MDIC OVERVIEW

Pamela Goldberg

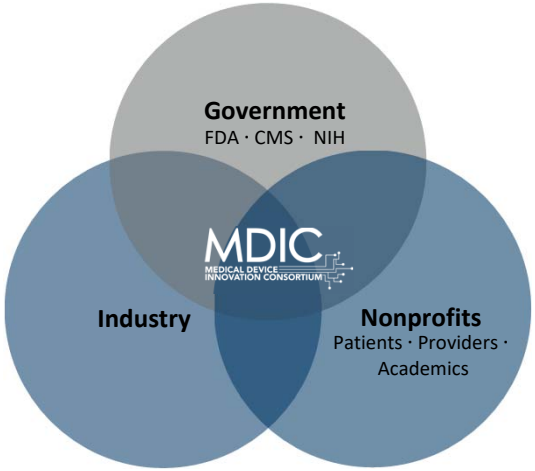
President and CEO

November 4, 2019

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
Align. Achieve. Accelerate.

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.



Resources · People · Intellectual Capital

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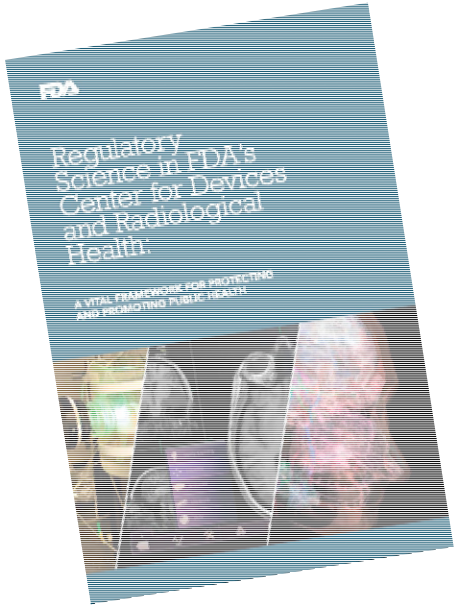
HIGHLIGHTS

- **63 participating member organizations**
- Leading resource on issues important to the Medtech innovation ecosystem
- Initiated nine projects
- Congressional testimony on modernizing clinical trials
- $35M + funding from grants and contracts for Program initiatives

Defining Regulatory Science



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

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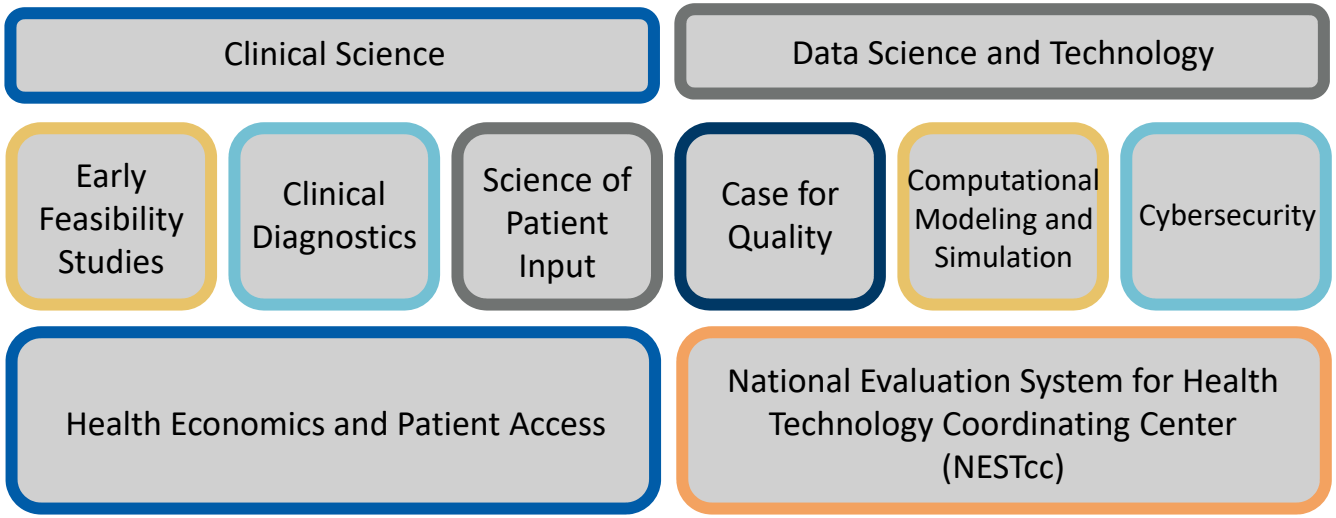
"What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research."

