NEST
Coordinating Center
An initiative of MDIC

**Strategic & Operational Planning: 2017 - 2022**

January 2019 | Version 1

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).

The NESTcc Ecosystem
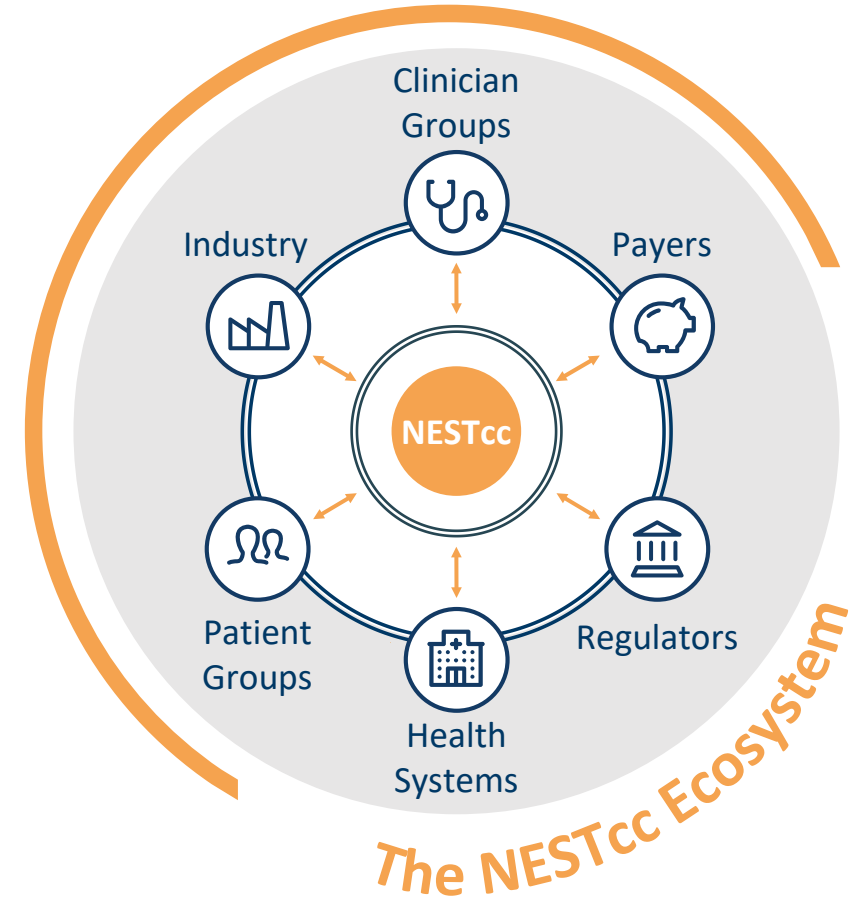
NESTcc GOALS

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
- Establish NESTcc Data Network and begin testing the capacity of the Network
- Develop draft data quality and methods frameworks
- Initiate sustainability planning
- Ensure buy-in for NESTcc from key stakeholders

By end of December 2019

- Conduct case studies to show the ROI of RWE
- NESTcc is operational
- Ensure governance is consistent with NESTcc structure and strategy
- Establish mature Data Network with data quality and methods frameworks
- Deploy viable sustainability plan

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 with 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**

1 ESTABLISH NESTcc GOVERNANCE

2019 STRATEGIC PRIORITY

- Ensure NESTcc governance is consistent with sustainability plans and adapt accordingly, if needed

2019 OPERATIONAL MILESTONES

1.1   Report regularly to the MDIC Board

1.2   Work collaboratively with the FDA to meet FDA priorities, including MDUFA and FDARA requirements

1.3   Conduct annual revision of the NESTcc Charter

1.4   Produce a mid-year staffing assessment based on the findings of the NESTcc sustainability plan

1.5   Review governance structure based on sustainability plan

1.6   Ensure functioning of the subcommittees

1.7   Manage the ongoing RWE assessment

To achieve success for developing NESTcc's Data Network, NESTcc will:

2019 STRATEGIC PRIORITIES

- Establish mature Data Network with data quality and methods standards
- Become a preferred resource for industry and other stakeholders for RWE studies

2019 OPERATIONAL MILESTONES

2.1 Develop and implement the Data Quality and Methods Frameworks

2.2 Develop and implement a blueprint for active surveillance through NESTcc

2.3 Expand the Data Network and explore options for using data sources outside the U.S.

2.4 Develop ROI case studies to describe the value of utilizing RWE

2.5 Execute agreements to enhance operational simplicity

2.6 Receive interim results and lesson learned from round one test-cases

2.7 Launch round two test-cases

2.8 Develop process for launching first non-NESTcc funded project to utilize the Data Network

2.9 Implement a transparent triage system for Data Network requests

To achieve success for establishing the sustainability of NESTcc, NESTcc will:

2019 STRATEGIC PRIORITIES

- Develop and implement a sustainable business plan, including products and services and a staffing model.

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 the business plan
3.4	Implement the approved business plan
3.5	Develop products and services
3.6	Engage stakeholders to use NESTcc products and services

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

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	Solicit ecosystem feedback for the Data Quality and Methods frameworks
4.5	Disseminate learnings from the test-cases
4.6	Disseminate NESTcc progress through peer reviewed publications

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

1	2	3	4
Establish NESTcc **Governance**	Develop NESTcc's **Role**	Establish NESTcc's **Value**	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 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

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

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			