NEST

National Evaluation System for health Technology

Coordinating Center

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NESTcc Executive Director

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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

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 Planning Board

2016

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

2017

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

NESTcc DEVICE NETWORK TIMELINE 2018

- Establish initial **NESTcc Data Network** with 11 collaborators
- **Implement test-cases** with manufacturers and NESTcc network collaborators
- Work with stakeholders to **establish data quality and methods standards as well as operating processes**
- **Identify gaps in data infrastructure** to support robust medical device studies and find solutions
- **Expand NESTcc Data Network**

FRAMEWORK STRATEGY TO ACHIEVE ESTABLISHED GOALS

To achieve success, NESTcc will focus on four strategic priority areas outlined in the Strategic and Operational Plan:

1. Establish NESTcc **Governance**
2. Develop NESTcc's **Role**
3. Establish NESTcc's **Value**
4. Ensure NESTcc **Stakeholder Engagement**

1 ESTABLISH NESTcc GOVERNANCE

NESTcc will establish an effective governance structure to support short-term activities and long-term goals.

ACTIVITIES TO DATE

- Selected NESTcc **Executive Director**
- Established functional and efficient NESTcc **Governing Committee**
- Grew NESTcc team to include **five full-time staff** members
- Approved **four** NESTcc Governance **Subcommittees**
- Finalized NESTcc **Mission** and **Vision** Statements

UPCOMING ACTIVITIES

- **Selection of Chair and Lead Director** for NESTcc Governing Committee
- **Amend Governing Committee Charter** to reflect changes
- Launch the **Methods Consultation Subcommittee** and **Data Quality Consultation Subcommittee**

1 ESTABLISH NESTcc GOVERNANCE

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

1 ESTABLISH NESTcc GOVERNANCE: SUBCOMMITTEES

NESTcc is launching four subcommittees to achieve sustainability and establish its value in the medical device ecosystem.

NESTcc GOVERNING COMMITTEE MEMBERS

CHARTER

Make recommendations related to the NESTcc Charter and determination of roles and responsibilities between NESTcc governing and decision-making entities

SUSTAINABILITY

Provide strategic input to the development and implementation of the business, operating, and financial NESTcc sustainability models

STAKEHOLDERS SELECTED THROUGH A PUBLIC CALL

DATA QUALITY

Establish data quality standards and address issues with data quality, particularly as they impact NESTcc's mission

METHODS

Develop a research agenda identifying critical issues in methods across the TPLC and establish methods standards to include device specific considerations

2 DEVELOP NESTcc'S ROLE: THREE-PRONGED APPROACH

NESTcc is building a sustainable network of collaborators committed to advancing RWE generation.

Engage

- 11 **Demonstration Projects** covering a range of uses of Real World Evidence
- 7 **case-studies** underway to describe the **value** for industry stakeholders of using RWE

Leverage

- **11 NESTcc network collaborators** are pioneering the establishment of NESTcc's Data Network.
- **7 RWE test-cases** are launching to demonstrate proof of concept.

Transform

- Continue to identify barriers for **research-ready medical device data infrastructure** with our partners
- Establish **data quality** and **methods standards** through **subcommittees** of experts

2 DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

NESTcc's role will be established through use cases that span the Total Product Life Cycle (TPLC) and include interventional and observational study designs.

Engage

Leverage

Transform

PRIORITY USE CASES

Pre-Market: PMA, 510(k), De Novo

Using RWE to inform pre-market development or incremental improvement of medical devices

Label Expansion

Using RWE in a regulatory submission to support an expanded indication for use of medical devices already on the market

Post-Market Approval Studies (PAS)

Using generated RWE to track medical device's safety and effectiveness as part of its condition of approval

Surveillance

Using generated RWE to track and document medical device safety and effectiveness for products on the market

Coverage

Using generated RWE to support coverage and reimbursement decisions by public and private payers

2 DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Demonstration Projects are led by experts in the medical device field and are testing innovative approaches to evidence generation using Real-World Data (RWD) across device types and the TPLC.

