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NESTcc Call for Concepts Public Webinar

Rachael L. Fleurence, PhD
NESTcc Executive Director

January 4, 2018

WELCOME!

Rachael L. Fleurence, PhD | NESTcc Executive Director

- Joined MDIC from the Patient-Centered Outcomes Research Institute (PCORI) where she has led PCORI's initiative to build the National Patient-Centered Clinical Research Network, or PCORnet, since 2012.
- Served on a number of Boards and Steering Committees, including most recently the National Medical Device Evaluation System Planning (NEST) Planning Board, the Medical Device Innovation Consortium (MDIC) Board and the SMART IRB Steering Committee, an effort to streamline IRB reviews across academic research institutions.
- Served as chair of the PCORnet Executive Committee, and vice-chair of the PCORnet Council.
- Previously worked in the private sector in health outcomes research and has authored multiple peer-reviewed publications.

Dr. Fleurence received a BA from Cambridge University (United-Kingdom), a MA in business management from ESSEC-Paris (France), and a MSc and PhD in health economics from the University of York (United-Kingdom).

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HISTORY OF NESTcc

The National Evaluation System for health Technology's (NEST) vision is to improve the use of Real-World Evidence (RWE) generated in the routine course of care.

Planning Board convened by the **Duke-Margolis Center for Health Policy** envisioned NEST as a voluntary network of data collaborators

FDA awarded a grant for the NEST Coordinating Center (NESTcc) to the **Medical Device Innovation Consortium (MDIC)**

Executive Director of NESTcc selected

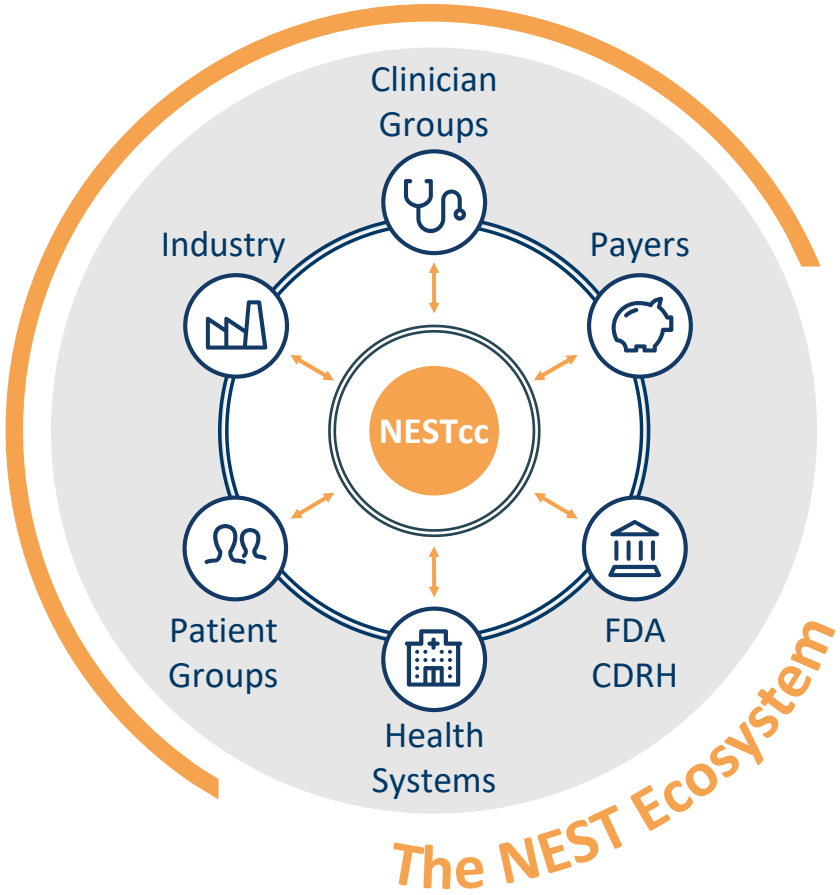
NESTcc **Governing Committee** selected

NESTcc **Strategic and Operational Plan (v1)** developed

NESTcc'S ROLE IN THE ECOSYSTEM

NESTcc will serve as a catalyst to support the timely and reliable development of high-quality RWE.

