



Strategic & Operational Planning: 2017 - 2022

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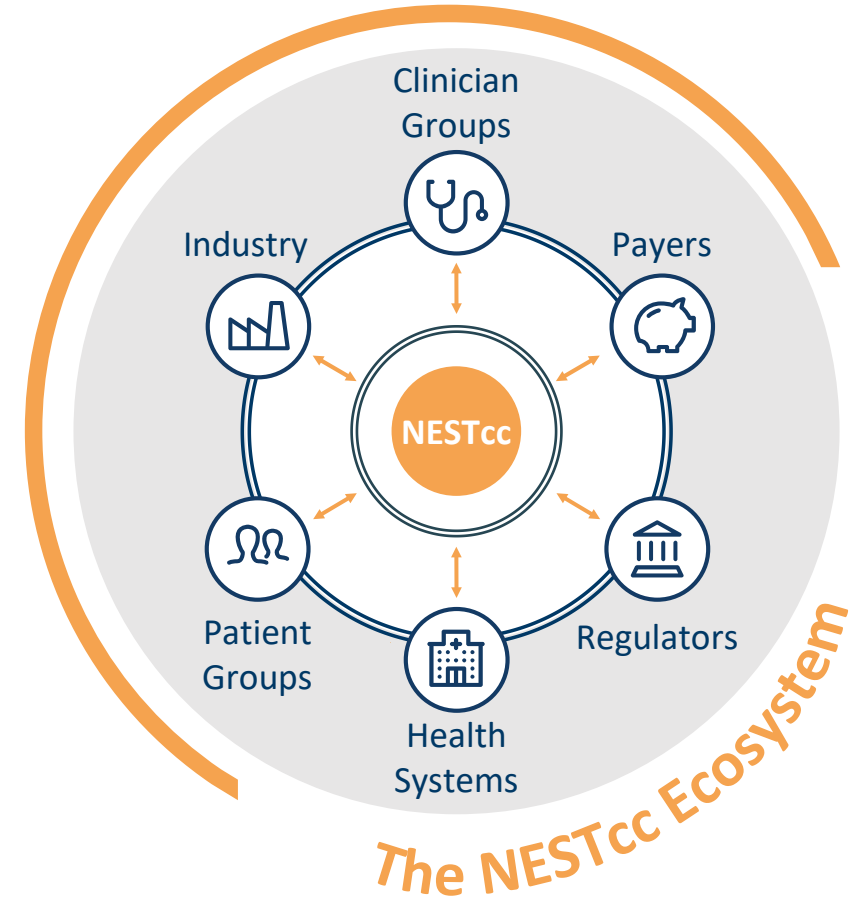
NESTcc's ROLE IN THE ECOSYSTEM

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



FRAMEWORK STRATEGY TO ACHIEVE ESTABLISHED GOALS

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

1 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

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

2 2019 STRATEGIC PRIORITIES

- Establish mature Data Network with Data Quality and Methods Frameworks

2019 OPERATIONAL MILESTONES

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

3 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

4 2019 STRATEGIC PRIORITIES

- Establish NESTcc as the front-door to conducting RWE studies

2019 OPERATIONAL MILESTONES

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



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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



3. 2018 – REVIEW OF STRATEGIC & OPERATIONAL ACHIEVEMENTS

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)

2018:	JAN	FEB	MAR	APR	MAY	JUN
Governance	<p>◆ Assessment RFP responses due</p>	<p>◆ Approved four GC subcommittees</p>		<p>◆ Initiated RWE assessment</p>		<p>◆ Announced Methods and Data Quality Subcommittees</p>
Role	<p>◆ Expanded NESTcc Data Network with round 2 of MOUs</p>	<p>◆ Hosted Data Strategy Convening</p>		<p>◆ Initiated RWE value case-studies</p>		<p>◆ Launched test-case projects with NESTcc Network Collaborators</p>
Value	<p>◆ Developed business model (Phase I sustainability planning)</p>	<p>◆ Solicited stakeholder feedback on business model</p>		<p>◆ Launched Sustainability Subcommittee</p>		
Engagement		<p>◆ Launched nestcc.org update</p>		<p>◆ Developed strategic communications plan</p>	<p>◆ Launched nestcc.org update</p>	<p>◆ Launched public Front Door on nestcc.org</p>

4. SIX-MONTH SELECT KEY MILESTONES (JULY – DECEMBER 2018)

2018:	JUL	AUG	SEP	OCT	NOV	DEC
Governance			 Revise GC Charter	 Appoint GC Chair and Vice Chair		 Data Quality and Methods Subcommittees release draft standards
Role	 Post second round of calls for test-case concepts			 Announce Round 1 test-cases		
Value			 Initiate Market Analysis and Business Plan Development		 Complete Market Analysis	
Engagement	 Communications Manager joins NESTcc		 Share early learnings from test-case projects	 Host consultation sessions with stakeholders at MedTech		