



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

September 2018 | Version 5

## 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.



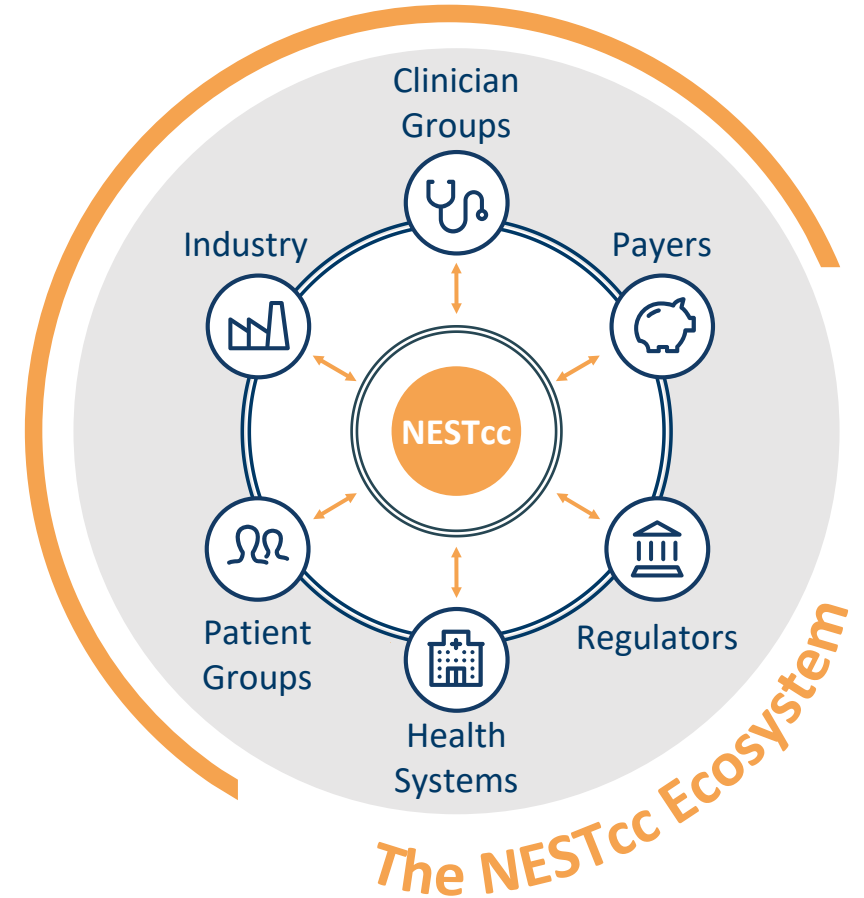
## NESTcc'S ROLE IN THE ECOSYSTEM

### 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).



### 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 processes for reducing transaction costs
- 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 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

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

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- 1.3 Initiate an assessment of RWE activities

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

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

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- 1.6 Establish roles and responsibilities for the governance of NESTcc