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NESTcc DEMONSTRATION PROJECTS

- Led by experts in the field from academia, industry, and the FDA
- Identify **barriers and strengths** of using RWE in medical device studies
- Have potential for **scalability** across healthcare systems, device types, and manufacturers—using projects already underway
- Inform **NESTcc's strategy** and form NESTcc's learning network

NESTcc 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
- Identify areas where NESTcc could play a role in **reducing transaction costs**

TARGETED PROJECTS TO DEVELOP NESTcc AS A LEARNING NETWORK

2 DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

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

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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
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; □ Diagnostics; ○ Traditional

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DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Project Title	PIs	Orgs.	Project Overview
Developing and Implementing Sustainable Real-World Evidence (RWE) Infrastructure for In Vitro Diagnostics (IVDs) Through Systemic Harmonization and Interoperability for Enhancement of Laboratory Data (SHIELD)	Michael Waters, PhD (FDA)	U.S. Food and Drug Administration (FDA); Collaborators include: 5 government offices, 7 IVD manufacturers, 5 healthcare systems, and 10 professional organizations and standards developers	• Study Design: Harmonization and mapping of IVD related codes (i.e., LOINC®, SNOMED-CT, and UCUM) • NESTcc Use-Case: infrastructure to support IVDs future pre- and post-market needs • Population/Device: pilots planned in 1) testing for antimicrobial susceptibility/resistance, 2) opioid screening and confirmatory testing, 3) testing for acute kidney injury, and 4) diagnosis of sepsis. • RWD/Methods: mapping of relevant codes • Significance: improve interoperability of information related to IVDs
Electrophysiology Predictable and Sustainable Implementation of National Registries (EP PASSION)	Rich Dujmovic, MSEM (Boston Scientific); Heidi Hinrichs, MS (Abbott); Darrell Johnson, MBA (Medtronic); Kevin Mitchell (BIOTRONIK, Inc.); David Slotwiner, MD (Heart Rhythm Society)	Abbott; American College Cardiology (ACC); BIOTRONIK, Inc.; Boston Scientific; Duke; Heart Rhythm Society (HRS); LivaNova (Sorin); Medtronic; U.S. Food and Drug Administration (FDA); Yale	• Study Design: observational study • NESTcc Use-Case: Post-approval studies, future • Population/Device: new and substantially modified pacing and defibrillation leads • RWD/Methods: by linking administrative claims, electronic health records, remote monitoring and periodic patient contacts • Significance: use of RWD to increase efficiency and lower cost as well as capture a larger, more representative assessment of device performance

Feasibility Study to Evaluate the use of mHealth as Data Source in Post-Market Surveillance	Rachel Lampert, MD (Yale)	Me2Health, Medtronic, Yale University	• Methodology:
			  • Prospective, non-randomized, observational, single-center study using an mHealth app (Hugo) to aggregate data from patient portals and share with manufacturer for safety event reporting and comparison to traditional collection methods
			• Proposed Research Outputs:
			  • Data analysis; Final report

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DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Project Title	PIs	Orgs.	Project Overview
ICD Registry DELTA Active Surveillance Pilot Study	Frederic S. Resnic, MD (Lahey Hospital and Medical Center)	American College of Cardiology (ACC); Lahey Hospital and Medical Center (Tufts University School of Medicine) NCDR ICD Registry; U.S. Food and Drug Administration (FDA) - CDRH	• Study Design: observational study • NESTcc Use-Case: surveillance • Population/Device: high-energy implantable cardiac defibrillator (ICD) leads • RWD/Methods: NCDR ICD Registry/the propensity-matched survival method • Significance: Validation of time-dependent adverse event surveillance projects. Possible alternative to post-approval studies.
Lung-RADS Assist: Artificial Intelligence Model Verification, Reporting, and Monitoring	Keith Dreyer, DO, PhD (Massachusetts General Hospital)	American College of Radiology *Implementation Sites:* Brigham & Women's, Massachusetts General Hospital *Radiology Workflow Companies:* GE Healthcare, Nuance *Algorithm Vendors:* Aidence, Enlitic, Infervision, Mindshare Medical	• Study Design: Artificial Intelligence (AI) validation study and AI surveillance model • NESTcc Use-Case: pre-market (model validation) and post-market (model performance) • Population/Device: Lung cancer screening/AI algorithm • RWD/Methods: Use of the ACR Lung CT Screening Reporting and Data System (Lung-RADS) to test and deploy the AI algorithm • Significance: example of use of RWD to test and validate an AI algorithm. Learnings will be scalable to other disease areas.

