



Keynote: Progress on the NEST Coordinating Center



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The Ecosystem Challenge

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

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



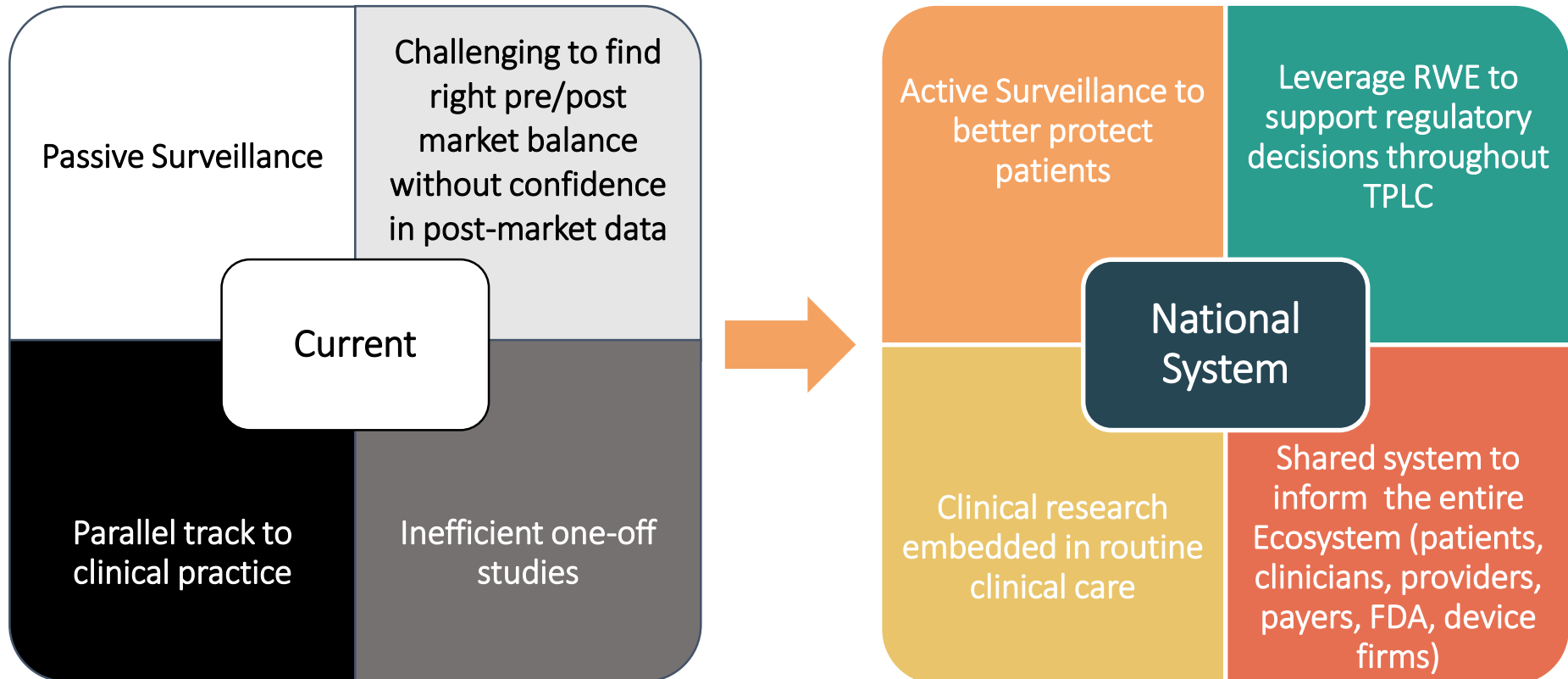
Purchasing decisions and quality of care for health systems



Coverage decisions for public and private payers

A National System Paradigm Shift

Enabling the responsible collection and use of Real-World Evidence (RWE) generated in the routine course of care is central to an ongoing paradigm shift





NESTcc's Role in the Ecosystem

NESTcc should serve as a catalyst within the ecosystem to support the timely and reliable development of high-quality RWE