- Jeffrey Shuren, MD, JD
Director of CDRH
MedPage Today, December 4, 2012

MDIC Initiatives and Program Areas

MDIC's activities advance the medical device regulatory process for patient benefit.



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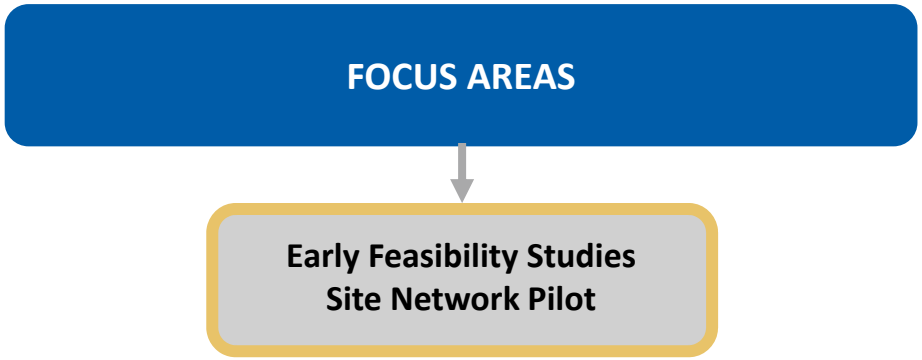
Early Feasibility Studies

Advancing regulatory science through innovations in medical device clinical trial efficiency and cost-effectiveness.



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Champion: Chip Hance | CEO | Regatta Medical

Program Director: Liliana Rincon-Gonzalez| MDIC

FDA

Contact: Andrew Farb, MD| Chief Medical Officer | Office of Cardiovascular Devices, CDRH

Contact: Maureen Dreher, PhD | Acting Assistant Director, Policy and Operations Team | Office of Clinical Evidence & Analysis

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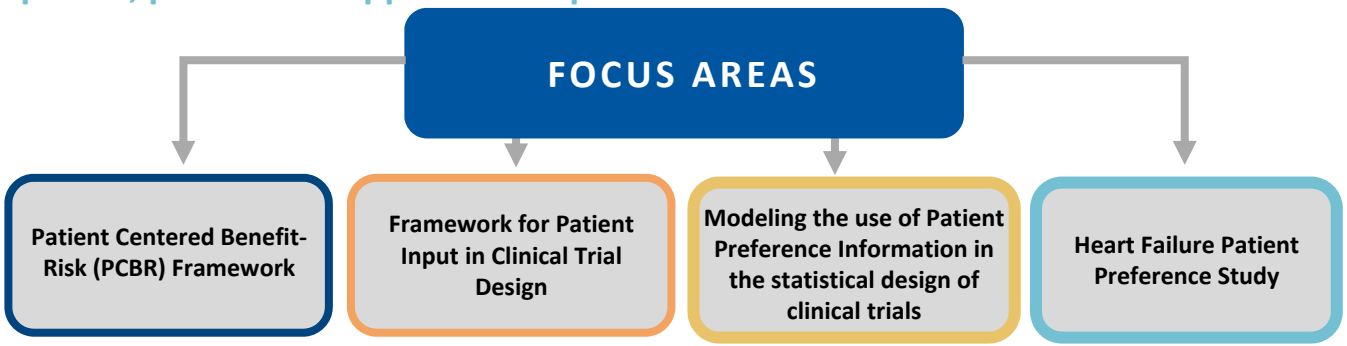
Science of Patient Input

Advancing the science of patient input and improve our ability to include patient perspectives in the development, pre-market approval and post-market evaluation of medical devices.



