MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

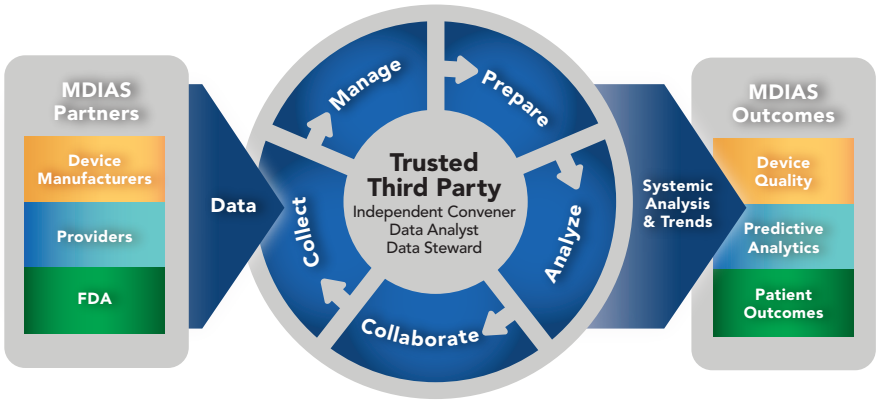
MEDICAL DEVICE INFORMATION ANALYSIS & SHARING (MDIAS)

An Initiative of the Case for Quality Collaborative Community (CfQcc)

A wealth of data are collected during the medical device development process and in real-world environments. But these data vary in quality and format and are currently siloed within organizations for privacy and proprietary reasons. Developing an independent third party to collect and analyze these data can help identify trends in device quality and safety and provide powerful insights for improving outcomes while safeguarding data.

CfQcc Medical Device Information Analysis & Sharing (MDIAS)

The MDIAS Initiative focuses on building a data-sharing collaboration to analyze and share medical device data from various public and non-public sources to improve healthcare outcomes. Data will be safeguarded by an independent trusted third party (TTP) to foster broad participation and engagement.



HOW TO GET INVOLVED

Learn more.
Get to know MDIAS! For more information, contact Alan Baumel, CfQcc Program Director, at abaumel@mdic.org.

Share your ideas.
If you have an idea for this project, we want to hear from you. Please reach out to Alan Baumel, CfQcc Program Director, at abaumel@mdic.org.

CASE FOR QUALITY COLLABORATIVE COMMUNITY (CfQcc)

The MDIAS Initiative is an effort of the Case for Quality Collaborative Community (CfQcc). CfQcc offers a unique forum for medical device stakeholders to move beyond baseline regulatory compliance activities and collaboratively develop sustained predictive practices that advance medical device quality and safety to achieve better patient outcomes.

Collaborative Communities provide a forum for public and private sector members to proactively work together to achieve common objectives and outcomes. FDA does not lead Collaborative Communities, and their work does not replace established regulatory mechanisms. However, FDA may choose to participate in a Collaborative Community and support, leverage, and/or adopt solutions that emerge.

GET INVOLVED WITH THE MDIAS INITIATIVE TODAY

Contact Alan Baumel, Program Director for CfQcc, at abaumel@mdic.org.

About MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, industry, nonprofits, and patient organizations to improve the processes for development, assessment, and review of new medical technologies. We are working toward faster, safer, and more cost-effective innovation for patient benefit.

MDIC has been formed to add value at the intersecting needs of the medical device industry, the FDA, and the related organizations that are together responsible for a vibrant medical device industry that serves the public health needs of the United States.

Vision

MDIC, through its public-private partnership, aims to advance regulatory science in the medical device industry. MDIC will coordinate 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.

Initiatives and Programs

MDIC's initiatives focus on four areas, each of which has one or more programs to meet a specific need:

1. Clinical Science – Addresses the biggest 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

- Clinical Diagnostics
- Early Feasibility Studies
- Science of Patient Input

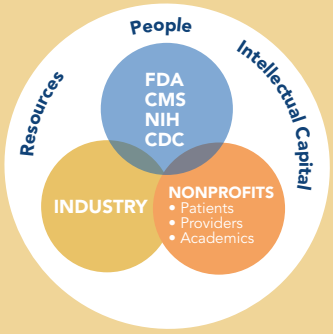
2. Data Science & Technology – Fulfills the promise of advances in data analysis by creating tools and methods to use advanced data analysis techniques and new technology to accelerate the collection of clinical data, remove barriers to patient access, and monitor product safety, quality, and effectiveness

- Case for Quality Collaborative Community
- Computational Modeling and Simulation
- Cybersecurity
- External Evidence Methods
- Systemic Harmonization and Interoperability Enhancement for Lab Data (SHIELD)
- 5G-Enabled Health Technologies

3. Health Economics & Patient Value – Creates predictability and transparency of evidentiary requirements for coverage and improves pathways for coverage, coding, and payment to speed patient access and amplify the patient voice in selection of treatment options

4. National Evaluation System for Health Technology Coordinating Center (NESTcc) – Works with stakeholders across the medical device ecosystem to catalyze the timely, reliable, and cost-effective development of Real-World Evidence to enhance regulatory and clinical decision-making.

MDIC COLLABORATORS



LEARN MORE ABOUT MDIC

Learn more about MDIC by visiting www.mdic.org, sending a message to info@mdic.org, or calling (202) 828-1600.

MDICx Series

WEBINARS BY MDIC

MDIC's informative series of online workshops, the MDICx series, features emerging trends in medical technology, regulatory science, MDIC projects, and subject matter experts sharing perspectives, progress, and opportunities. Visit mdic.org/mdicx-series to view upcoming webinars or submit a proposal.

MDIC ANNUAL PUBLIC FORUM

Every year, MDIC's Annual Public Forum (APF) brings together MDIC members and the broader medical device and diagnostics community to share insights on current trends in regulatory science and the progress MDIC has made in advancing the field. Learn more at https://apf.mdic.org/agenda/

Past panel topics have included:

- Developing a patient-centered regulatory strategy
- Assessing the Use, Impact, and Role of RWE in the U.S. and EU
- Mitigating cybersecurity risks to ensure device security and patient safety

Past guest speakers have included:

- FDA Commissioners Hahn, Gottlieb, and Califf; Acting Commissioner Sharpless
- Tamara Syrek Jensen, Director of the Coverage and Analysis Group, CMS
- Danelle Miller, Vice President, Global Regulatory Policy & Intelligence - Roche Diagnostics

MEMBERSHIP

MDIC members are leaders in the medical technology industry. MDIC focuses on providing patients access to innovative medical technologies, so many of our members are companies that can help us serve this mission. Member organizations are substantially involved in medical and/or medical device research, development, treatment, or education; the promotion of public health; or expertise in regulatory science.