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

IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

14 September 2021

Masaaki Ohtsuka, DITTA Chair

Secretary General, JIRA

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协会 China Association for Medical Devices Industry · ABiMED Associação Brasileira da Indústria de Alta Tecnologia de Produtos para a Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · ITAC Information Technology Association of Canada

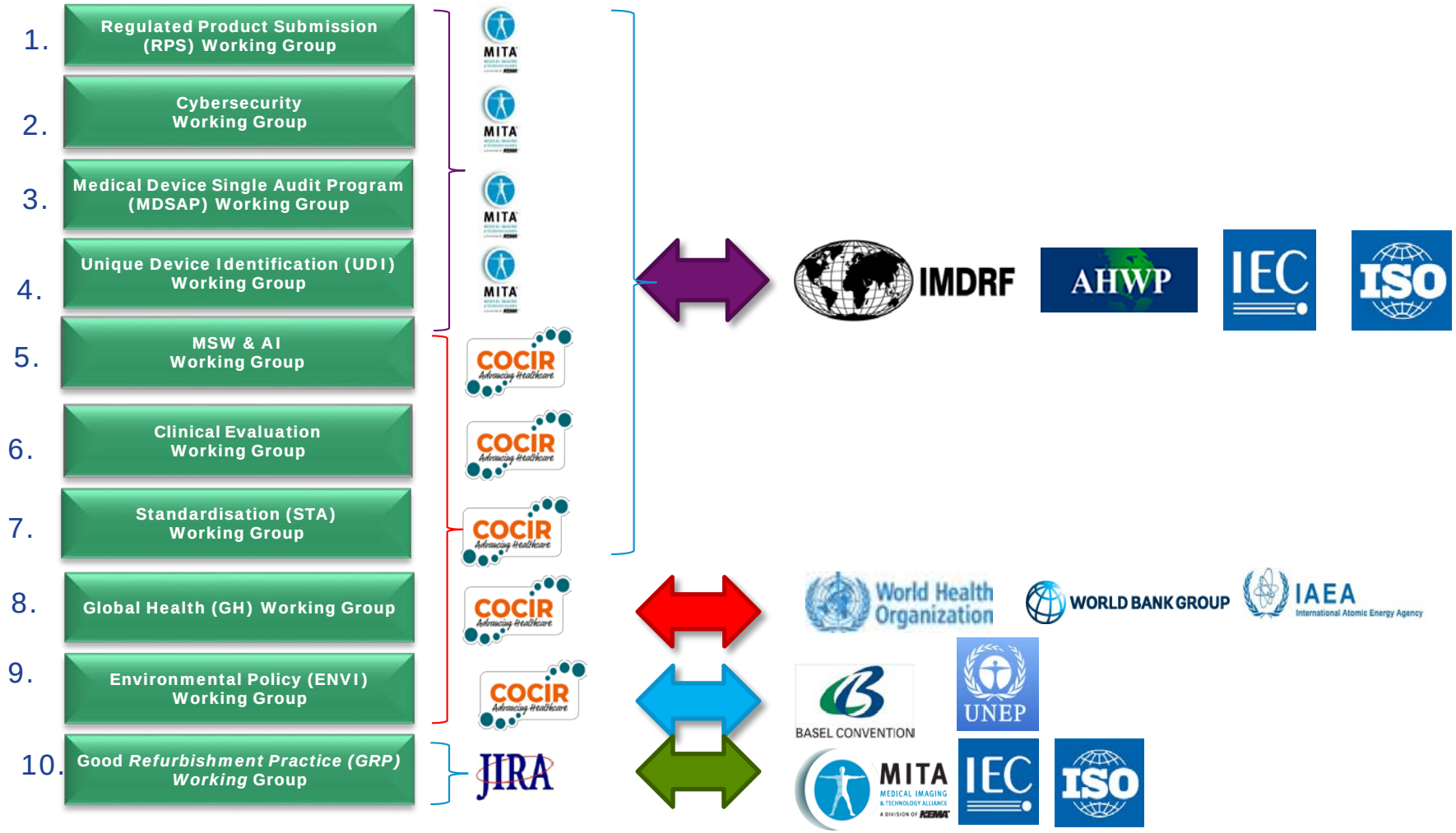
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