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Committee chair: Barry Liden | VP, Patient Engagement | Edwards Lifesciences

Program Director: Liliana Rincon Gonzalez| MDIC

FDA

Contact: Michelle Tarver | Director, Patient Science & Engagement Program

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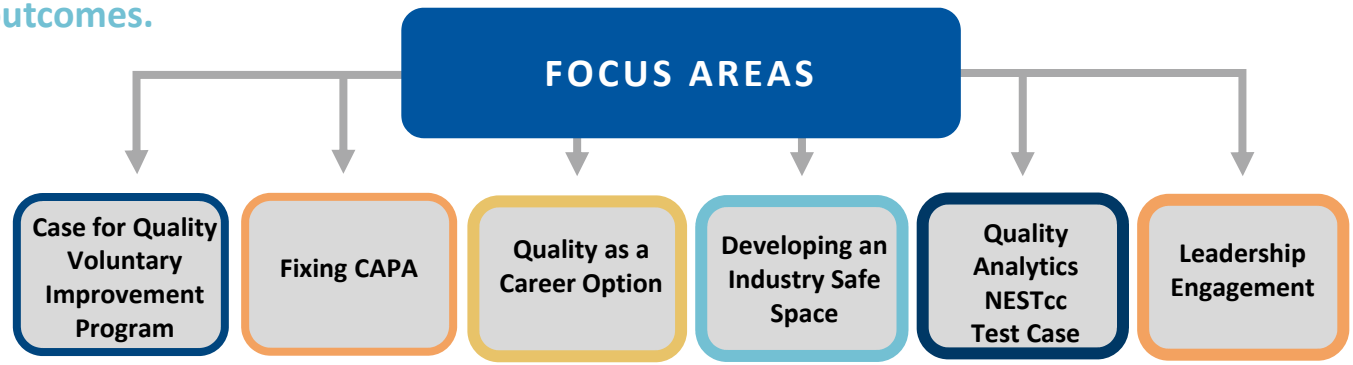
Case for Quality

Elevating the focus of all medical device stakeholders from baseline regulatory compliance to sustained, predictive practices that advance medical device quality and safety to achieve better patient outcomes.



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Committee chair: Joe Sapiente| VP, Quality Assurance and Regulatory Affairs, Hologic

Vice President: Jon Hunt | MDIC

FDA

Contact: Cisco Vicenty| Program Manager, Case for Quality | CDRH

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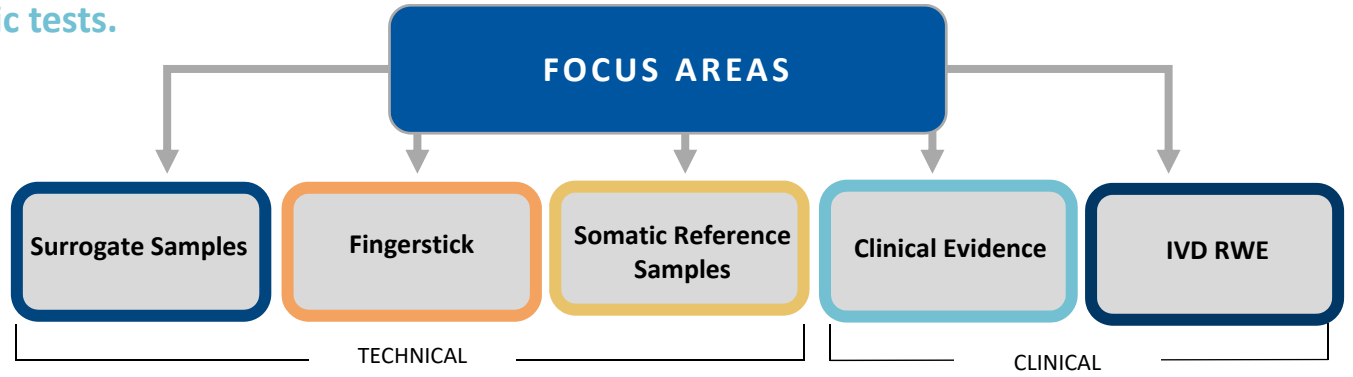
Clinical Diagnostics

Fostering innovation and speed patient access to new IVD tests by developing new tools and methods that will improve processes to assess safety, effectiveness and the value proposition of diagnostic tests.



