



**Rachel Rath, MPH**

NESTcc Deputy Director

NESTcc Call For Concepts Public Webinar:  
Second Round of Real-World Evidence Test-Cases

July 27, 2018

## CALL FOR CONCEPTS WEBINAR AGENDA

---



### Welcome

---

### NESTcc Overview and Current Activities

---

### Review Call for Concepts for Broad Test-Cases

---



#### **Resources:**

*Open Opportunity for Second Round of Real-World Evidence Test-Case announcement and submission form*

---

## TERMINOLOGY DEFINITIONS

---

**NESTcc Data Network:** A network of organizations to help determine current capabilities, gaps, and priority areas of Real-World Data (RWD) and Real-World Evidence (RWE) for the medical device landscape.

**NESTcc Network Collaborator:** A range of organizations, companies, and collaborators that will be a resource of high-quality Real-World Data that include but are not limited to: Health Systems, Health Payers, Registries, Patient- or Device-Generated Data, Analytics Offerings, etc. These partnerships will help set data quality and methods standards for clinical studies due to their access to EHR and private claims data as well as linkage data with coverage information.



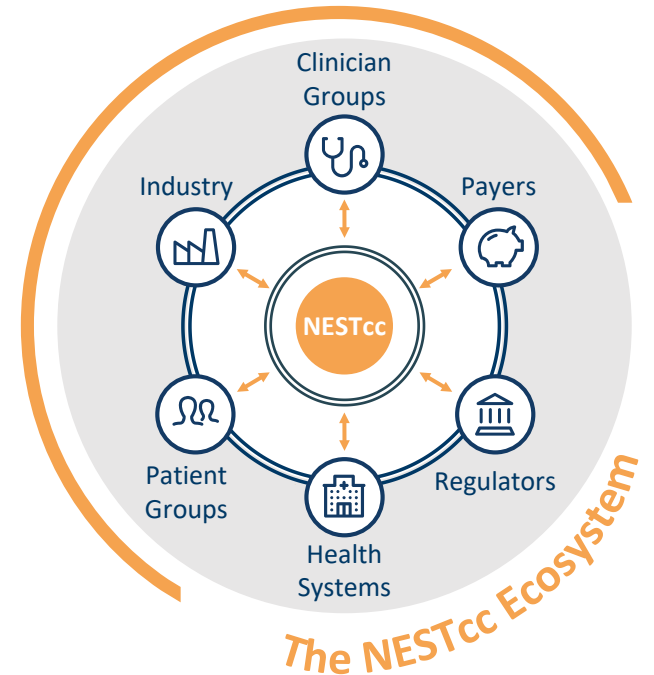
# NESTcc IN A SNAPSHOT

## 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 NEST envisioned as a **voluntary data network** of collaborators by Brookings Planning Board and Medical Device Registry Task Force
- 2016 FDA awarded grant for NESTcc to **Medical Device Innovation Consortium (MDIC)**
- 2017 NESTcc multi-stakeholder **Governing Committee** selected
- 2018 Initial **NESTcc Data Network** formed and testing initiated
- NESTcc **Data Quality** and **Methods Committees** formed
- NESTcc announces **Second Round of RWE Test-Case Call for Concepts**, and a targeted call for **Patient-Generated health Data (PGD)**



## NESTcc DEVICE NETWORK TIMELINE 2018

---

- Establish initial **NESTcc Data Network** with 11 Network Collaborators
- Implement test-cases** with manufacturers and NESTcc Network Collaborators
- Establish **Data Quality** and **Methods standards** as well as initial **NESTcc operating processes**
- Identify **optimal uses of NESTcc Data Network and gaps** (e.g. UDI) that need addressing
- Expand NESTcc Data Network** to include additional Network Collaborators



**CURRENT DATA NETWORK  
ACTIVITIES**

## BUILDING NESTcc'S DATA NETWORK

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

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



## BUILDING NESTcc'S DATA NETWORK

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



Completed Capabilities Surveys

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

Survey respondents represent:



150  
Hospitals



3,042+  
Outpatient Clinics

Patient data represents:



469M+

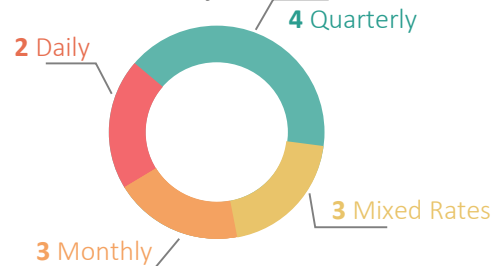
Patient Records

Common data models:

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

Network Collaborators report regular data

refreshes:



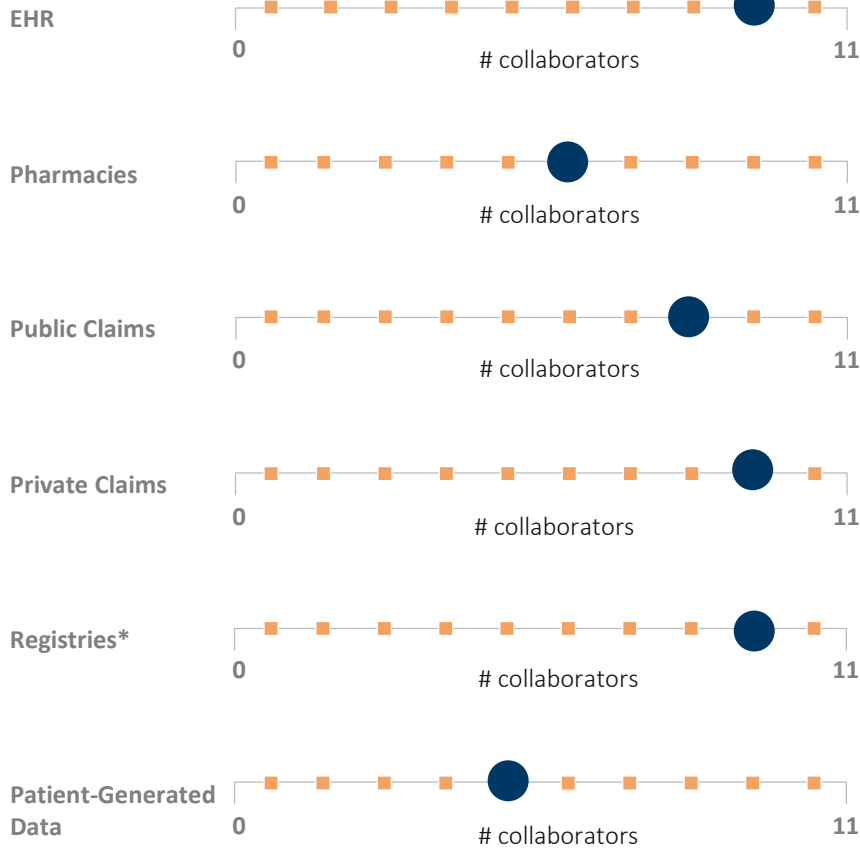
Most cited expertise:

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

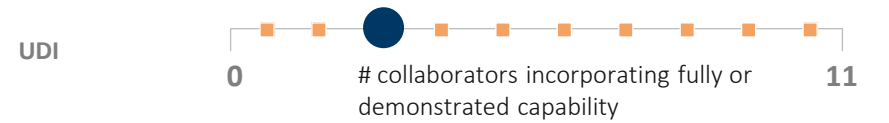
## CLOSER LOOK AT NESTcc'S DATA SOURCES

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)



## ROUND 1 RWE TEST-CASES: SUMMARY OF PROJECT SLATE

High-level concepts of each test-case currently in development are summarized below:

TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT	PRODUCT(S)	AREA
Label Expansion	Stent graft component product	Vascular
Pre-market Submission	Topical Skin Adhesive	Dermatology
Post-market Surveillance	Knee replacement	Orthopedics
Post-market Surveillance	Bone Distractor	Orthopedics
Post-market Surveillance	Spinal decompression device	Orthopedics
Move from General to Specific Indication	Device used for soft tissue ablation	Surgery (Oncology)
Label Expansion	Catheters used in Rx of Atrial Fibrillation	Cardiovascular
Patient Management Clinical Guidelines	Anti-coagulation dosage post mechanical heart valve (MHV) replacement	Cardiovascular

---

**BROAD RWE TEST-CASE  
CALL FOR CONCEPTS**

---

## CONCEPTS FOR BROAD RWE TEST-CASE ANNOUNCEMENT

NESTcc is interested in receiving recommendations from industry, health system providers, and health payers for test-cases using RWE that could be executed with NESTcc's Network Collaborators.

### MISSION OF TEST-CASES

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



Explore the feasibility for industry to use Real-World Data sources (EHR, public and private claims, registries, etc.) offered by NESTcc's Network Collaborators.



