



Rachael L. Fleurence, PhD

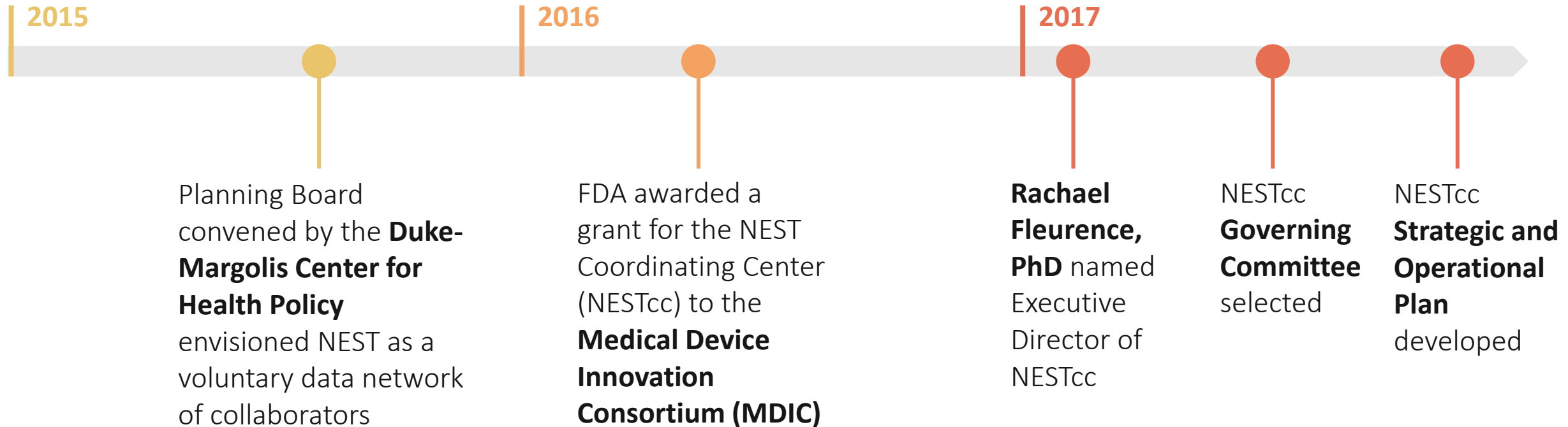
NESTcc Executive Director

April 19, 2018

**Establishing the National Evaluation
System for health Technology
Coordinating Center (NESTcc)**

HISTORY OF NEST

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.



THE ECOSYSTEM CHALLENGE

The health care ecosystem is united behind the need to improve patients' timely access to safe and effective devices as well as to improve the quality of life for patients with medical devices.

NESTcc was developed to tackle the lack of **high quality, near real-time, and low cost evidence** to support:



Regulatory decision-making across the Total Product Life Cycle (TPLC) for the **FDA and medical device industry**



