



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

December 2017 | Version 2

## 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 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 go-to resource for industry and other stakeholders for RWE studies
- Deploy viable financial sustainability plan
- Establish NESTcc as go-to front-door to conduct 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 data network partners
- Selected initial three rounds of Demonstration Projects (3-10 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

*\* Activities are still underway and are on-track to be completed by the end of December 2017.*



# 1 ESTABLISH NESTcc GOVERNANCE

To achieve success for establishing NESTcc governance, NESTcc will:

## 2018 OPERATIONAL MILESTONES

- 1.1 Report regularly to the MDIC Board (ongoing)

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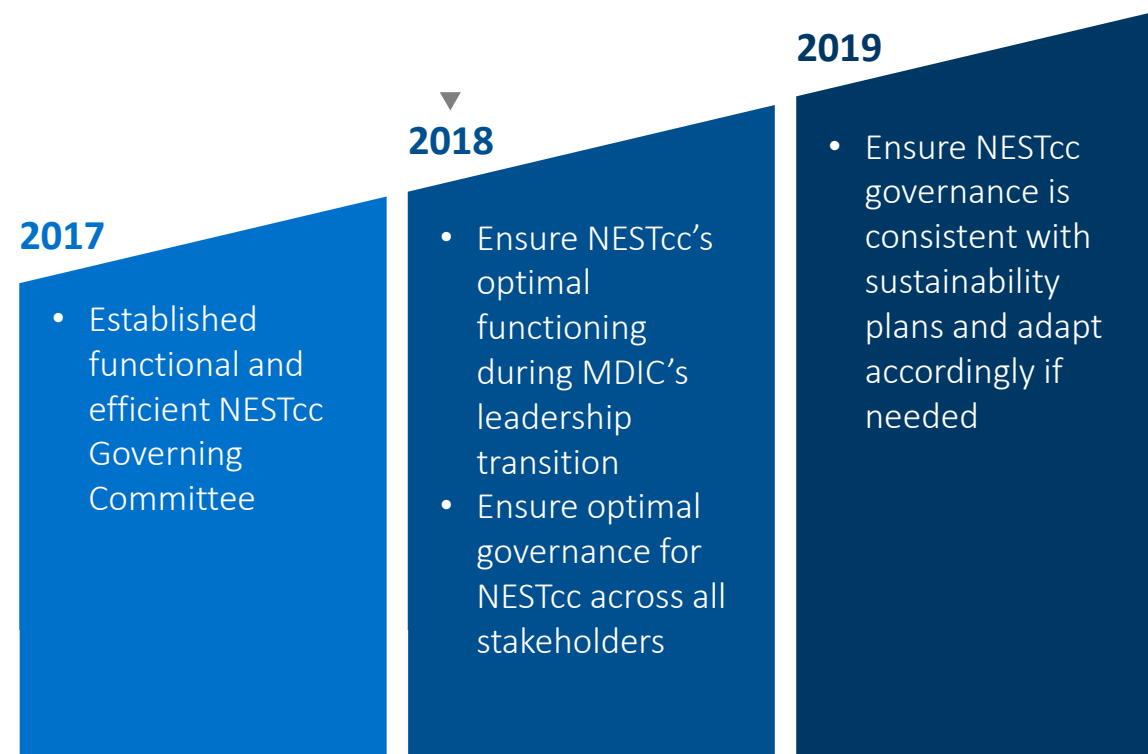
- 1.2 Work collaboratively with the FDA to meet FDA requirements (ongoing)

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- 1.3 Initiate an assessment of RWE activities (issue RFP for contractor)

## 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 and launch initial test-cases elicited from industry

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- 2.2 Make the case for the use of RWE to industry and other stakeholders through a case-study report (issue RFP for contractor)