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Committee Chair: Danelle Miller, JD | **Vice President, Global Regulatory Policy and Intelligence** | Roche Diagnostics

Program Director: Carolyn Hiller, MBA | MDIC

FDA

Contact | Zivana Tezak, PhD | **Associate Director for Science and Technology** | Office of In Vitro Diagnostics and Radiological Health

Contact: Marina Kondratovich, PhD | **Associate Director for Clinical Studies** | Office of In Vitro Diagnostics and Radiological Health

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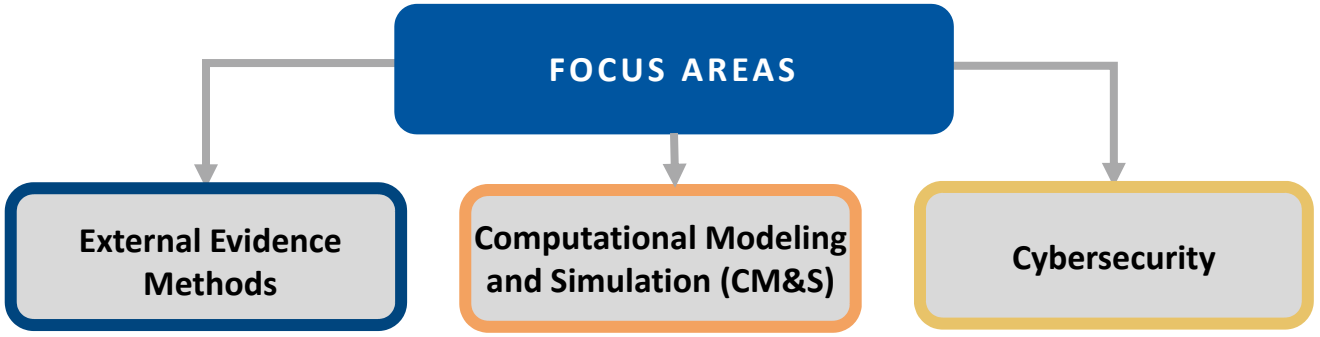
Data Science & Technology

Creating regulatory-grade 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.



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Champion: Randy Schiestl | Global Operations & Technology | Boston Scientific

Program Director: Jithesh Veetil| MDIC

FDA

EEM Contact: Ram Tiwari, PhD | Director, Division of Biostatistics; Office of Clinical Evidence & Analysis, OPEQ | CDRH

CM&S Contact: Tina Morrison, PhD | Deputy Director, Division of Applied Mechanics | Office of Science & Engineering Laboratories (OSEL) | CDRH

Cybersecurity Contact: Suzanne Schwartz, MD | Director, Office of Strategic Partnerships & Technology Innovation (Acting) | CDRH

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Health Economics and Patient Access

Promoting predictability of evidentiary processes, improving pathways for coverage to speed patient access, and ensuring that patient perspectives are considered.

INITIAL PROJECT INITIATIVE

HEPA Member Survey and Survey Report

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Champion: Mike Minogue | President and CEO | Abiomed

FDA

Contact: Jeff Shuren, MD, JD | Director, Center for Devices and Radiological Health | CDRH

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NEST Coordinating Center

NESTcc is an initiative of MDIC that aims to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE), and innovative research.

Concept

2012 — FDA proposed the development of a **national system**

2015 — NESTcc envisioned as a **voluntary data network** of collaborators by Planning Board

Building Capacity

2016 — FDA awarded funding for NESTcc to **Medical Device Innovation Consortium (MDIC)**

2017 — NESTcc **Executive Director** named and **Governing Committee** selected

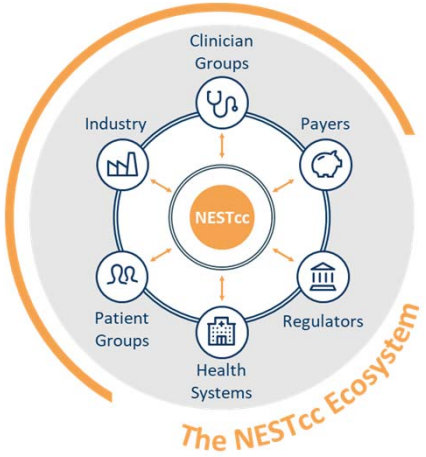
Network Development

2018 — Initial NESTcc **Data Network** formed

Utilization & Expansion

2019 — Interim and Final Results from **Round 1 and Round 2 Test-Cases**

2022 — NESTcc **fully launched and operational**



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Contact: Rachael Fleurence, PhD | NESTcc Executive Director, MDIC

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President & CEO
MDIC Board Chair
MDIC Executive Committee

Michael R. Minogue | ABIOMED Inc.
President, CEO and Chairman

Rick Geoffrion | Mitralign, Inc.
President & CEO
MDIC Executive Committee and
Finance Committee Vice-Chair

