A Public-Private Partnership collaborating on Regulatory Science to make patient access to new medical device technologies faster, safer and more cost-effective

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Align › Achieve › Accelerate

Bill Murray, President & CEO
Dawn Bardot, PhD, VP Technology Innovation
March 17, 2017
Background: Regulatory Science

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products

Advances in regulatory science benefits patients by speeding the rate of important technologies reaching market

Advances in regulatory science reduces time and resources needed for device development, assessment, and review. For example:

- Can lead to quicker, more efficient device approvals
- Can decrease the size and duration of pre-market clinical trials

Faster, Safer, More Cost-effective

FDA Strategic Plan, August 2011
Advancing Regulatory Science at FDA
Background: CDRH Strategic Priorities

Strategic priorities for the Center for Devices and Radiological Health (CDRH) emphasize the need for stakeholder partnerships across the entire Medical device ecosystem.

**2014 – 2015**

- Strengthen the Clinical Trial Enterprise
- Strike the Right Balance Between Premarket and Postmarket Data Collection
- Provide Excellent Customer Service

**2016 – 2017**

- Establish a National Evaluation System for Medical Devices (NEST)
- Partner with Patients
- Promote a Culture of Quality and Organizational Excellence
From Dr. Shuren’s presentation to the Medical Device Innovation Consortium’s (MDIC) Chief Medical/Chief Science Officer meeting on September 20, 2016:

**Background: Flexible Regulatory Paradigms Applied Across the Total Product Life Cycle**

**CDRH Vision**

**Patient-Centered, TPLC Approach Benefit-Risk Tradeoffs**

- Postmarket Benefit-Risk Draft Guidance (2016)

**Evidence Generation**

- **Clinical Trials**
  - Early Feasibility Study Paradigm Guidance (2013)

- **Regulatory Science**
  - MDDT Pilot Program

- **Real-World Evidence**
  - RWE Draft Guidance (2016)
  - Unique Device Identification Final Rule (2013)

**Premarket-Postmarket Balance**

- Expedited Access Pathway Program (2015)

**Science of Patient Input**

- Patient Preference Information Guidance (2016)
- Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project

**NEST**

**MDIC**
What is MDIC?

MDIC is the Medical Device Innovation Consortium. Formed in late 2012, the Medical Device Innovation Consortium (MDIC) brings together representatives of the FDA, NIH, CMS, industry, and non-profits and patient organizations to improve the processes for development, assessment and review of new medical technologies.

MDIC members share a vision of providing patients with timely access to high-quality, safe, and effective medical devices. MDICs primary areas of focus include:

1. Develop **Regulatory Science Tools** that can be used to transform the development, assessment and review of new medical technologies for patient benefit.