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DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Project Title	PIs	Orgs.	Project Overview

Post-Market Medical Device Surveillance With a Novel mHealth Platform	Joseph Ross, MD (Yale), Nilay Shah, PhD (Mayo Clinic)	Center for Excellence in Regulatory Science and Innovation (CERSI), Johnson & Johnson, Me2Health, U.S. Food and Drug Administration (FDA), Yale-Mayo Clinic	• Methodology:
			  • Feasibility study using an mHealth app to merge together four data sources into a research-ready database
			• Proposed Research Outputs:
			  • Research database; Feasibility study

Registry Assessment of Peripheral Interventional Devices (RAPID) - Superficial femoral and Popliteal Evidence Development (SPEED) as First Device Evaluation Project	Jack Cronenwett, MD (SVS), Jose Pablo Morales, MD (FDA), Robert Thatcher, MBA (4C Medical Technologies)	MDEpiNet Executive Operations Committee; Over 36 organizations, including 3 registries/societies, 7 federal agencies, 12 device manufacturers, and 16 other related companies/organizations	• Study Design: observational study (getting more information) • NESTcc Use-Case: Pre-market/Objective Performance Criteria development – potential to support label expansions • Population/Device: Peripheral Vascular Intervention (PVI) Devices • RWD/Methods: linkages with CATH PVI registry • Significance: use of RWD to develop OPCs which once available could accelerate regulatory decisions
SAFE STEMI for Seniors: An International CRN-Based Prospective Randomized IDE Study of Labelling for Diagnostic and Therapeutic Devices Used in Seniors Suffering Heart Attack	David F. Kong, MD (DCRI), Mitchell W. Krucoff, MD (DCRI), Roseann White, MA (DCRI)	CDRH; CMS; Duke University/Duke Clinical Research Institute (DCRI); Harvard University Quantitative Angiographic Core Laboratory; MDEpiNet PASSION CV Programs; Medtronic; NCDR; Terumo; Volcano/Philips	• Study Design: prospective randomized study • NESTcc Use-Case: Pre-market/Investigational device exemption (IDE) study for regulatory labelling of two devices, IFR diagnostic wires and therapeutic DES • Population/Device: seniors undergoing urgent PCI for STEMI • RWD/Methods: linkages with CATH PCI registry and Medicare Claims data (ascertainment of AEs) • Significance: use of RWD in an IDE study to increase efficiency and lower cost of traditional clinical trial

2 DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Project Title	PIs	Orgs.	Project Overview

Use of EHR-Based Data Network to Support Evidence Generation Across the Total Product Life Cycle (TPLC)	Joseph Drozda, MD (Mercy), Darrell Johnson, MBA (Medtronic)	Medtronic, Mercy	• Methodology:
			  • Application of a systematic EHR data access and usage process including tools and techniques
			  • Cross-functional, cross-institutional collaboration and reviews (e.g. with other hospital systems or working groups)
			• Proposed Research Outputs:
			  • Technical data warehouse and cloud infrastructure
			  • Data network value and usability assessment
			  • Systems, processes and workflow adjustments
			  • Recommendations regarding functions and activities for a sustainable NESTcc including a framework, requirements, and guidelines

