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September 22, 2017

BUSINESS DAY

F.D.A. Seeks to Tighten Regulation of All-Metal Hip Implants

By BARRY MEIER JAN. 16, 2013

After an estimated 500,000 patients in the United States have received a type of artificial hip that is failing early in many cases, the [Food and Drug Administration](#) is proposing rules that could stop manufacturers from selling such implants.

Under the proposal, which the agency is expected to announce on Thursday, makers of artificial hips with all-metal components would have to prove the devices were safe and effective before they could continue selling existing ones or obtain approval for new all-metal designs.

The Washington Post

The battle over Essure



Some people see a breakthrough in female contraception. Others see a dangerous medical device.

To Your Health

FDA toughens warning that uterine procedure can spread cancer

By **Brady Dennis** November 24, 2014 

The Food and Drug Administration strengthened its warnings Monday against the use of a controversial uterine surgical technique, recommending that doctors avoid using laparoscopic power morcellators to remove uterine growths in the vast majority of women because of the risk of spreading hidden cancers.



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 access to **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



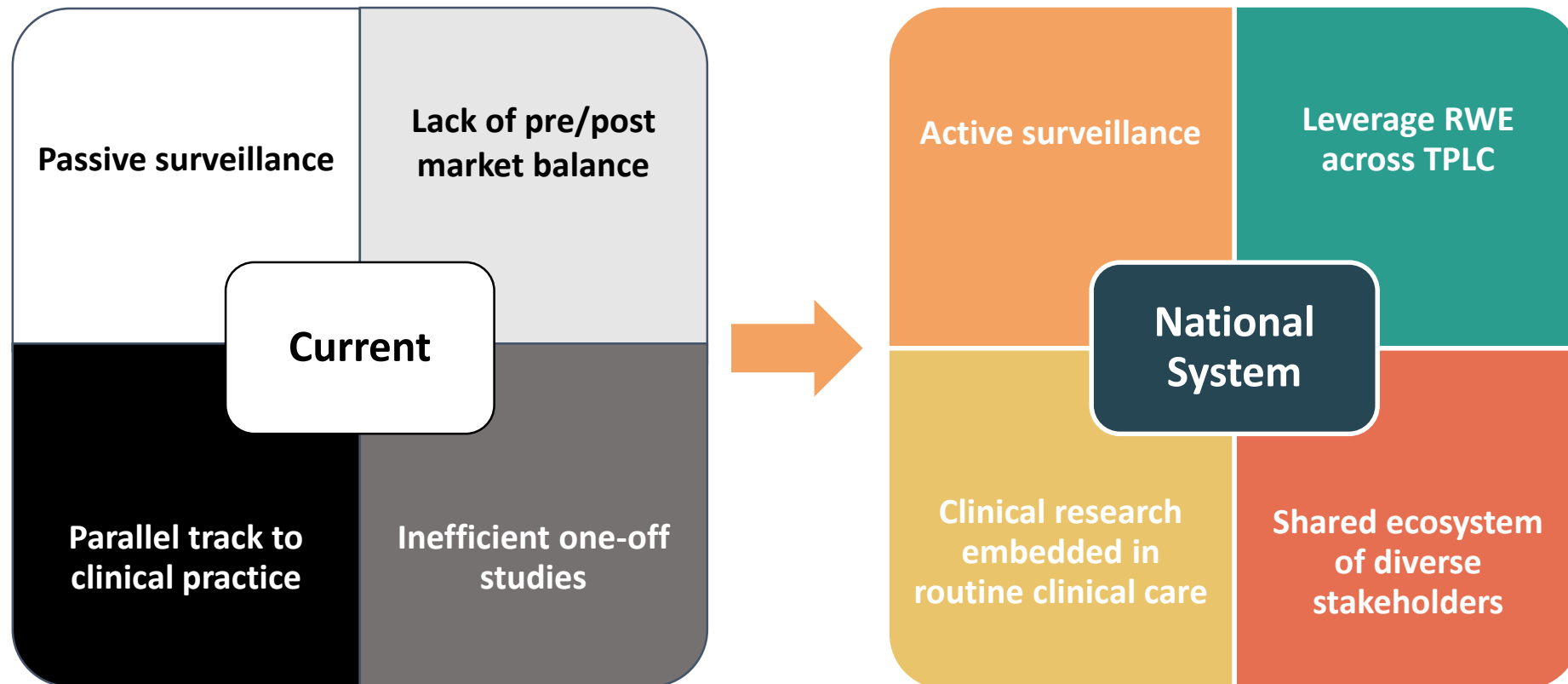
Purchasing decisions and quality of care for health systems



