



Strategic & Operational Planning: 2017 - 2022

June 2018 | Version 4

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.



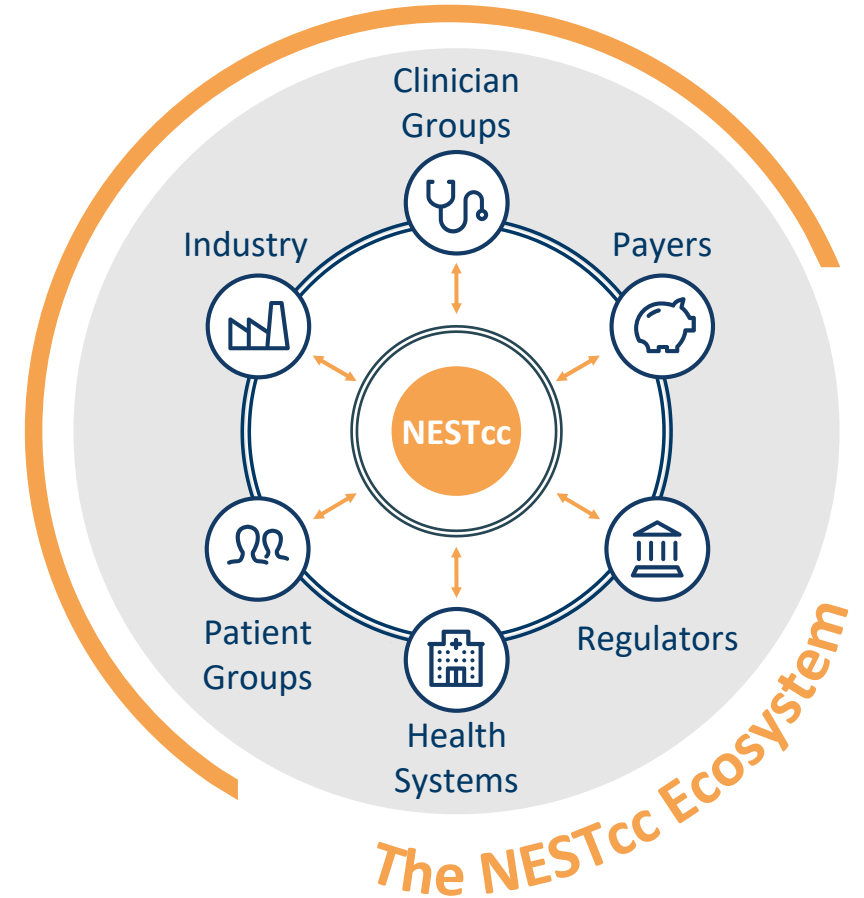
NESTcc'S ROLE IN THE ECOSYSTEM

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 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 leading resource for industry and other stakeholders for RWE studies
- Deploy viable financial sustainability plan
- Establish NESTcc as the front-door to conducting 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



FRAMEWORK STRATEGY TO ACHIEVE ESTABLISHED GOALS

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 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

1 ESTABLISH NESTcc GOVERNANCE

To achieve success for establishing NESTcc governance, NESTcc will:

2018 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 Initiate an assessment of RWE activities

- 1.4 Launch four subcommittees: Charter, Sustainability, Methods, and Data Quality

- 1.5 Establish membership for Methods and Data Quality Subcommittees through a public call

