IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

16:25 – 16:40

The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA)

Patrick Hope

Chair, The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA)

European Commission

European Union

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IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

March 28, 2023

Patrick Hope, DITTA Chair

Executive Director, Medical Imaging and Technology Alliance

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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

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DITTA: 11 WORKING GROUPS

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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1. OUTCOMES OF IMDRF / DITTA/GMTA JOINT WORKSHOP ON POSTMARKET

(Attendees: 200+ registered)

Attendees: Patient, health care professionals, regulators, and industry

Themes:

- Safety notification and vigilance, including common terminology and templates;
- Identification and traceability of data (UDI)
- Risk-based differentiation for post-market
- Collection of data from users including health professionals
- Real-world evidence:
  - Build on existing guidances;
  - Enable access to data;
  - Advance stakeholder partnerships

- Post-market for software:
  - Not different from traditional medical device post-market
  - Education and clarify on reportability criteria
  - Importance of interoperability
- Post-market for AI
  - Focus on training, clarity on intended use
  - Consideration of various sources and types of bias
- Conclusion: Working toward harmonization

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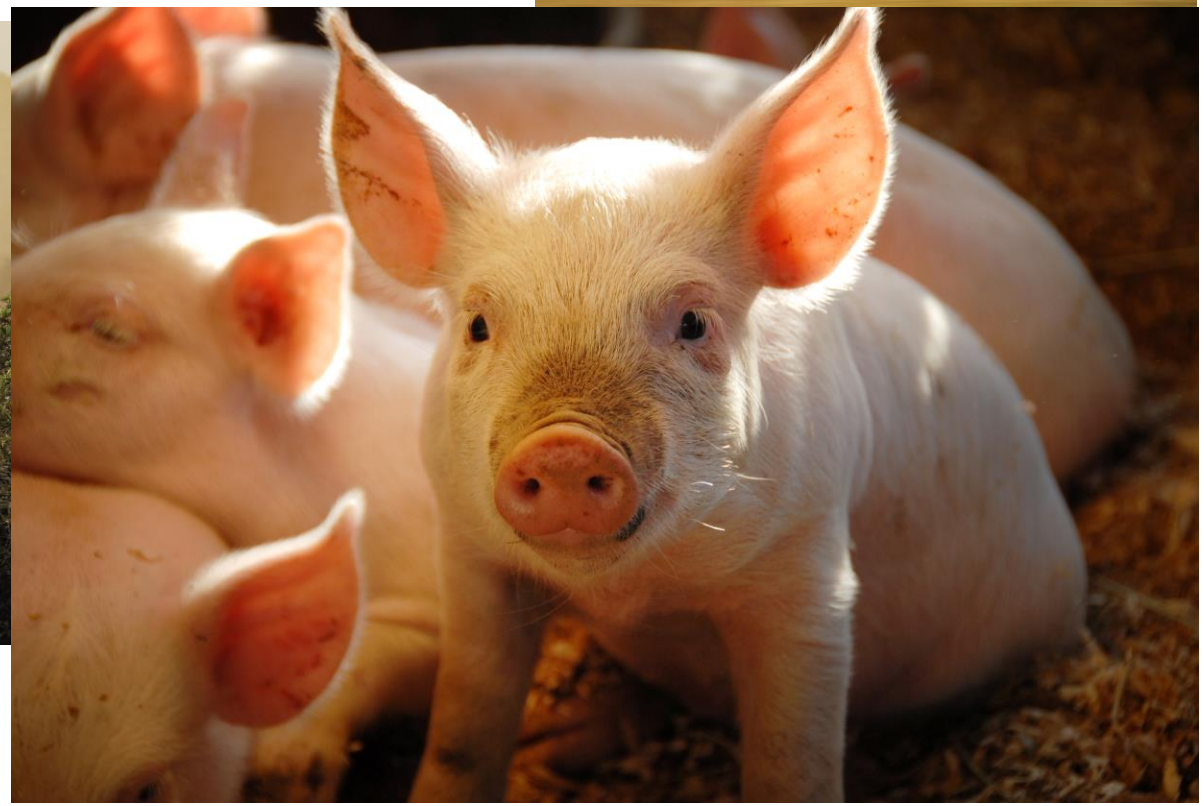
McDonald's™