Coverage decisions for public and private payers

A NATIONAL SYSTEM PARADIGM SHIFT

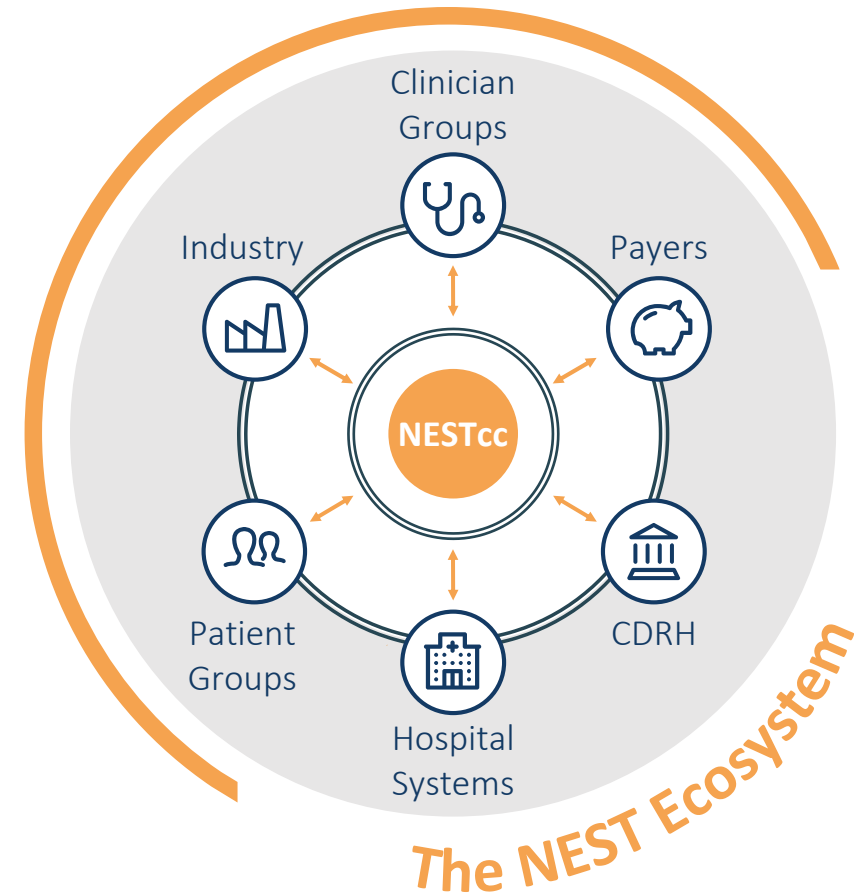
Enabling the responsible collection and use of Real-World Evidence (RWE) generated in the routine course of care is central to an ongoing paradigm shift.



NESTcc'S ROLE IN THE ECOSYSTEM

NESTcc should serve as a catalyst 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 analytics solutions
- Set **data quality and methods standards**, provide certifications, and conduct evaluations
- Offer **products and services** of value to key stakeholders in the ecosystem to support a sustainable NESTcc



The following principles will guide NESTcc's structure and activities to help achieve its mission.

NESTcc will likely:

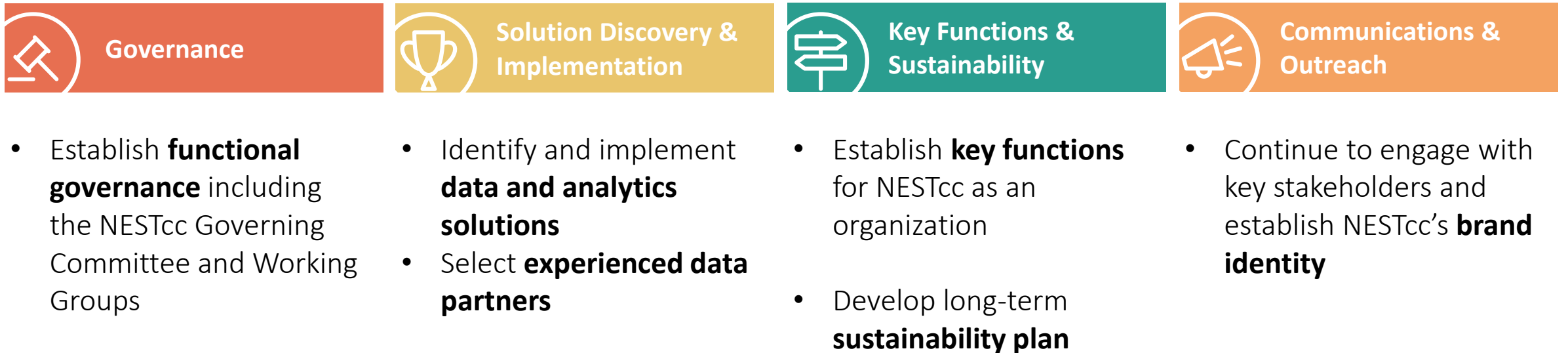
- ✓ Have a **modular, flexible, and decentralized structure** allowing for optimal solutions taking place concurrently
- ✓ Be a **catalyst/broker of solutions**, supporting competition between solutions
- ✓ Set **data and methods standards**, provide certifications, and conduct assessments

NESTcc will likely not be:

- ✗ A 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

STRATEGIC OBJECTIVES: 2017-2022

In its first five years, NESTcc will focus on establishing an organizational structure, defining its role in the ecosystem, and building stakeholder awareness.



IMPLEMENTING STRATEGIC OBJECTIVES

To operationalize these strategic objectives, NESTcc has initiated the following key activities.



NESTcc Governing Committee Selection

Complete



Data and Analytics Solutions and Partnerships

In Progress



Call for Demonstration Projects

In Progress

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

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**

Johnson & Johnson Medical Devices

VANCE MOORE

Mercy Health

WILLIAM MURRAY

Medical Device Innovation Consortium (MDIC)

JEFFREY SHUREN

FDA, CDRH

SHARON TERRY

Genetic Alliance

DIANE WURZBURGER – MITA Nominee

GE Healthcare

MARC BOUTIN

National Health Council

TAMARA SYREK-JANSEN

Center for Clinical Standards and Quality

■ Trade Association Nominees





NESTcc is seeking data partners and solutions to collaborate with to advance evaluation and use of high-quality RWD from various sources.

Data and Analytics Partners:

- Health Systems: EHR, hospital billing/claims data
- Health Payers: EHR/claims data
- Registries
- Sources of patient- or device-generated data



Data and Analytics Solutions:

- Data network solutions
- Analytics offerings



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



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PARTNERS

What progress has been made?

To date, memorandums of understanding (MOU) have been signed with **nine collaborators**:

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

What's next?

- Establish **standards for data quality and methods**
- Convene **Working Group on Methods and Standards**
- **Develop webinars** to begin collaborating with data partners



SOLUTIONS

Posted a Request for Information (RFI) and currently reviewing submissions

- Continue to review RFI submissions and **make final solution selections**



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



In July 2017, NESTcc issued a call for Demonstration Projects to help NESTcc develop and operationalize methods to conduct high-quality studies in the medical device space and to identify gaps that need to be addressed.

WHAT IS A

Demonstration Project?

Projects that further the use of RWE within the medical device ecosystem

Why Demonstration Projects?

- **Promote scalability and identify gaps** through lesson sharing
- **Develop 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**
- **Inform NEST's strategy**



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



Future Demonstration Project calls will target projects that address gaps identified during the first round of review.

What did we see in the first round?

- Proof that there are **interested, high-quality** projects currently underway
- Emphasis on **post-market** space
- Many projects with **single sponsors** representing the medical device space



What are we looking for next?

In future Demonstration Project calls, NESTcc will target projects that:

- Address the **pre-market** space
- Have **multiple sponsors**, including small medical device companies
- Relate to **imaging technology, clinical labs, and Class II** devices



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

1

Announce first set of Demonstration Projects

- Plan for issuing targeted set of Demonstration Projects based on gaps identified in current projects
-

2

Establish formal partnerships with key data partners

- Develop processes for evaluating data quality and robustness of analytic methods
 - Identify barriers and solutions for conducting clinical research studies in the medical device, imaging, and labs spaces
-

3

Create NESTcc Organizational Structure

- Based on NESTcc operational goals and core capabilities, develop organizational structure
- Develop sustainability plan post MDUFA IV funding
- Specify how companies large and small will work with the NESTcc



www.nestcc.org



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