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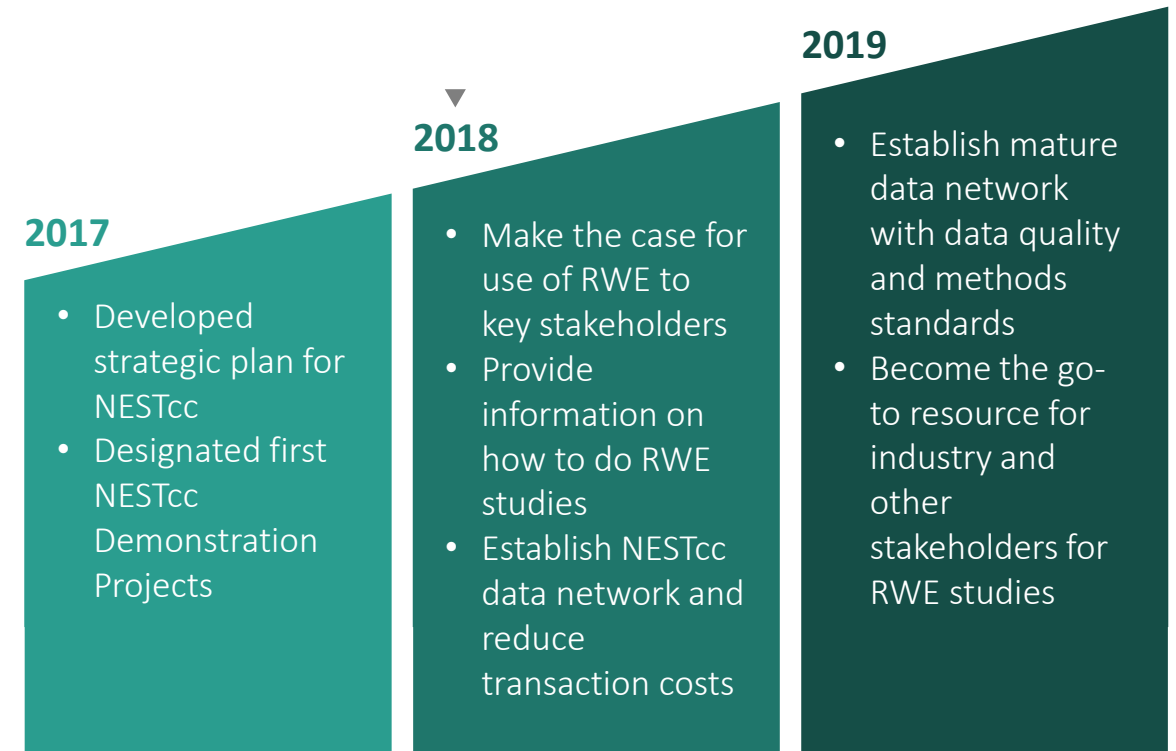
- 2.3 Provide information ("living playbook") for conducting RWE studies across use-cases and device types, including methodological standards (collaborate with MDEpiNet)

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- 2.4 Identify priority areas for reducing transaction costs for conducting studies and provide resources to address

### 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

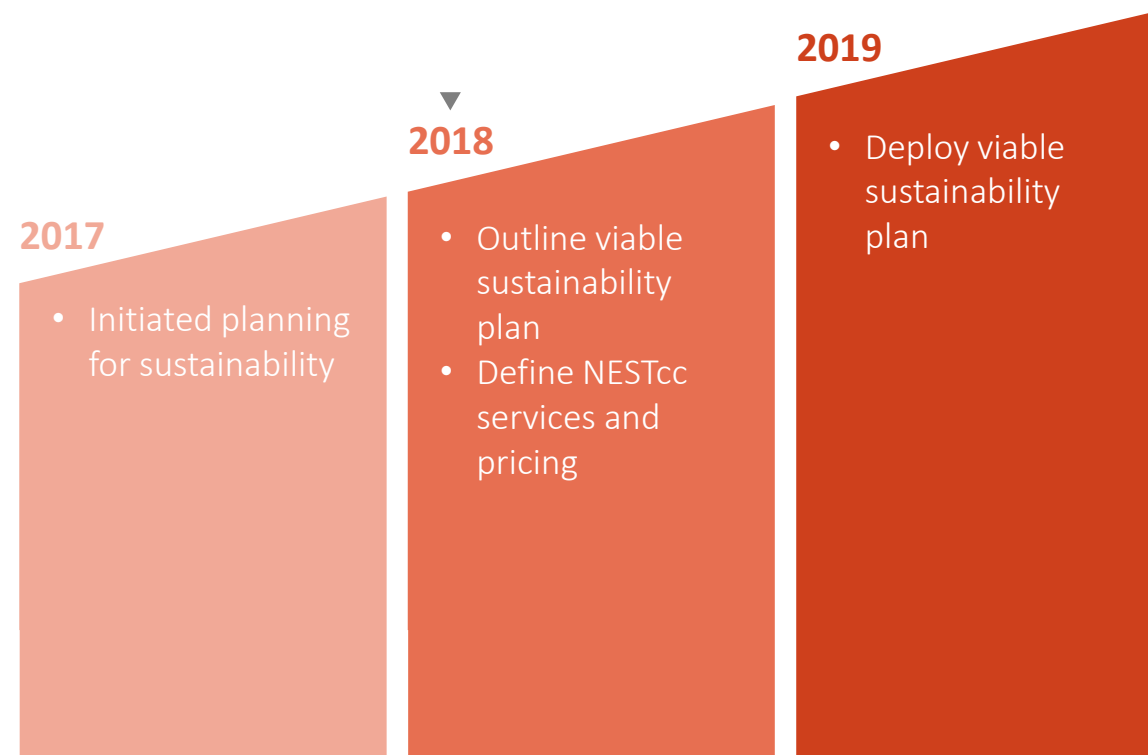
- 3.1 Establish pricing models for NESTcc functions and services