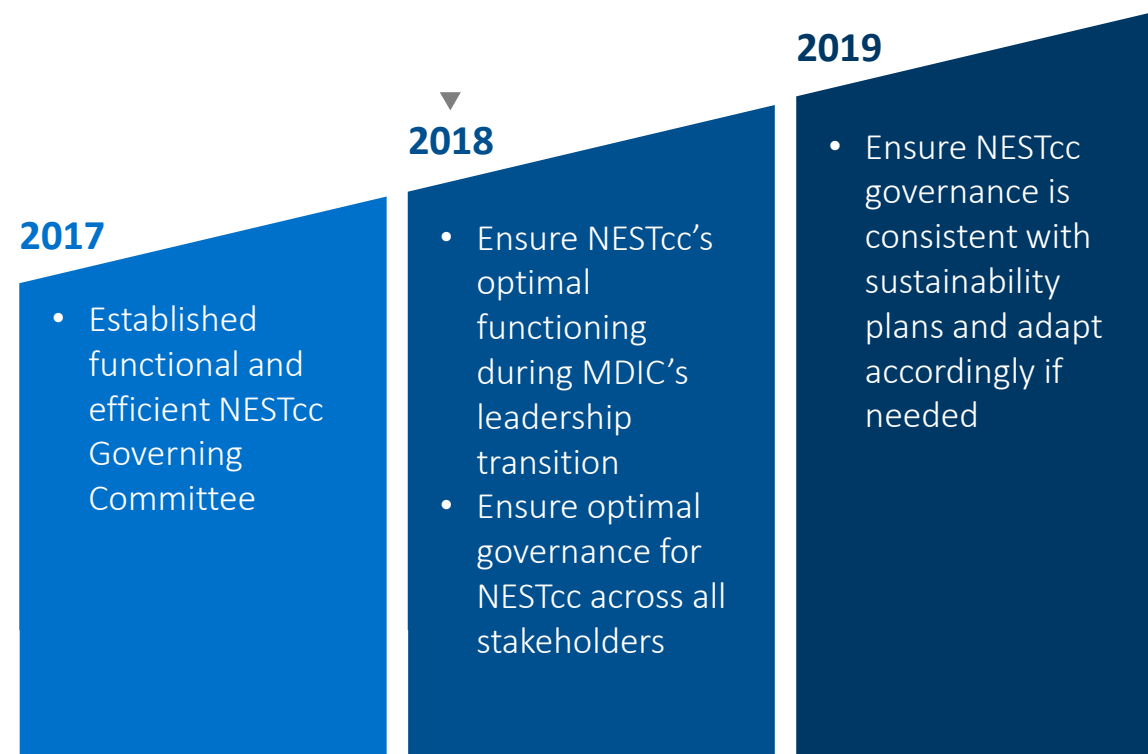
- 1.6 Establish roles and responsibilities for the governance of NESTcc

- 1.7 Conduct annual revision of the NESTcc Charter

- 1.8 Select permanent Governing Committee Chair and a Vice Chair

STRATEGIC PRIORITIES

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



2 DEVELOP NESTcc'S ROLE

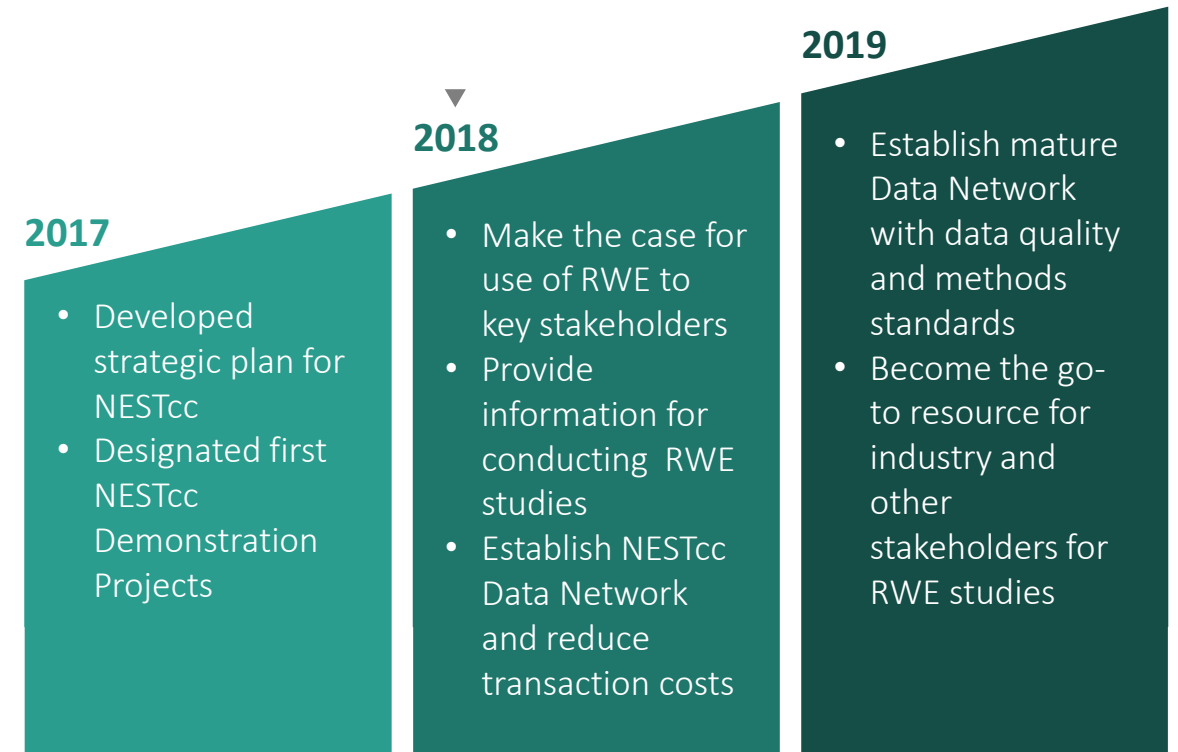
To achieve success for developing NESTcc's role, NESTcc will:

2018 OPERATIONAL MILESTONES

- 2.1 Establish NESTcc Data Network with a mechanism to solicit interest for working with NESTcc through an online Front Door (Consultation Form)
- 2.2 Launch initial test-cases along the Total Product Life-Cycle (TPLC) and subsequent rounds of broad and targeted test-cases
- 2.3 Make the case for the use of RWE to industry and other stakeholders through a case-study report
- 2.4 Convene Demonstration Projects to solicit shared learnings and challenges
- 2.5 Identify priority areas for reducing transaction costs
- 2.6 Develop data quality standards through the Data Quality Subcommittee
- 2.7 Work with the Methods Subcommittee to develop methods standards and information ("living playbook") for conducting RWE studies across use-cases and device types

STRATEGIC PRIORITIES

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



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.

PRIORITY USE CASES



Pre-Market: PMA, 510(k), De Novo

Using RWE to inform pre-market development or incremental improvement of medical devices



Label Expansion

Using RWE in a regulatory submission to support an expanded indication for use of medical devices already on the market



Post-Market Approval Studies (PAS)

Using generated RWE to track medical device's safety and effectiveness as part of its condition of approval



Surveillance

Using generated RWE to track and document medical device safety and effectiveness for products on the market



Coverage

Using generated RWE to support coverage and reimbursement decisions by public and private payers



3 ESTABLISH NESTcc'S VALUE

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

2018 OPERATIONAL MILESTONES

- 3.1 Develop a preliminary business model

- 3.2 Launch the Sustainability Subcommittee to support the management and direction of planning for NESTcc's sustainability

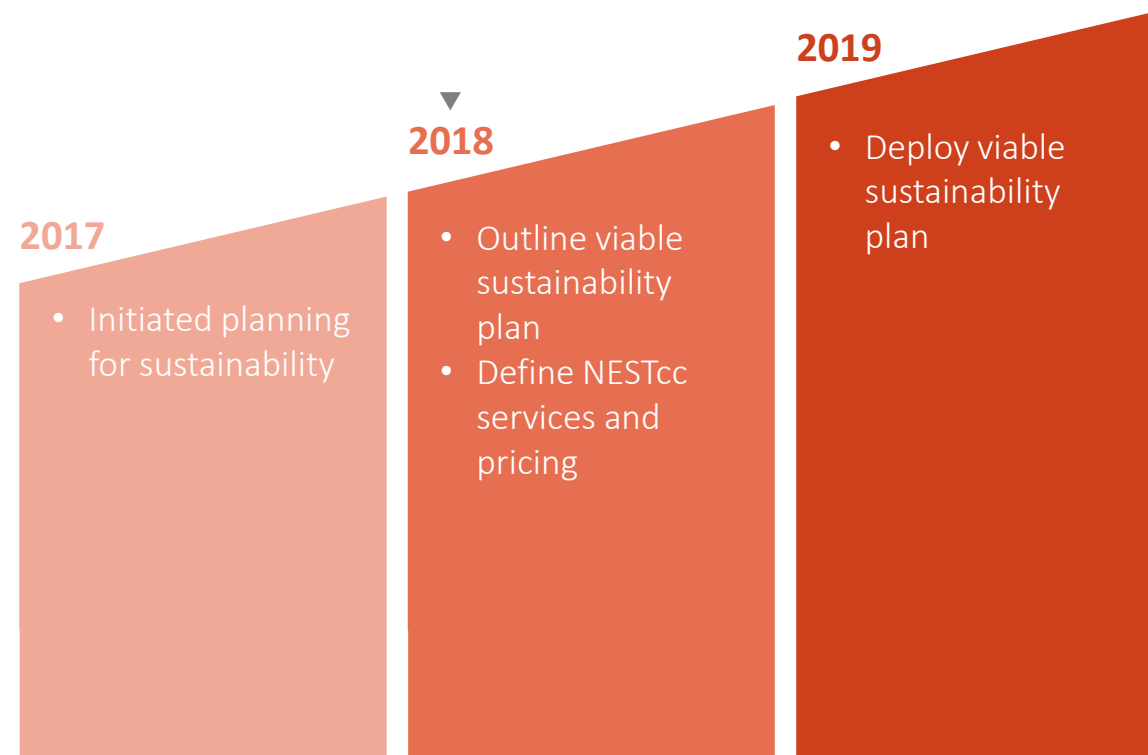
- 3.3 Secure a consultant to partner with NESTcc to develop a comprehensive market analysis and develop a business plan