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2. DITTA PRIORITY

- **Global harmonization and convergence of medical device regulations**

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3. Feedback on IMDRF Work items

- Good Regulatory Review Practices (GRRP)
- Medical Device Cybersecurity Guide (CYBER)
- Artificial Intelligence Medical Devices (AIMD)
- Software as a Medical Device (SaMD)
- Standards
- Unique Device Identification Application Guide (UDI)
- Medical device single audit program (MDSAP)

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3. Feedback on IMDRF Work items

1. Good Regulatory Review Practices (GRRP)

- DITTA welcomes 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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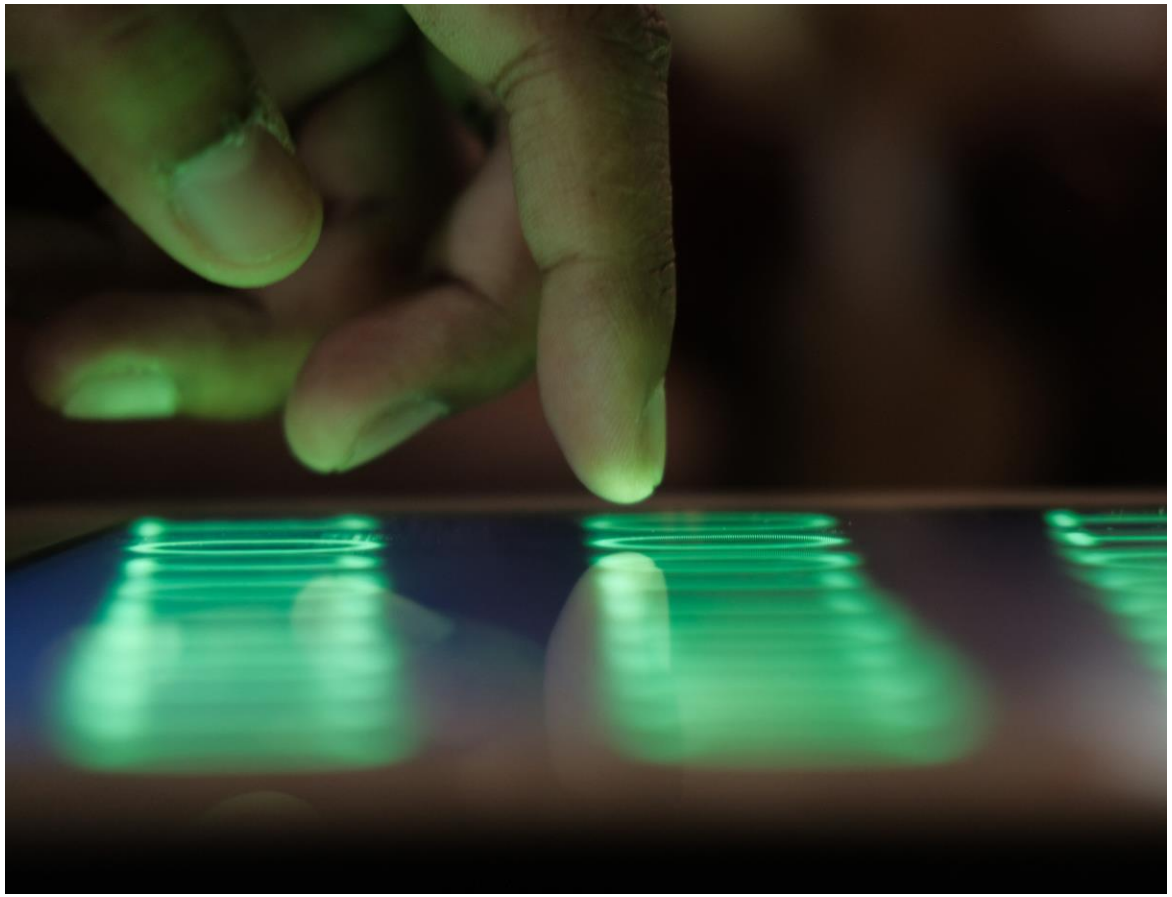
3. Feedback on IMDRF Work items

