



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



IMDRF International Medical
Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

Tuesday 17 September 2019, Ekaterinburg, Russia

Nicole Denjoy, DITTA Chair

Secretary General, COCIR

Delivered by Annika Eberstein, COCIR/DITTA





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

DITTA GLOBAL PRESENCE



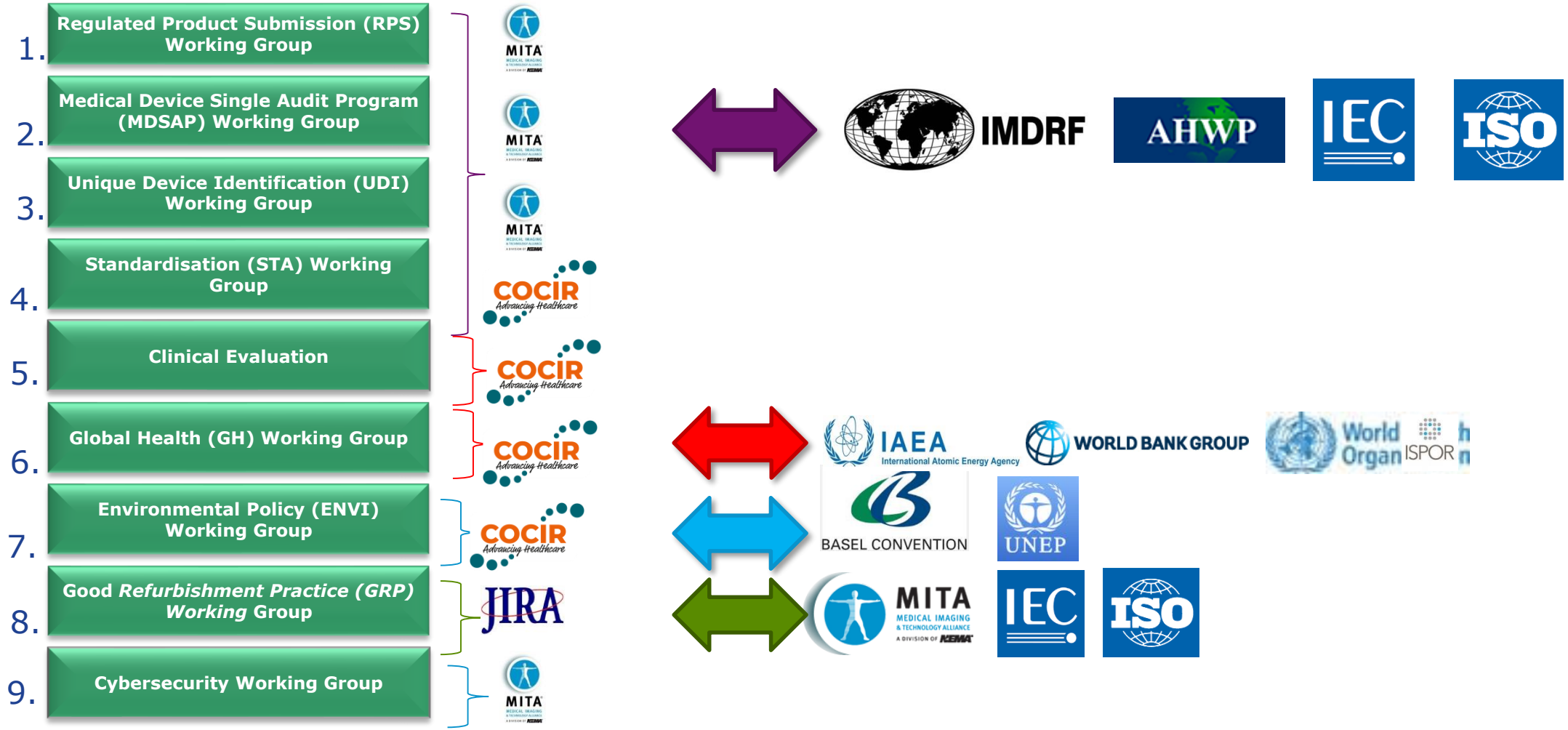
- 2018: DITTA as a recognized non state actor in official relations with WHO
- 2016: DITTA MoU with the World Bank
- 2015: DITTA was granted a NGO status with WHO
- 2014: DITTA has official liaison with AHWP





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

DITTA: 9 WORKING GROUPS





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

TABLE OF CONTENTS

1. On-going IMDRF work items

- Key Points
- Conclusions

2. Other topics

- Unique Device Identification (UDI)
- Medical Device Single Audit Program (MDSAP)
- Outcomes of IMDRF / DITTA Workshop on Artificial Intelligence





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

1. DITTA FEEDBACK ON ON- GOING IMDRF WORK ITEMS

1. Cybersecurity

2. Clinical Evaluation

3. Standards

4. Regulated Product Submission (RPS)





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

1.1. KEY POINTS (1)

1. Cybersecurity

1. Support endorsement of cybersecurity guidance for public consultation – looking forward to further refinement
2. Suggest discussion on feasibility and implementation of the document in each jurisdiction

2. Clinical Evaluation

1. Support endorsing the draft guidance documents for publication
2. Support adoption of New Work Item on Post-Market Clinical Follow-Up





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

1.2. KEY POINTS (2)

3. Standards

1. Ensure the implementation of the guidance on optimizing standards for regulatory use
2. Support operationalisation of IMDRF liaison to ISO and IEC
3. Align mechanisms for recognition of standards across jurisdictions

4. Regulated Product Submission (RPS)

1. Recognize the value of a globally harmonized ToC as a foundation to support a future global single submission format
2. Support focus on ToC stabilization and implementation

5. Good Regulatory Review Practice (GRRP)

1. Recognize the value of work in GRRP WG
2. Plan to submit feedback on consultation document on recognition of CABs





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

1.3. CONCLUSIONS

- 1. Cybersecurity** – Support endorsement of cybersecurity guidance for public consultation - looking forward to further refinement
- 2. Clinical Evaluation** – Support endorsing the draft guidance documents for publication & adoption of NWIP on PMCF
- 3. Standards** – Support operationalization of IMDRF liaison to ISO and IEC
- 4. RPS** – Support focus on ToC stabilization and implementation
- 5. GRRP** – Support on-going work & plan to submit feedback





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

2.1. UNIQUE DEVICE IDENTIFICATION (UDI)

- Commend IMDRF for work completed with the UDI Working Group
 - Application guide
 - Use of Data Elements
- Support consistent implementation globally, including nomenclature
- Principles: flexibility, availability of guidance and mapping documents
- Encourage adoption and use of IMDRF guidance and tools by IMDRF member countries
- Emphasize commonality for key aspects of a UDI system





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

2.2. MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

- Continuing strong industry support for MDSAP programme
- Desire to have additional jurisdictions accept MDSAP Reports in place of their need for audits





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

2.3. OUTCOMES OF IMDRF / DITTA WORKSHOP ON AI

Goal: discussion on the opportunities and challenges of Artificial Intelligence in healthcare

Attendance: over 100 participants

Speakers: regulators, healthcare professionals & industry from 7 jurisdictions

Key Take-Aways:

- High level of interest and engagement from all stakeholders
- Necessity for harmonised healthcare-specific AI terminology
- Consider enriching existing IMDRF guidance to foster more convergence
- Issue of access to high-quality data





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

THANK YOU!
Спасибо!

www.globalditta.org

Follow us on  @DITTA_online

