance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Annual GC Charter revision</td>
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<tr>
<td>Assessment RFP responses due</td>
<td>Initiate assessment</td>
<td>Appoint new GC Chair</td>
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<tr>
<td><strong>Role</strong></td>
<td>Expand data network partner MOUs in round 2</td>
<td>Data Strategy convening</td>
<td>Initiate RWE Value Case Studies</td>
<td>Methods playbook drafted</td>
<td>Launch test-case projects with NESTcc data network partners</td>
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<tr>
<td><strong>Value</strong></td>
<td>High-level business model developed</td>
<td>Stakeholder feedback solicited for business model</td>
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<tr>
<td><strong>Engagement</strong></td>
<td>Launch website v2</td>
<td>Strategic communications review</td>
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<td>Launch website v3</td>
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