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Challenges with Registries and Opportunities through NESTcc

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Registries have historically played an important role in the regulatory space for medical devices.

- Examples of high-quality registries:
  - Transcatheter Valve Therapy Registry (TVT-R), American College of Cardiology and the Society of Thoracic Surgeons
  - National Cardiovascular Disease Registries, American College of Cardiology
  - Vascular Quality Initiative (VQI), Society of Vascular Surgeons (SVS)
  - International Consortium of Orthopedic Registries (ICOR)
- New developments in **Coordinated Registry Networks**, linking existing registries with claims data and EHRs have started, including international registries

Registries are currently the main source of RWE decisions by FDA-CDRH.

National Registries in CDRH "RWE" decisions (2017):

- **15** Post-Approval Studies
- **1** Continued Access Study
- **8** Pre-Market Studies (including labeling expansion)
- **7** Post-Market Surveillance Studies (522)

International Registries are being leveraged for:

- **3** Post-Approval Studies

Source: FDA-CDRH Staff

CHALLENGES WITH REGISTRIES

Although registries are a main source of RWE, challenges exist:

- x High cost of developing and maintaining registries
- x Impact of operator characteristics and learning curve
- x Registries cannot be developed for all devices and all disease areas
- x Representation of real-world sample

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NESTcc Mission Statement

To accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research.

History of NESTcc

2015
- NESTcc envisioned as a voluntary data network of collaborators by Planning Board

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

2017
- **Executive Director** of NESTcc named
- NESTcc multi-stakeholder **Governing Committee** selected
- NESTcc **Strategic and Operational Plan** developed

2018
- Initial NESTcc **Data Network** formed and testing initiated
- NESTcc **Data Quality** and **Methods Subcommittees** formed

ESTABLISHING THE NESTcc DATA NETWORK

NESTcc has established relationships with 12 Network Collaborators that represent more than 195 hospitals and 3,942 outpatient clinics to advance evaluation and use of high-quality Real-World Data (RWD) from various sources.

TO DATE, MEMORANDA OF UNDERSTANDING (MOUs) HAVE BEEN SIGNED WITH 12 NETWORK COLLABORATORS:

NESTcc surveyed its Network Collaborators to determine current capabilities, gaps, and priority areas.

Network Collaborators

Duke University Health System • HealthCore • Lahey Clinic • Mayo Clinic • MDEpiNet • Mercy • Mid-South • NYC-CDRN • OneFlorida • PEDSnet • Vanderbilt University • Yale New Haven Health System

Network Collaborators represent:

195
Hospitals

3,942+
Outpatient Clinics

Patient data represents:

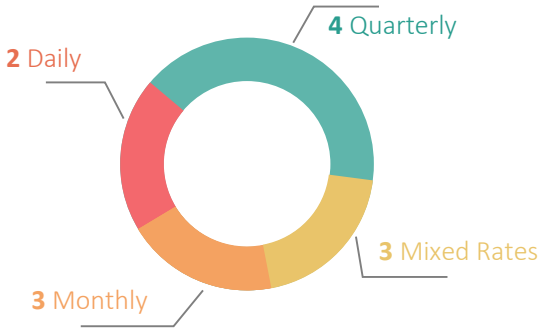
494M+*
Patient Records

*Does not account for duplicate records

Common data models:

- ✓ I2b2
- ✓ OMOP
- ✓ PCORnet
- ✓ Sentinel

Network Collaborators report regular data refreshes:



Most cited expertise:

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

Numbers reflect data as of February 2018

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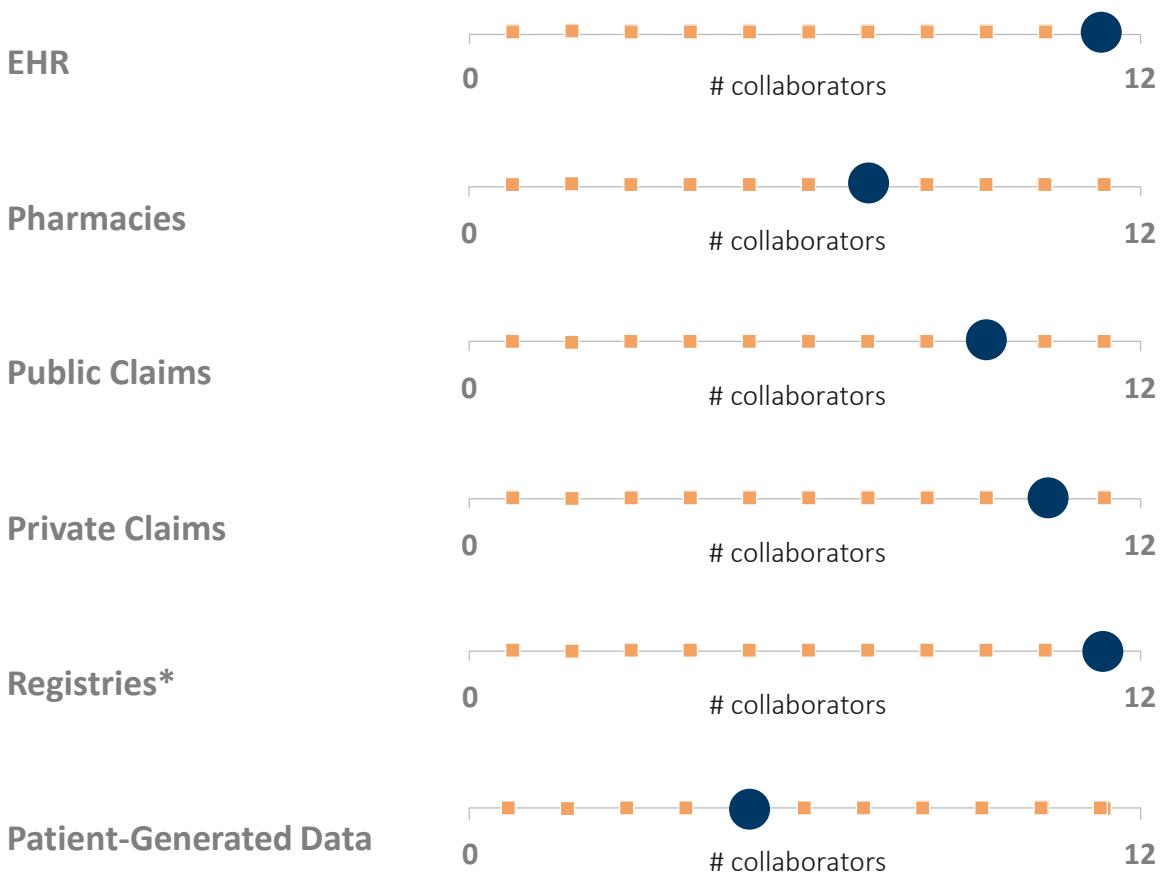
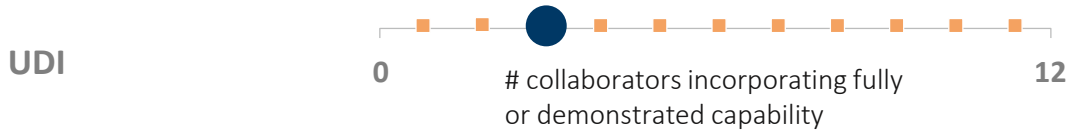
The collaborators comprising the NESTcc Data Network have access to a range of available data sources, including those listed below.

AVAILABLE DATA SOURCES



UDI IMPLEMENTATION



***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)

Beginning in December 2017, NESTcc solicited submissions from industry for RWE test-cases that will be implemented across Network Collaborators.

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

GOALS OF TEST-CASES

- Solicit test-cases from medical device manufacturers to understand their **evidence generation needs**
- Explore NESTcc **Network Collaborators'** ability to capture the data needed to support a range of studies and analyses
- Test and understand the unique **capabilities** of the NESTcc Data Network
- Assess the **feasibility** of NESTcc's envisioned Data Network

LAUNCHING THE FIRST ROUND OF TEST-CASES

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There are 8 initial test-cases with 8 – 12 month timelines:

TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT	PROJECT TITLE	REGULATORY PATHWAY	TECHNOLOGY OF INTEREST	DISEASE AREA
Pre-market Submission	Comparative Effectiveness of Alternative Approaches for Wound Closure	510(k)	Wound Closure	Dermatology
Label Expansion	Testing the Use of Real-World Data from Three Unique Sources to Expand Indications	PMA	Endovascular Therapies	Vascular
Label Expansion	The Feasibility of Using Real- World Data in the Evaluation of Cardiac Ablation Catheters	PMA	Ablation Catheters	Cardiology
Label Expansion	Real-World Clinical Outcomes in Patients with Mechanical Heart Valve Replacement and Anticoagulation Variability	PMA	Mechanical Aortic Heart Valves	Cardiology
Label from General to Specific Indication	Feasibility of Using Real-World Data to Evaluate Thermal Ablation of Liver Tumors	510(k)	Ablation Device	Surgery
Postmarket Surveillance	Testing the Feasibility of Registry and Claims Data Linkages	510(k)	Total Joint Arthroplasty (TJA), Primary Total Knee Arthroplasty	Orthopedics
Postmarket Surveillance	Developing Capacity to Conduct Proactive Post Marketing Safety Surveillance of Craniomaxillofacial Distractors Using Electronic Health Record Data	510(k)	Craniomaxillofacial Distractors	Orthopedics
Postmarket Surveillance	Developing Capacity to Conduct Proactive Post Marketing Safety Surveillance of Intervertebral Body Fusion Devices Using Electronic Health Record Data	510(k)	Intervertebral Body Fusion Devices	Orthopedics

