DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

September 26, 2023

Patrick Hope, DITTA Chair

Executive Director, Medical Imaging and Technology Alliance

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协 China Association for Medical Devices Ind · ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

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DITTA Global Presence

2018: DITTA recognized as a non state actor in official relations with WHO
2016: Signed MoU with the World Bank
2015: Granted NGO status with WHO
2014: Established official liaison with now-GHWP

DITTA: 11 WORKING GROUPS

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1. Regulated Product Submission (RPS) Working Group — MITA
2. Cybersecurity Working Group — MITA
3. Medical Device Single Audit Program (MDSAP) Working Group — MITA
4. Unique Device Identification (UDI) Working Group — MITA
5. MSW & AI Working Group — COCIR
6. Clinical Evaluation Working Group — COCIR
7. Standardisation (STA) Working Group — COCIR
8. Good Regulatory Review Practices (GRRP) Working Group — JIRA
9. Global Health (GH) Working Group — COCIR
10. Environmental Policy (ENVI) Working Group — COCIR
11. Good Refurbishment Practice (GRP) Working Group — JIRA

IMDRF, GHWP, IEC, ISO

World Health Organization, World Bank Group, IAEA International Atomic Energy Agency

BASEL CONVENTION, UNEP, IEC, ISO

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GMTA-DITTA WORKSHOP OVERVIEW

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2. DITTA PRIORITIES

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- Global harmonization of medical device regulations
- Convergence of regulatory frameworks
- Regulatory reliance
- Support training and capacity building

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3. Feedback on IMDRF Work items and other relevant topics

- Good Regulatory Review Practices (GRRP)
- Medical Device Cybersecurity Guide (CYBER)
- Artificial Intelligence /Machine/Learning-enabled Devices (AI/ML)
- Software as a Medical Device (SaMD)
- Standards
- Unique Device Identification Application Guide (UDI)
- Medical device single audit program (MDSAP)
- RPS/eSTAR
- Health Equity

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3. Feedback on IMDRF Work items

1. Good Regulatory Review Practices (GRRP)

- DITTA welcomed the publication of the IMDRF N71 "Medical Device Review Report: Guidance regarding information to be included"
- DITTA supports further development of key elements for the CAB review system

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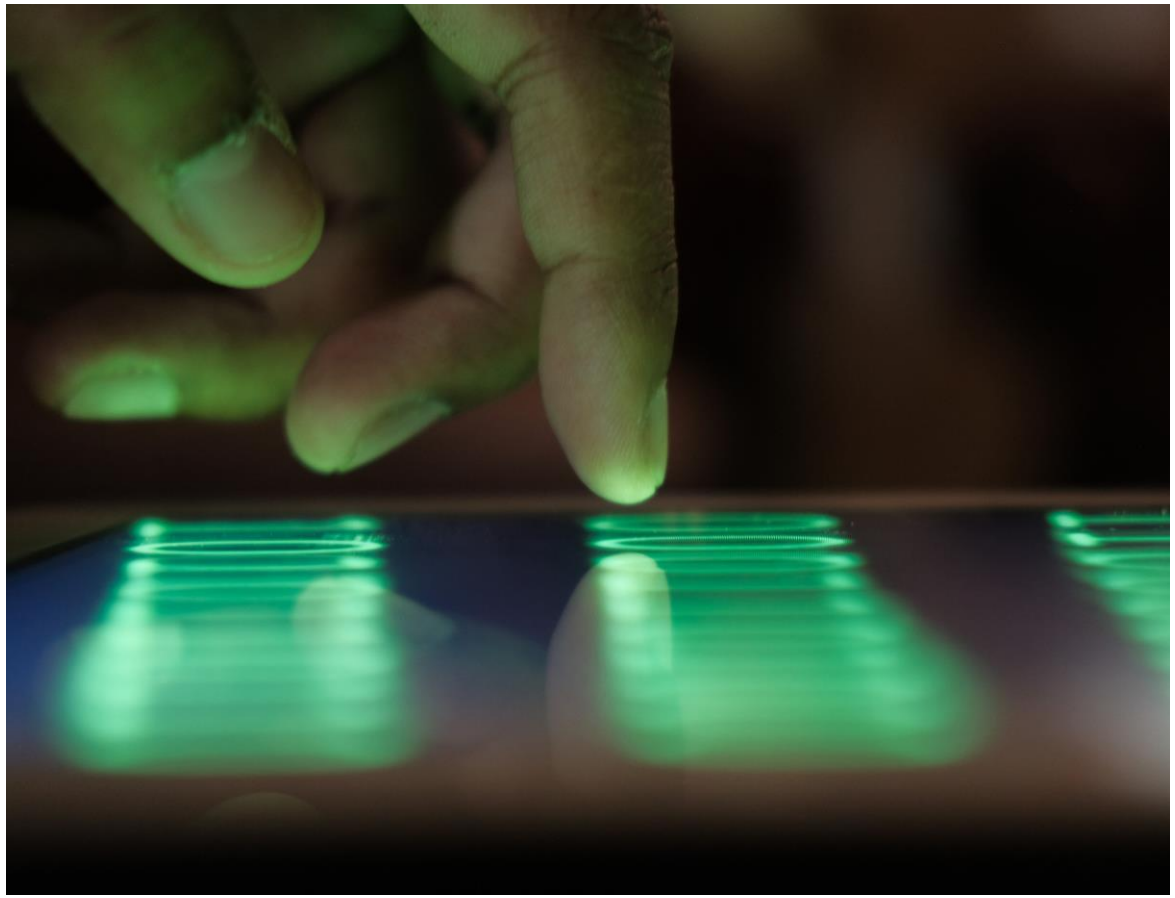
3. Feedback on IMDRF Work items

2. Medical Device Cybersecurity Guide (CYBER)

- DITTA is committed to working with the IMDRF to ensure that medical devices are deployed securely on networks and operate in a safe, effective way.

