

Real World Evidence Generation in the 21st Century: National Evaluation System for health Technology (NEST)



MEDICAL DEVICE INNOVATION CONSORTIUM

Align › Achieve › Accelerate

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IDEAL Conference Presentation
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Vision and Mission of the National Evaluation System for health Technology Coordinating Center (NESTcc)

Vision

A real-world data powered national evaluation system to generate better evidence more efficiently for use throughout the medical device total product lifecycle.

Mission

Establish and operate the decentralized, federated NESTcc based on the foundational principles of trust, transparency, scalability, sustainability and accountability serving device manufacturers, payers, regulatory agencies, patient groups, physicians, providers and other relevant stakeholders.



MDIC NEST Coordinating Center

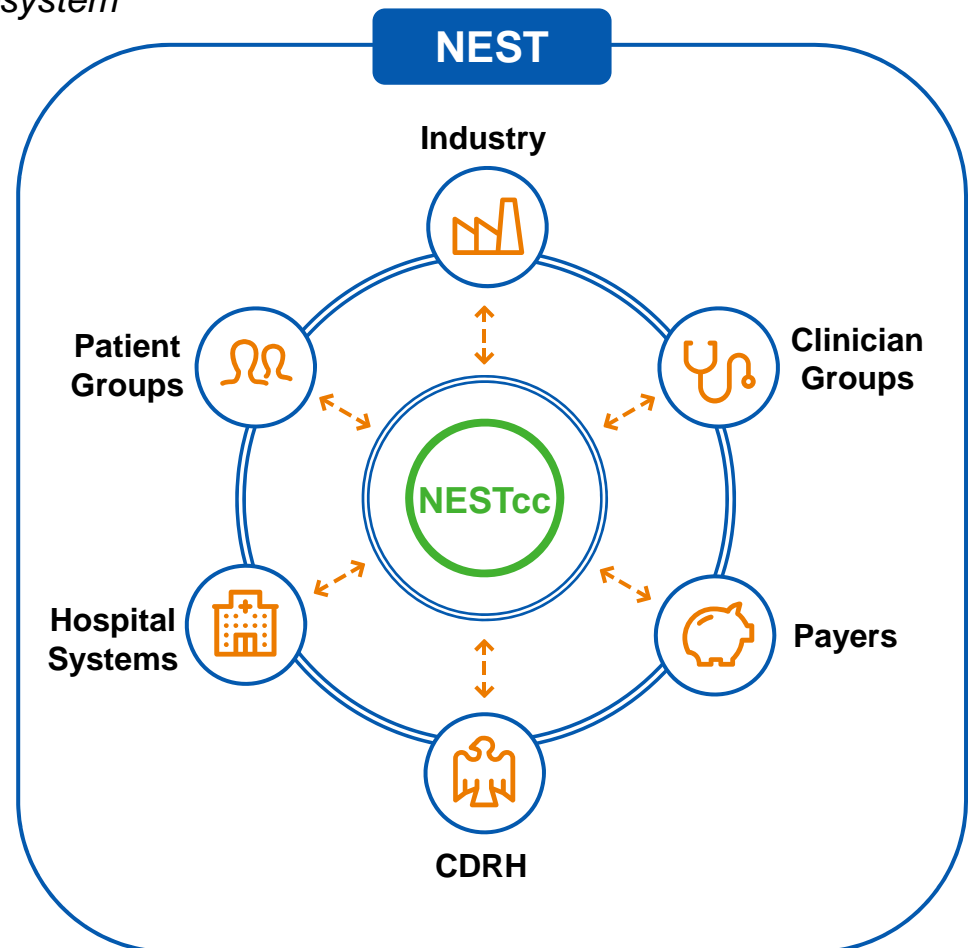
MDIC's vision is to establish and operate **the decentralized, federated NESTcc** based on the foundational principles of **trust, transparency, scalability, sustainability and accountability** serving stakeholders throughout the medical device ecosystem

Objectives for the NESTcc

1. Broad **stakeholder engagement** including public input
2. Establishment of CC **independence from bias** from any single stakeholder's interests
3. **Decentralized data flow and evaluation systems** rather than a single centralized device evaluation program
4. Common data **analytical and report "standards"** rather than a "standardization" of mandatory set of data fields and reports
5. Open science **principles of transparency** of governance, coordinating processes and policies, and data access
6. **Active oversight** of the critical data flow and key operation components employing audit, certification and performance reporting to ensure compliance with standards and reporting recommendations

