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

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 · Kmdica Korea Medical Devices Industrial Coop. Association · ITAC Information Technology Association of Canada

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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: 9 WORKING GROUPS

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

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1. DITTA FEEDBACK ON ON-GOING IMDRF WORK ITEMS

1. Cybersecurity
2. Clinical Evaluation
3. Standards
4. Regulated Product Submission (RPS)

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 Support endorsing the draft guidance documents for publication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

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

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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

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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

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

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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

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THANK YOU!
Спасибо!

www.globalditta.org

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