Medical Device Innovation Consortium

Digital Health Panel Discussion
Our Panel

Cassie Scherer
Director of Regulatory Policy, U.S.
Global Regulatory Policy, Medtronic

Eric Friedman
co-founder of Fitbit
Fitbit's VP of research at Google.

Heidi Dohse
Founder Tour de Heart

Bakul Patel, MSEE, MBA
Director, Digital Health Center of Excellence
Director, Digital Health Division Center for Devices and Radiological Health Food and Drug Administration

Jithesh Veetil, PhD
Program Director, Data Science and Technology, MDIC

Jon Hunt, PhD
Vice President, Clinical Science and Technology
MDIC
MDIC Overview

Jon P Hunt, PhD | Vice President, Clinical Science & Technology
Who We Are

MDIC is a 501 (c)(3) and public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit through multiple pre-competitive regulatory science projects.

66 participating member organizations

300+ subject matter experts involved in working groups

70+ resources available to download in our digital resource library

35+ active working groups and committees

Government
FDA · CMS · NIH · BARDA · CDC · NIST · AHRQ · NRC Canada

Industry
Device · Diagnostics · Digital Health

Non-Profits
Patients · Providers · Academics

Resources · People · Intellectual Capital
Our Core Initiatives and Program Areas

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

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<th>DATA SCIENCE AND TECHNOLOGY</th>
<th>HEALTH ECONOMICS AND PATIENT VALUE</th>
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<td>Real-World Evidence • Patient Preference Research</td>
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<td>• Science of Patient Input</td>
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<td>• External Evidence Methods • SHIELD • 5G- Enabled Health Technologies</td>
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**NEST COORDINATING CENTER (NESTcc)**

- Real-World Evidence • Research Methods • Data Quality • Research Implementation • Data Network • Active Surveillance • Unique Device Identifier Adoption • Collaborative Community

**Advanced Manufacturing**

- Improving Quality and Safety

[Launching Soon]
Data Science and 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.
Synergies, crossover from DST

Objective of the Digital Health Vertical
To collaboratively and strategically advance science and evidence for high-quality digital health technologies in an efficient, risk-based approach, leveraging the new relationships with developers, patients, and providers, to shape and inform the regulatory strategies, policies, and processes to accelerate digital health innovation, drive synergies and advance best practices.
Digital Health and Technology

Reboot of Data Science and Technology. Aligning Current and New Initiatives under a New MDIC “Core Program”.

- Artificial Intelligence/Machine Learning
- Computatio nal Modeling & Simulation
- Cybersecurity
- SHIELD
- 5G-Enabled Health Technologies
- Pathology Innovation Collaborative Community
- Advanced Manufacturing
- Case for Quality Collaborative Community
- New DH Initiatives