3. Artificial Intelligence/Machine Learning-enabled (AI/ML)

- DITTA supports the development of IMDRF guidance on Good Machine Learning Practice and Pre-Determined Change Control Plans.



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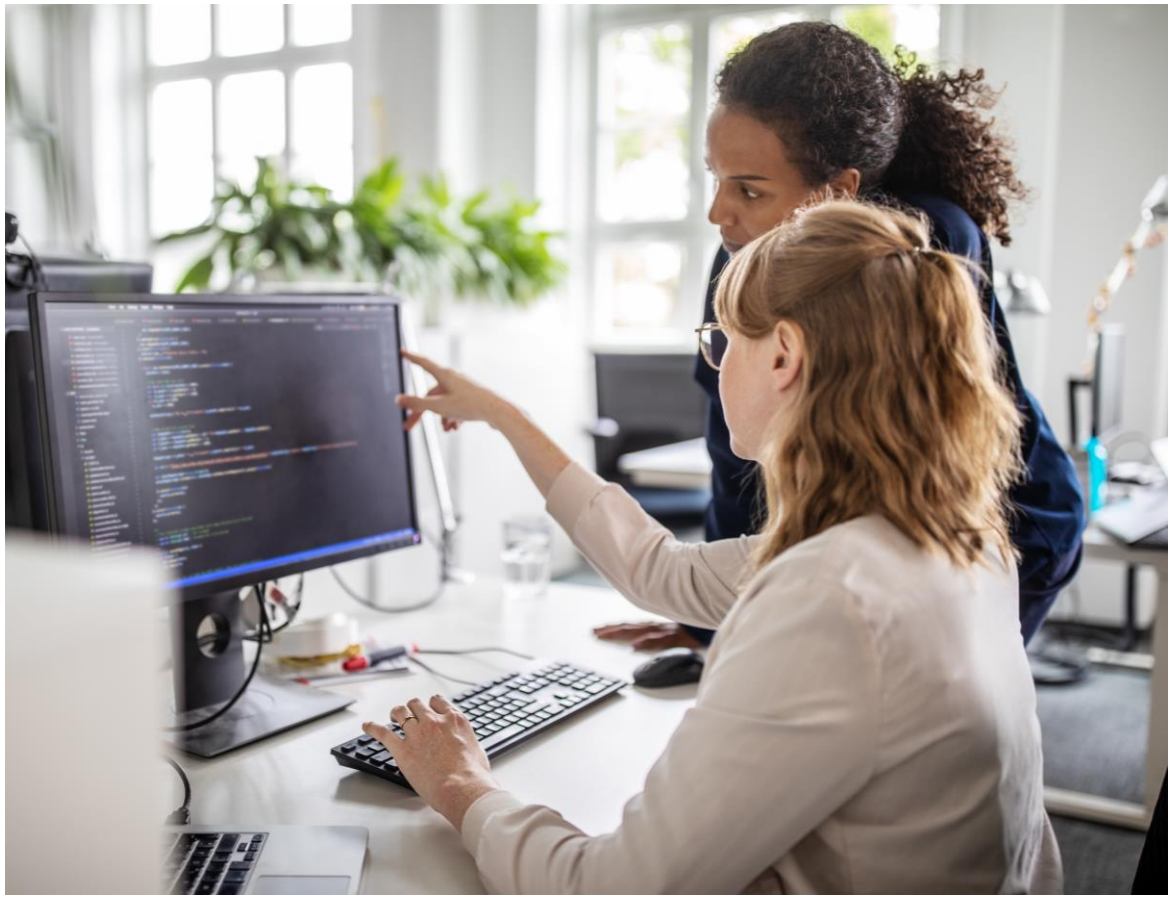

4. Software as a Medical Devices (SaMD)

- Support current activity to revise the existing SaMD documents.
- "SaMD Key Definitions (N10)" and on "Possible Framework for Risk Categorization and Corresponding Considerations (N12)"

5. Standards -Improving the quality of international medical device standards for regulatory use

- International standards are vital for global convergence
- Support "Standards Liaison Program Framework" (IMDRF/Standards WG/N72)
- IMDRF should actively use its liaison status at ISO and IEC to ensure regulators' input into development of standards for regulatory use is implemented.

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3. Feedback on IMDRF Work items

6. Unique Device Identification Application Guide (UDI)

- See DITTA Whitepaper on UDI: *Challenges with Implementing Global Unique Device Identification Requirements and Solutions*
- Support global harmonization of UDI requirements via implementation of the existing IMDRF documents
- Recommend updating documents:

"IMDRF/UDI WG/N53 "Use of UDI Data Elements across different IMDRF Jurisdictions"

"IMDRF/UDI WG/N48 "Application Guide"

7. Medical device single audit program (MDSAP)

- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits
- DITTA encourages jurisdictions to become Members or Affiliates of the MDSAP Consortium

3. Feedback on Other Regulatory Initiatives

8. RPS/eSTAR

- DITTA members are participating in the eSTAR joint pilot with US FDA and Health Canada
- We welcome additional jurisdictions participating in future eSTAR expansion

9. **Health Equity**

- DITTA shared comments in support of the *Guiding Principles to Support Medical Device Health Equity*
- Support including additional factors such as socioeconomic and age

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THANK YOU!

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