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

## CONCEPT DETAILS AND REQUIREMENTS

---

NESTcc is interested in receiving a broad range of test-cases. The following eligibility criteria and priority areas listed were informed by the first round of test-cases submitted.

### ELIGIBILITY CRITERIA

---

- Concepts may be submitted by:
  - Medical device, imaging, and diagnostics technology manufacturers
  - Multi-industry collaborations (submitting through an organization or association as a third-party convener)
  - Health system providers and health payer groups
- Projects that are not currently underway

### PRIORITY AREAS

---

- Test-cases addressing FDARA and MDUFA IV requirements, especially evidence supporting a **new clearance or approval**
- Test-cases intended for pre-market (new clearance or approval) and coverage (payer) decision purposes
- Imaging or diagnostic technologies
- Technologies to diagnose and treat cancer



## TEST-CASE EXAMPLES

---

The following are two examples of test-case concepts, supplementing information available in the Call for Concepts.

### **ORTHOPEDIC TEST-CASE**

---

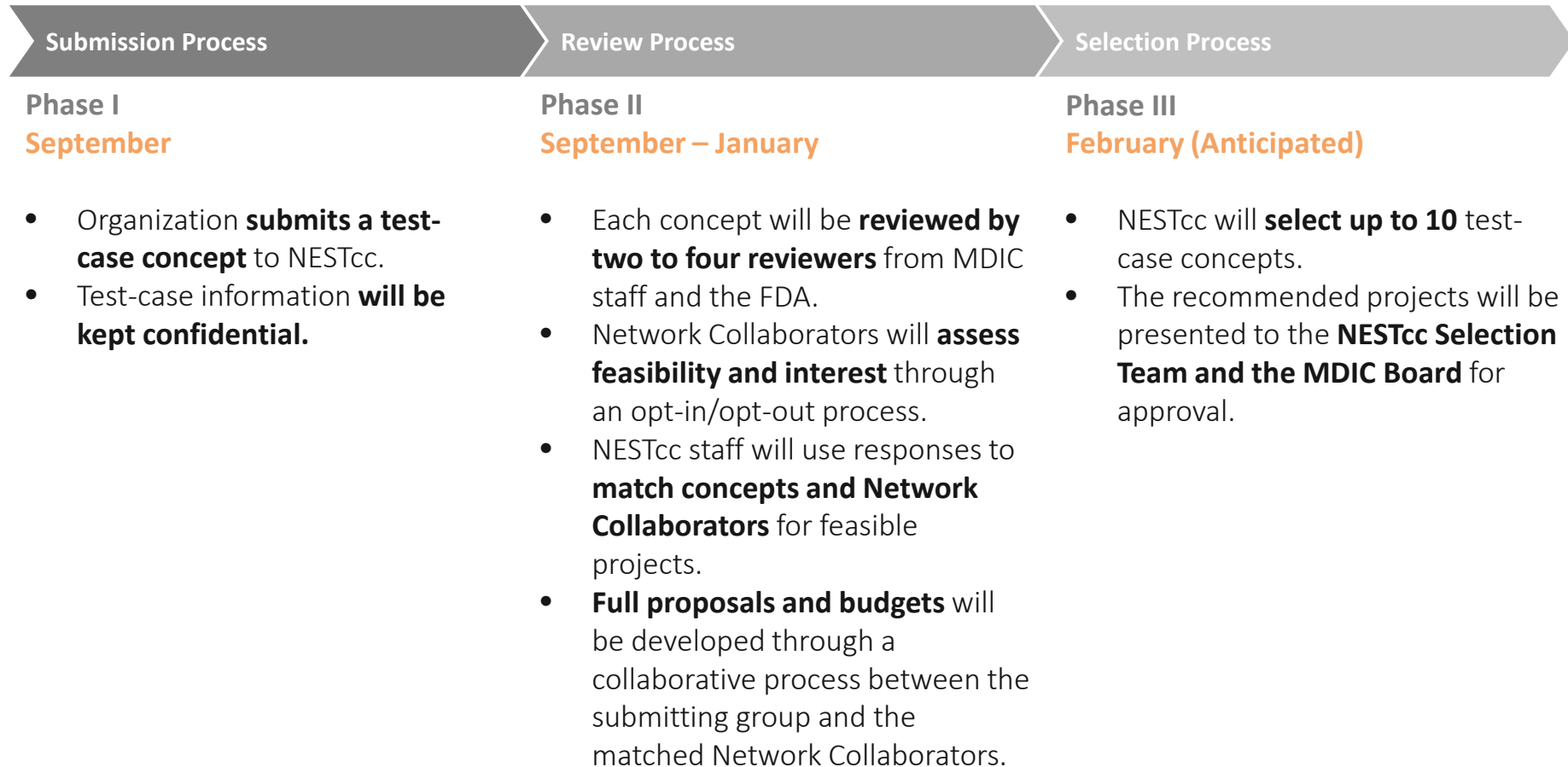
- ✓ Explore the feasibility of using Real-World Data (RWD) for proactive post-market surveillance.
- ✓ Assess the availability of data for regulatory obligations (necessary data elements, estimation of sample size, and representativeness of the sample for purposes of generalizability to the patient population of users) for one orthopedic device.
- ✓ The population of interest is pediatric patients undergoing craniofacial reconstruction.
- ✓ Develop capacity to coordinate data access through data use agreements, common data models or interoperability of data elements for analysis, linkage opportunities and decreased risk to patient privacy.