Use of Linked Implantable Device/Medicare Data to Assess Association Between Device Diagnostics and Patient Outcomes	Brett Atwater, MD (Duke), Jonathan Piccini, MD (Duke)	Abbott; Department of Population Health; Duke University (Duke Clinical Research Institute (DCRI); Duke Center for Arrhythmia Research & Treatment Innovation)	• Study Design: retrospective observational study • NESTcc Use-Case: label expansions and post market assessments • Population/Device: implantable cardioverter defibrillator and pacemakers • RWD/Methods: linkages of remote-monitoring data (Merlin.Net) with CMS Medicare data to explore association between stored device diagnostics and clinical and economic outcomes • Significance: novel exploration of linkages of device-generated data with claims data to support clinical evidence generation
Vascular Implant Surveillance and Interventional Outcomes Network (VISION)	Philip P. Goodney, MD, MS and Art Sedrakyan, MD, PhD (Society for Vascular Surgery Patient Safety Organization)	Society for Vascular Surgery Patient Safety Organization (SVS-PSO); U.S. Food and Drug Administration (FDA); Weill Cornell Medical Center	• Study Design: observational study • NESTcc Use-Case: post-market reporting, post-market surveillance • Population/Device: Over 65 (looking to expand to under 65)/vascular devices such as those used for endovascular abdominal aortic aneurysm repair • RWD/Methods: clinical registry (SVS-PSO registry) and Medicare Claims and New York State Registry data (SPARCS) • Significance: use of RWD to increase efficiency, validity and cost of device surveillance

2 DEVELOP NESTcc'S ROLE: DEMONSTRATION PROJECTS

Demonstration Projects generate value across the development of NESTcc, informing strategy and execution.

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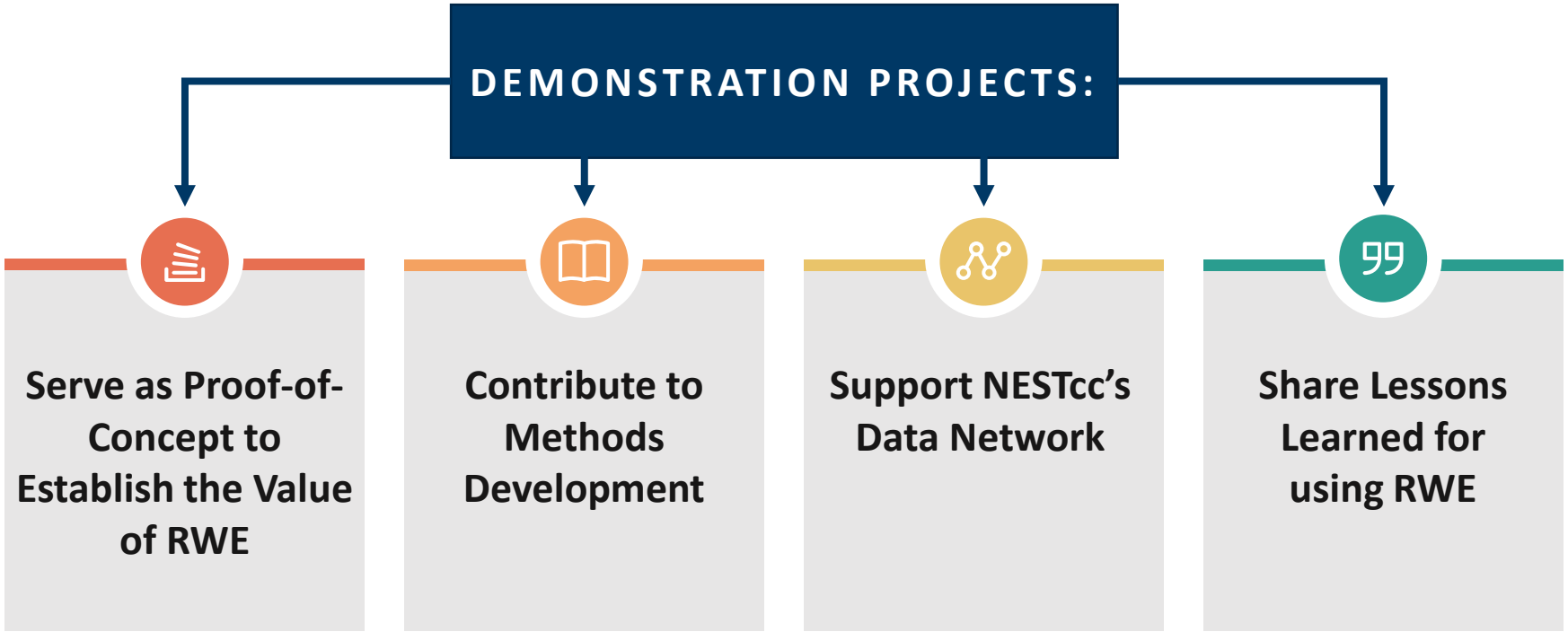

