NEST

National Evaluation System for health Technology

Coordinating Center

Strategic & Operational Planning: 2017 - 2022

March 2018 | Version 3

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.

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
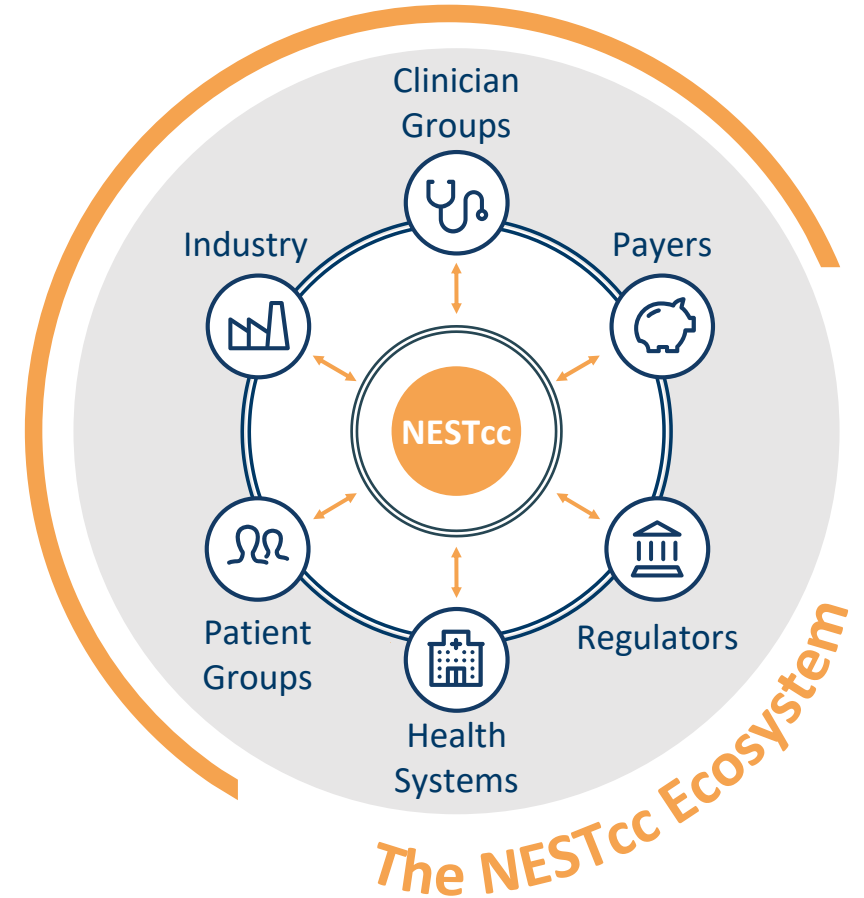
NESTcc GOALS

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
- 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

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

To achieve success for establishing NESTcc governance, NESTcc will:

⚙ 2018 OPERATIONAL MILESTONES

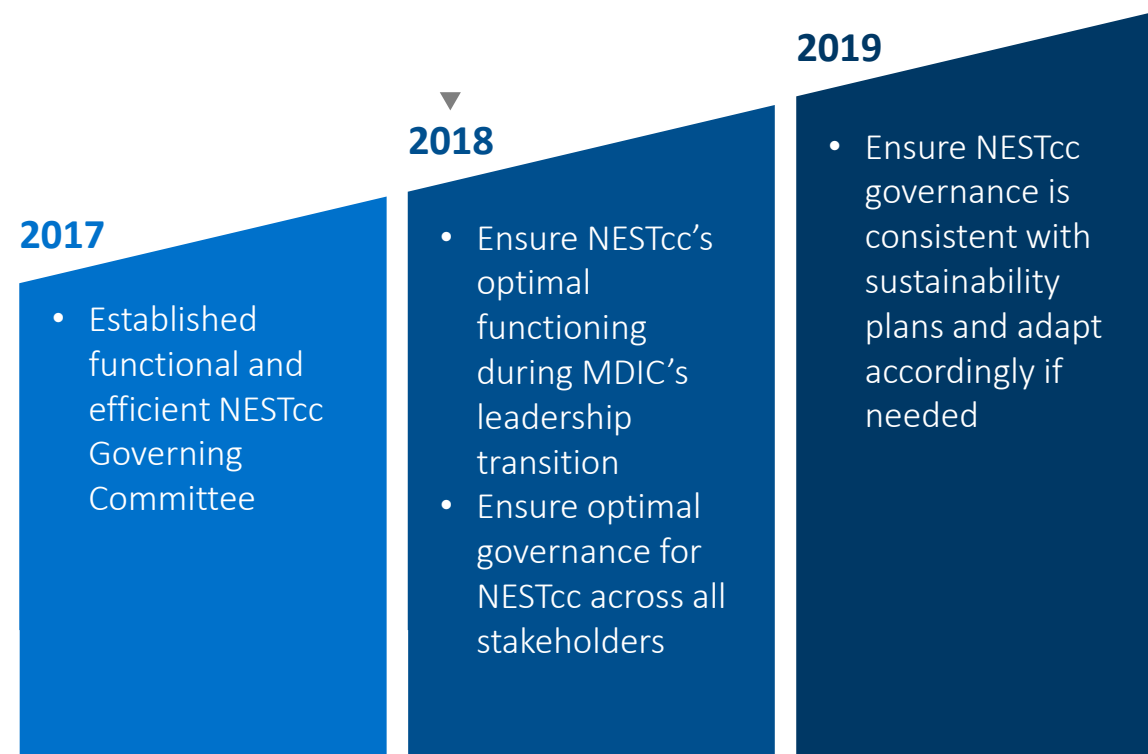|	
1.1	Report regularly to the MDIC Board
1.2	Work collaboratively with the FDA to meet FDA requirements
1.3	Initiate an assessment of RWE activities
1.4	Launch four subcommittees: Charter, Sustainability, Methods, and Data Quality
1.5	Post a public call to solicit membership to two open subcommittees: Methods and Data Quality
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