These NESTcc objectives build on NEST planning board report* developed by the Duke-Margolis Center for Health Policy

* Duke-Margolis Center. *The National Evaluation System for health Technology (NEST): Priorities for Effective Early Implementation*. 2016





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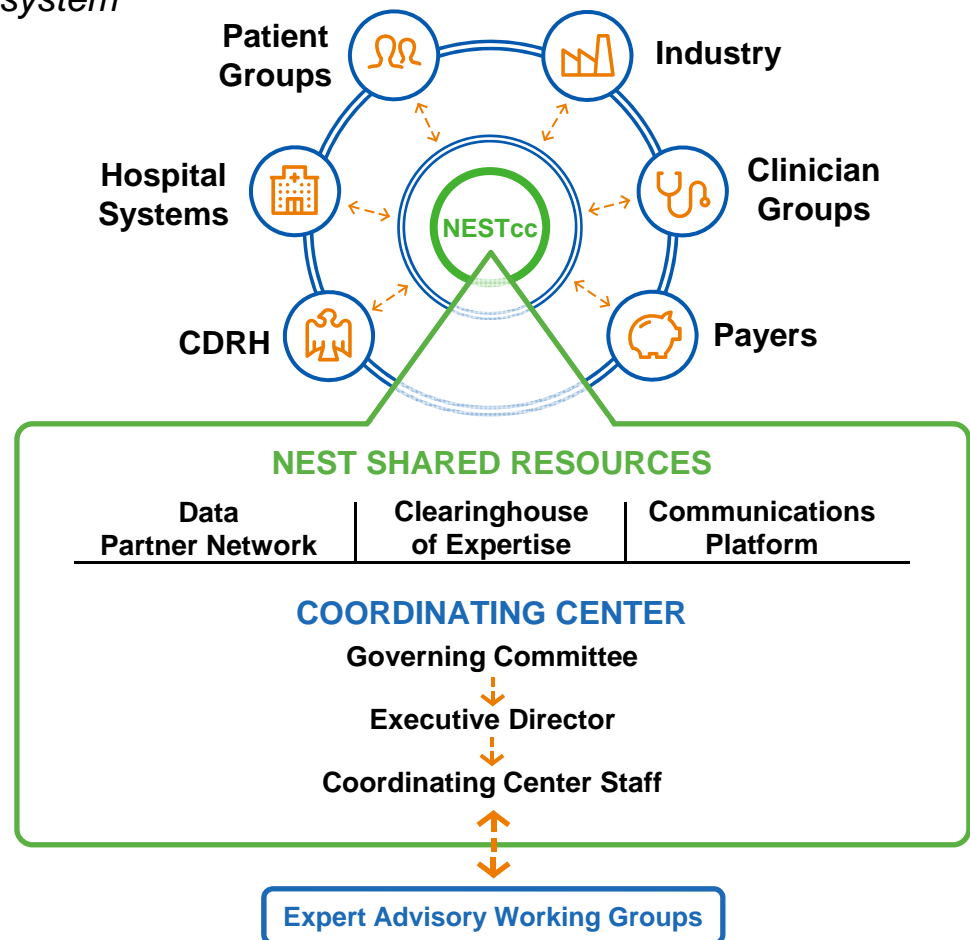
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In September 2016 FDA awarded a \$3M grant for the NESTcc to the Medical Device Innovation Consortium (MDIC) with an expected \$6M per year for five years from MUDFA

Aims from the MDIC proposal include:

-  **Establish a governance** committee of the key stakeholders charged with inaugurating the NEST CC that is inclusive, patient-focused, and anchored in equity and transparency.
-  **Establish scope, strategy** (decentralization, stakeholder engagement, independence from bias, open science and data sharing, objective prioritization), **structure** (primary data processes and secondary data and results dissemination), **standards** (data, methods, reporting, and data access, audit and certification), in a **decentralized and federated NEST**.
-  Guarantee an **inclusive pathway** for competitive **innovation** and continual modernization through decentralized data warehousing and integration.
-  **Conduct pilot projects** to develop, verify and operationalize methods of evidence generation and data use, demonstrate scalability across healthcare systems and device types and manufacturers, and prove out principles of NEST sustainability.



What is MDIC?

