



**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*





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



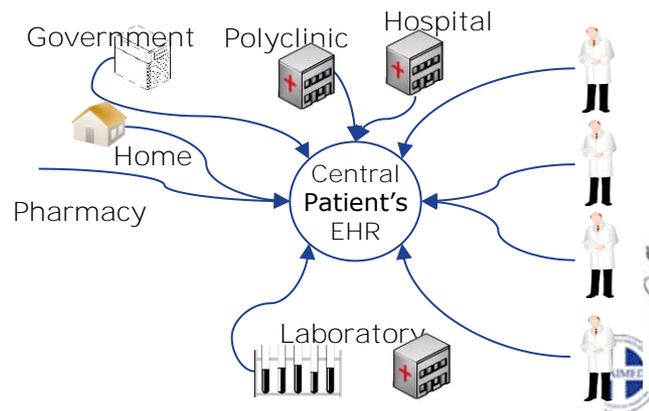
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe



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





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

# DITTA GLOBAL PRESENCE



**IMDRF**



**AHWP**



**IAEA**  
International Atomic Energy Agency



**IEC**



**ISO**



**WORLD BANK GROUP**



**World Health Organization**



**JIRA**

**MEDEC**



**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 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



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



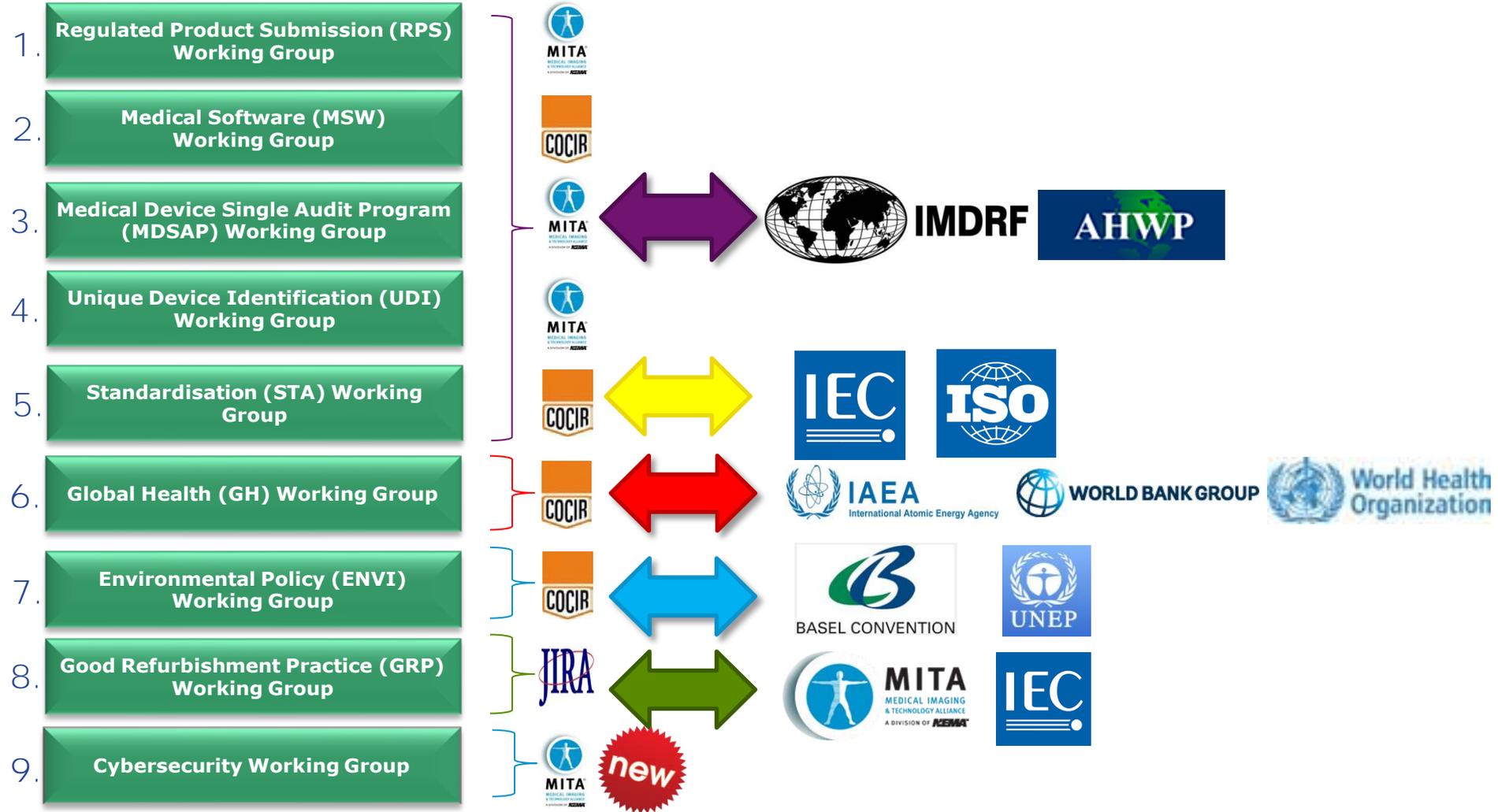
中国医疗器械行业协会  
China Association for Medical Devices Industry





**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

- DITTA feed-back on open IMDRF topics including outcome of workshops on RPS and standards
  - RPS
  - Standards
  - MDSAP
  - SaMD
  - Cybersecurity
- DITTA views on IMDRF strategy 2020
- DITTA views on IMDRF items not open to industry
- Other DITTA initiatives





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

# 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?*





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

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

# 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.*





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

# 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.*





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

# 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





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

# 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





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

# 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





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

# 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





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

# 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





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

# 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





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

THANK YOU!

[www.globalditta.org](http://www.globalditta.org)

Follow us on Twitter! @DITTA\_online