Clinical decision-making for **patients and clinicians**



Purchasing decisions and quality of care for **health systems**



Coverage decisions for public and private **payers**

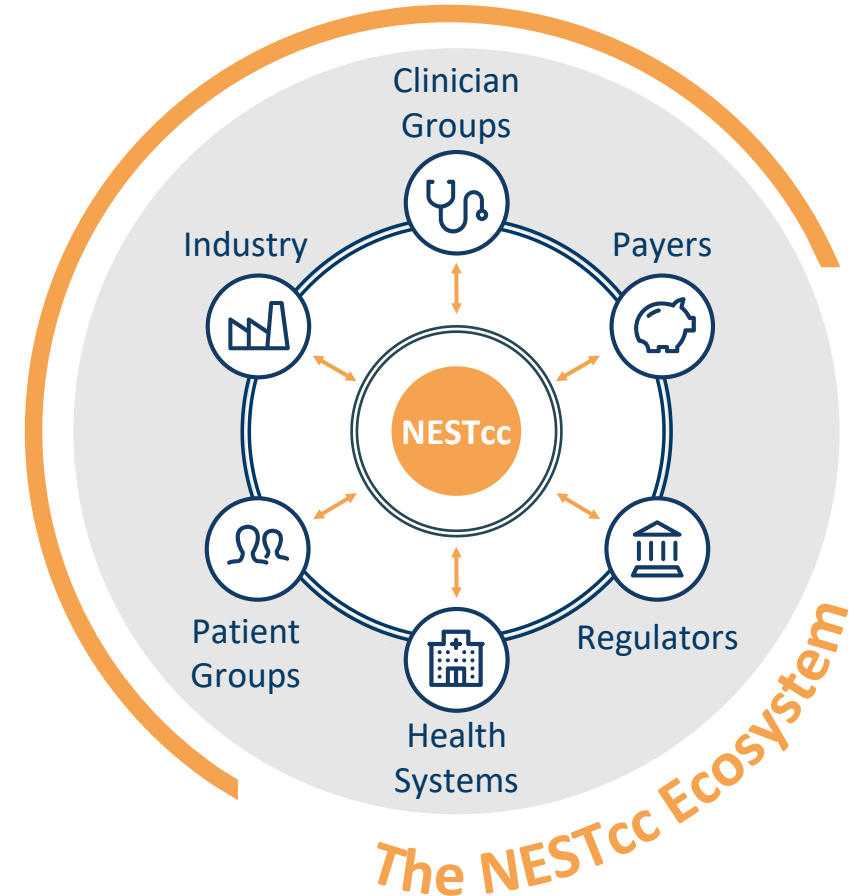
NESTcc'S ROLE IN THE ECOSYSTEM

Mission

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

Vision

To be the leading organization within the health technology and medical device ecosystem for conducting efficient and timely high-quality Real-World Evidence (RWE) studies throughout the Total Product Life Cycle (TPLC).



What value is NESTcc adding to the ecosystem that is not already there ?



ESTABLISH NESTcc GOVERNANCE

Through an open call for nominations published in January 2017, the inaugural NESTcc Governing Committee was formed.

The NESTcc Governing Committee represents a **diverse set of stakeholder groups**, including:



PATIENT
REPRESENTATIVES



CLINICIANS



FEDERAL
REPRESENTATION



PAYERS



HEALTH
SYSTEMS



MEDICAL DEVICE
EXPERTS

NESTcc GOVERNING COMMITTEE

The NESTcc Governing Committee represents stakeholders across the medical device ecosystem.

NAOMI ARONSON

Blue Cross Blue Shield Association (BCBSA)

KATHLEEN BLAKE

American Medical Association (AMA)

MARK DEEM – MDMA Nominee

The Foundry, LLC

PAMELA GOLDBERG

Medical Device Innovation Consortium (MDIC)

BILL HANLON – ACLA Nominee

LabCorp/Covance

ADRIAN HERNANDEZ

Duke Clinical Research Institute (DCRI)

HARLAN KRUMHOLZ

Yale University

ELIZABETH MCGLYNN

Kaiser Permanente

MICHELLE MCMURRY-HEATH – AdvaMed Nominee

*Interim Governing Committee Chair
Johnson & Johnson Medical Devices*

VANCE MOORE

Mercy Health

JEFFREY SHUREN

FDA, CDRH

SHARON TERRY

Genetic Alliance

DIANE WURZBURGER – MITA Nominee

GE Healthcare

MARC BOUTIN

National Health Council

TAMARA SYREK JENSEN

Center for Clinical Standards and Quality, CMS

■ Trade Association Nominees



Launching the NESTcc Data Network

DEVELOP NESTcc'S ROLE

NESTcc will develop its role to build a sustainable network of collaborators committed to advancing RWE generation.

Engage

- Designated 11 **NESTcc Demonstration Projects** to learn opportunities and challenges of using RWE to meet regulatory and coverage requirements
- Initiated **analysis of the value for industry stakeholders of RWE**

Leverage

- Executed MOUs with initial set of **11 NESTcc network collaborators** to begin to establish NESTcc's Data Network launch
- Began implementing feasibility testing with network collaborators for **test-cases** from industry

Transform

- In 2018, will identify barriers for **research-ready medical device data infrastructure** and work to address these
- In 2018, will establish **data quality** and **methods standards**



DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

NESTcc is focusing on leveraging RWE in use cases across the total product life cycle.