Title: Testing the Feasibility of Registry and Claims Data Linkages

Technology of Interest: Total Joint Arthroplasty (TJA); Primary Total Knee Arthroplasty (TKA)

Participating Network Collaborators: HealthCore; Mayo Clinic

TOTAL KNEE ARTHROPLASTY

This project aims to conduct **anonymous data linkages** of Registry data with Real-World Data (RWD) sources, including private claims databases within the NESTcc Network Collaborators, from Mayo Clinic (Optum Labs) and HealthCore. A data linkage, supported by Weill-Cornell Medical College as an honest broker, will be put in place between **AJRR and HealthCore**, which has longitudinal data through private payer claims on **~350,000 TKA patients**. In addition, data will be collected through **OptumLabs**, with data on over **121,000** total knee arthroplasty (TKA) patients, and analyzed through Mayo Clinic.

Linkages provide a valuable resource for determining more accurate **device performance, survivorship, and surgical outcomes**, thereby supporting standardized **post-market surveillance** reporting mechanisms. The specific aim is to conduct a descriptive study to evaluate the clinical outcomes of TKA implant **survivorship, mortality, revision/reoperation, readmission, and Emergency Department** visit following TKA 2012-2017 for private health plan members. This study has implications for future anonymous data linkages with additional private payer claims sources and for additional orthopedic procedures.

ROUND TWO TEST-CASES ARE IN PROGRESS

NESTcc initiated a second round of test-cases in July 2018 which included on general announcement and one targeting Patient-Generated health Data (PGD).

Round 2

July – Sept. 2018
Call for concepts announced and submissions due

Oct. – Nov. 2018
Feasibility and matching process to identify project teams

Dec. 2018 – Jan. 2019
Proposal Development among teams

February 2019
Final selection and approvals leading to project awards

CONCEPTS FOR TARGETED PGD TEST-CASE ANNOUNCEMENT

NESTcc requested concept submissions from industry, health system providers, health payers, health payers, academia, and non-profits for test-cases using PGD that could be executed with NESTcc's Network Collaborators.

MISSION OF TEST-CASES

Test-case concepts should **seek to understand the patient perspective** on the health outcomes associated with the treatment of their condition. The evidence generated should constitute useful inputs into regulatory decision-making. The goals of the test-cases include:

- Explore the feasibility of generating and using patient-data for regulatory and coverage purposes using the NESTcc Data Network and designing the infrastructure necessary to support this.
- Improve understanding of the opportunities and challenges of using the NESTcc Data Network to support studies that capture and evaluate PGD to identify and measure health outcomes that matter most to patients.
- Provide learnings to advance patient input and involvement in the regulatory process.
- Contribute to NESTcc's development of operational processes (e.g., contracting, IRB, data sharing agreements, publication policies).

TYPES OF PGD

- Patient-reported data
- Task-based measures collecting objective measurements
- Sensor data/wearables
- Patient preference information (PPI)
- Patient experiences and general patient perspectives on their care

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PGD offers a combination of unique challenges and unique opportunities to fill gaps in real-world data:

CHALLENGES

- Barriers to patient participation and representativeness of population
- Retention in real-world environment
- Lack of clearly defined frameworks and validation for patient reported outcomes (PROs)
- Data quality concerns with self-tracked data

OPPORTUNITIES

- Address data categories not often considered in clinical research including patient perspective on quality of life and patient care
- Utilize data collected outside of a clinical setting, such as through smartphones
- Provide a more holistic view of a patient's health over time

KEY TAKEAWAYS FROM EARLY IN THE PGD TEST-CASE PROCESS

Submissions were due on September 19, 2018. After a review and selection process, a subset of the submissions are with the Network Collaborators for consideration. Initial takeaways from the submissions include:

- There was a **high level of engagement** and number of submissions
- Submissions came from a **range a stakeholder groups**
- Proposals utilizing a **range of types of PGD** were submitted
- **Diversity of projects** were submitted in terms of disease areas, device types, and study design
- We are **on schedule** to select the slate of projects in February 2019 *(stay tuned)*

CONNECT WITH NESTcc

Explore opportunities to connect with NESTcc online with the following resources:

Contact us to develop a partnership
NESTcc@mdic.org

Connect with us on Twitter
@NESTccMedTech

Check out our updates on the website
www.nestcc.org

Explore open opportunities for engagement
nestcc.org/opportunities

Initiate a request to use the NESTcc Data Network
nestcc.org/consultation

www.nestcc.org

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