MDIC: OVERVIEW PRESENTATION

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BACKGROUND

Who we are and what we do.
WHAT IS MDIC?

A 501 (c)(3) and public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.
DEFINING REGULATORY SCIENCE

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.
"What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research."

- Jeffrey Shuren, MD, JD
  Director of CDRH
  MedPage Today, December 4, 2012
MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.
MDIC PROMOTES REGULATORY SCIENCE INNOVATION

Create A Forum For Collaboration & Dialogue

- Flexible governance structure
- Multi-stakeholder involvement
- Focus on patient benefit

Make Strategic Investments In Regulatory Science

- Improve efficiency and cost-effectiveness
- Focus on unmet needs
- Improve innovation cycle time

Provide Tools To Drive Innovation

- Evidence generation
- Patient engagement & access
- Quality and patient safety

MDIC strategies facilitate stakeholder collaboration to expedite regulatory science innovation and ensure broad-based benefits.
OUR PROGRAMS

MDIC is advancing regulatory science to benefit patients.
OUR CORE INITIATIVES DRIVE OUR SHARED VISION WITH CDRH

MDIC facilitates a number of programs and activities that support CDRH strategic priorities. These programs are housed within four core initiatives of MDIC.

CLINICAL SCIENCE

DATA SCIENCE AND TECHNOLOGY

HEALTH ECONOMICS AND PATIENT ACCESS

NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY COORDINATING CENTER (NESTcc)
CLINICAL SCIENCE

Addresses barriers to collecting adequate clinical evidence in the support of new medical technology by creating blueprints for innovative clinical trials techniques, developing standards and metrics for effective clinical trial designs and encouraging the collection of adequate and appropriate clinical and patient preference data.

- Early Feasibility Study (EFS)
- Science of Patient Input (SPI)
- Clinical Diagnostics (CDx)
DATA SCIENCE AND TECHNOLOGY

Creating tools and methods to use advanced data analysis techniques and new technology to accelerate the collection of clinical data, remove barriers to patient access and monitor product safety, quality and effectiveness.

- Case for Quality (CfQ)
- Computational Modeling and Simulation (CM&S)
- External Evidence Methods
- Cybersecurity
HEALTH ECONOMICS AND PATIENT ACCESS

Aims to create predictability and transparency of evidentiary requirements for coverage and improve pathways for coverage, coding and payment to speed patient access and amplify the patient voice in selection of treatment options.

- Promote predictability of evidentiary processes
- Improve pathways for coverage, coding and payment to speed patient access
- Compliment existing efforts of trade associations
MDIC’S NEST COORDINATING CENTER

NESTcc Mission

MDIC’s National Evaluation System for health Technology Coordinating Center (NESTcc) accelerates the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE), and innovative research.

History of NESTcc

- 2012 - 2015
  - FDA proposed the development of a national system

- 2016
  - NESTcc envisioned as a voluntary data network of collaborators by Planning Board

- 2017
  - FDA awarded grant for NESTcc to Medical Device Innovation Consortium (MDIC)

  - NESTcc Executive Director named and Governing Committee selected

  - NESTcc Strategic and Operational Plan developed

- 2018
  - Initial NESTcc Data Network formed and testing initiated

  - NESTcc Data Quality and Methods Subcommittees formed
BOARD OF DIRECTORS

World-class representatives from the medical device industry, government, and patient groups working together to advance the mission of MDIC.
2019 BOARD OF DIRECTORS

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MDIC Board Chair

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Chairman of the Board

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Executive Director

Doug Fridsma, MD, Ph D | AMIA
President and Chief Executive Officer
MEMBERSHIP

Members actively work in collaboration with FDA, CMS, NIH, industry, and non-profits to influence and drive regulatory science innovation that accelerates patient access to medical devices of public health importance.
MEMBERSHIP WITH MDIC

MDIC members provide guidance and leadership through collaboration to develop solutions for regulatory, scientific, and health economic challenges within the medical device and diagnostic industry.
# MDIC MEMBER ORGANIZATIONS

1. Abbott
2. Abiomed, Inc.
3. AHRQ
4. AIMBE
5. AMIA
6. ANSYS
7. Avanos Medical
8. BARDA
9. Baxter
10. BBraun Medical
11. Becton Dickinson
12. Bioventus
13. Boston Biomedical
14. Boston Scientific
15. CDC
16. CMS
17. Cook Medical
18. CVRx
19. Dassault Systemes
20. Edwards Lifesciences
21. Exact Sciences Corporation
22. FDA
23. Focused Ultrasound Foundation
24. Fujirebio Diagnostics, Inc.
25. Genomic Health
26. Hologic
27. IBM-Watson
28. ICON
MDIC MEMBER ORGANIZATIONS

29. Imricor Medical Systems
30. Insulet Corporation
31. Integra
32. IT’IS-USA Foundation
33. Johnson and Johnson
34. LivaNova
35. Medical Alley
36. Medtronic
37. Mitralign
38. NIH
39. NORD
40. NRC
41. Nuvaria Inc.
42. PCORI
43. PEW
44. Philips
45. Reggata Medical
46. Roche
47. SEMDA
48. Southern Research Inst
49. Stryker
50. Sysmex Americas, Inc.
51. TGEN
52. ThermoFisher Scientific
53. WL Gore
54. Zimmer Biomet