Ability to Support Use Cases Across the Total Product Life Cycle (TPLC)

	Principle Investigator(s), Demonstration Project	Pre-Market: Pre-Market Approval, 510(k), De Novo	Label Expansion	Post-Market: including Post- Approval Studies (PAS)	Surveillance	Coverage
Engage Leverage Transform	Morales, Cronenwett, Thatcher: RAPID	○				
	Kong, White, Krucoff: SAFE-STEMI	○				
	Dreyer: Lung-RADS	△		△		
	Waters: SHIELD			□		
	Goodney, Sedrakyan: Vascular Implant Networks				○	
	Resnic: ICD-DELTA				○	
	Dujmovic, Hinrichs, Johnson, Slotwiner: EP PASSION			○		
	Atwater & Piccini: Medicare & Implantables			○		
	Lampert: mHealth			○		
	Johnson & Drozda: EHR-Based Data Network	○				
	Ross & Shah: mHealth			○		

Pre-Market

Regulatory Decision

Post-Market



Key

△	Imaging	○	Traditional
□	Diagnostics		

DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

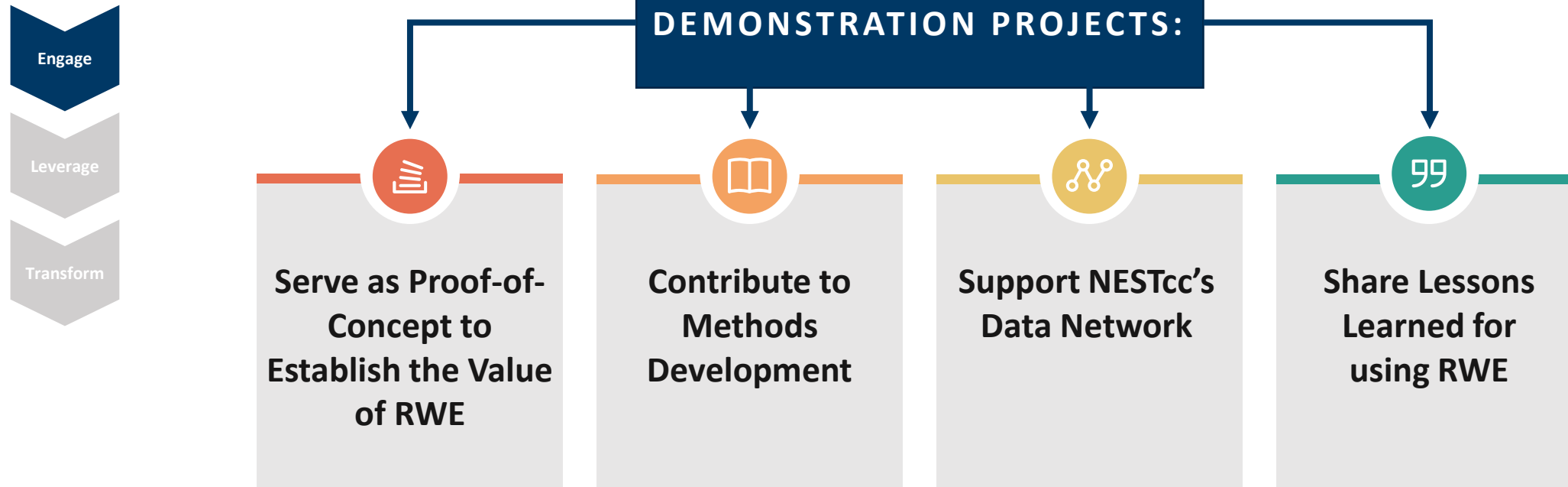
NESTcc Demonstration Projects are studies that contribute to the field of RWE within the medical device ecosystem. While ranging in scope and size, Demonstration Projects are expected to:



- ✓ Develop, verify, and operationalize methods of evidence generation and data use in the pre- and post-market space
- ✓ Demonstrate scalability across healthcare systems, device types, and manufacturers
- ✓ Demonstrate impact on patients by stimulating innovation in medical device innovation and decreasing the timeline for development and market launch
- ✓ Inform NESTcc's strategy as it builds out critical functions and processes for a future sustainable organization

DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Demonstration Projects derive value across the development of NESTcc, informing NESTcc's strategy and execution.