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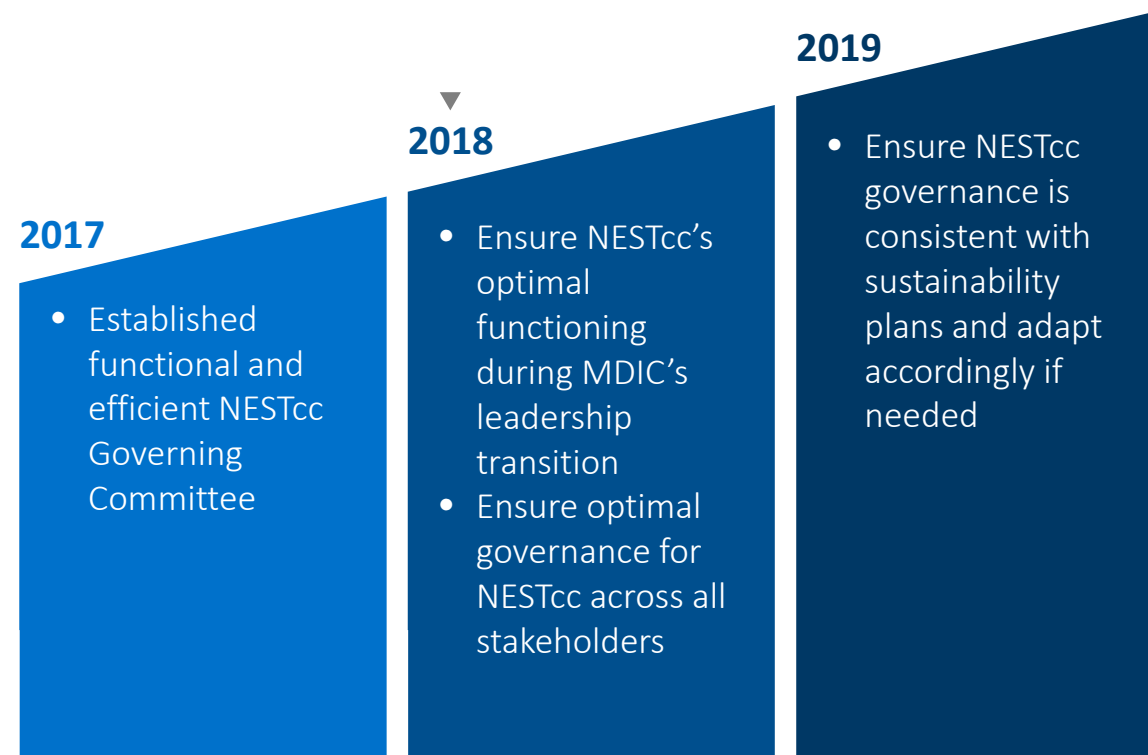
- 1.7 Conduct annual revision of the NESTcc Charter

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- 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

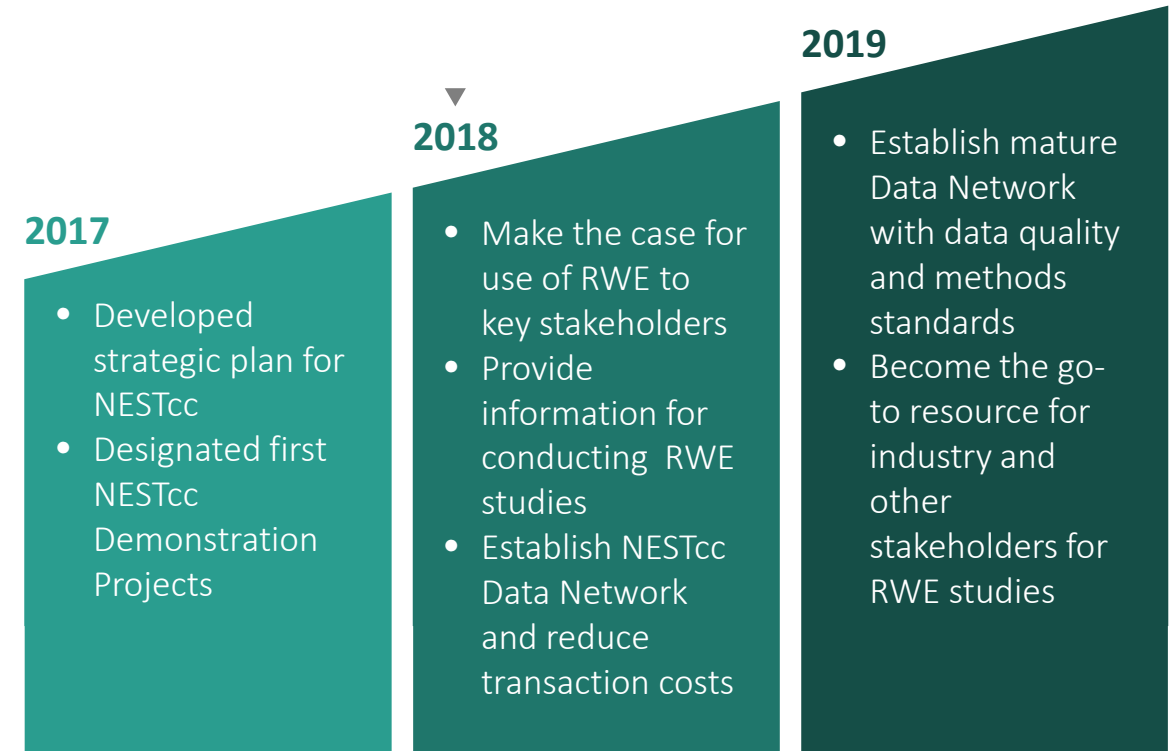
To achieve success for developing NESTcc's role, NESTcc will:

### 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:





### 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

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

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

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- 3.4 Establish pricing models for NESTcc functions and services

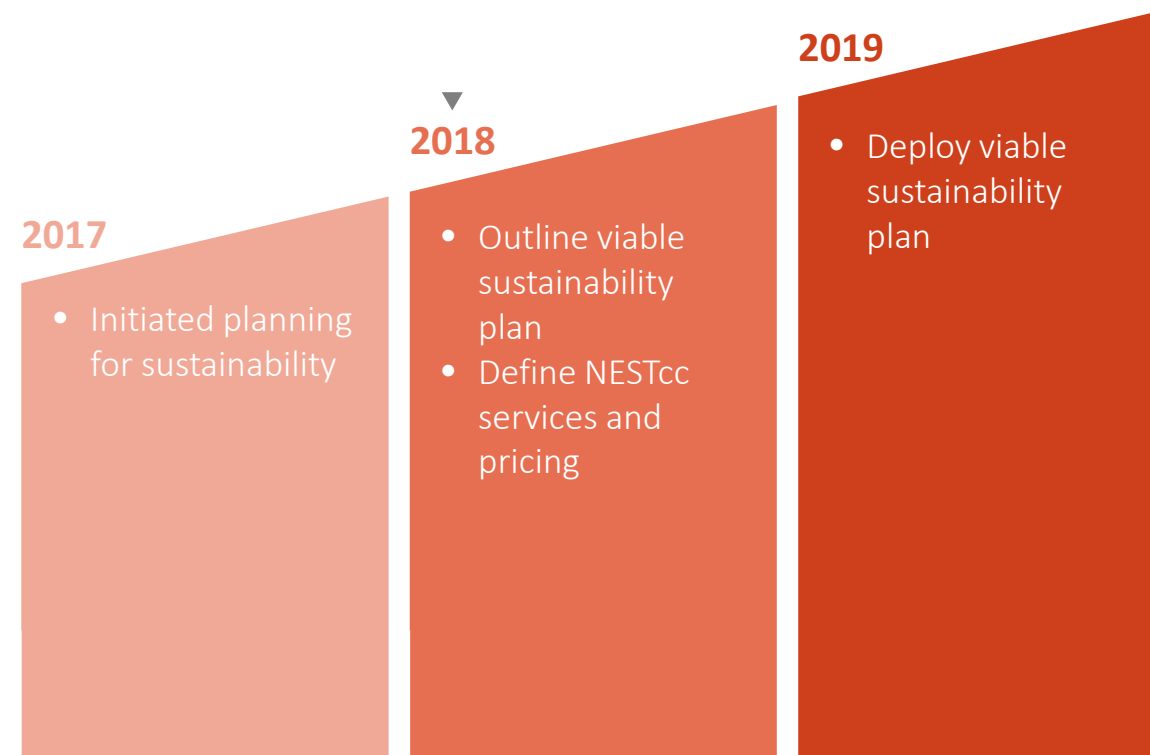
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- 3.5 Solicit stakeholder feedback to ensure the business model aligns with their needs

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#### 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

