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 battle over Essure

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

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.
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
## EMERGING GUIDING PRINCIPLES

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

<table>
<thead>
<tr>
<th><strong>NESTcc will likely:</strong></th>
<th><strong>NESTcc will likely not be:</strong></th>
</tr>
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<tbody>
<tr>
<td>Have a <strong>modular, flexible, and decentralized structure</strong> allowing for optimal solutions taking place concurrently</td>
<td>A centrally-organized or a one-size-fits-all solution (e.g., NESTcc will not host data)</td>
</tr>
<tr>
<td>Be a <strong>catalyst/broker of solutions</strong>, supporting competition between solutions</td>
<td>A provider or developer of solutions</td>
</tr>
<tr>
<td>Set <strong>data and methods standards</strong>, provide certifications, and conduct assessments</td>
<td>An implementer of solutions</td>
</tr>
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</table>
In its first five years, NESTcc will focus on establishing an organizational structure, defining its role in the ecosystem, and building stakeholder awareness.

- Establish **functional governance** including the NESTcc Governing Committee and Working Groups
- Identify and implement **data and analytics solutions**
- Select **experienced data partners**
- Establish **key functions** for NESTcc as an organization
- Develop long-term **sustainability plan**
- Continue to engage with key stakeholders and establish NESTcc’s **brand identity**
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.

**GOVERNING COMMITTEE**

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
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](http://www.nestcc.org)
NESTcc is seeking data partners and solutions to advance evaluation and use of high-quality RWD from various sources.

**What progress has been made?**
To date, memorandums of understanding (MOU) have been signed with **nine collaborators**: Duke University Health System ● Healthcare ● 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](http://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](http://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](http://www.nestcc.org)
Announce first set of Demonstration Projects
  • Plan for issuing targeted set of Demonstration Projects based on gaps identified in current projects

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

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