MDIC is a 501(c)(3) non-profit organization and is the first-ever public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit



Our Mission: Faster, Safer and more Cost-effective innovation for Patient Benefit

MDIC HIGHLIGHTS



59 participating member organizations



Leading resource on issues important to the Medtech innovation ecosystem



6 Projects have been initiated



Congressional testimony on modernizing clinical trials



Over \$4.4m funding from grants and contracts for Program initiatives.



The Strategy to Operationalize NESTcc

The NEST Coordinating Center (NESTcc) will be operationalized in three phases of activity

1

Phase 1

- Conduct **Landscape Analysis**
- Hire **Executive Director** - Complete
- Establish NESTcc **Governing Committee** with representation from patients, federal agencies, industry, clinicians, hospitals, and health plans

2

Phase 2

- Initiate focused **demonstration projects** centered on high-risk category devices that require tracking and EHR data from hospital systems that use modern means of data collection

3

Phase 3

- Demonstration projects will **establish sustainability** of the NESTcc to the broader medical technology ecosystem



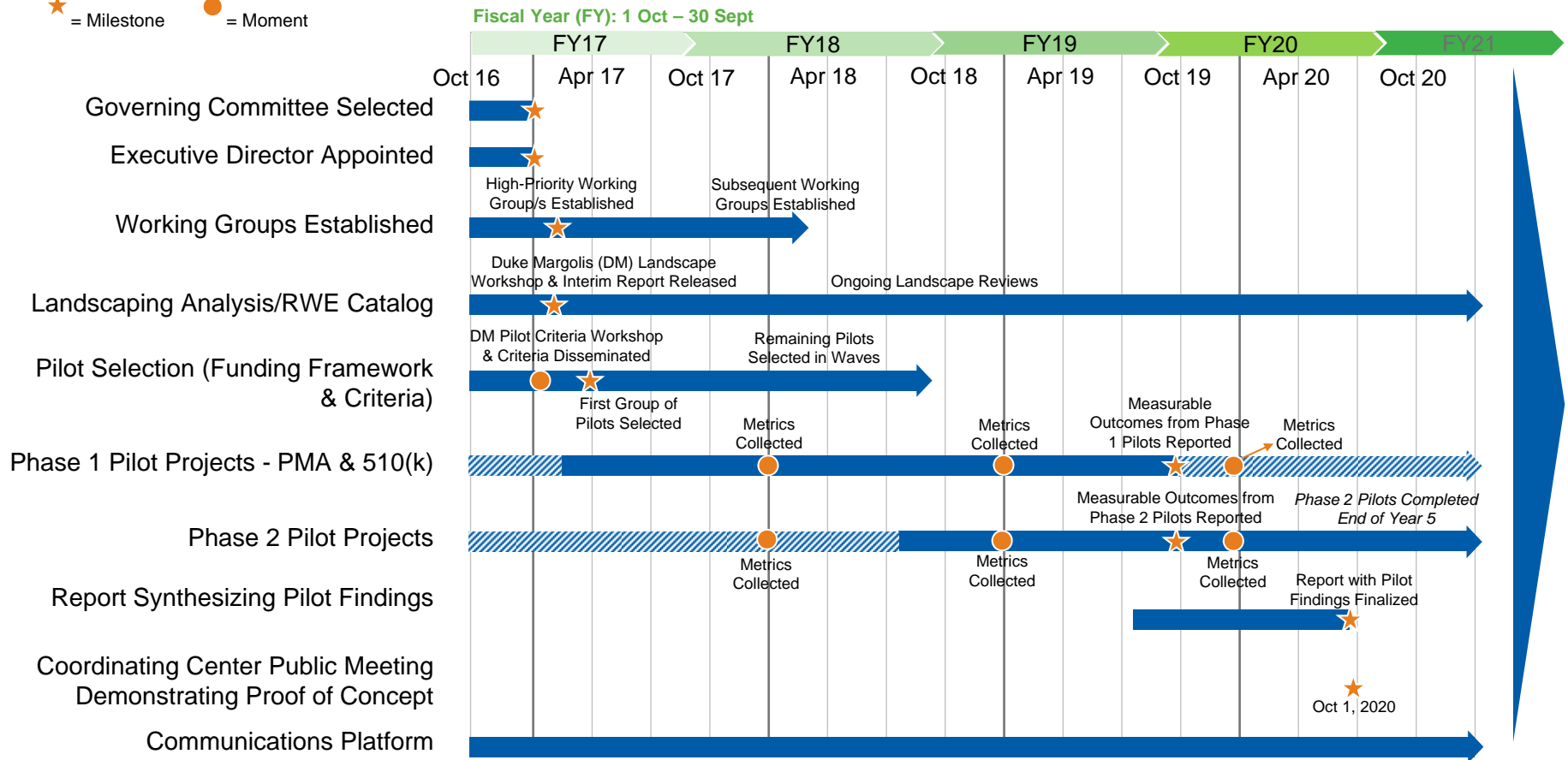
MDIC has received letters of support from strategic patient and industry partners indicating commitment to developing demonstration projects