- Establish **partnerships** with a range of organizations, companies, and collaborations that provide data and analytics solutions
- Set **data quality standards** for data collaborators and **methods standards** for observational and randomized studies
- Offer **added value** through products and services to key stakeholders in the ecosystem



STRATEGY TO ACHIEVE SUCCESS

To achieve success, NESTcc will focus on four strategic priority areas:

A complete version of the NESTcc strategic plan is available at www.nestcc.org and can be downloaded here.

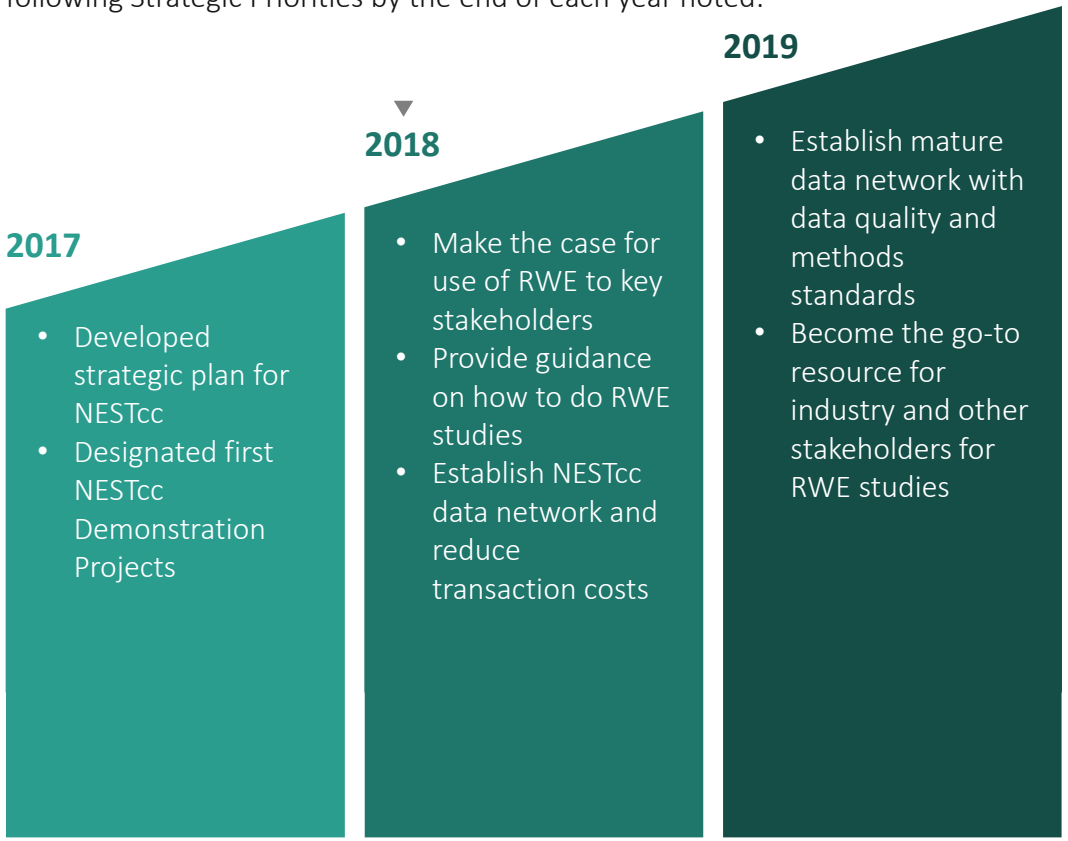
Implementing NESTcc test-cases will support the development of NESTcc's role.