2 DEVELOP NESTcc'S ROLE: LAUNCHING TEST-CASES

NESTcc solicited submissions from industry for RWE test-cases that it 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.

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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

2 DEVELOP NESTcc'S ROLE: LAUNCHING 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.

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Submission Deadline – January 31, 2018

NESTcc received **nine test-cases** as a result of its Call for Concepts from medical device manufacturers.

Review and Selection – February 2018

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

Feasibility Conversations – March and April 2018

NESTcc network collaborators will be consulted to **assess the feasibility** of seven test-cases using Concept Proposals submitted by manufacturers.

January → February → March/April

SNAPSHOT OF TEST-CASES

- ✓ Represent both small and large manufacturers
- ✓ Span the Total Product Life Cycle (TPLC) including pre-market, patient management and clinical guidelines, label expansion, and post-market surveillance
- ✓ Cover a range of device types including dermatology, cardiovascular, vascular, orthopedics, and surgery

2 DEVELOP NESTcc'S ROLE: LAUNCHING 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:

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TOTAL-PRODUCT LIFE CYCLE (TPLC) ALIGNMENT	PRODUCT(S)	AREA
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

2 DEVELOP NESTcc'S ROLE: LAUNCHING TEST-CASES

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

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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.

2 DEVELOP NESTcc'S ROLE: LAUNCHING TEST-CASES

NESTcc has identified a test-case examining a Class I, dermal adhesive used for surgical or trauma-induced wound closures and lacerations that is undergoing feasibility testing with network collaborators.

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TOPICAL SKIN ADHESIVE (TSA) TEST-CASE EXAMPLE

- ✓ Explore the feasibility of using Real World Data (RWD) for a retrospective analysis to assess the safety and effectiveness of existing wound closure methods (TSA, staples, sutures, and combinations) for surgical wounds or lacerations
- ✓ Develop the value proposition for a new device to bring to the U.S. market that is currently approved in EU and not in the U.S.
- ✓ The population of interest is patients with wounds from surgical incisions or trauma-induced lacerations with at least six months of data available.
- ✓ 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.

2 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:

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DukeHealth

HealthCore

Lahey Hospital & Medical Center

MAYO CLINIC

MDEpiNetPPPMDEpiNetPPPMDEpiNetPPP

Mercy

OneFlorida Clinical Research Consortium

PEDSnet A Pediatric Learning Health System

VANDERBILT UNIVERSITY MEDICAL CENTER

Weill Cornell Medicine

Yale

2 DEVELOP NESTcc'S ROLE: BUILDING A DATA NETWORK

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

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NESTcc Network Collaborators Surveyed

Duke University Health System • HealthCore • Lahey Clinic • 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