Shacey Petrovic| Insulet
President and CEO
MDIC Executive Committee and
Membership Committee Chair

Pamela Goldberg | MDIC
President & CEO

Randall Schiestl | Boston Scientific Corporation
VP, Global Operations and Technology

Mark Carlson, MD, MSc | Abbott
Division Vice President and Chief Medical Officer

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Executive Director

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MDIC Executive Committee and Finance Committee Chair

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Director of CDRH
MDIC Executive Committee and Membership Committee Vice-Chair

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EVP & General Counsel

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Director, Research Sciences and Strategic Directions

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Chief Medical Officer, Medical Devices
MDIC Executive Committee

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Dana McMahon | Stryker Corp.
Chief Legal Counsel

Tamara Syrek Jensen, JD | CMS
Director, Coverage and Analysis Group

Steve Ferguson | Cook Group Inc.
Chairman of the Board

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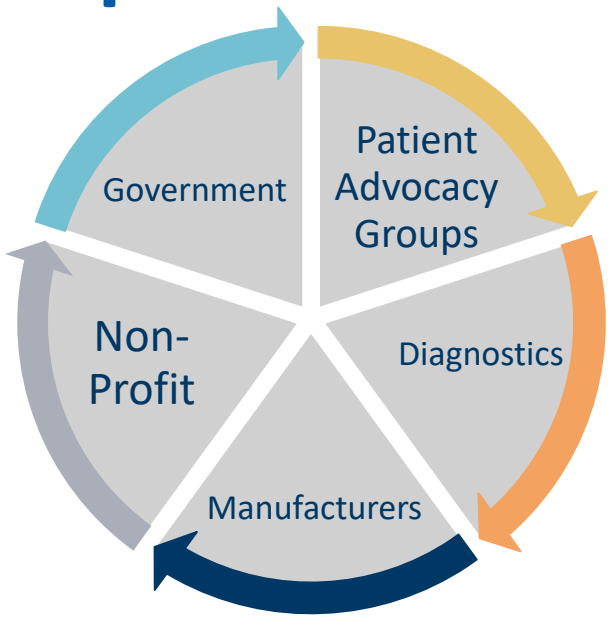
MDIC Membership Within the Ecosystem



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.

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CURRENT MEMBERSHIP ORGANIZATIONS

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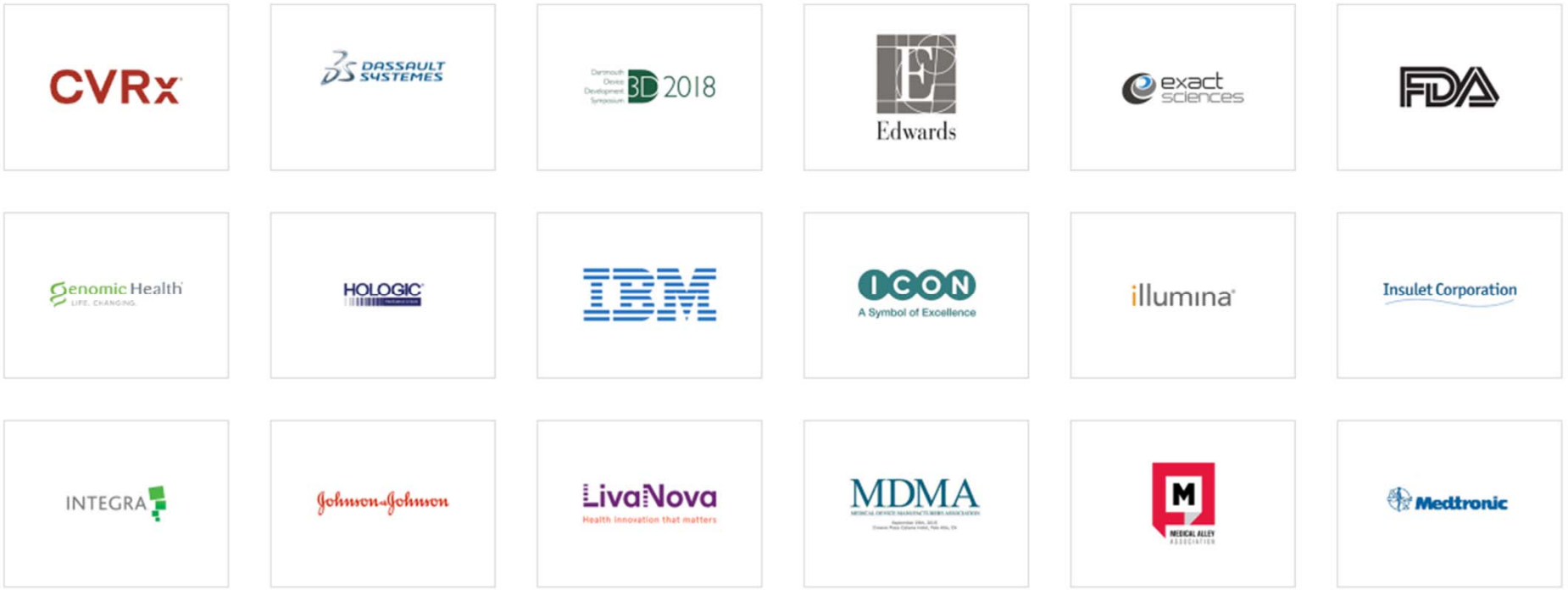