DITTA GLOBAL PRESENCE

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

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

DITTA: 10 WORKING GROUPS



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

TABLE OF CONTENTS

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

1. DITTA FEEDBACK ON IMDRF WORK ITEMS

1. Clinical Evaluation
2. Artificial Intelligence
3. Standards
4. Cybersecurity
5. Regulated Product Submission (RPS)
6. MDSAP
7. Good Regulatory Review Practice (GRRP)
8. UDI

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

KEY POINTS

1. Clinical Evaluation

- DITTA supports the New Work Item Proposal on Multi-Regional Clinical Trials

2. Artificial Intelligence

- DITTA supports endorsement of the draft guidance on terminology & definition for Machine Learning for public consultation

3. Standards

- DITTA emphasizes that international standards are vital for global convergence
- DITTA urges IMDRF to operationalize its liaisons to ISO and IEC to ensure regulators' input into development of standards for regulatory use

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

KEY POINTS

4. Cybersecurity

- DITTA supports the IMDRF Cybersecurity WG's proactive and intensive work on SBOM and Legacy devices.
- DITTA released the white paper “Best Practices for Cybersecurity Information Sharing” in June 2021 to address the importance of information sharing with healthcare providers and share how can it be achieved.

https://www.globalditta.org/media-centre/positions-papers/article/white-paper-best-practices-for-sharing-cybersecurity-information.html

5. RPS

- DITTA supports further work on Table of Contents as essential building block towards Single Review Program

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

KEY POINTS

6. MDSAP

- DITTA continues to support the MDSAP program and encourages continuous improvement of the program based on experience and input from manufacturers, AOs, and regulators
- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits
- DITTA encourages the MDSAP Consortium membership to add Affiliate Members

7. Good Regulatory Review Practice (GRRP)

- DITTA supports to move towards a single regulatory premarket review process to satisfy in whole or in part the needs of multiple regulatory jurisdictions for selected medical devices

Note: Goal of GRRP: *"The goal is to promote global harmonization in the premarket review processes."*

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

KEY POINTS

8. UDI

- DITTA appreciates that IMDRF co-hosted the joint workshop on UDI Global Harmonization

- DITTA supports global harmonization of UDI requirements

- DITTA strongly recommends updating document IMDRF/UDI WG/N53 FINAL:2019 “Use of UDI Data Elements across different IMDRF Jurisdictions”

IMDRF / DITTA VIRTUAL WORKSHOP ON UDI 9 SEP. 2021

UDI GLOBAL HARMONIZATION

Workshop Objectives:

- Provide an overview of IMDRF work on UDI
- Better understand how UDI is implemented in various jurisdictions
- Evaluate the experience/what industry found when applying UDI for medical devices, how UDI is used by healthcare providers
- Exchange views on how UDI can be better implemented towards global convergence

Attendance: 771 registered participants, 432 attendees
(regulators, auditing organisations, healthcare providers, scientific societies and industries)

Speakers: 7 speakers from 5 jurisdictions, 1 speaker form healthcare provider, 3 speakers from industry

- IMDRF Jurisdictions: Australia TGA, Brazil ANVISA, European Commission, Japan MHLW, U.S. FDA
- Healthcare Providers: Geisinger Health System, USA
- Industries: DITTA, GMTA, KMDIA

IMDRF / DITTA VIRTUAL WORKSHOP ON UDI 9 SEP. 2021

Conclusion:

- IMDRF guidance documents on UDI were big step towards global convergence and very valuable for regulators & Industry
- There is still some way to go towards a global UDI system
- To continue monitoring the implementation of UDI guidance documents in different jurisdictions, including regular updates of IMDRF N53
- On-going, practical, exchanges between regulators and users are necessary to address concrete issues of divergence (e.g. UDI triggers, further harmonization of data elements) potentially resulting in further updates to N48
- Beyond regulatory use, work remains to be to promote use of UDI by healthcare systems and healthcare delivery organizations, for clinical, research & innovation purposes

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

THANK YOU!

www.globalditta.org

Follow us on @DITTA_online

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance A Division of NEMA · THAIMED · IMEDA · 中国医疗器械行业协会 China Association for Medical Devices Industry · abimed Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · ITAC Information Technology Association of Canada