DEVELOP NESTcc'S ROLE: TEST-CASES

NESTcc solicited submissions from industry for RWE test-cases that we will seek to implement with 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

Engage

Leverage

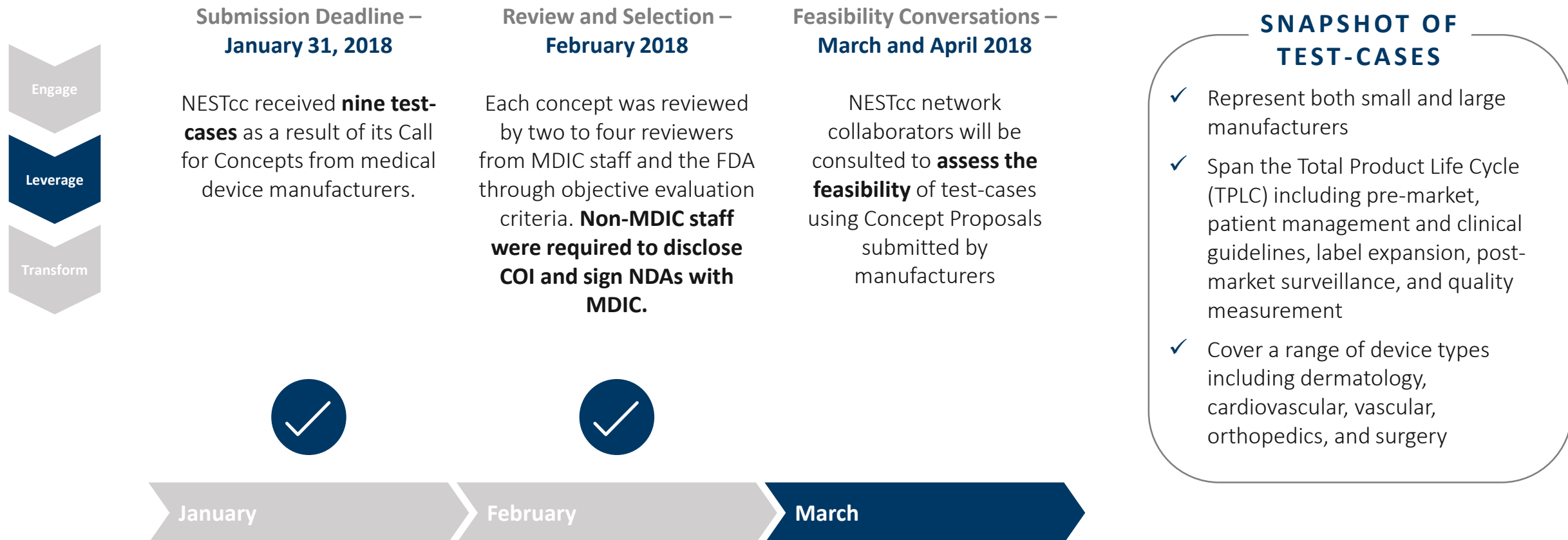
Transform



- 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

DEVELOP NESTcc'S ROLE: TEST-CASES

NESTcc solicited submissions from industry for RWE test-cases to assess feasibility. Test-cases are intended to explore network collaborators' ability to capture data needed to support a range of studies and analyses.



DEVELOP NESTcc'S ROLE: TEST-CASES

To better understand the capabilities of its Data Network, NESTcc is facilitating collaboration between network collaborators and test-case manufacturers, whose de-identified concepts are summarized below:

	TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT	PRODUCT(S)	AREA
 Engage Leverage Transform	Pre-Market Submission	Topical Skin Adhesive	Dermatology
	Label Expansion	Devices used in Rx of Atrial Fibrillation	Cardiovascular
	Label Expansion	Stent graft component product	Vascular
	Move from General to Specific Indication	Device used in surgery	Surgery
	Post-market Surveillance	Knee replacement	Orthopedics
	Post-market Surveillance	Various Devices	Orthopedics
	Patient Management Clinical Guidelines	Anti-coagulation dosage following mechanical heart valve (MHV) replacement	Cardiovascular
	Quality Measurement	Endoscopes	General Hospital Device

DEVELOP NESTcc'S ROLE: TEST-CASES

NESTcc has identified two test-cases examining orthopedic devices that are undergoing feasibility testing with network collaborators.

