NESTcc’s ROLE IN THE ECOSYSTEM

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 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 the NESTcc Data Network
- Designate first NESTcc Demonstration Projects
- Initiate planning for sustainability

By end of December 2018
- Ensure functional governance given MDIC leadership changes
- Establish NESTcc Data Network and begin testing the capacity of the Data Network
- Develop draft Data Quality and Methods Frameworks
- Initiate sustainability planning
- Ensure buy-in for NESTcc from key stakeholders

By end of December 2019
- NESTcc is operational
- Ensure NESTcc governance is consistent with intended structure and strategy for sustainability and adapt accordingly, if needed
- Establish mature Data Network with Data Quality and Methods Frameworks that can support externally sponsored projects
- Become a preferred resource for industry and other stakeholders for RWE studies
- Establish NESTcc as the front-door to conducting RWE studies

By end of December 2022
- NESTcc is fully operational
- NESTcc has sustainable revenue streams
- Offer a range of compensated services, including access to a Data Network and reduced transaction costs
- NESTcc is a recognized partner-for conducting RWE studies within the medical device ecosystem
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
**ESTABLISH NESTcc GOVERNANCE**

### 2019 STRATEGIC PRIORITIES

- NESTcc is operational
- Ensure NESTcc governance is consistent with intended structure and strategy for sustainability and adapt accordingly, if needed

### 2019 OPERATIONAL MILESTONES

<table>
<thead>
<tr>
<th>1.1</th>
<th>Report regularly to the MDIC Board</th>
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<tbody>
<tr>
<td>1.2</td>
<td>Work collaboratively with the FDA to meet FDA priorities, including MDUFA and FDARA requirements</td>
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<td>1.3</td>
<td>Conduct annual revision of the NESTcc Charter</td>
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<td>1.4</td>
<td>Produce a mid-year staffing assessment based on the findings of the NESTcc sustainability plan</td>
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<td>1.5</td>
<td>Review governance structure to ensure NESTcc has the necessary freedom to operate based on the recommended sustainability plan</td>
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<td>1.6</td>
<td>Identify and mitigate perceived and real conflicts of interest, within the intended operating structure</td>
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<td>1.7</td>
<td>Ensure functioning of the Subcommittees and Task Forces</td>
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<tr>
<td>1.8</td>
<td>Manage the ongoing RWE assessment</td>
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### 2019 STRATEGIC PRIORITIES

- Establish mature Data Network with Data Quality and Methods Frameworks

### 2019 OPERATIONAL MILESTONES

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Develop and implement the Data Quality and Methods Frameworks</td>
</tr>
<tr>
<td>2.2</td>
<td>Develop and implement a Roadmap for active surveillance through NESTcc</td>
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<tr>
<td>2.3</td>
<td>Expand the Data Network and explore options for using data sources outside the U.S.</td>
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<td>2.4</td>
<td>Develop ROI case studies to describe the value of utilizing RWE</td>
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<td>2.5</td>
<td>Execute agreements to enhance operational simplicity</td>
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<td>2.6</td>
<td>Receive interim results and lessons learned from Round 1 Test-Cases</td>
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<tr>
<td>2.7</td>
<td>Launch Round 2 Test-Cases</td>
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<td>2.8</td>
<td>Develop processes for launching first non-NESTcc funded project to utilize the Data Network</td>
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<td>2.9</td>
<td>Implement a transparent triage system for Data Network requests</td>
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<tr>
<td>2.10</td>
<td>Characterize data assets available through the NESTcc Network Collaborators</td>
</tr>
<tr>
<td>2.11</td>
<td>Implement data curation metrics such as storage systems, completeness, and interoperability of data</td>
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</tbody>
</table>
ESTABLISH NESTcc’s SUSTAINABILITY

2019 STRATEGIC PRIORITIES

- Become a preferred resource for industry and other stakeholders for RWE studies

2019 OPERATIONAL MILESTONES

3.1 Complete market analysis

3.2 Develop a complete business plan

3.3 Obtain approvals from the Governing Committee and MDIC Board of Directors for a business plan that mitigates risks identified throughout the business planning process, including real and perceived conflicts of interest, and enhances NESTcc’s freedom to operate to deliver results in 2019

