



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

October 27, 2020

AGENDA

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



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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.

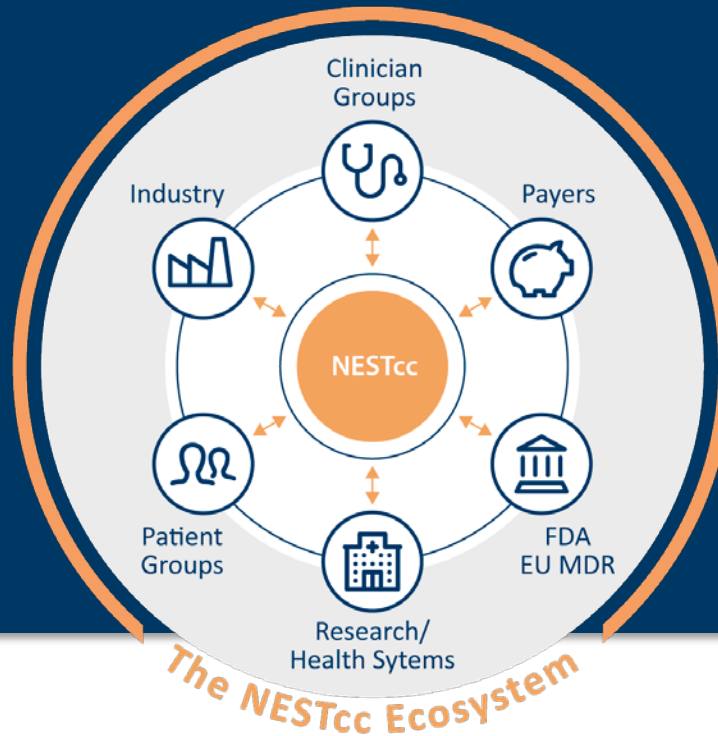


In 2016, MDIC was awarded a grant to establish the **NEST Coordinating Center (NESTcc)** as an operational business unit within MDIC that provides:

- 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

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.

NESTcc CONCEPT TO REALITY



MDUFA IV COMMITMENTS

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



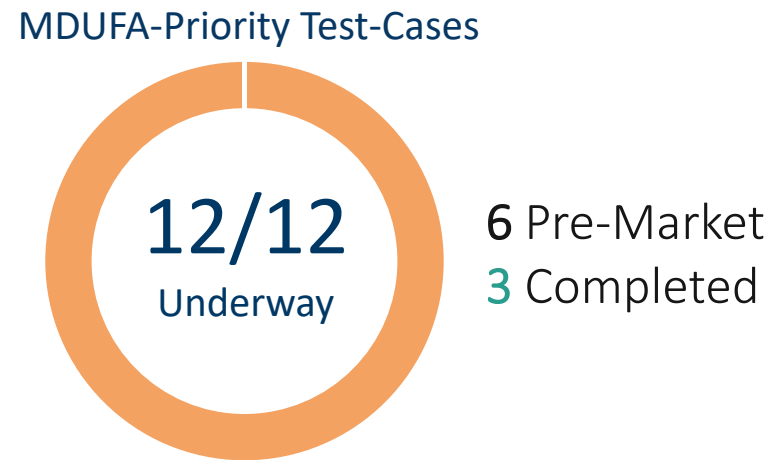
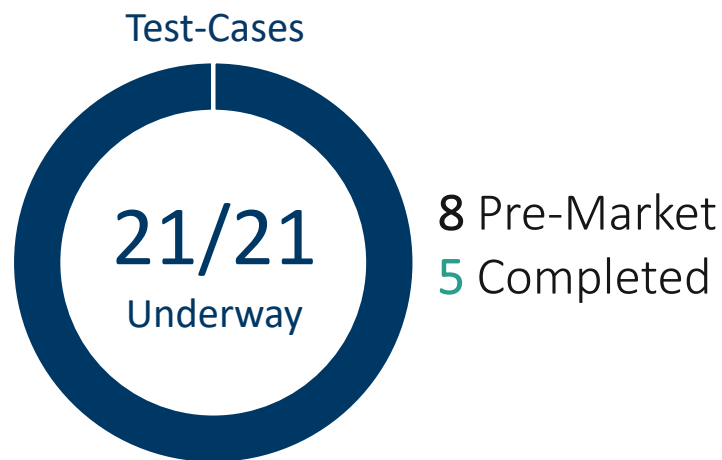
MDUFA COMMITMENT | IMPLEMENTATION OF RWE PILOTS (TEST-CASES)