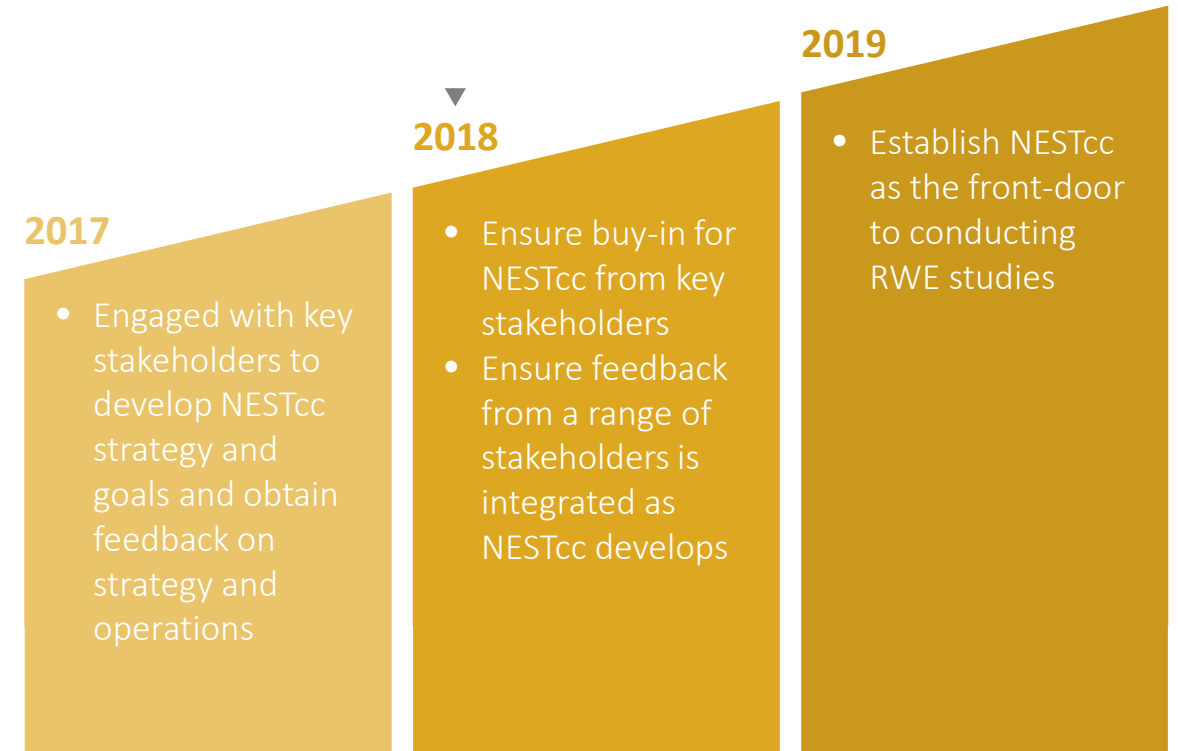
To successfully engage stakeholders from across the ecosystem, NESTcc will:

### 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
<b>Governance</b>	<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>
<b>Role</b>	<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>
<b>Value</b>	<p>◆ Developed business model (Phase I sustainability planning)</p>	<p>◆ Solicited stakeholder feedback on business model</p>		<p>◆ Launched Sustainability Subcommittee</p>		
<b>Engagement</b>		<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
<b>Governance</b>			 Revise GC Charter  Appoint GC Chair and Vice Chair			 Data Quality and Methods Subcommittees release draft standards
<b>Role</b>	 Post second round of calls for test-case concepts			 Execute standard NDAs and MSAs  Announce Round 1 test-cases		 Launch Round 2 test-case projects
<b>Value</b>			 Initiate Market Analysis and Business Plan Development		 Complete Market Analysis	 Release draft Business Plan
<b>Engagement</b>	 Communications Manager joins NESTcc		 Share early learnings from test-case projects  Host consultation sessions with stakeholders at MedTech	 Launch nestcc.org update		



 [www.nestcc.org](http://www.nestcc.org)

 [@NESTccMedTech](https://twitter.com/NESTccMedTech)

 [nestcc@mdic.org](mailto:nestcc@mdic.org)

## 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

