MDICx: Medical Device Cybersecurity Benchmarking via MedTech Joint Security Plan

October 19, 2020
MDIC OVERVIEW

Jithesh Veetil, PhD
Program Director, Data Science & Technology

October 2020
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**

- 50+ participating member organizations
- Leading resource on issues important to the MedTech innovation ecosystem
- Most of the projects in pre-competitive space, No advocacy/lobbying
- Congressional testimony on modernizing clinical trials
- $40M + funding from grants and contracts for Program initiatives
MDIC was established in 2012 to advance Regulatory Science for Devices & Diagnostics

“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

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

Data Science and Technology
- Case for Quality
- Computational Modeling and Simulation
- Digital Health, 5G, Cybersecurity

Health Economics and Patient Access

National Evaluation System for Health Technology Coordinating Center (NESTcc)
To learn more about MDIC & opportunities to collaborate in various initiatives

Web: www.mdic.org
Email: jveetil@mdic.org
Jessica Wilkerson
Senior Policy Advisor, FDA
Greg Garcia
Executive Director, HSCC
HSCC Joint Cybersecurity Working Group Primer for the Medical Device Innovation Consortium

October 19, 2020

Greg Garcia
Executive Director
Greg.Garcia@HealthSectorCouncil.org
Critical Infrastructure

Systems and assets, whether physical or virtual, so vital to the United States that their incapacitation or destruction ... would have a debilitating impact on security, ... economic security, ... public health or safety, or any combination of those matters.

§1016(e) of the USA Patriot Act of 2001 (42 U.S.C. §5195c(e))
What Is the Health Sector Coordinating Council?

The cross-sector coordinating body representing one of 16 critical infrastructure sectors organized under Presidential Executive Order (PPD-21)

As a “Critical Infrastructure Partnership Advisory Council”, exempted from Federal Advisory Committee Act requirements to protect ongoing sensitive deliberations with government

A trust-community partnership convening companies, non-profits and industry associations across six subsectors

**Mission:** to identify cyber and physical risks to the security and resiliency of the sector, and develop planning guidance in a 3-year Sector Specific Plan and implementing task groups for mitigating those risks

Focused on longer-term critical infrastructure policy and strategy, complementing the operational Health Information Sharing and Analysis Center.
Health Care Industry Cybersecurity (HCIC) Task Force – Six Imperatives and 105 Action Items

1. Define and streamline leadership, governance, and expectations for healthcare industry cybersecurity.
2. Increase the security and resilience of medical devices and health IT.
3. Develop the healthcare workforce capacity necessary to prioritize and ensure cybersecurity awareness and technical capabilities.
4. Increase healthcare industry readiness through improved cybersecurity awareness and education.
5. Identify mechanisms to protect R&D efforts and intellectual property from attacks and exposure.
6. Improve information sharing of industry threats, risks, and mitigations.
2019-2020 Guidance Publications

- Sept. 22, 2020  Health Industry Cybersecurity Supply Chain Risk Management
- May 18, 2020  Health Industry Cybersecurity Tactical Crisis Response
- May 14, 2020  Health Industry Cybersecurity Protection of Innovation Capital
- March 11, 2020  Health Industry Cybersecurity Information Sharing Best Practices
- March 9, 2020  Management Checklist for Teleworking Surge During COVID-19
- October 9, 2019  Health Industry Cybersecurity Matrix of Information Sharing Organizations
- June 17, 2019  Health Industry Cybersecurity Workforce Guide
- January 28, 2019  Medical Device and Health IT Joint Security Plan (JSP)
- January 2, 2019  Health Industry Cybersecurity Practices (HICP)
Greg Garcia
Executive Director
Greg.Garcia@HealthSectorCouncil.org

Allison Burke
Program Operations Lead
Allison.Burke@HealthSectorCouncil.org

https://HealthSectorCouncil.org
Chris Tyberg
Division VP, Head of Product Security at Abbott

Tyrone Heggins
Cybersecurity Officer, Americas at BD
MedTech Cybersecurity Maturity Benchmarking

Chris Tyberg, Division VP, Head of Product Security at Abbott
Tyrone Heggies, Cybersecurity Officer, Americas at BD
Our common goals

Across the industry, we all strive to:

1. Protect patient safety and privacy
2. Increase cyber resilience
3. Accelerate cybersecurity maturity
Benchmarking cybersecurity

Where does your organization stand?

The JSP Maturity Model Metrics include:

- Organization
- Risk Management
- Design Control
- Compliant Handling
Accelerating improvement

... by encouraging organizations to:

- Measure cybersecurity maturity
- Share scores for anonymous benchmarking
- Implement improvement plans
- Develop improvement plans
- Track progress

(MDIC logo)
Contribute to the JSP Maturity Model

3 ways to join MDIC in this effort

Help us develop a benchmarking tool based on the CMMI

Use the tool to gauge your organization’s cyber maturity

Contribute your organization’s metrics anonymously

Contact CYBERSECURITY@MDIC.ORG to participate.
How To Get Involved?

Enroll in the pilot project

Contact: Jithesh Veetil, Program Director MDIC: cybersecurity@mdic.org

WEBSITE: https://mdic.org/program/cybersecurity/
How To Get Involved?

Request for Proposals (RFP) will be open from October 2 – October 30, 2020

Contact: Jithesh Veetil, Program Director MDIC: cybersecurity@mdic.org

WEBSITE: https://mdic.org/program/cybersecurity/
Q&A Open Discussion