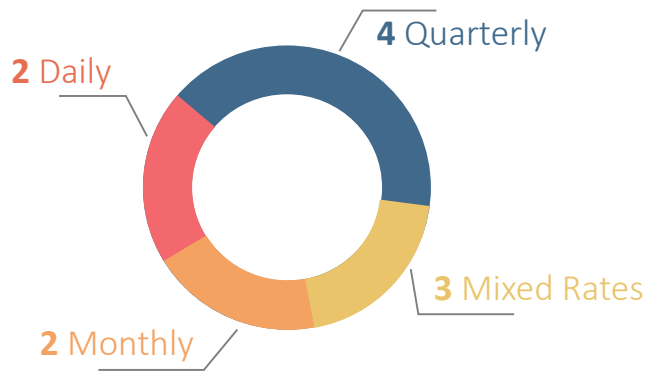
Patient data represents:

469M+ Patient Records

Common data models:

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

Respondents report regular data refreshes:



Most cited expertise:

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

2 DEVELOP NESTcc'S ROLE: BUILDING A DATA NETWORK

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

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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)

2 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.

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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 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)

3 ESTABLISH NESTcc'S VALUE

NESTcc will establish its value to achieve full operability and sustainability.

ACTIVITIES TO DATE

- Developed NESTcc **business model** with stakeholder feedback
- Established and launched **Sustainability Subcommittee**
- Announced Sustainability Request for Proposals (RFP) requiring plan for **Market Analysis** and **Business Plan Development**

UPCOMING ACTIVITIES

- Identify and select **contractor** to fulfill Sustainability RFP
- Develop **business plan** inclusive of a financial model and operating model
- Establish **pricing models**

3 ESTABLISH NESTcc'S VALUE: SUSTAINABILITY PLANNING

NESTcc has launched its Sustainability Subcommittee to provide strategic input to the development and implementation of business, operating, and financial sustainability models

SUBCOMMITTEE MEMBERS

Mark Deem

Pamela Goldberg

Bill Hanlon

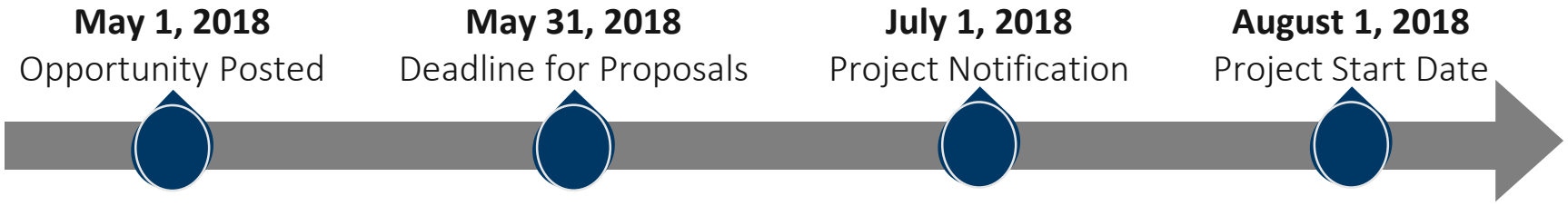
Adrian Hernandez

Vance Moore

REQUEST FOR PROPOSALS (RFP)

- NESTcc announced an RFP seeking contractor support to develop sustainability planning for the long-term viability and sustainability of NESTcc after the initial U.S. Food and Drug Administration (FDA) MDUFA funding.
- Sustainability RFP includes two separate scopes of work:
  - Market Analysis
  - Business Plan Development

Anticipated RFP Timeline



4 ENSURE NESTcc STAKEHOLDER ENGAGEMENT

NESTcc will ensure effective communication to engage key stakeholders across the medical device ecosystem.