📌 STRATEGIC PRIORITIES

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

2017
- Established functional and efficient NESTcc Governing Committee

2018
- Ensure NESTcc's optimal functioning during MDIC's leadership transition
- Ensure optimal governance for NESTcc across all stakeholders

2019
- Ensure NESTcc governance is consistent with sustainability plans and adapt accordingly if needed
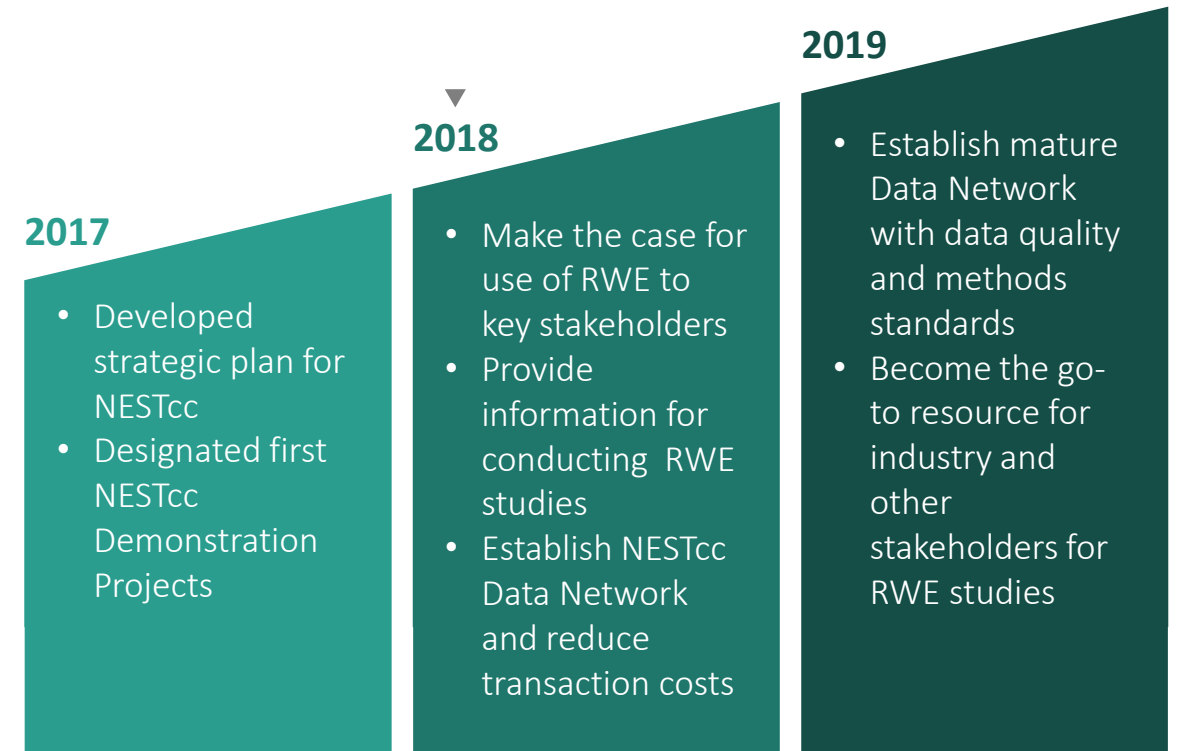
To achieve success for developing NESTcc's role, NESTcc will:

2018 OPERATIONAL MILESTONES

2.1   Establish NESTcc Data Network

2.2   Launch initial test-cases elicited from industry

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:

2017
- Developed strategic plan for NESTcc
- Designated first NESTcc Demonstration Projects

2018
- Make the case for use of RWE to key stakeholders
- Provide information for conducting RWE studies
- Establish NESTcc Data Network and reduce transaction costs

2019
- Establish mature Data Network with data quality and methods standards
- Become the go-to resource for industry and other stakeholders for RWE studies

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	Label Expansion	Post-Market Approval Studies (PAS)	Surveillance	Coverage
Using RWE to inform pre-market development or incremental improvement of medical devices	Using RWE in a regulatory submission to support an expanded indication for use of medical devices already on the market	Using generated RWE to track medical device's safety and effectiveness as part of its condition of approval	Using generated RWE to track and document medical device safety and effectiveness for products on the market	Using generated RWE to support coverage and reimbursement decisions by public and private payers

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 the business plan, operating model, and financial model

3.4 Produce a comprehensive market analysis and competitive landscape analysis

3.5 Establish pricing models for NESTcc functions and services

3.6 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:

2017
- Initiated planning for sustainability

2018
- Outline viable sustainability plan
- Define NESTcc services and pricing

2019
- Deploy viable sustainability plan

ENSURE NESTcc STAKEHOLDER ENGAGEMENT

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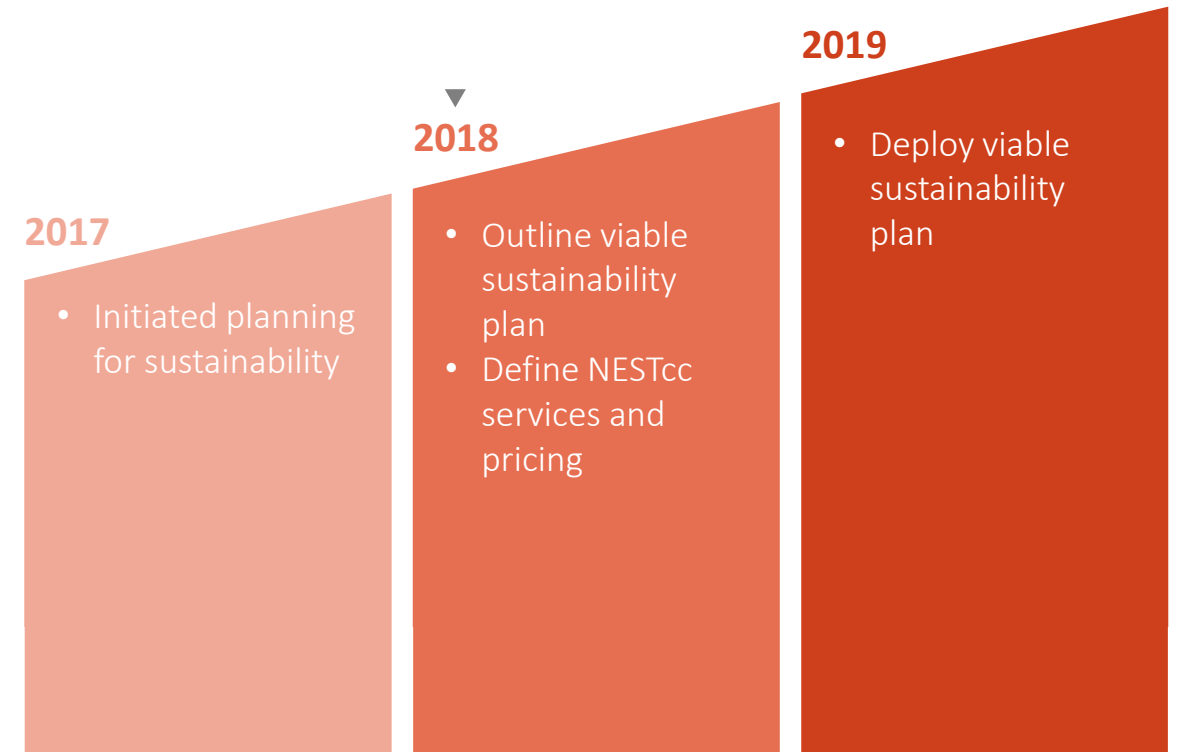
To successfully engage stakeholders from across the ecosystem, NESTcc will:

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

STRATEGIC PRIORITIES

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

2017
- Engaged with key stakeholders to develop NESTcc strategy and goals and obtain feedback on strategy and operations

2018
- Ensure buy-in for NESTcc from key stakeholders
- Ensure feedback from a range of stakeholders is integrated as NESTcc develops

2019
- Establish NESTcc as the front-door to conducting RWE studies
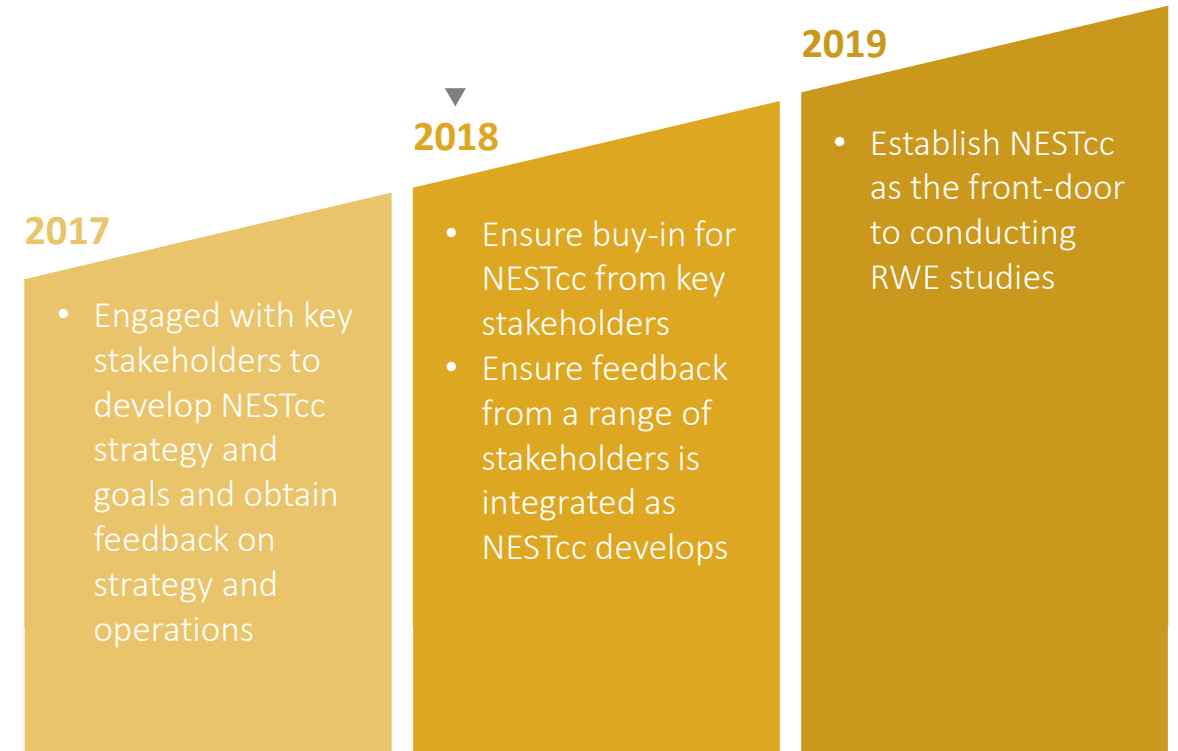
SIX-MONTH SELECT KEY MILESTONES FOR THE FUTURE

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2018:	JAN	FEB	MAR	APR	MAY	JUN
Governance	◆ Assessment RFP responses due	◆ Approved four GC subcommittees	◆ Initiate RWE assessment	◆ Appoint new GC Chair		◆ Revise GC Charter
Role	◆ Expanded NESTcc network with round 2 of MOUs	◆ Hosted Data Strategy Convening	◆ Initiate RWE value case-studies		◆ Finalize Data Quality and Methods Subcommittees	◆ Launch test-case projects with NESTcc network collaborators
Value	◆ Developed business model (Phase I sustainability planning)	◆ Solicited stakeholder feedback on business model	◆ Launch Sustainability Subcommittee		◆ Initiate operating/financial models and business plan development (Phase II sustainability planning)	
Engagement		◆ Launched nestcc.org update		◆ Develop strategic communications plan	◆ Launch nestcc.org update	

www.nestcc.org

@NESTccMedTech

nestcc@mdic.org