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- 3.2 Solicit stakeholder feedback to ensure the value of NESTcc products and services to customers

#### 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

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- 4.2 Establish forums to integrate feedback from key stakeholders and enlist their collaboration in building out NESTcc

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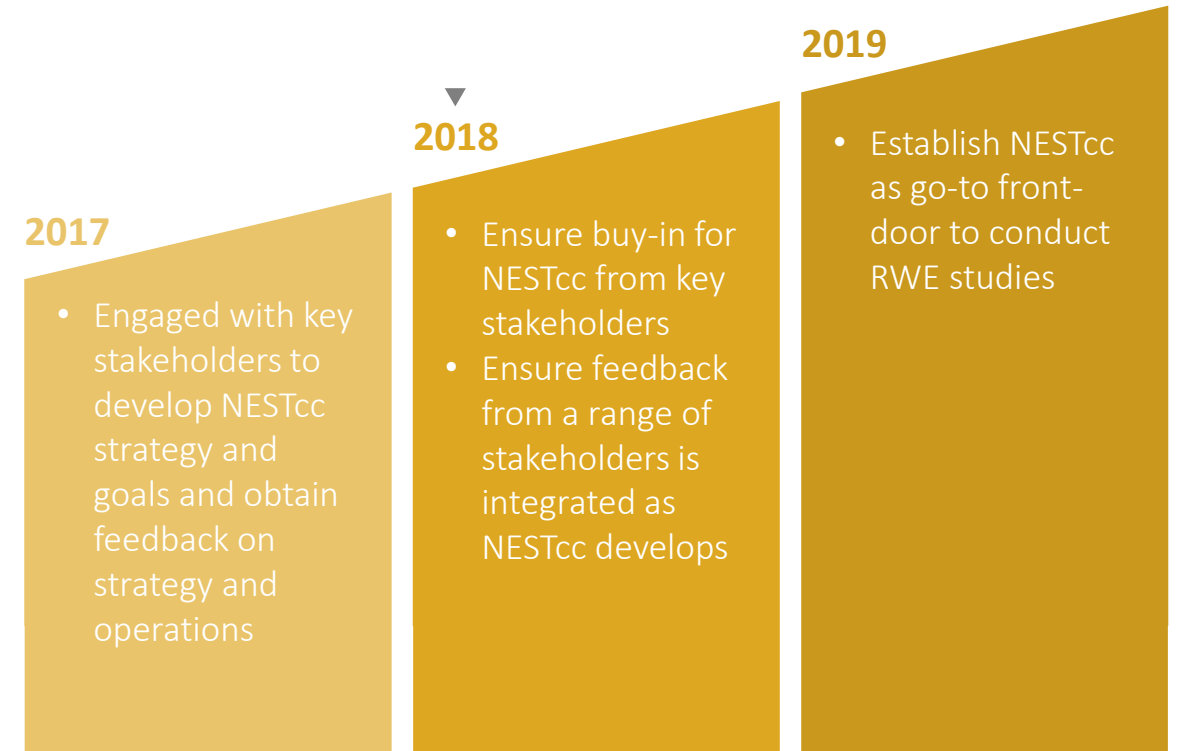
- 4.3 Establish the NESTcc brand and increase awareness (ongoing)

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- 4.4 Identify collaboration opportunities with MDEpiNet (ongoing)

### 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 FOR THE FUTURE

2018:	JAN	FEB	MAR	APR	MAY	JUN
<b>Governance</b>	 Assessment RFP responses due	 Initiate assessment	 Appoint new GC Chair			 Annual GC Charter revision
<b>Role</b>	 Expand data network partner MOUs in round 2	 Data Strategy convening	 Initiate RWE Value Case Studies	 Methods playbook drafted	 Launch test-case projects with NESTcc data network partners	
<b>Value</b>	 High-level business model developed	 Stakeholder feedback solicited for business model				
<b>Engagement</b>		 Launch website v2		 Strategic communications review	 Launch website v3	



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