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

INTRODUCTION TO DITTA

IMDRF Open Forum

September 20, Ottawa, Canada

DITTA Chair Patrick Hope

Executive Director, MITA

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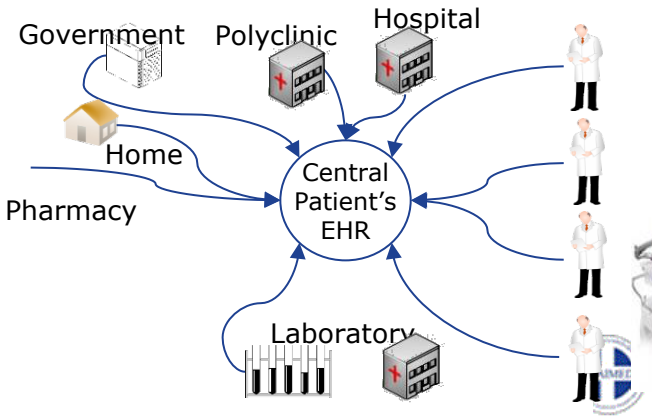
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe

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

Board of Directors

DITTA Chair:
Patrick Hope, MITA Executive Director
DITTA Vice-Chairs:
Nicole Denjoy, COCIR Secretary General
Satoshi Kimura, JIRA Executive 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 or COCIR

TCONs: as needed

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DITTA: 9 WORKING GROUPS

1. Regulated Product Submission (RPS) Working Group — MITA
2. Medical Software (MSW) Working Group — COCIR
3. Medical Device Single Audit Program (MDSAP) Working Group — MITA
4. Unique Device Identification (UDI) Working Group — MITA
5. Standardisation (STA) Working Group — COCIR

3. ⟷ IMDRF, AHWP, IEC, ISO

6. Global Health (GH) Working Group — COCIR

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

7. Environmental Policy (ENVI) Working Group — COCIR

7. ⟷ BASEL CONVENTION, UNEP

8. Good Refurbishment Practice (GRP) Working Group — MITA

8. ⟷ MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA, IEC, ISO

9. Cybersecurity Working Group — MITA — new

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  - MDSAP
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  - Cybersecurity
- DITTA views on IMDRF strategy 2020
- DITTA views on IMDRF items not open to industry
- Other DITTA initiatives

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RPS GENERAL FEEDBACK

General Comments-

- In order for the program to be successful, industry believes that regulators must be willing to commit to and adopt, at a minimum, the final Table of Contents (ToC) in order to further support the RPS Program.
- Industry needs more details of current, overall strategy and timeline.

Specific Comments-

- If all parties agree and commit that RPS is indeed beneficial, a plan must be developed that clearly defines:
  - Table of Contents (ToC)
    - *What is considered acceptable submission criteria?*
    - *Industry has supported the TOC pilot but requires information as to which regulators are committed to using the ToC (common file folder format) and the timeline to do so.*
    - *We further believe that the content of the ToC be consistent among regulators to the fullest extent possible and that regional variations should be minimized.*
  - Electronic format & submission tool
    - *What is the resource commitment from both industry and regulators to develop a system/tool for the RPS program?*
    - *What has been evaluation of HL 7 vs other alternatives in terms of cost, implementation, updates, etc*
    - *What are the plans and expected resources for developing and maintaining the electronic submission system / tool?*

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RPS
OUTCOME OF WORKSHOP

- Nearly 150 people attended the RPS workshop
- Key Takeaways:
  - Health Canada presented a case for their commitment to ToC
  - Survey results verified barriers to participation (costs, commitment)
  - Industry believes ToC needs work and we need a majority of regulators to use it
  - Industry needs to better understand the benefit of ToC

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STANDARDS

- DITTA strongly believes in international standards being the most valuable tool for regulatory convergence
- Standards needed technical specification benefitting all stakeholders
- DITTA supports the IMDRF Standards WG, appreciates its report, and notes that:
  - *The report is comprehensive and informative with forward-looking recommendations;*
  - *Contribution of all IMDRF members demonstrate high relevance;*
  - *Focus is on IMDRF regulator's participation to standards.*