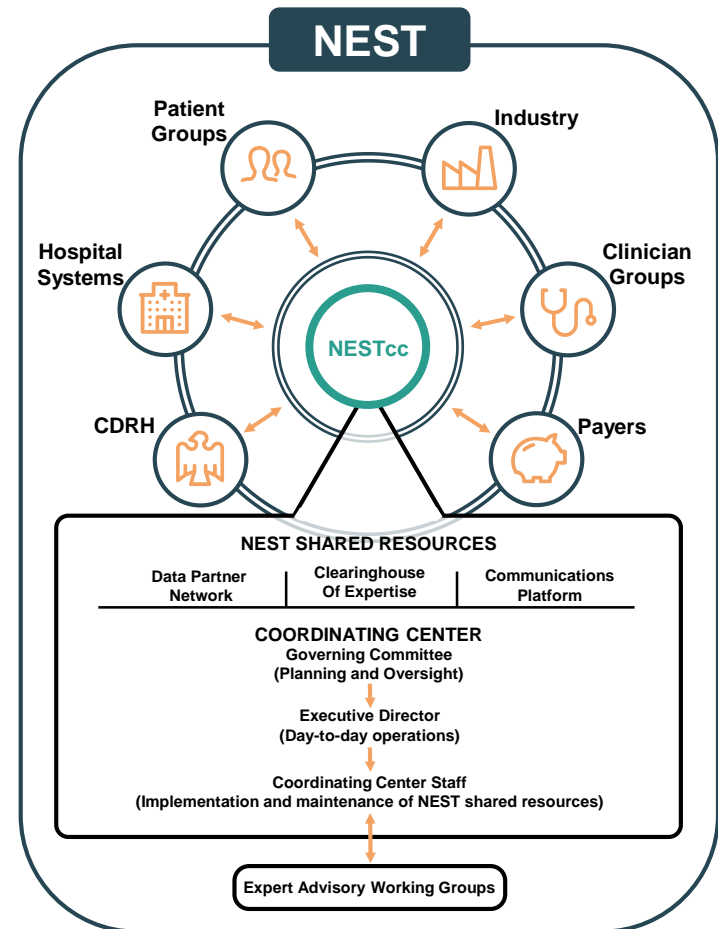
Establish partnerships with a range of organizations, companies and collaborations that provide data and analytic solutions



Set standards, provide certifications, conduct audits, and lead methods development



Offer products and services of value to key stakeholders in the ecosystem that will support a future small and efficient core NESTcc team post-MDUFA funding



Guiding Principles

NESTcc's structure and activities will be guided by the following principles:

NESTcc will likely:



Have a modular, flexible and decentralized structure allowing for optimal solutions taking place concurrently



Be a catalyst/broker of solutions, supporting competition between solutions



Set data and methods standards, provide certifications and conduct assessments

*NESTcc will likely **not** be:*



Centrally organized or a one size fits all solution (e.g., NESTcc will not host data)



A provider or developer of solutions



An implementer of solutions

Governing Committee Composition

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

Naomi Aronson

Executive Director, Clinical Evaluation, Innovation, and Policy, *Blue Cross Blue Shield Association (BCBSA)*

Kathleen Blake

Vice President, Healthcare Quality, *American Medical Association (AMA)*

Mark Deem – MDMA Nominee

Managing Partner, *The Foundry, LLC*

Bill Hanlon – ACLA Nominee

Chief Development Officer and Head of Global Regulatory Affairs, *LabCorp/Covance*

Adrian Hernandez

Professor of Medicine, Duke School of Medicine; Director, Research, Quality and Outcomes *Duke Heart*; Director, Health Services and Outcomes Research, *DCRI*

Harlan Krumholz

Professor of Medicine and Epidemiology & Public Health, *Yale University*; Director of the Yale Center for Outcomes Research and Evaluation (CORE), *Yale University*

Elizabeth McGlynn

Vice President, Kaiser Permanente Research, *Executive Director, KP Center for Effectiveness & Safety Research, Kaiser Permanente*

Michelle McMurry-Heath – Advamed Nominee

WW Vice President Regulatory Affairs, Johnson & Johnson Medical Devices

Vance Moore

President, Business Integration, *Mercy Health*

William Murray

President and CEO, *MDIC*

Jeffrey Shuren

Director, *CDRH*

Sharon Terry

President and CEO, *Genetic Alliance*

Diane Wurzbarger – MITA Nominee

Executive, Regulatory Affairs, GE Healthcare

Marc Boutin

CEO, *National Health Council*

Tamara Syrek-Jansen

Director, Coverage and Analysis Group, *Center for Clinical Standards and Quality*