ORTHOPEDIC TEST-CASE EXAMPLE I



- ✓ Explore the feasibility of using real world data (RWD) for proactive post-market surveillance that fulfills regulatory obligations (necessary data elements, sufficient sample size, and representativeness of the sample for purposes of generalizability to the patient population of users) for three orthopedic devices.
- ✓ The population of interest is patients undergoing craniofacial reconstruction (mostly pediatric patients), spinal decompression/intervertebral body fusion, and ligament/tendon joint attachment.
- ✓ The project will explore proactive surveillance for each device of interest.

ORTHOPEDIC TEST-CASE EXAMPLE II

- ✓ Evaluate the feasibility of combining a limited sample of registry data with private claims payments from NESTcc network collaborators.
- ✓ Project will look at primary total knee replacement surgical procedures and implants in younger (<65 years of age) patients.
- ✓ Outcomes of interest will include readmission, reoperation, and revision (removal of implant).
- ✓ The project will look at 90 day, 1 year, and 2 year post-surgery data, as available from collaborators.

DEVELOP NESTcc'S ROLE: BUILDING A 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 11 COLLABORATORS:

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



DEVELOP NESTcc'S ROLE: BUILDING A DATA NETWORK

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



Network Collaborators

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

Network collaborators represent:



150
Hospitals



3,042+
Outpatient
Clinics

Patient data represents:



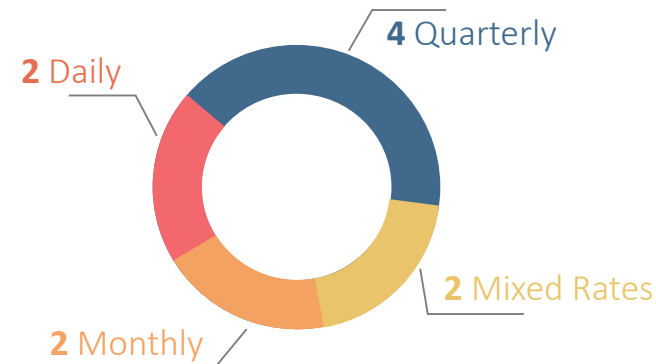
469M+

Patient
Records

Common data models:

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

*Collaborators report
regular data refreshes:*

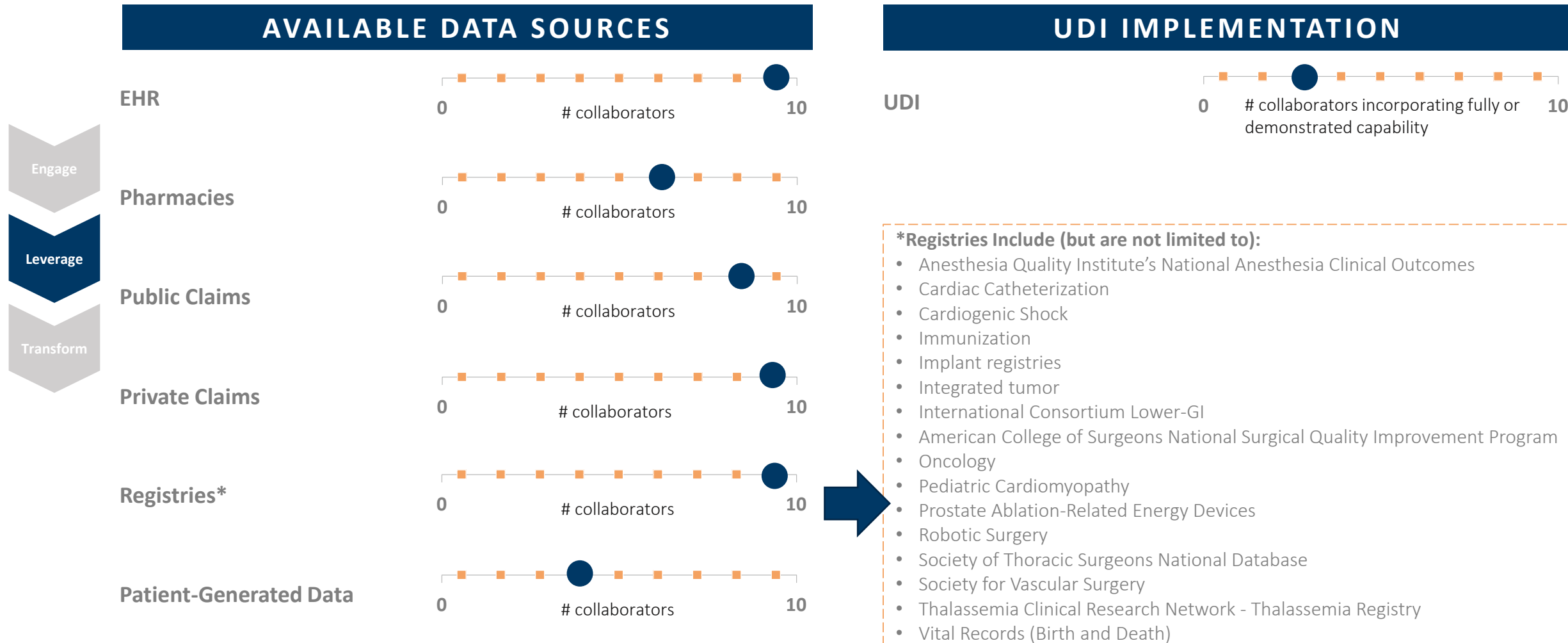


Most cited expertise:

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

DEVELOP NESTcc'S ROLE: BUILDING A DATA NETWORK

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



DEVELOP NESTcc'S ROLE: BUILDING A DATA NETWORK

NESTcc will support its Data Network by helping streamline administrative processes, reducing transaction costs, and offering research assistance.



REDUCING TRANSACTION COSTS

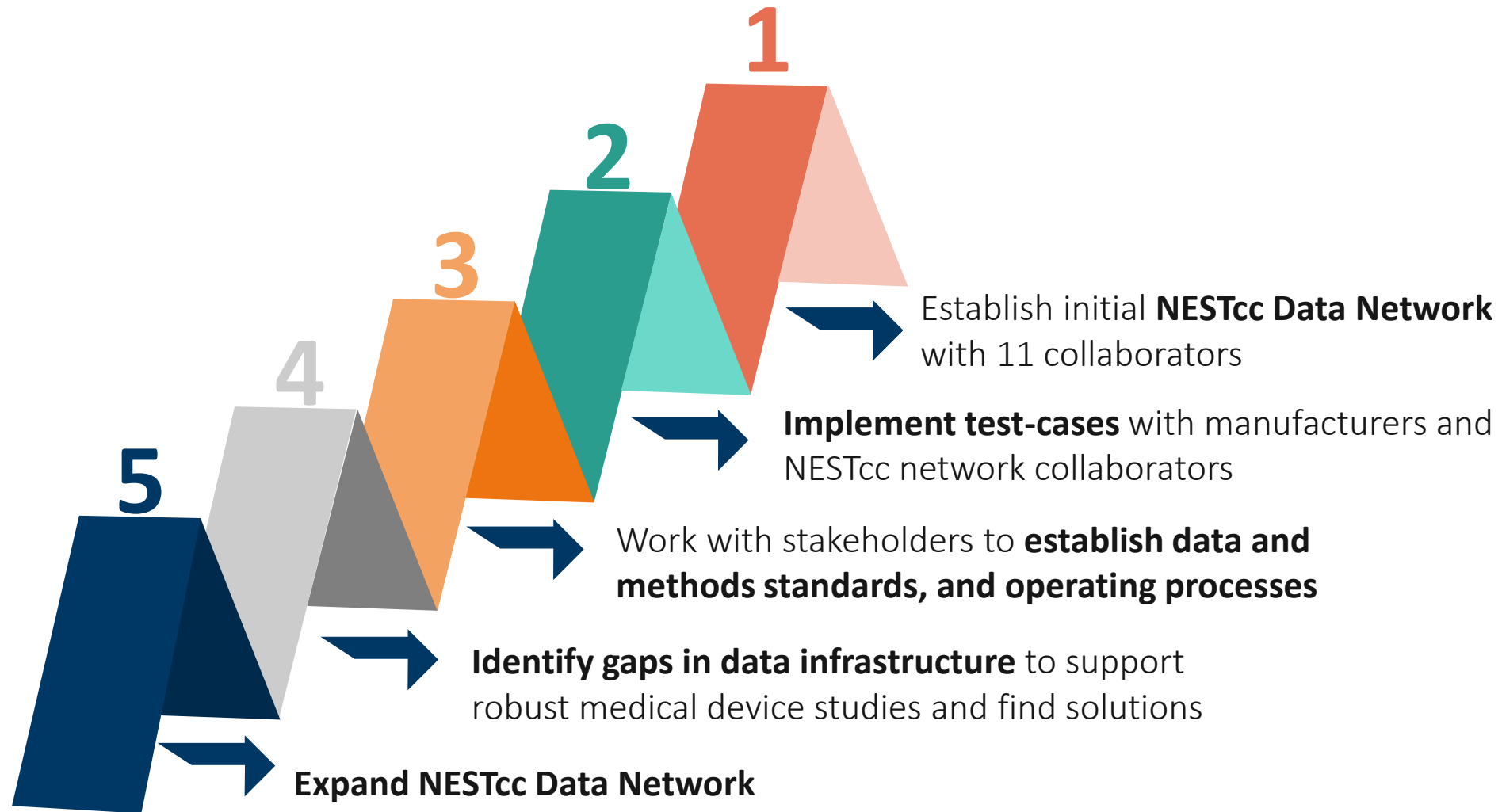
- ☐ Putting in place an umbrella non-disclosure agreement (NDA) with NESTcc Network Collaborators
- ☐ Developing a participation agreement defining roles and responsibilities of NESTcc and Network Collaborators
- ☐ Developing a Master Services Agreement between the Network Collaborators and the NESTcc to accelerate contracting time