2018 OPERATIONAL MILESTONES

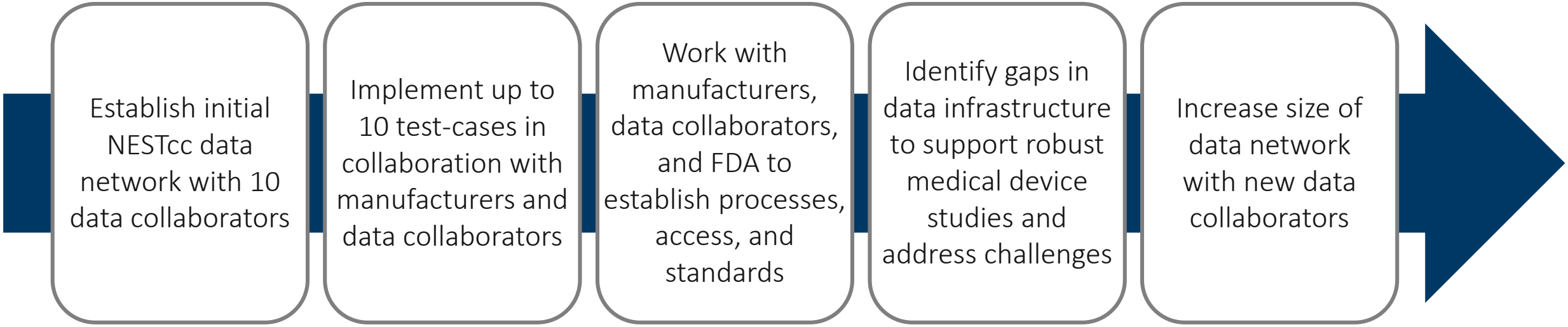
2.1	Establish NESTcc data network and launch initial test-cases elicited from industry
2.2	Make the case for the use of RWE to industry and other stakeholders through a case-study report (issue RFP for vendor)
2.3	Provide guidance ("living playbook") for conducting RWE studies across use-cases and device types, including methodological standards (collaborate with MDEpiNet)
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 DATA NETWORK TIMELINE 2018



ESTABLISHING NESTcc's DATA NETWORK

NESTcc has established relationships with data collaborators to advance evaluation and use of high-quality RWD from various sources.

TO DATE, MEMORANDA OF UNDERSTANDING (MOUs) HAVE BEEN SIGNED WITH TEN COLLABORATORS:

Duke University Health System • Healthcore • Lahey Clinic • Mayo Clinic • Mercy Health • PEDSnet • Vanderbilt University Medical Center • University of Florida Health System • Weill-Cornell Medical Center • Yale New Haven Health System

OVERVIEW: DATA CAPABILITIES SURVEY

NESTcc surveyed its data network to determine current capabilities, gaps, and priority areas.

Capabilities Surveys Completed

Duke University Health System • HealthCore • Kaiser Permanente • Mayo Clinic • Mercy • OneFlorida • PEDSnet • Vanderbilt University • Weill-Cornell Medical Center • Yale New Haven Health System

Survey respondents represent:

55 Hospitals

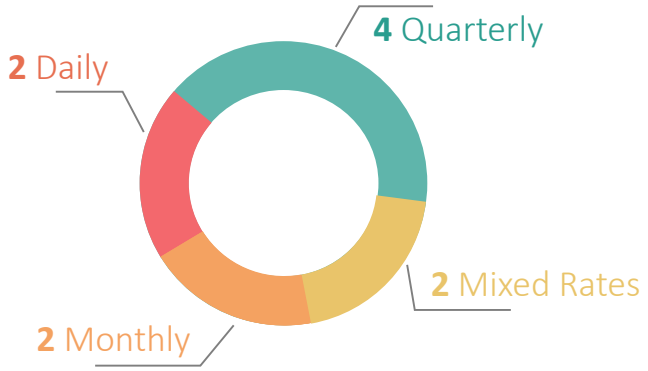
250 Outpatient Clinics

Patient data represents:

146M+ Patient Records

344M+ Unique Patient Encounters

Respondents report regular data refreshes:



Most cited expertise:

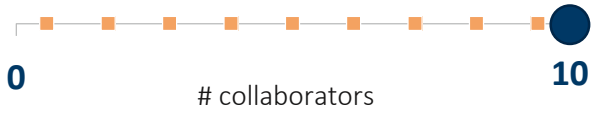
- ✓ Cardiovascular and Cardiac Surgery
- ✓ Women's Health
- ✓ Neurosurgery
- ✓ Gastroenterology
- ✓ Orthopedic

A CLOSER LOOK AT NESTcc's DATA NETWORK

The collaborators comprising the NESTcc data network each have access to EHR data and private claims data, while subsets of the collaborators have linkages with additional data sources and public coverage data:

DATA SOURCES

EHR



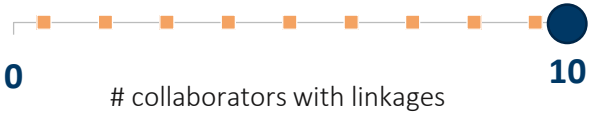
Pharmacies

Patient-Generated Data

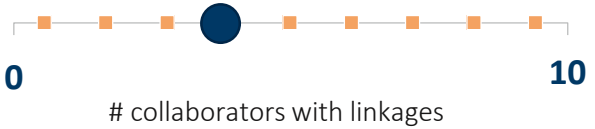
Registries*

LINKAGES TO COVERAGE DATA

Private Claims



Medicare



Medicaid

***Registries Include (but are not limited to):**

- Anesthesia Quality Institute's National Anesthesia Clinical Outcomes
- Cardiac Catheterization
- Cardiogenic Shock
- Immunization
- Implant registries
- Integrated tumor
- International Consortium Lower-GI
- American College of Surgeons National Surgical Quality Improvement Program
- Oncology
- Pediatric Cardiomyopathy
- Prostate Ablation-Related Energy Devices
- Robotic Surgery
- Society of Thoracic Surgeons National Database
- Society for Vascular Surgery
- Thalassemia Clinical Research Network - Thalassemia Registry
- Vital Records (Birth and Death)

Data is organized by each individual data network collaborator.

Common Data Models (CDM)

In addition to health-system specific CDMs, all participating collaborators use at least one of the follow CDMs, with PCORnet being the most common:

- I2b2
- OMOP
- PCORnet
- Sentinel

Data Types

Types of data available from data network collaborators include but are not limited to the following:

- Clinical
- Demographics
- Diagnostic
- Encounters
- Enrollment
- Patient-Reported Outcomes
- Pharmaceutical
- Procedures
- Vital Data

Implementation of UDI

Four data network collaborators have demonstrated capabilities of incorporating UDI, either in Demonstration Projects or fully.

SUBMIT CONCEPTS FOR REAL-WORLD EVIDENCE TEST-CASES

NESTcc is interested in receiving recommendations from medical device manufacturers for test-cases using Real-World Data that could be implemented with NESTcc's first set of data collaborators.

Test-cases are being sought to assess feasibility and are intended to explore the data collaborators' ability to capture the data needed to support a range of studies and analyses.

GOALS OF TEST-CASES

Explore the feasibility for industry to use Real-World Data sources offered by NESTcc's initial set of collaborators. Other sources of Real-World Data could be explored if needed (e.g., registries, de-identified claims data, patient-generated data)

Identify areas where NESTcc could play a role in reducing transaction costs (e.g., contracting, IRB, data sharing agreements, publication policies)

TEST-CASE EXAMPLES

NESTcc is interested in receiving a broad range of test-cases. The Call for Concepts outlines these examples of test-cases:

A diagnostic technology approved for adults is widely used in practice in the pediatric population. A test-case could explore the feasibility of using high-quality EHR data from pediatric hospitals to support a label expansion.

A manufacturer has in-house device-generated data. A test-case could involve exploring the feasibility of linking this data with corresponding EHR data in health systems to generate a dataset with clinically-meaningful efficacy and safety outcomes.

A manufacturer has an in-house registry mandated for high-risk Class III implants. A test-case could involve feasibility of linking this data to health system data to enrich it with long term clinical data.

Example of Collaboration Underway as of 12/17

A large diagnostic equipment manufacturer and the PEDSnet (consortium of eight Children's Hospitals) are reviewing clinical data in a pediatric population on the use of a diagnostic instrument indicated for adults.

TEST-CASE EXAMPLES, CONT'D

Test-cases limited to descriptive data on demographics, devices, event rates, etc., will also be considered.

- What is the 30-day event rate for men versus women for a cardiovascular procedure using a medical device?
- What is the change in utilization for X products from 2016 to 2017 for men, women, and children?
- What percentage of men versus women had X clinical outcome 30, 90, 180 days after Y procedure?

