



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

DITTA Update

GHWP 26 Annual Meeting

16 February 2023

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DITTA GRP Vice Chair





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DITTA GLOBAL PRESENCE



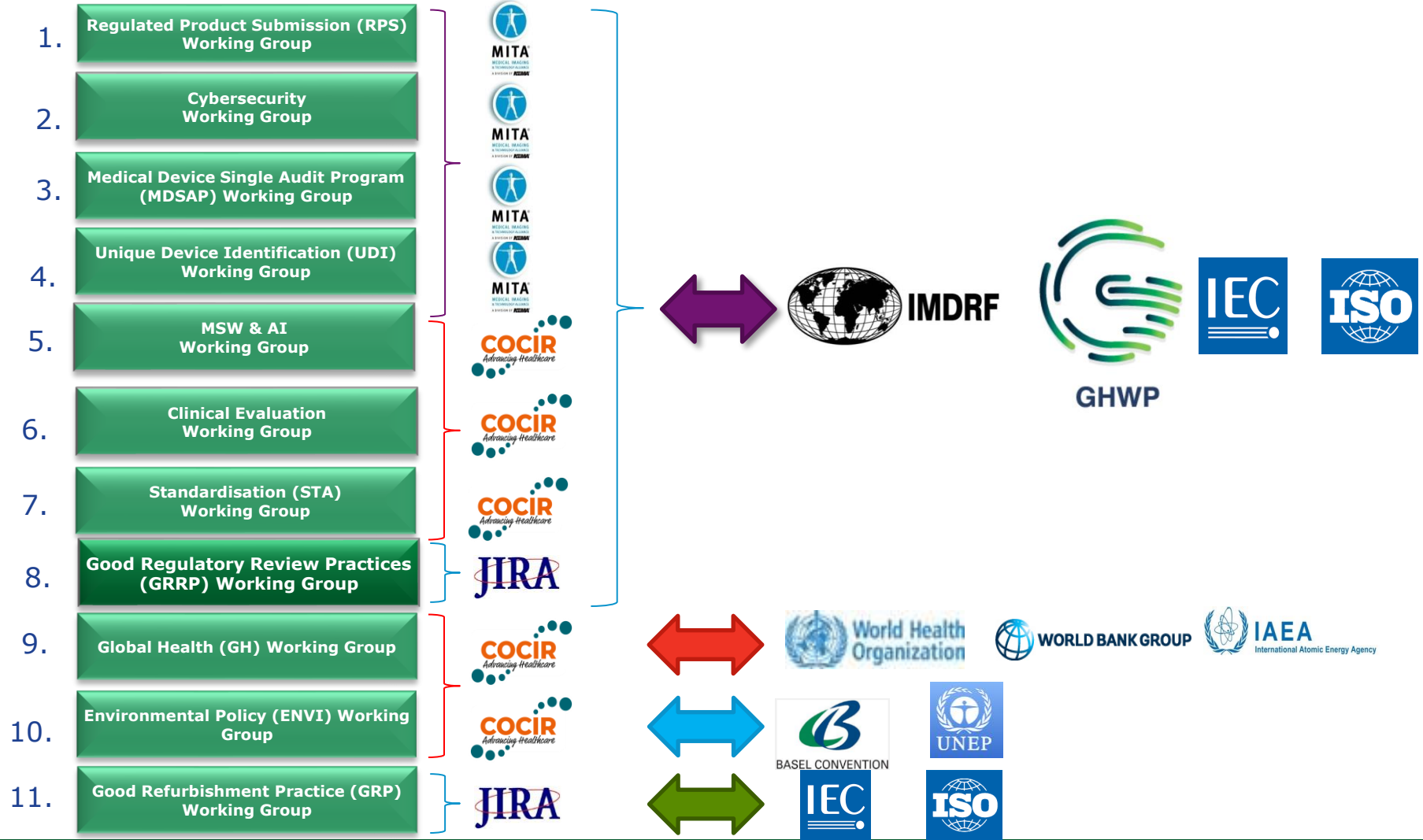
- 2018: DITTA recognized as a non state actor in official relations with WHO
- 2016: DITTA MoU with the World Bank
- 2015: DITTA was granted an NGO status with WHO
- 2014: DITTA has official liaison with AHWP





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DITTA: 11 WORKING GROUPS



New Working Group





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DITTA FEEDBACK ON WORK ITEMS FOR HARMONIZATION

- 1. DITTA Priorities**
- 2. Medical Device Cybersecurity Guide (CYBER)**
- 3. Artificial Intelligence Medical Devices (AIMD)**
- 4. Software as a Medical Device (SaMD)**
- 5. Good Regulatory Review Practices (GRRP)**
- 6. Standards** - Improving the quality of international medical device standards for regulatory use
- 7. Unique Device Identification Application Guide (UDI)**
- 8. Good Refurbishment Practice (GRP)**





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1. DITTA Priorities

Global Health

Support easier access and increased use of medical technology in Lower- and Middle-Income Countries through official relations with the World Health Organization and by improving procurement practices through partnership with the World Bank.

Regulations & Standards

Advocate an industry-friendly regulatory environment accelerating access to market. Support the convergence of regulatory frameworks and promote the use of international standards

Digital Health/Cybersecurity

Contribute to the convergence of globally harmonised regulatory approaches and monitors progress in various jurisdictions. Share industry best practices and guidelines that manufacturers can implement to improve their cybersecurity capabilities.

Environment

Promote alignment on environmental legislation , monitor developments globally and promote the adoption of Good Refurbishment Practice.





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KEY POINTS

2. Medical Device Cybersecurity (CYBER)

- DITTA remains actively engaged with IMDRF CYBER WG in the goal to publish "Cybersecurity for Legacy MD" and "SBOM" documents
- DITTA is committed to working in ensuring that medical devices are deployed securely on networks and operate in a safe, effective way and, planning to author whitepapers, as needed, for the IMDRF final documents when available

3. Artificial Intelligence Medical Devices (AIMDs)

- DITTA welcomes the publication of IMDRF/AIMD WG /N67:2022 "Machine Learning-enabled Medical Devices: Key Terms and Definitions "
- DITTA supports the development of IMDRF guidance on Good Machine Learning Practice and Pre-Determined Change Control Plans





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KEY POINTS

4. Software as a Medical Device (SaMD)

- DITTA welcomes the ongoing revision of existing IMDRF SaMD documents.

5. Good Regulatory Review Practice (GRRP)

- DITTA welcomes the progress of the draft N71 “Marketing Review Report Work Instruction” and supports the development of key elements for the CAB review system
- DITTA suggests IMDRF move toward the implementation of the CAB review system





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KEY POINTS

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

- DITTA emphasizes that international standards are vital for global convergence and welcomes the “Standards Liaison Program Framework” (IMDRF/Standards WG/N72)

7. UDI

- DITTA supports global harmonization of UDI requirements
- DITTA working on a whitepaper, recommends updating documents, “IMDRF/UDI WG/N53 “Use of UDI Data Elements across different IMDRF Jurisdictions” “IMDRF/UDI WG/N48 “Application Guide”





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KEY POINTS

8. Good Refurbishment Practice (GRP)

- Successful workshop and meetings so far on import of refurbished medical devices to Vietnam
- Promotion of IEC 63077:2019 Good Refurbishment Practices for medical imaging equipment





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DITTA EXPERTS IN GHWP

- DITTA experts participate in several GHWP working groups, sometimes as experts from GHWP member economies
- DITTA experts also participate in workshops

And ...

- DITTA is gladly willing to collaborate with GHWP on additional subjects.





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THANK YOU!

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