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.

**HIGHLIGHTS**

- 54 participating member organizations
- Leading resource on issues important to the MedTech innovation ecosystem
- Launched 12+ initiatives
- 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.

"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.

- **Clinical Science**
  - Early Feasibility Studies
  - Clinical Diagnostics
  - Science of Patient Input
  - Health Economics and Patient Access

- **Data Science and Technology**
  - Case for Quality
  - Computational Modeling and Simulation
  - Cybersecurity
  - National Evaluation System for Health Technology Coordinating Center (NESTcc)
Early Feasibility Studies

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

FOCUS AREAS

- Site Network Pilot
- Contracting
- Regulatory
- Budgeting

MDIC

Champion: Chip Hance | CEO | Regatta Medical
Program Director: Liliana Rincon-Gonzalez, PhD | MDIC

FDA

Contact: Andrew Farb, MD | Chief Medical Officer | Office of Cardiovascular Devices, CDRH
Contact: Maureen Dreher, PhD | Assistant Director, Division of Clinical Science & Quality | Office of Clinical Evidence & Analysis, Office of Product Evaluation & Quality