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 Medical Devices (AIMD)

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



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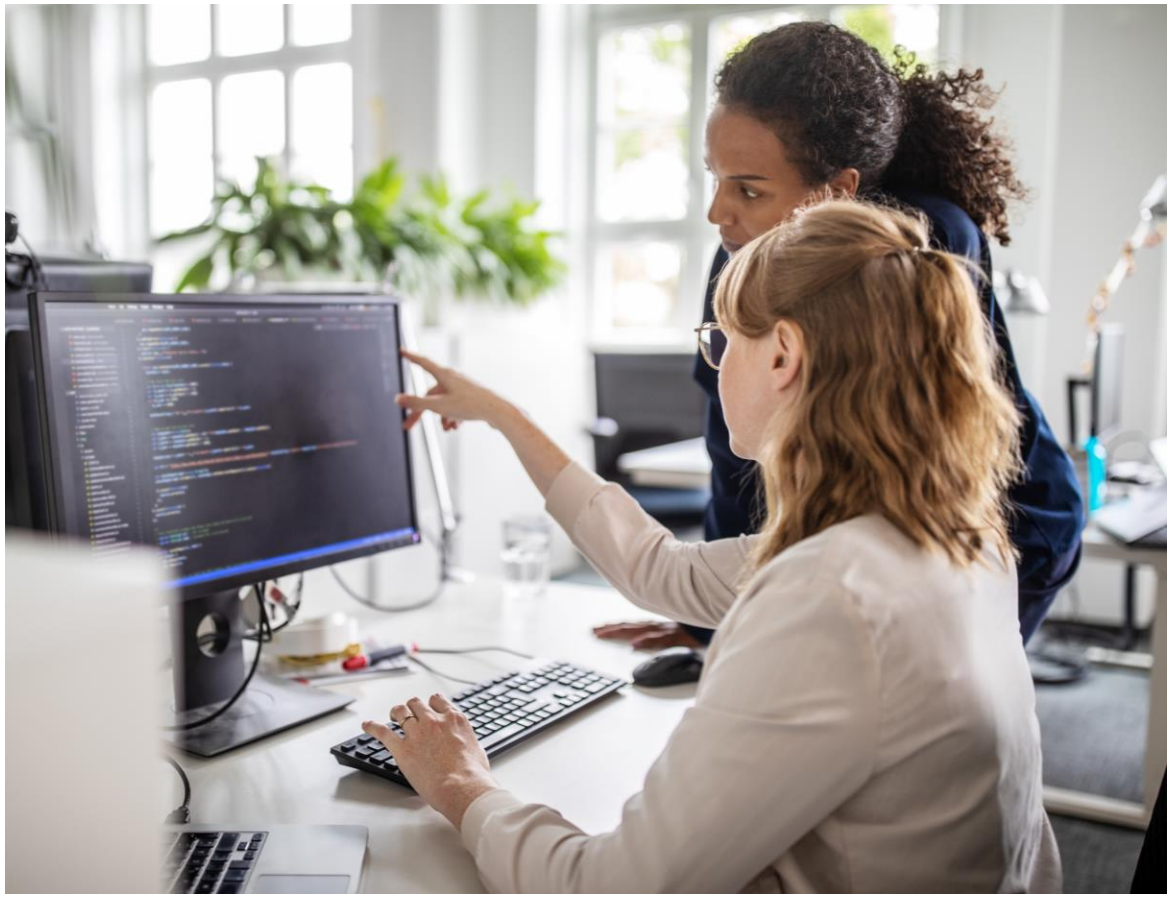
3. Feedback on IMDRF Work items



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)

- Support global harmonization of UDI requirements
- 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

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THANK YOU!

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