MDUFA Milestone Suggested Roadmap

Initiatives supporting NESTcc operationalization and long-term sustainability are planned for rollout between FY17 and FY21

★ = Milestone ● = Moment



▨ Accommodates Differences in Project Tenure and Complexity

<http://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf>



Short and Long-Term Vision

The long-term vision for NESTcc is rooted in early operationalization activities including leadership recruitment, stakeholder engagement, and pilot initiation

NOTIONAL: 5 YEAR VISION



- The Coordinating Center Serves as the Center for the Medical Device Ecosystem
- Value of RWE in Health Care Decision-Making is Clearly Defined
- Standards/Methods are Developed Collaboratively and Integrated in FDA/NEST Guidance
- All Pilots Are Implemented; New Pilots Are Explored
- Best Practices are Integrated in Educational, Industry, and Community Efforts
- NEST is Financially Sustainable with a Business Model that Supports Long-Term Growth For Medical Device Development, Assessment, Review and Patient Safety

WHAT DOES SUCCESS LOOK LIKE IN YEAR 1?

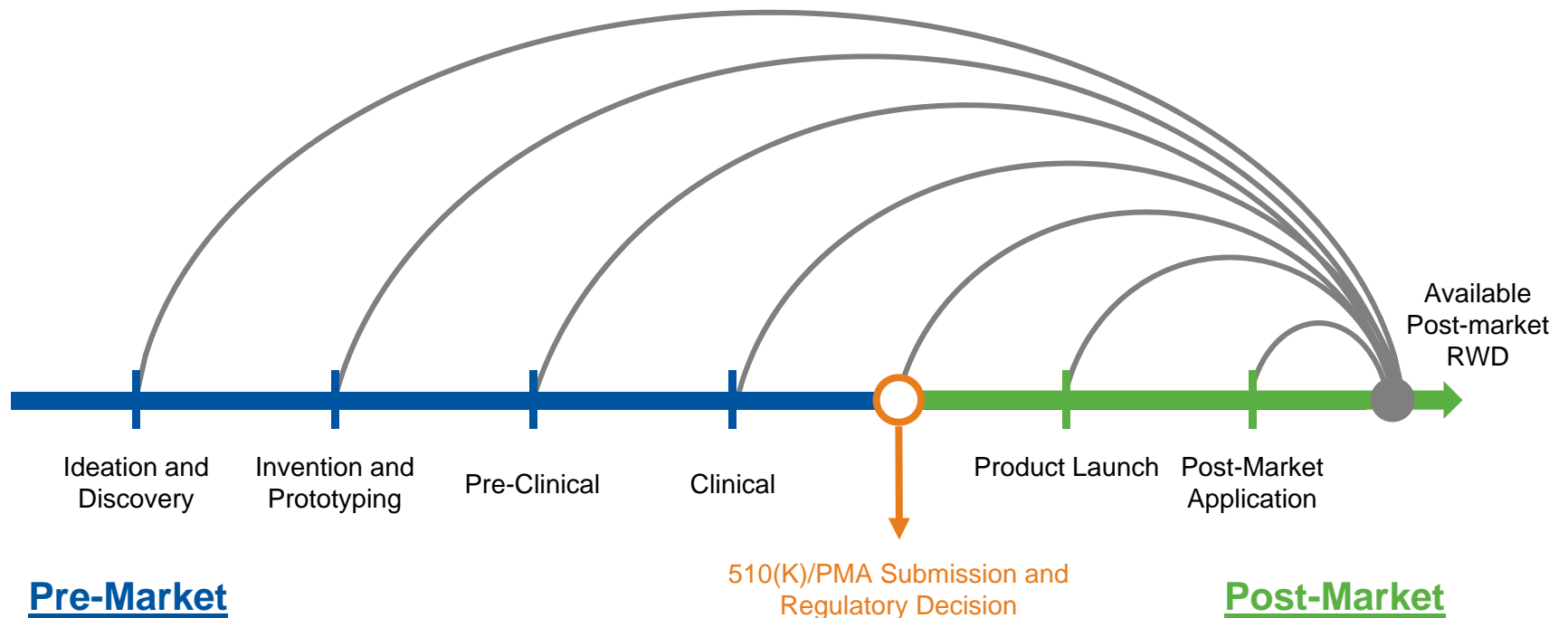


- Executive Director Hired
- Governing Committee Established
- Value-Proposition and Sustainability Plans Are Created
- First Round of Pilots Are Implemented with Clearly Defined Future Value Goals
- Requirements for the Communication Platform are Drafted
- High-Priority Working Groups Are Established and Aligned with Pilot Project Topics/Needs



Total Product Life Cycle Feedback Loop

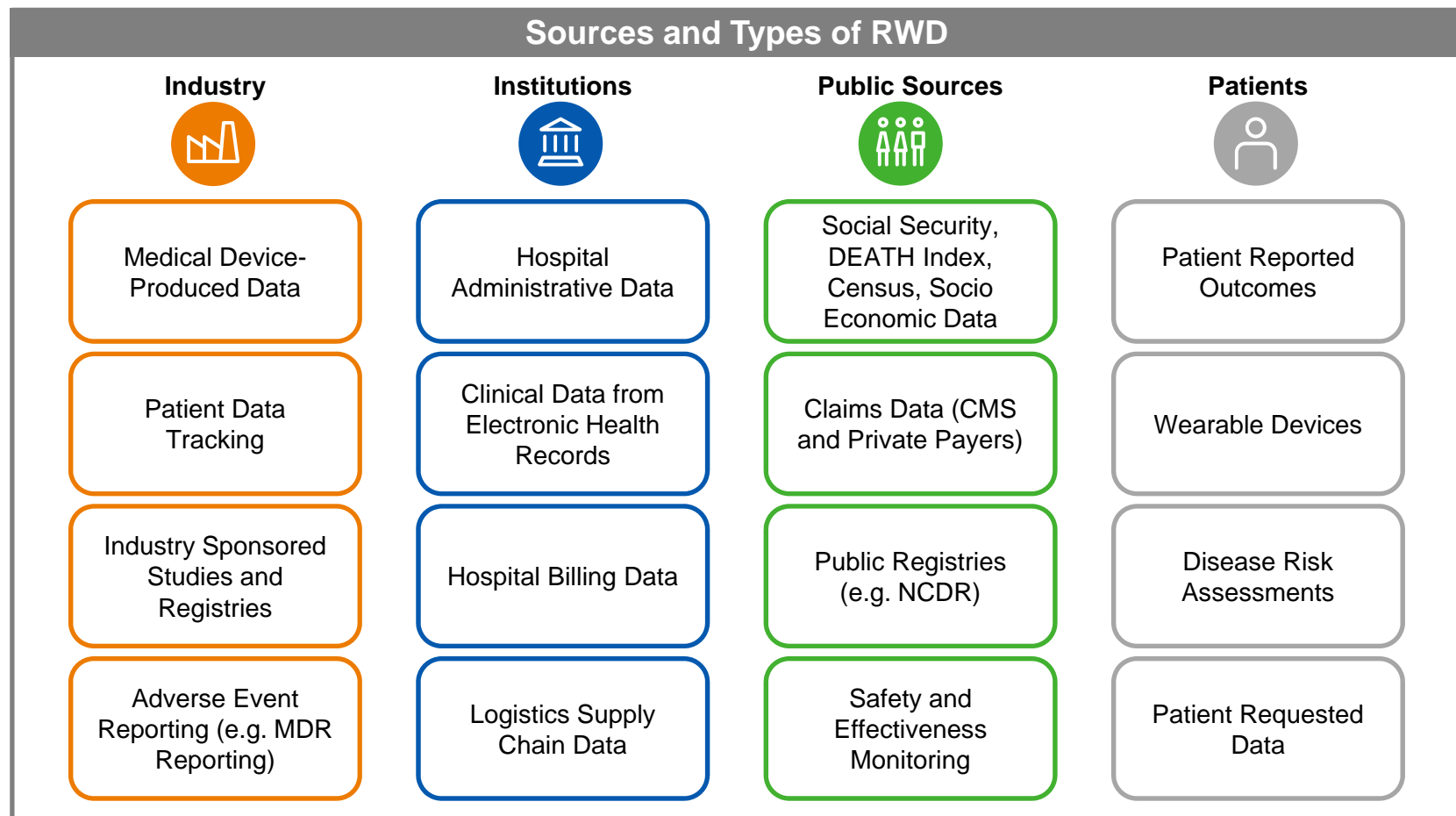
In an ideal state, a more robust post-market surveillance system would facilitate the feedback of RWD collected to both the pre-market and post-market phases of product development