- 3.4 Establish pricing models for NESTcc functions and services

- 3.5 Solicit stakeholder feedback to ensure the business model aligns with their needs

STRATEGIC PRIORITIES

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



4 ENSURE NESTcc STAKEHOLDER ENGAGEMENT

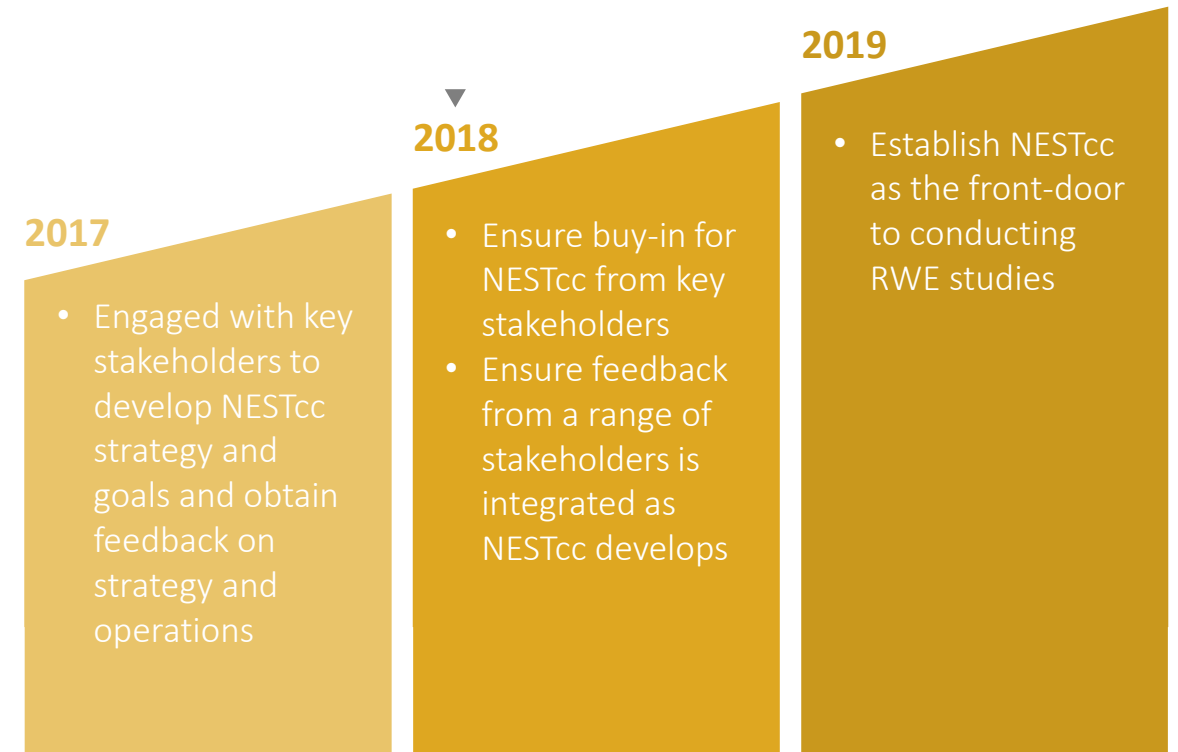
To successfully engage stakeholders from across the ecosystem, NESTcc will:

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 Post public calls for opportunities to enhance stakeholder participation with NESTcc
- 4.4 Establish the NESTcc brand and increase awareness
- 4.5 Identify collaboration opportunities with MDEpiNet
- 4.6 Engage in targeted conversations with potential industry partners to develop targeted projects and potential Network Collaborators to consider joining the NESTcc Data Network

STRATEGIC PRIORITIES

















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



SIX-MONTH SELECT KEY MILESTONES ACHIEVED TO DATE

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>

SIX-MONTH SELECT KEY MILESTONES FOR THE FUTURE

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		 Execute standard NDAs and MSAs	 Announce Round 1 test-cases	 Complete RWE value case-studies	 Launch Round 2 test-case projects
Value		 Initiate Market Analysis and Business Plan Development			 Complete Market Analysis	 Release draft Business Plan
Engagement	 Communications Manager joins NESTcc		 Share early learnings from test-case projects	 Host consultation sessions with stakeholders at MedTech	 Launch nestcc.org update	 Solicit stakeholder feedback on NESTcc communications activities



 www.nestcc.org

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