INTRODUCTION TO DITTA

IMDRF Open Forum
September 20, Ottawa, Canada
DITTA Chair Patrick Hope

Executive Director, MITA
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.
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

**Working Groups**

**One Chair, Two Vice-Chair per Working Group**

**Members:**
- Mixture of trade associations and company experts
- Coordination: MITA or COCIR

**TCONs:**
- DITTA: one per month
- TCONs: as needed
DITTA: 9 WORKING GROUPS

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
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group
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- DITTA feed-back on open IMDRF topics including outcome of workshops on RPS and standards
  - RPS
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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
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?
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
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.
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.
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
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
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
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
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
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
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
THANK YOU!

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