Sources of Real-World Data

Real-World Data (RWD) includes data collected from sources outside of traditional clinical trials and Real-World Evidence (RWE) is the evidence derived from aggregation and analysis of RWD elements





Uses of RWD and RWE

Uses of RWD and RWE are as diverse as their sources, offering potential benefits to all members of the medical device ecosystem



Comparative Effectiveness

RWD can be used to compare the performance, safety profile, and effectiveness of one medical product with another by examining patient outcome data.



Cost-benefits

RWE can help stakeholders to identify devices that can help reduce costs or increase cost-savings through reduced hospitalization time, better clinical outcomes, or fewer adverse events.



Expanded Indications for Use

RWE can be analyzed to determine the safety and effectiveness of off-label use. This evidence of off-label use of a product can support a submission for an expanded indication of use.



Generalize or Confirm Findings from Randomized Clinical Trials (RCTs)

RWE can help corroborate generalizability of findings discovered through clinical trials in real-world populations. The use of RWE can help to understand any differences seen in outcomes or performance across study and real-world populations.



Improved Clinical Care Guideline

RWE may support better clinical guidelines as more information on the effectiveness of products in various patient populations is shared with providers.



Patient Outcomes

RWE can help demonstrate nuances in device performance across specific patient populations to help patients and clinicians make more informed health care decisions.



