Virtual Public Meeting - Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027

October 27, 2020
Introduction to NEST, MDIC, and NESTcc (5 minutes)

- Overview
- Timeline

MDUFA IV Commitments (15 minutes)

- Overview
- Progress to Date
- Lessons Learned

Moving Forward (10 minutes)

- Completion of Commitments
- Focus on Long-term Sustainability
A key challenge across the medical device landscape is how to ensure timely access to technology while also providing evidence to guide safe and appropriate use.

Traditional sources of evidence for pre-market approvals are costly, time-consuming, delay access for consumers, and may not reflect a device’s true benefit-risk profile.

Reliance on traditional clinical trials and passive surveillance of safety events has also limited the ability to generate evidence of longer-term safety and durability of devices following approval.

The current fragmented health care ecosystem makes the seamless, timely, cost-effective use of health data to generate high-quality evidence needed more challenging.

To expedite the delivery of life-saving and quality of life-enhancing medical devices to patients, public/private stakeholders are increasingly seeking to leverage evidence from non-traditional data sources.
NEST, MDIC, AND NESTcc

The **National Evaluation System for health Technology (NEST)** is a national system developed to efficiently generate better evidence for medical device evaluation and regulatory decision-making.

NEST is operated by the **Medical Device Innovation Consortium (MDIC)**, a public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.

In 2016, MDIC was awarded a grant to establish the **NEST Coordinating Center (NESTcc)** as an operational business unit within MDIC that provides:

- Governance for the NEST ecosystem
- Development AND maintenance of the research infrastructure
- Guidelines for methodology and data quality
- Insight into the strengths and limitations of RWD data sources
NESTcc MISSION AND VISION

Mission
To catalyze the timely, reliable, and cost-effective development of Real-World Evidence (RWE) to enhance regulatory and clinical decision making.

Vision
To be the leading organization within the health technology and medical device ecosystem for conducting efficient and timely high-quality RWE studies throughout the total product lifecycle (TPLC).

Established by the U.S. Food and Drug Administration, NESTcc is an independent coordinating center driving quality and efficiency in the use of real-world data (RWD) to inform medical device development and evaluation.

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NESTcc CONCEPT TO REALITY

2012
FDA proposed the development of a **national system**

2016
FDA awarded funding for NESTcc to **Medical Device Innovation Consortium (MDIC)**

2017
NESTcc **Governing Committee** selected

2018
Initial NESTcc **Research Network** formed

2019
NESTcc **Data Quality** and **Methods Subcommittees** formed

21 NESTcc **Test-Case** research projects selected

2020
NESTcc **Research Methods Framework** and **Data Quality Framework** released

**Launch of NEST 1.0** to coordinate studies for medical device ecosystem

**Expansion of Research Network** with new Network Collaborators

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NESTcc is advancing towards completion of the four key commitments in the MDUFA IV commitment letter.

- Implementation of RWE pilots (Test-Cases)
- Independent assessment of Test-Cases
- Public meeting to review Test-Case progress
- Focus on long-term self-sustainability
All of the NESTcc Test-Case projects are in progress, with five completed.

**MDUFA Commitment Letter**

"By the end of FY2019, NEST will implement pilots for at least two product codes (and related product codes), one of which will cover devices approved through the PMA process and the other of which will cover devices cleared through the 510(k) process."

**Current Status**

**Test-Cases**
- 21/21 Underway
- 8 Pre-Market
- 5 Completed

**MDUFA-Priority Test-Cases**
- 12/12 Underway
- 6 Pre-Market
- 3 Completed
The RAND Corporation has initiated a rolling assessment of the Test-Cases as each project concludes.

**MDUFA Commitment Letter**

“At the conclusion of the pilots, an independent third-party will conduct an assessment to evaluate the strengths, limitations, and appropriate use of RWE for informing premarket decision-making for multiple device types.”

**Current Status**

- Test-Case surveys have been finalized
- Assessment of completed Test-Cases has begun
- Assessment will continue until 21 Test-Cases are final
The NEST Forum took place on September 22, 2020.

**MDUFA Commitment Letter**

“No later than October 1, 2020, the Coordinating Center will hold a public meeting to review and evaluate the progress and outcomes (as of the date of the public meeting) of the pilots described in (H)(1) above.”