### **TOPICAL SKIN ADHESIVE (TSA) TEST-CASE**

---

- ✓ Develop the value proposition for a new device to bring to the US market that is currently approved in the EU and not in the US.
- ✓ The population of interest is patients treated for wound closure with at least six months of data available.
- ✓ Explore the feasibility of using Real-World Data (RWD) for a retrospective analysis to evaluate the outcomes of alternative approaches for skin closure methods (TSA, staples, sutures, and combinations) for skin wounds.
- ✓ Assessing outcomes of interest such as the type of surgery, the type of wound or surgical laceration, and adverse events or complications, as well as efficacy and cost-effectiveness.

## SUBMISSION, REVIEW AND SELECTION PROCESS



## ADDITIONAL CONSIDERATIONS

---

- ✓ NESTcc may request additional information from submitters to facilitate its matching process.
- ✓ Funds from NESTcc will be available to support the selected test-cases. Funding will go to Network Collaborators participating in the projects.
- ✓ NESTcc will request full project proposals and budgets at later date.
- ✓ NESTcc anticipates providing \$250-550k per project, depending on the award structure and number of participating Network Collaborators participating in each project.

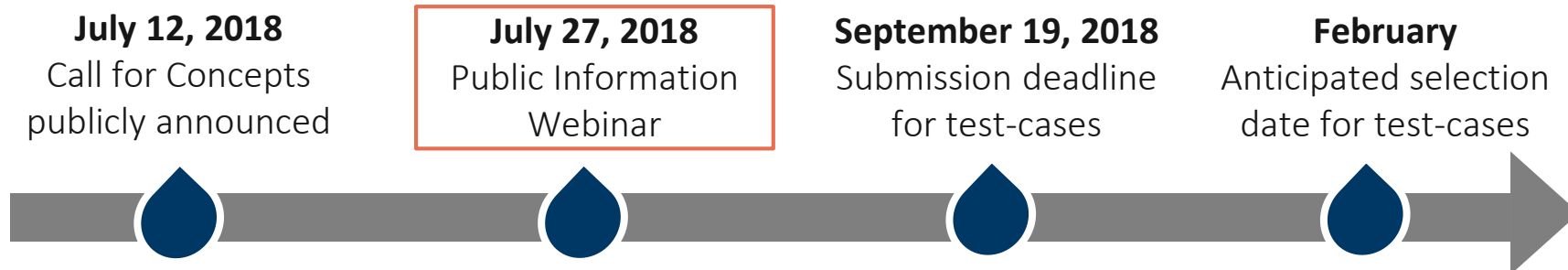
## KEY DATES AND REMINDERS

---

### SUBMISSION REMINDERS

- Submissions for test-case concepts should be submitted to NESTcc Project Manager, Tiffany Abushaikha, at [NESTcc@mdic.org](mailto:NESTcc@mdic.org).
- The deadline for submitting concepts is 5p.m. EDT on September 19, 2018.
- A required submission template is available [here](#), and can also be found at <https://nestcc.org/opportunities/>.
- The concept submission must not exceed two (2) pages.
- Please direct all questions to the NESTcc team at [NESTcc@mdic.org](mailto:NESTcc@mdic.org).

### OPPORTUNITY TIMELINE







[www.nestcc.org](http://www.nestcc.org)



[@NESTccMedTech](https://twitter.com/NESTccMedTech)



[nestcc@mdic.org](mailto:nestcc@mdic.org)