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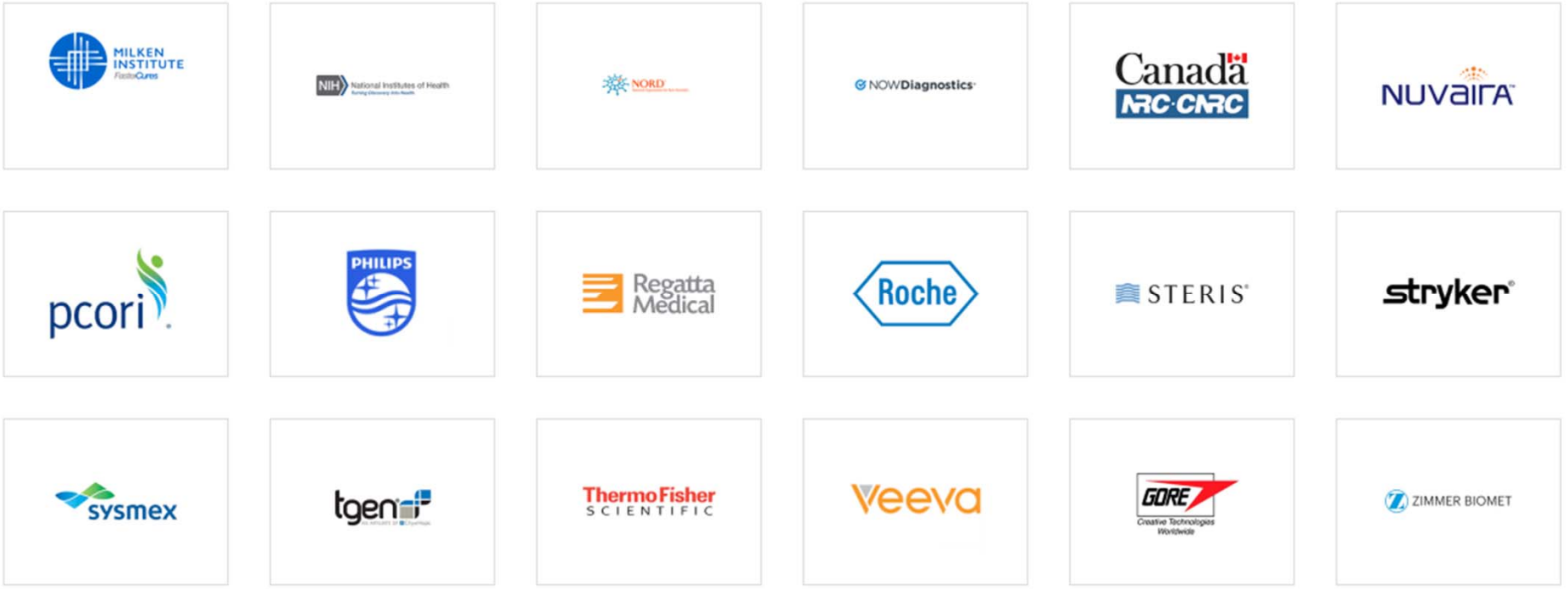

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Not pictured: 10x Genomics, Now Diagnostics

Questions?


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1501 Wilson Blvd.
Suite 910
Arlington, VA 22209

info@mdic.org

202-828-1600

www.mdic.org