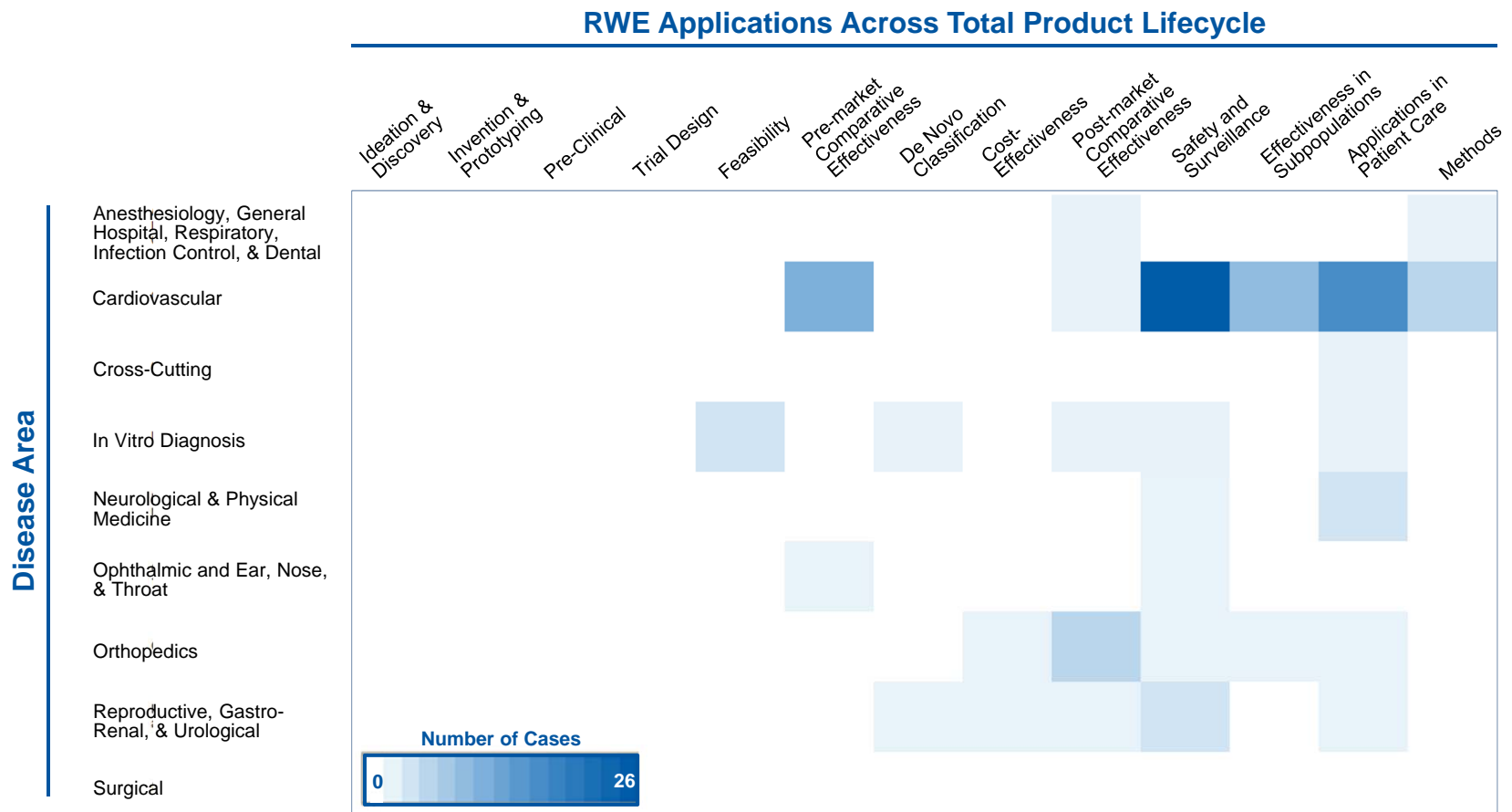
Product Safety and Performance

RWD from post-approval data collected through routine care or specific registries can identify trends in patient outcomes or higher risks of adverse events.



Real-World Evidence Heat Map

To gain a better understanding of the activity of RWE application across the TPLC, a heat map was developed using case studies shared by stakeholders and or collected during research





Early Findings: Emerging Gaps

The interim landscape analysis has pinpointed several emerging gap areas that may benefit from future demonstration projects.

RWE Across the Pre-Market

There is an opportunity to incorporate RWE across the pre-market. Current activities are concentrated in the post-market areas. Feeding information gained through the post-market into the pre-market will help condense the TPLC, and potentially remove pre- and post-market distinctions.

Data Integration and UDI Implementation

- UDI remains key to data integration. The removal of data silos will help with further use of RWE as more data is available for investigation.

Data Access and Cost

- Clear understanding on the cost to access RWE, sharing agreements to access data, and reduction of data costs will help increase the adoption of RWE.

Patient and Data Privacy

- Patient buy-in is essential to the availability and implementation of RWE. Securing and protecting Patient data and privacy is paramount.

Engaging Payers

- Payers have important RWD related to the care and outcomes of patients that can help improve future devices. Communicating the value of RWE will help improve access to RWD.



What Does This Mean for You?

How can NEST benefit your organization or stakeholder constituencies?



Patients

Early engagement to guide product development and regulatory expectations



Government

Higher quality regulatory submissions for product approval and reimbursement



Clinicians

“One-stop shop” for safety and efficacy information



Hospitals

Higher quality products for patients



Payers

Reduced health care costs due to higher quality products



Device Industry

Reduced costs of product development and total time to decision, and better assurance to patient safety



Research Organizations

Increased access to high-quality audited data and leading medical device research



Mission-Focused Investors

Improved medical devices on the market to solve pressing health needs



Other Professional Organizations

Better achieve mission goals of developing safe and effective medical devices



Learn More about MDIC and NEST

Visit our website at: <http://mdic.org>

The screenshot shows the MDIC website header. On the left is the MDIC logo with the text "MEDICAL DEVICE INNOVATION CONSORTIUM". On the right are buttons for "Follow" and "become a Member", along with social media icons for LinkedIn, Twitter, and YouTube. Below the header is a blue navigation bar with links: "About", "Projects", "News & Events", "MDICx Series", "MDIC Public Meetings", and "Contact Us". The main banner features the text "WE WILL ADVANCE REGULATORY SCIENCE" in white on a blue background, with a microscope icon and a green bar at the bottom.

Events

Latest News