Strategic Objectives 2017-2022

Strategic objectives focus on establishing NESTcc's organizational structure, defining role in the ecosystem, and raising awareness among stakeholders



Governance

- Recruit and onboard Executive Director
- Select inaugural Governing Committee
- Establish and maintain functional and efficient governance



Solution Discovery & Implementation

- Identify data and analytic solutions within the ecosystem that meet NESTcc's goals
- Form strategic alliances with key partners to explore opportunities to participate in NEST
- Act as a catalyst to implement data and analytic solutions to the ecosystem
- Continuously update data and analytic solutions to stay abreast of technological advances



Key Functions & Sustainability

- Define NESTcc's organizational model and structure, and key functions
- Develop NESTcc's business plan, including proposed products and services
- Develop sustainability model
- NESTcc is fully sustainable, independent entity, with revenue to support key functions



Communications & Outreach

- Ensure NESTcc mission and progress is known to key stakeholders
- Establish brand recognition
- Disseminate learnings through NESTcc communications
- Publically communicate progress and outcomes of NESTcc and impact on the ecosystem

Process for Leveraging Ecosystem Solutions

Area 1: Issue Call for Existing Projects (July 2017, rolling monthly thereafter)

- Identify projects already underway, and funded by other sources, with *high impact* potential
- NESTcc resources will be used for convenings

Area 2: Issue Targeted Calls for New Projects (September 2017 and onward)

- Call for projects to address major gaps identified as mission-critical – see box (list under development)

Area 3: Issue Request for Information for Data and Analytics Solutions (September 2017 and onward)

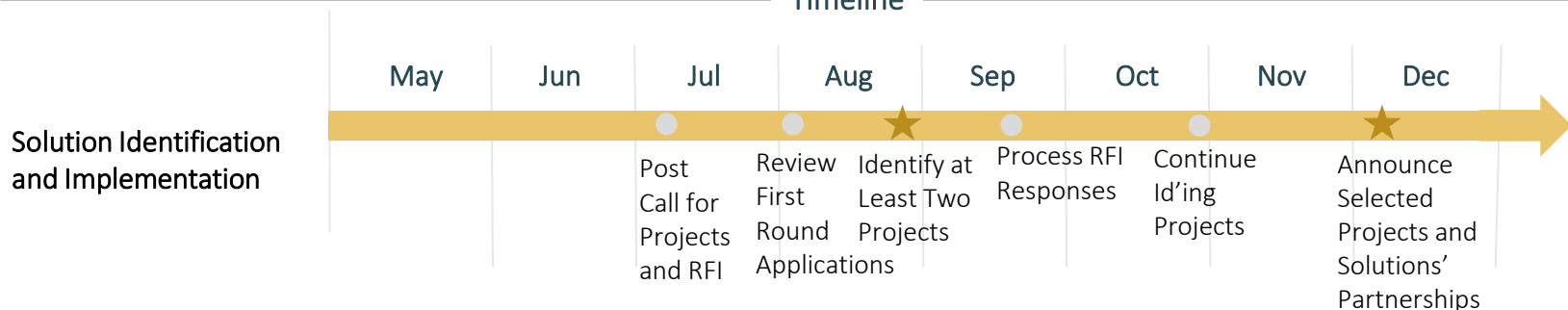
- RFI to identify companies, organizations, collaborations and strategically coordinated registries from the private and non-profit sector that can offer third-party solutions

Mission Critical Gaps for Demonstration Projects (Area 2)

Feedback Welcome! Ideas Under Construction

- Piloting UDI implementation in partner health systems
- Benefit/Risk or safety study linking company medical device registry with health system data
- Benefit/Risk or safety study using patient generated or device generated data
- Tools for active surveillance, including patient- or device--generated data, automated signal detection
- Models to improve Medical Device Reporting
- Models for embedded trials in registries or health systems for IDE studies
- Analytical and Statistical Methods specific to medical device research (see MDTRF report)

Timeline



NESTcc Milestones – July 2017

NESTcc is off to a great start with several important activities already underway:

Selection & first meeting of the inaugural Governing Committee



Data and Analytics Solutions for Medical Device Evidence Generation RFI



Call for initial NEST Demonstration Projects



To learn more about these activities please visit www.nestcc.org