**Current Status: Completed**

- 302 unique attendees joined the virtual event
- Results from five completed Test-Cases highlighted
- All session recordings are available

[nestcc.org/events/nest-forum](http://nestcc.org/events/nest-forum)
MDUFA COMMITMENT | FOCUS ON LONG-TERM SELF-SUSTAINABILITY

On June 30, 2020, NESTcc launched NEST 1.0 for revenue generation and external funding.

**MDUFA Commitment Letter**

“The NEST Coordinating Center will seek ways in which to make NEST financially self-sustaining so as not to rely on MDUFA user fees in the long term unless FDA and Industry determine continued user fee support is warranted and provides a sufficient return on investment.”

**Current Status**

- Go-to-market plan in execution
- Development of early sales pipeline
  - Outreach
  - Engaged
  - Touch Points
  - Presentations
  - Active Deals

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LESSONS LEARNED

The Test-Case projects have yielded key lessons learned, which continue to inform NESTcc’s focus and efforts.

1. Select Test-Cases were funded for a Phase 2 as the results generated were promising to pursue additional research.

2. Test-Case projects connected siloed data for research across different institutions, geographies, and RWD sources.

3. Test-Case projects demonstrated the ability to facilitate collaboration between interdisciplinary team members across multiple Network Collaborator organizations.

4. Initial contracting challenges contributed to delays in the launch of several Test-Case projects, requiring efficiencies.
   • Challenges included data sharing and use agreements, as well as subaward contracting.

5. The NESTcc Research Methods Framework and Data Quality Framework have a role in defining principles for study design and data validation.

6. The creation of a centralized research infrastructure where participating Network Collaborators may contribute data would help alleviate contracting issues related to data sharing.
NESTcc PROGRESS TO DATE

Summary of NESTcc efforts in completing MDUFA IV commitments.

- Implementation of RWE pilots (Test-Cases)
  5 completed; 16 in progress

- Independent assessment of Test-Cases
  In progress

- Public meeting to review Test-Case progress
  Completed September 22

- Focus on long-term self-sustainability
  Launched June 30; In progress
DIRECTION FOR THE FUTURE

NESTcc will continue to build on our foundation to deliver on the vision of RWE for the medical device ecosystem.

Completion of Commitments

• Completion, assessment, and dissemination of Test-Cases

Advancement of Research

• Next iteration of Research Methods and Data Quality Frameworks

Focus on Long-term Self-sustainability

• Demonstrate value of RWE for key stakeholders
• Address challenges in the medical device ecosystem
Objective #1: Explore the feasibility for medical device ecosystem stakeholders to work RWD sources and NESTcc’s initial set of Network Collaborators

Objective #2: Help identify areas where NESTcc could play a role in creating efficiencies

21 Total NESTcc Test-Case Projects

NESTcc’s Test-Cases reflect the diversity of types of medical devices available and the different use of data in pre-market and post-market settings.
NESTcc RWE RESEARCH OBJECTIVES

NESTcc will continue to execute the 21 Test-Case projects, disseminate learnings, and advance the evaluation of real-world evidence.

NESTcc Approach

- Implement quality improvement initiatives
- Actively participate in study design
- Facilitate discussions with key stakeholder groups

Completion Goals

- Finalize all Test-Cases by June 2022
- Share Test-Case findings through “mini forums”
- Complete independent assessment of Test-Cases
FOCUS ON SELF-SUSTAINABILITY

Continue to evolve NESTcc’s commercial capabilities as the organization advances the generation and use of RWE.

NESTcc Approach

- Develop and refine systematic processes
- Hire and train staff for applicable regulations and guidance
- Implement culture of client satisfaction

Completion Goals

- Finalize QMS to be ISO 13485 compliant
- Design SOPs for operational excellence
- Publish revised Frameworks by Q1 2022
Quality *Evidence* by Design

NEST enables the generation of timely, high-quality evidence to ensure the availability of safe, effective, and innovative technologies for patients.

- **Curating the right data sources and research expertise** to meet specific objectives – across device types, disease areas, and the TPLC
- **Catalyzing transparent, traceable RWD provenance**, leading to actionable evidence for clinical, regulatory, or reimbursement decision-making
- **Creating a safe harbor for effective, objective research** as a neutral, nonprofit organization informed by diverse stakeholders, including FDA