ACTIVITIES TO DATE

- Established NESTcc's **brand** and developed **targeted communications materials** for key stakeholder groups
- Launched NESTcc **communications channels**
  - NESTcc Website (nestcc.org)
  - Twitter (@NESTccMedTech)
  - LinkedIn (linkedin.com/company/nest-cc)
- Held **speaking roles** at 50+ conferences and events since September 2017

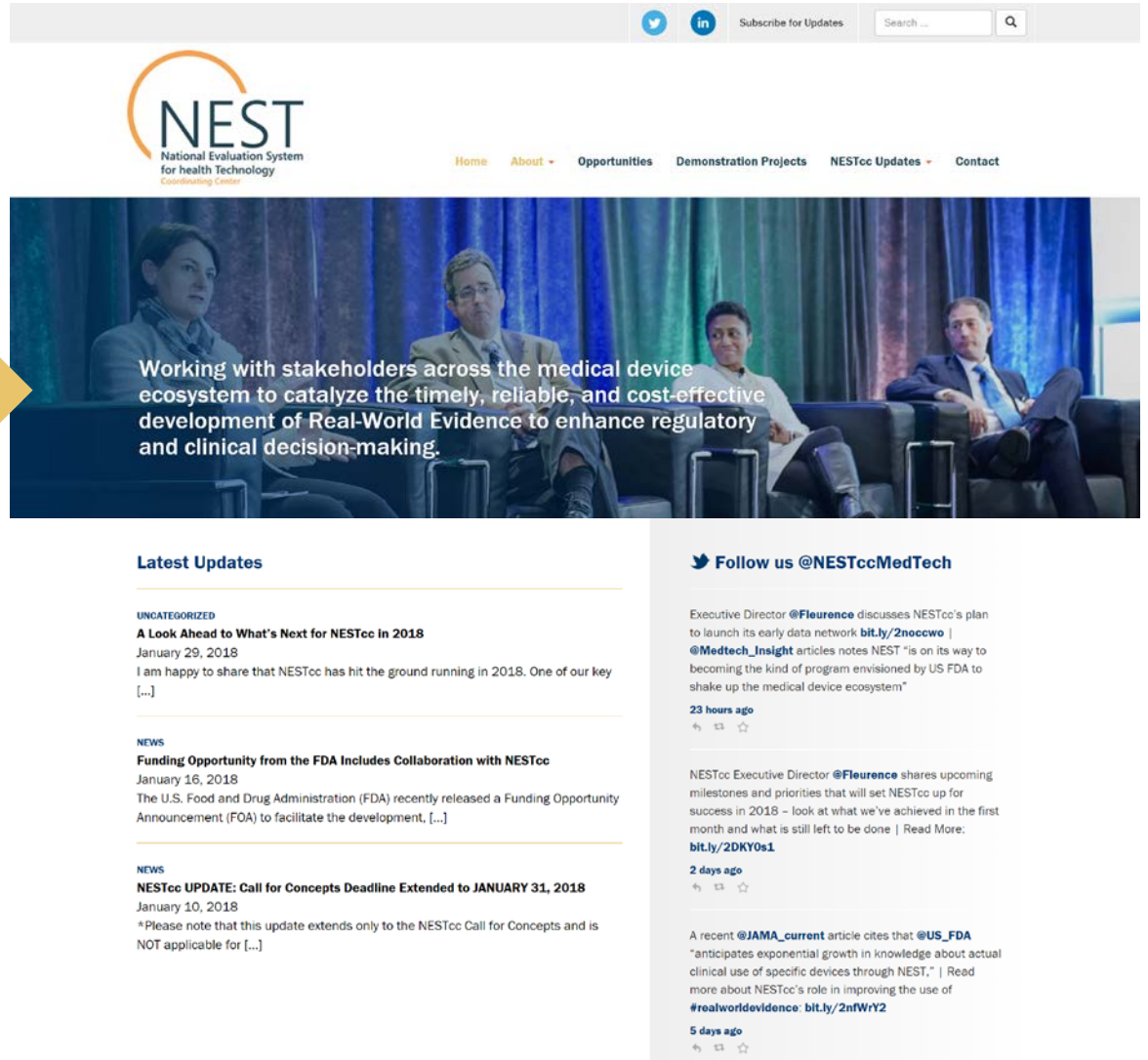
UPCOMING ACTIVITIES

- Engage and collect feedback from **key stakeholders** across the medical device ecosystem
- Finalize and launch NESTcc **Strategic Communications plan**