Non-Exhaustive Examples of Devices/Procedures of Interest

- Hip replacement devices
- Knee replacement devices
- Vascular procedures/devices (includes peripheral, AAA, carotid and vascular access/catheters)
- Spine surgery procedures/devices
- Cardiac valve replacement
- Atrial fibrillation ablation procedures/devices
- ICD/cardiac resynchronization therapy (CRT) implantation
- Coronary stents
- Robotic and other less invasive surgery
- Ophthalmic procedures/devices
- Surgical mesh

OVERALL PROCESS AND APPROACH TO CONFIDENTIALITY

Proposed Overall Process | **Review Process** | **Selection Process**

- **January 17th:** Manufacturer submits a test-case concept to NESTcc staff. Test-case information **will be kept confidential** by NESTcc staff. Review and selection process takes place, accounting for conflict of interest and confidentiality requirements. *(See next slides)*
- **February:** A subset of the NESTcc Governing Committee (GC) will recommend up to 10 test-cases. Based on the review, GC members will exclude representatives from industry and health systems, and will be required to keep information confidential. *(See next slides)*
- **March:** Contracts will be put in place between MDIC and manufacturer or data collaborator, or manufacturer and data collaborator; confidentiality requirements will be specified.

Optional: Manufacturer may request to sign Non-Disclosure Agreement (NDA) with NESTcc team between now and January 17th (deadline for submission) or any time during the process. The NDA should allow NESTcc to use de-identified, high level information on the test-case for NESTcc's communications.

REVIEW AND SELECTION PROCESS

- Each concept will be reviewed by **two to four** reviewers from MDIC staff and the FDA through objective evaluation criteria. Non-MDIC staff will disclose COI and sign NDAs with MDIC.

- NESTcc data collaborators may be consulted to **assess the feasibility** of test-cases using the de-identified Concept Proposals. If not already covered under an NDA, prior approval from manufacturer about level of disclosure of information will be sought by NESTcc staff.

- NESTcc Executive Director will use reviewer comments to **recommend a slate** of test-cases to Selection Team composed of members of the NESTcc Governing Committee

REVIEW AND SELECTION PROCESS, CONT'D

Proposed Overall Process | Review Process | **Selection Process**

- The Selection Team will be composed of a subset of NESTcc Governing Committee members **who are not affiliated** with NESTcc data network collaborators and who do not represent industry.
- NESTcc will **select up to 10** viable test-cases based on test-case alignment to NESTcc's strategic priorities and need for collaboration with NESTcc. Selection will be based on the following review criteria:
    - Organization Eligibility
    - Portfolio Alignment
    - Test-Case Description
- NESTcc will **initiate discussions** between the organization submitting the test-case concept and NESTcc data collaborators with prior approval from the manufacturer.
- NESTcc will **work collaboratively** with medical device manufacturers and health data collaborators to execute the test-case.

FINANCIAL CONSIDERATIONS

- After preliminary selection, NESTcc may request additional information such as a full project proposal—including a budget—that may be subject to additional review and approval prior to moving forward.
- Funds from NESTcc may be available to support the selected test-cases.
- NESTcc funds may be awarded to the manufacturer (particularly small manufacturers) or data collaborators or both, depending on the impact, size and scope of the project.
- It is anticipated that NESTcc may provide up to 250k dollars per test-case. This statement does not commit NESTcc to funding any test-cases for any amount.
- It is anticipated that any test-case will most likely involve an agreement or contract between the manufacturer and the data collaborator, independent of NESTcc. NESTcc will not receive or analyze data at this stage.

QUESTIONS AND ANSWERS

Please direct all questions to the NESTcc team at NESTcc@mdic.org. You are also invited to submit your question now using the WebEx "Questions" tab on the right hand side of your screen.

KEY REMINDERS

Submission Reminders

1. Recommendations for test-case concepts should be submitted to MDIC NESTcc Program Manager, Hither Jembere, at NESTcc@mdic.org. Manufacturers wishing to set up a NDA prior to submission should also send a request using this contact information.
2. Deadline for submitting concepts is 5p.m. EST on January 17, 2018.
3. Required submissions template is available here, and can also be found at nestcc.org/opportunities. Submissions must not exceed two pages.

Opportunity Timeline

December 4, 2017
Call for Concepts publicly announced

January 4, 2018
Call for Concepts Webinar

January 17, 2018
Submission deadline for test-cases

TBD
Preliminary selection date for test-cases

NEST
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