TYPES OF RESEARCH OFFERED

- ☐ Prep to research questions (e.g. size and type of patient population with a specific condition or device)
- ☐ Identification of patients for clinical trials and identification of clinical trial sites
- ☐ Retrospective observational studies with de-identified data
- ☐ Prospective observational studies with patient consent
- ☐ Patient surveys and patient-generated data with patient consent
- ☐ Interventional/randomized studies (not in the short term)





NESTcc PROGRESS: A SNAPSHOT

Selected Teams for RWE Assessment and Value Analysis Initiatives



Initial Data Network Underway

NESTcc Network Collaborators Represent:



Collaborators



150 Hospitals



3,042+ Outpatient Clinics

Designated Demonstration Projects

24 Total Submitted

11 Total Selected

Primary Focus Area

2 Surveillance

6 Post-Market

3 Pre-Market



@NESTccMedTech



www.nestcc.org

Governing Committee Activity



Seven Governing Committee Meetings

Average attendance of 11/15 members per meeting

Business Plan Input



- Data Collaborators
- Industry
- Other Stakeholders

Communications Platforms Launched



June 2017

NESTcc Twitter (@NESTccMedTech)



November 2017

NESTcc LinkedIn

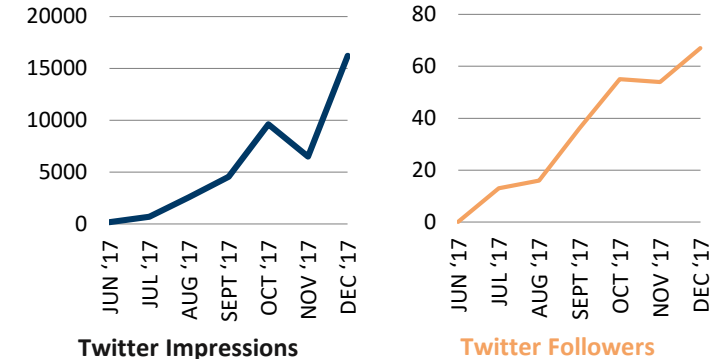


December 2017

NESTcc Website (www.nestcc.org)



Social Media Engagement



Events and Conferences

2017 Key Conference Presentations

- September**
 - ◆ RAPS
 - ◆ IMDRF Open Stakeholder Day
 - ◆ NIH Grand Rounds
 - ◆ AdvaMed MedTech Conference
- October**
 - ◆ MDIC Annual Public Forum
 - ◆ MDEpiNet Annual Meeting
 - ◆ ICHOM
- November**
 - ◆ TCT 2017

Upcoming Events and Conferences

Confirmed

- Health Datapalooza – April 26-27, 2018
- FDA/Xavier MedCon Conference – May 1-4, 2018
- ISPOR Baltimore – May 19-23, 2018

Submitted

- Academy Health 2018 ARM – June 24-26, 2018
- RAPS Regulatory Convergence 2018 – October 1-4, 2018



www.nestcc.org



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



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