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



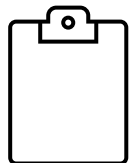
MDUFA COMMITMENT | INDEPENDENT ASSESSMENT OF TEST-CASES

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.”

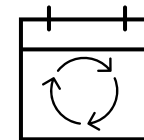
Current Status



Test-Case surveys
have been finalized



Assessment of completed
Test-Cases has begun



Assessment will continue
until 21 Test-Cases are final

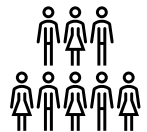


The NEST Forum took place on September 22, 2020.

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.”

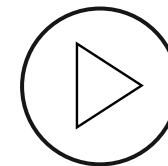
Current Status: Completed



302 unique attendees
joined the virtual event



Results from five completed
Test-Cases highlighted



All session recordings
are available

nestcc.org/events/nest-forum



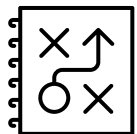
MDUFA COMMITMENT | FOCUS ON LONG-TERM SELF-SUSTAINABILITY

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

MDUFA Commitment Letter

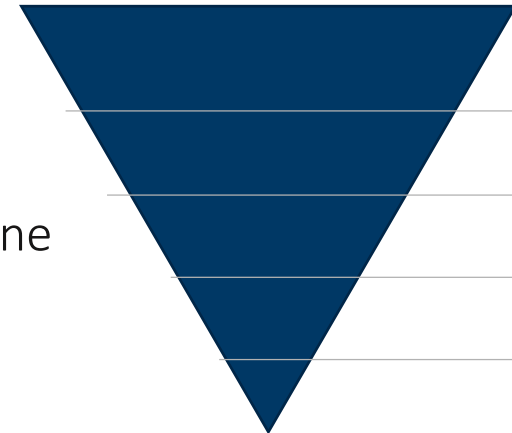
“The NEST Coordinating Center will seek ways in which to make NEST financially self-sustaining so as not to rely on MDUFA user fees in the long term unless FDA and Industry determine continued user fee support is warranted and provides a sufficient return on investment.”

Current Status



Go-to-market plan
in execution

Development of
early sales pipeline



Outreach

Engaged

Touch Points

Presentations

Active Deals



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



EXPERIENCE

SNAPSHOT

- | | |
|--|---|
|  Cardiology (5) |  Pre-Market (6) |
|  Cardiovascular (2) |  Post-Market (3) |
|  Dental (1) |  Label Expansion (5) |
|  Dermatology (1) |  Surveillance (10) |
|  ENT (1) |  Coverage (3) |
|  Mental health (1) | |
|  Oncology (1) | |
|  Orthopedics (5) | |
|  Respiratory (2) |  510(k) (6) |
|  Urology (2) |  PMA (8) |

 Disease Area
  TPLC Stage
  Regulatory Pathway

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

- 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

PARTNERS¹



¹Not pictured, The Women's Health Technology Coordinated Registry Network (WH-CRN)

NESTcc RWE RESEARCH OBJECTIVES

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

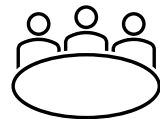
NESTcc Approach

- 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.

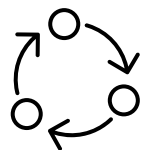
NESTcc Approach

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

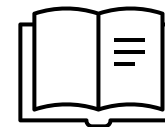
Completion Goals



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





 www.nestcc.org

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