2. Establish the **National Evaluation System for health Technology (NEST) Coordinating Center (CC)**.

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

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.**
<table>
<thead>
<tr>
<th>Name</th>
<th>Organization/Title</th>
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<tr>
<td>Allan Coukell</td>
<td>The Pew Charitable Trusts - Director of Drugs and Medical Devices MDIC Vice-Chair</td>
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<td>Michael R. Minogue</td>
<td>Abiomed, Inc.- President, CEO and Chairman MDIC Board Chair</td>
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<td>Peter Arduini</td>
<td>Integra LifeSciences- President, CEO and Director MDIC Membership Committee Chair</td>
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<td>William A. Hawkins III</td>
<td>Immucor, Inc.- Lead Director Retired Chairman &amp; CEO, Medtronic</td>
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<td>Randall Schiestl</td>
<td>Boston Scientific Corporation- VP, Global Operations and Technology</td>
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<tr>
<td>Jeffrey Shuren, MD, JD</td>
<td>CDRH, FDA- Director, Center for Devices and Radiological Health Food and Drug Administration MDIC Membership Committee Vice-Chair</td>
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<td>Chip Hance</td>
<td>Creganna Medical - Former Chief Executive Officer</td>
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<td>Nadim Yared</td>
<td>CVRx- President &amp; CEO</td>
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<td>Aran Maree, MD</td>
<td>Johnson &amp; Johnson- Chief Medical Officer, Medical Devices &amp; Diagnostics</td>
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<td>Ross Jaffe, MD</td>
<td>National Venture Capital Association, Director; Versant Ventures Managing Director</td>
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<td>Richard Naples</td>
<td>BD- Executive VP and Chief Regulatory Officer</td>
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<td>Richard E. Kuntz, MD, MSc</td>
<td>Medtronic, Inc.- Sr. VP and Chief Scientific, Clinical &amp; Regulatory Officer</td>
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<td>William V. Murray</td>
<td>MDIC - President &amp; CEO</td>
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<td>Bryan Olin, PhD</td>
<td>LivaNova, Inc.- VP, Clinical, Quality &amp; Regulatory</td>
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<td>Beth Stauble</td>
<td>Stryker Corp.- VP Global Regulatory Affairs and Quality Assurance</td>
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<td>Joseph Woody</td>
<td>Acelity - President &amp; CEO</td>
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<td>Peter Saltonstall</td>
<td>NORD- President &amp; CEO</td>
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<td>Tamara Syrek Jensen, JD</td>
<td>CMS- Director, Coverage and Analysis Group</td>
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<td>Mark Carlson, MD</td>
<td>St. Jude Medical- VP Global Clinical Affairs and Chief Medical Officer</td>
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<td>Kris Kandarpa, MD, PhD</td>
<td>NIBIB, NIH- Director, Research Sciences and Strategic Directions</td>
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<td>Steve Ferguson</td>
<td>Cook Group Inc.- Chairman of the Board</td>
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<td>Rachael Fleurence, PhD</td>
<td>PCORI- Program Director</td>
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<td>Rick Geoffrion</td>
<td>Mitralign, Inc.- President &amp; CEO</td>
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<td>Caroll Neubauer</td>
<td>B. Braun of America, Inc.- Chairman &amp; CEO</td>
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MDIC Membership Roster

1. Abbott
2. Abiomed
3. Acelity
4. AdvaMed
5. AIMBE
6. ANSYS
7. B Braun
8. BARDA
9. Baxter
10. BD
11. Boston Biomedical Associates
12. Boston Scientific
13. CD-adapco
14. CMS
15. Cohera Medical
16. Cook Group
17. CR Bard
18. Creganna Medical
19. CVRx
20. Dartmouth Device Development Symposium
21. Edwards Lifesciences
22. Exact Sciences Corp
23. Exponent, Inc.
24. FasterCures
25. FDA
26. Feinstein Institute for Medical Research
27. Focused Ultrasound Foundation
28. HeartFlow
29. Holaira
30. ICON plc
31. Imricor
32. Integra Lifesciences
33. IT’IS-USA
34. Johnson & Johnson
35. LivaNova
36. MDMA
37. Medical Alley
38. Medidata Solutions
39. Medtronic
40. Mitralign
41. NAMSA
42. NIH
43. NORD
44. NRC
45. NSF International
46. NVCA
47. NxThera
48. PCORI
49. The Pew Charitable Trusts
50. Roche
51. SEMDA
52. SIMULIA
53. Southern Research Institute
54. St. Jude Medical
55. Stryker Corp.
56. Sysmex Americas
57. Terumo BCT
58. W.L. Gore
59. Zimmer Biomet

Updated 2/03/17
MDIC Strategies

MDIC strategies facilitate stakeholder collaboration to expedite regulatory science innovation and ensure board-based benefits

Create A Forum For Collaboration & Dialogue

- Establish a transparent and flexible governance structure
- Ensure involvement from regulators, manufacturers, and other appropriate stakeholders
- Implement appropriate intellectual property and data sharing policies

Make Strategic Investments In Regulatory Science

- Establish working groups to identify and prioritize key issues
- Develop procedures for requesting and evaluating project proposals and for selecting centers to conduct the research
- Invest in programs aimed at improving the throughput of innovation

Provide Tools To Drive Innovation

- Provide education about the medical device regulatory process and new tools, standards and test methods
- Develop searchable databases and links to relevant reports and methods
- Hold an annual medical device regulatory science symposium
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 device manufacturers, payers, regulatory agencies, patient groups, physicians, providers and other relevant stakeholders.

