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

DITTA REPORT

IMDRF Open Stakeholder Forum

18 September 2018, Beijing, China

DITTA Chair Patrick Hope

Executive Director, MITA

COCIR JIRA MEDEC 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 health

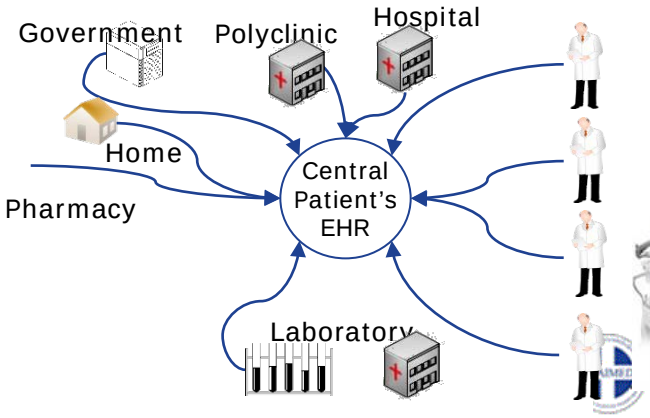
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe

DITTA covers the following industry sectors:

1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. and Radiopharmaceuticals

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle



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DITTA GLOBAL PRESENCE

DITTA GOVERNANCE

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Board of Directors

MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA · JIRA · COCIR

DITTA Chair:
Patrick Hope, MITA Executive Director
DITTA Vice-Chairs:
Nicole Denjoy, COCIR Secretary General
Kiyoshi Inaba, JIRA Business Execution Director

Members:
- Founding Organisations
- Executive Mgmt of each organisation
- Chairs of their International Groups

Steering Committee

Chair: DITTA Chair
Members:
- Heads of each organisation
- Leadership of their International Groups
- Leadership of DITTA WGs

TCONs: one per month

Working Groups

One Chair, Two Vice-Chair per Working Group
Members:
- Mixture of trade associations and company experts
- Coordination: MITA, JIRA, COCIR

TCONs: as needed

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DITTA: 10 WORKING GROUPS

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

MITA, COCIR, JIRA

IMDRF, AHWP, IEC, ISO

IAEA International Atomic Energy Agency, WORLD BANK GROUP, World Health Organization

BASEL CONVENTION, UNEP

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PRESENTATION OUTLINE

DITTA feedback on IMDRF Topics:

1. Regulated Product Submission (RPS)
2. Unique Device Identification (UDI)
3. Cybersecurity
4. Standards
5. Clinical Evaluation
6. Medical Device Single Audit Program (MDSAP)

GOAL: Global Harmonization & Regulatory Convergence

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REGULATED PRODUCT SUBMISSION (RPS)

DITTA has found varying levels of ToC adoption between the IMDRF regulators

- Industry has requested that regulators provide information on their commitment to implement Table of Contents (ToC) format

Current Status of ToC Support:

- Regulators are evaluating the ToC as a submission format option
- There are still differences in the ToC content between different regulators
  - Therefore, the ToC is not globally harmonized, as was the goal of the work item
- Industry sees minimal adoption of a voluntary option as a burdensome approach over existing pathways

DITTA Position:

- Industry recognizes the value of a globally harmonized ToC as a foundation to support a future global single submission format

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UNIQUE DEVICE IDENTIFIER (UDI)

IMDRF UDI Working Group

- Goal: Develop UDI application guide based on draft provided by GMTA

Upcoming face-to-face meeting – Washington DC (October 15-19, 2018)

- International Workshop on Global Use & Application of UDI; joint presentation with GMTA/DITTA
- IMDRF UDI Working Group meeting – discussion and revision of UDI WG(PD1)/N48, N53 and N54 guidance
- Teleconferences ongoing through October to prepare for meeting content

Recommendations:

- Ensure consistent implementation of UDI globally
- Need to continue group education of industry challenges and provide examples
- Emphasize commonality for key aspects of a UDI system (use of accredited DI Issuing Agencies versus local identifiers, HL7 standard for data transmission, consistency in definitions of data elements, etc.)

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CYBERSECURITY

Our Goal:

- Enable patient safety and privacy through a regulatory and standards environment that emphasizes protection of the patient and the safeguarding of all associated sensitive information

DITTA Commends the Positive Step on Cybersecurity in the Last IMDRF Meeting in Shanghai

- The outcome statement: "The MC agreed to explore a possible NWIP pertaining to medical device cybersecurity for consideration at a future MC meeting."
- DITTA submitted the NWIP on medical device cybersecurity to the MC which was drafted through the discussion with some regulators

Our Suggestions:

- This work item should deal with the following concept:
  1. Recognize that cybersecurity is a shared responsibility among all stakeholders
  2. Promote broad information sharing policies
  3. Definition of terms and clarify the current understanding on medical device cybersecurity
- Our industries demand the consistency among the current IMDRF work items such as the Essential Principles (draft) which includes some security requirements

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STANDARDS

- **International consensus standards are key to safe medical devices**
- **They are the most effective means of demonstrating conformance to legal requirements and a powerful tool for regulatory convergence**

DITTA commends the IMDRF Standards WG and recommends:

1. *The adoption of the Guidance on improvement of standards*
2. *IMDRF to support active follow-up of the Guidance*
3. *IMDRF to establish a permanent structure for its standards activities*
4. *Extending the work item with comparison of national adoption programs and updating the list of commonly used standards*
5. *We would support a work item on single review*

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CLINICAL EVALUATION

DITTA Supports IMDRF Clinical Evaluation Working Group

- DITTA strongly supports the newly established IMDRF Working Group on Clinical Evaluation
- Any further regulatory convergence between jurisdictions on the rules for clinical evaluation and investigations is welcome

DITTA Position on Aims for International Standards:

- The overarching goal should be to act ethically and determine whether a clinical trial should be carried out, to avoid unnecessary Clinical Investigations according to the Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects by:
  - Accepting clinical trial data from other jurisdictions with demonstration of validity and justification of applicability to the domestic patient populations
  - Accepting clinical investigations based on device characteristics if this is according the State of the Art with demonstration of validity and justification of applicability

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MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

DITTA Continues to Support MDSAP & Harmonization in This Area

- We continue to have concerns about inadequate AO expertise in non-QMS parts of MDSAP (regulatory requirements) leading to variability within and between AOs in interpretation and scope, AO resource limitations, and delays in the issuance of certificates

General Feedback:

- Audit Organization (AO) capacity, leading to audit timing delays
- AOs taking significant time from audit completion to issue certificates
- Variability in AO approach and interpretation and limited knowledge of country regulatory requirements, leading to exceeding scope and/or authority within MDSAP
- Program not initially designed for matrixed organizations which leads to redundant auditing

Recommendations & Questions:

- Companion Document and/or audit model require updates to reflect industry, AO, and regulator experience and feedback, one year into MDSAP… Does the MDSAP Consortium plan to update these documents and if so, when? If not, how will the feedback / experience be captured in AO training?
- PAHO Regulatory Exchange Portal secure (REPs) database: What is the status and scope of this database? In the interim, how do regulators become aware of MDSAP scheduling and audit results?

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THANK YOU!

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www.globalditta.org

Follow us on @DITTA_online

Patrick Hope – phope@medicalimaging.org

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