4 ENSURE NESTcc STAKEHOLDER ENGAGEMENT

NESTcc launched its website in December as a public-facing forum for stakeholders to:

- ✓ Access the latest NESTcc news updates
- ✓ Stay up-to-date on NESTcc achievements with Executive Director and Guest Blogs
- ✓ Learn more about the NESTcc Team and Governing Committee
- ✓ Utilize opportunities to engage with NESTcc
- ✓ Follow NESTcc on Twitter



CONNECT WITH NESTcc

Contact us to develop a partnership
NESTcc@mdic.org

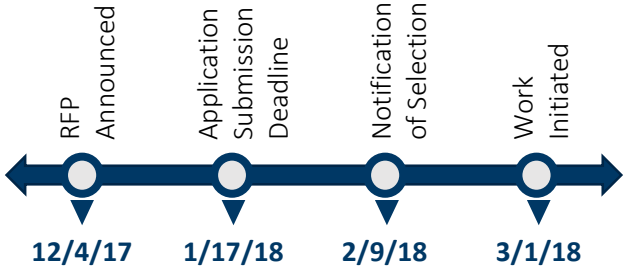
Connect with us on Twitter
@NESTccMedTech

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

Explore open opportunities for engagement
nestcc.org/opportunities

NESTcc PROGRESS: A SNAPSHOT

Selected Teams for RWE Assessment and Value Analysis Initiatives



Initial Data Network Underway

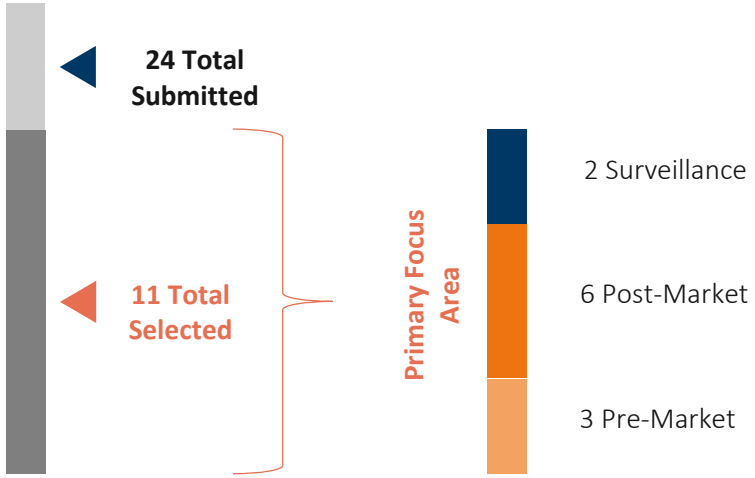
Completed Data Capabilities Surveys Indicate:

11

150 Hospitals

3,042+ Outpatient Clinics

Designated Demonstration Projects



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Slide Last Update: March 31, 2018

Governing Committee Activity

Seven Governing Committee Meetings

Average attendance of 11/15 members per meeting

Business Plan Input

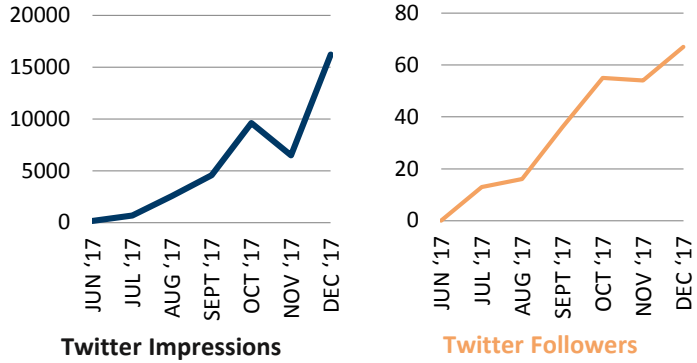
Communications Platforms Launched

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

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