3.4 Implement the approved business plan

3.5 Increase NESTcc’s operational capacity by developing products and services that offer RWE solutions to consumers

3.6 Engage stakeholders to use NESTcc products and services

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ENSURE NESTcc STAKEHOLDER ENGAGEMENT

2019 STRATEGIC PRIORITIES

4.1 Develop NESTcc as a Collaborative Community

4.2 Develop and implement targeted engagement strategies for high-priority stakeholders (e.g. FDA, MDEpiNet, Pediatric Device Consortia, and payers)

4.3 Enhance the recognition of the NESTcc brand, including the creation of a concise overview of NESTcc

4.4 Develop an engagement plan to establish NESTcc as the honest broker for developing high-quality RWE and support the transition into a nimble and flexible business

4.5 Solicit ecosystem feedback for the Data Quality and Methods Frameworks

4.6 Disseminate learnings from the Test-Cases

4.7 Disseminate NESTcc progress through peer-reviewed publications

2019 OPERATIONAL MILESTONES

• Establish NESTcc as the front-door to conducting RWE studies
1. INITIAL STRATEGIC PRIORITIES

In 2017 and 2018, NESTcc focused on advancing the following four strategic priorities:

1. Establish NESTcc Governance
2. Develop NESTcc’s Role
3. Establish NESTcc’s Value
4. Ensure NESTcc Stakeholder Engagement
2. 2017 – REVIEW OF STRATEGIC & OPERATIONAL ACHIEVEMENTS

**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 NESTcc network collaborators
- Selected initial three rounds of Demonstration Projects (11 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
### Governance

- Updated Governing Committee Charter
- Hosted monthly Governing Committee Meetings
- Launched four subcommittees: Charter, Sustainability, Methods, and Data Quality
- Approved a Governing Committee Chair, Vice Chair, and Treasurer
- Initiated RWE Assessment

### Role

- Established a consultation form to solicit interest for working with NESTcc
- Launched round one test-cases
- Convened Demonstration Projects to solicit shared learnings and challenges
- Developed draft data quality standards
- Developed a draft Methods playbook

### Value

- Launched the Sustainability Subcommittee
- Secured a contractor to complete the market analysis and develop a business plan

### Engagement

- Developed and launched a strategic communications plan
- Established forums to integrate feedback from key stakeholders
- Posted public calls for opportunities to enhance stakeholder participation
- Established the NESTcc brand and increased awareness of NESTcc
# 3. SIX-MONTH SELECT KEY MILESTONES (JANUARY – JUNE 2018)

<table>
<thead>
<tr>
<th>2018:</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Governance</strong></td>
<td>Assessment RFP responses due</td>
<td>Approved four GC subcommittees</td>
<td>Initiated RWE assessment</td>
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<td></td>
<td>Announced Methods and Data Quality Subcommittees</td>
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<tr>
<td><strong>Role</strong></td>
<td>Expanded NESTcc Data Network with round 2 of MOUs</td>
<td>Hosted Data Strategy Convening</td>
<td>Initiated RWE value case-studies</td>
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<td>Launched test-case projects with NESTcc Network Collaborators</td>
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<tr>
<td><strong>Value</strong></td>
<td>Developed business model (Phase I sustainability planning)</td>
<td>Solicited stakeholder feedback on business model</td>
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</tr>
<tr>
<td><strong>Engagement</strong></td>
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<td>Launched nestcc.org update</td>
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### 4. SIX-MONTH SELECT KEY MILESTONES (JULY – DECEMBER 2018)

<table>
<thead>
<tr>
<th>2018:</th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Governance</strong></td>
<td></td>
<td></td>
<td>Revise GC Charter</td>
<td>Appoint GC Chair and Vice Chair</td>
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<td>Data Quality and Methods Subcommittees release draft standards</td>
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<tr>
<td><strong>Role</strong></td>
<td></td>
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<td></td>
<td>Post second round of calls for test-case concepts</td>
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<tr>
<td><strong>Value</strong></td>
<td></td>
<td></td>
<td>Initiate Market Analysis and Business Plan Development</td>
<td></td>
<td>Complete Market Analysis</td>
<td></td>
</tr>
<tr>
<td><strong>Engagement</strong></td>
<td>Communications Manager joins NESTcc</td>
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<td>Share early learnings from test-case projects</td>
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<td>Host consultation sessions with stakeholders at MedTech</td>
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