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

Establishment of the NESTcc is intended to facilitate responsible sharing and efficient analysis of real-world evidence to inform and empower patients, accelerate medical device innovation, and improve health care outcomes.

- Passive Surveillance: Challenging to find the right pre/post market balance without confidence in post-market data. Parallel track to clinical practice, inefficient one-off studies.

- Active Surveillance to better protect patients: Leverage RWE to support regulatory decisions throughout TPLC. Embedded in Health Care System (collect data during routine clinical care). Shared system to inform the entire ecosystem (patients, clinicians, providers, payers, FDA, device firms).

- National System: Embedded in Health Care System (collect data during routine clinical care). Shared system to inform the entire ecosystem (patients, clinicians, providers, payers, FDA, device firms).
The MDIC is currently working to establish the NESTcc Governing Board and to initiate a series of demonstration projects capable of providing direct value to participating stakeholders.

**Phase 1**
Establish NESTcc Governing Board with representation from patients, federal agencies, industry, clinicians, hospitals, and health plans.

**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.

**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.
The NEST Coordinating Center (NESTcc) will be stood up through parallel activities over the first six months.

Critical Pathway

1. Appoint Interim Executive Director (ED)
2. Appoint ED
3. Appoint Governing Committee (GC)
4. Select and Disseminate Demonstration Project Selection Criteria
5. Launch First Round of Projects

NESTcc Six-Month Tactical Strategy

- GC Selected
  - GC Selection Criteria Approved
- ED Appointed
  - ED Hired
- Working Groups Established
  - Objectives of Analysis Confirmed
- Landscaping Analysis
  - Information Collected
  - Information Analyzed
  - Preliminary Findings Feed Project Selection Criteria
- Demonstration Project Selection
  - DP Selection Criteria Drafted
  - Draft DP Selection Criteria Are Shared with Stakeholders
  - DP Selection Criteria Edited by GC & GC Solicits Call for Projects
- Communications and Education Platform
  - Nest website URL active
  - Communication partner identified
  - Communications launch and roadshow
MDIC NESTcc Project Structure

MDIC Staff
- MarCom
- Ombudsman
- Data and Service

Executive Director

Governing Committee
MDIC Board Champion
FDA PI
MDIC members: industry, FDA, CMS, NIH, patients groups, nonprofits
SMEs: payers, clinicians, hospital systems, health insurance organizations, research organization and other as needed

Grant Review Committee

Working Groups
Standards & Processes
- Broad stakeholder representation

Engagement
- Broad stakeholder representation

Access
- Broad stakeholder representation

Protection of Patients
- Broad stakeholder representation

Sustainability
- Broad stakeholder representation
The NESTcc will include a variety of stakeholder voices when building the Governing Committee.
RWE Applications Across the Total Product Life Cycle

<table>
<thead>
<tr>
<th>Disease Area</th>
<th>Ideation &amp; Discovery</th>
<th>Invention &amp; Prototyping</th>
<th>Pre-Clinical</th>
<th>Trial Design</th>
<th>Feasibility</th>
<th>Pre-Market Comparative Effectiveness</th>
<th>De Novo Classification</th>
<th>Cost-Effectiveness</th>
<th>Post-Market Comparative Effectiveness</th>
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<th>Effectiveness in Subpopulations</th>
<th>Applications in Patient Care</th>
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Number of Cases

0 - 26
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

[www.NESTcc.org](http://www.NESTcc.org)