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STANDARDS & NWIEP

DITTA, initiating partner of the IMDRF project on Standards, **fully supports** the New Work Item Extension Proposal (NWIEP); including its recommendations:

- *All IMDRF members to continue to contribute;*
- *Establish a network of IMDRF regulatory authority (RA) experts (to become) active in standards development;*
- *Concrete plans are made for regulators involvement at IMDRF level in identified projects of specific TCs;*
- *Connection is made with review of (GHTF) Essential Principles.*

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STANDARDS OUTCOME OF WORKSHOP

- Successful workshop was attended by nearly 100 people

- Key takeaways:
  - Theme of “collaboration” throughout the afternoon
  - Inclusion of all stakeholders (especially regulators)
  - Prioritization of standards work
  - Continued education across stakeholders
  - Standards must be able to keep up with technology advances

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MDSAP

DITTA continues to support this initiative and efforts towards harmonization in this area.

General feed-back:

- Industry is concerned that 15-day window for manufacturers to provide a remediation plan in response to a finding of nonconformity is too narrow a timeframe.
- Challenges experienced in audits with AO variable interpretation (different auditors of same AO & different AOs) of country regulatory requirements and “outsourced activities”
- Challenges anticipated to meet Health Canada’s December 2018 deadline…. Availability of certified auditors in AOs is a barrier

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MDSAP SURVEY RESULTS

- DITTA conducted a member survey (11 Aug – 23 Aug) on MDSAP readiness, receiving 43 responses. Here are the topline results:
  - Only 2% said they would "opt-out" of Canadian market in order to avoid MDSAP
  - Of those that believe MDSAP is a long-term goal, only 20% said they would not be ready in 12 months
  - 67% said that they have either completed an MDSAP audit for Canada or will complete an audit by end of 2018
  - For those that have not completed an audit, 24% said the AO was not ready and 52% said the manufacturer site wasn't ready

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SAMD

Feedback - general:

- DITTA welcomes the current efforts in some jurisdictions to implement SaMD guidance documents
- DITTA hopes this sets an example for other jurisdictions

Feedback – clinical evaluation:

- DITTA has strongly supported the resolution of 1400+ comments and their incorporation into the SaMD: Clinical Evaluation draft.
  - *Suggestion for future use of ISO/IEC Comment Form for comment handling*
- The draft has pioneered the concept of clinical evaluation as applicable to SaMD
- Implementation details of the post market clinical evaluation have yet to be determined

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CYBERSECURITY

Background-

- Medical device cybersecurity is complex and its scope involves many actors. However, some jurisdictions have begun to address it by simply issuing guidances. DITTA supports a harmonized approach, and has organized a dedicated working group to contribute to global efforts on cybersecurity.

Cybersecurity policy-

- Medical Device cybersecurity efforts must be focused on ensuring the confidentiality, integrity and availability of devices' information assets. i.e. data, functions, software.
- It has to be clear, that manufacturers' measures for cybersecurity risk mitigation can only address the networked device, not the network itself, or its users
- Regulators must leverage appropriate existing standards and regulatory requirements to advance and retain alignment cybersecurity in healthcare

IMDRF STRATEGIC PLAN 2020

Development and Utilization of IMDRF Outputs:

- Working Groups should:
  - Continue to seek broad stakeholder engagement
  - Use ISO/IEC Comment Form as the norm going forward
  - Publish a roadmap to implementation in each member jurisdiction for each Work Item

- IMDRF WG IMDRF member jurisdictions should update stakeholders on their adoption/implementation of Outputs as part of their presentation at IMDRF Open Forum

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DITTA VIEWS ON OTHER IMDRF ITEMS IN WHICH INDUSTRY IS NOT INVOLVED

- Industry has critical obligations in the field of post market surveillance (reporting to regulators and directly connected with hospitals), and should be on the following Working Groups with IMDRF regulators:
    - Vigilance and Post market activities (besides NCAR system)
    - Adverse Event Reporting
- Industry is part of the solution and constitutes the regulated body

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THANK YOU!

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