



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

DITTA REPORT

IMDRF Open Forum

March 20, Shanghai, China

DITTA Chair Patrick Hope

Executive Director, MITA





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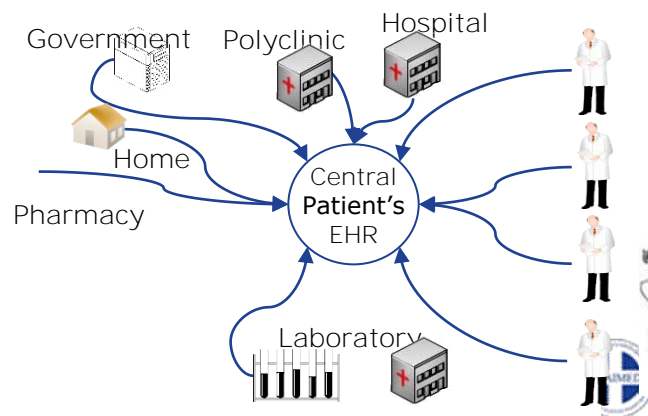
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe



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



IMDRF



AHWP



IAEA
International Atomic Energy Agency



IEC



ISO



WORLD BANK GROUP



World Health Organization



JIRA



MEDEC



MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA



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



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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, JIRA, COCIR

TCONs: as needed



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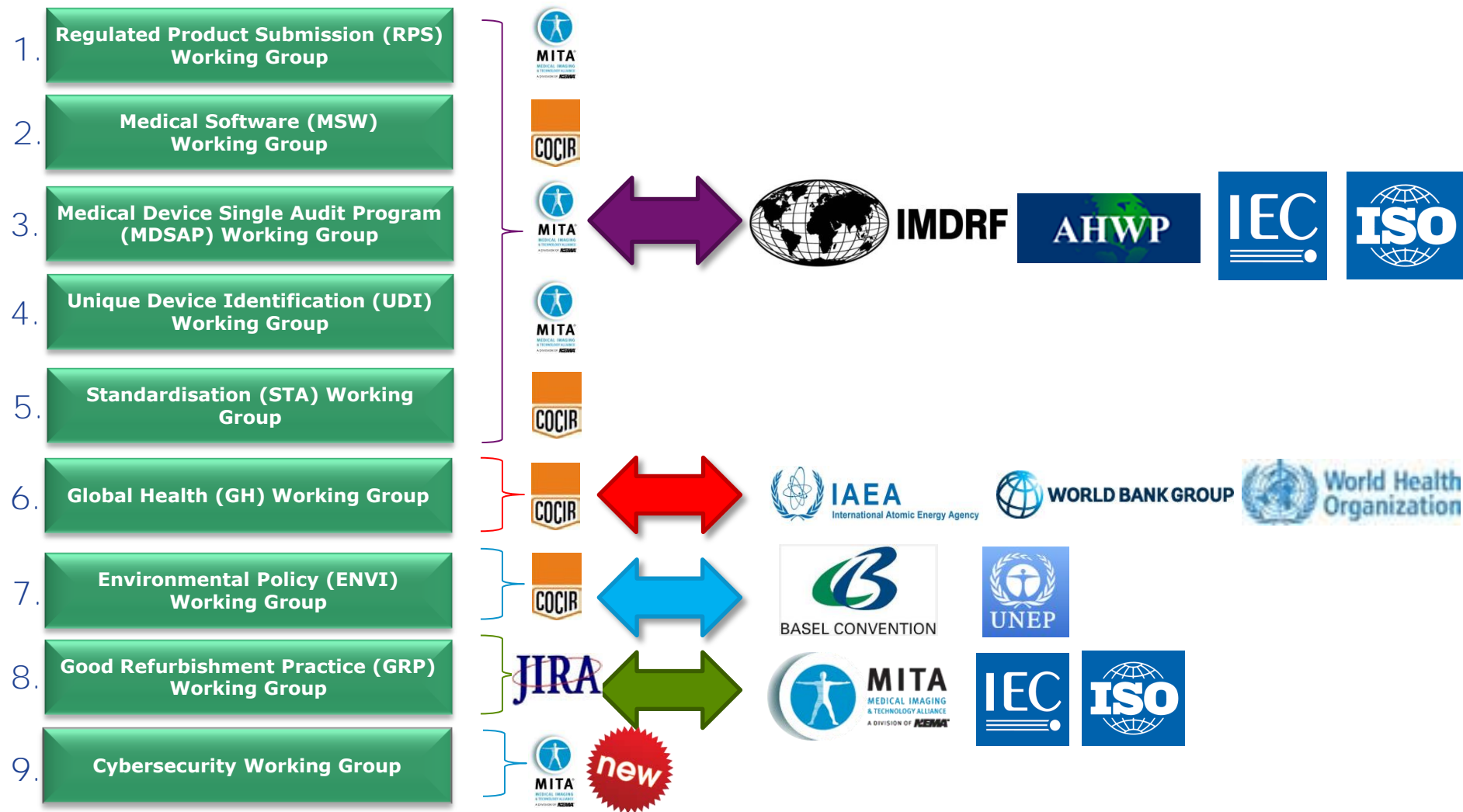
中国医疗器械行业协会
China Association for Medical Devices Industry





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DITTA: 9 WORKING GROUPS





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





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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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STANDARDS

DITTA strongly believes that international consensus standards help in demonstrating medical devices conform to legal requirements, and thus are key to safe medical devices and a most useful tool for regulatory convergence.

DITTA commends the IMDRF Standards WG for the draft Guidance, & notes:

- *It clearly exhibits IMDRFs recognition of the important role of consensus standards, and its wish to contribute to the development thereof;*
- *The Guidance should lead to more involvement of regulators in development of consensus standards, and enhanced adoption thereof for regulatory purposes;*
- *IMDRF should plan for pilot programs with Key Technical Committees in ISO and IEC, based on the Guidance (e.g. ISO/TC210, ISO/TC150, and IEC/TC62);*
- *IMDRF should establish a permanent structure for its standards activities.*





- DITTA continues to support this initiative and efforts towards harmonization in this area
- However, we continue to have significant concerns about the lack of training and resources to support notifying bodies and the issuance of certificates in a timely way

General feedback:

- Audit Organization (AO) inability to accommodate manufacturer demand (audit timing delays)
- A number of AOs not yet MDSAP certified
- AOs taking significant time from audit completion to issue certificates
- Variability in AO approach
- AO exceeding MDSAP scope and/or authority



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.

Policy Requirements

- Cybersecurity is accepted as a shared responsibility between all stakeholders, including regulators, manufacturers, healthcare providers, patients, and others.
- The role of global standards needs to be recognized. Standards are the backbone of industry self-regulation.
- Technology alone cannot provide security. Organizational processes and procedures must also be in place to ensure reliable cyber hygiene.
- Recognition of a device's finite lifecycle. The physical life of a device and the ongoing secure operation of that device may not align. Policies need to be developed which incentivize the transition of unsecure legacy products out of use.
- Information sharing policies should have clearly established legal guardrails and incentives for participation. Information sharing requirements, if implemented, should also extend to owners/users of medical devices



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CYBERSECURITY

Placeholder for workshop





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UDI

IMDRF UDI Working Group –

- Goal: Develop UDI application guide based on draft provided by GMTA
- Kickoff Dec 5th – draft provided to DITTA UDI working group for comments
- Periodic teleconferences to discuss and modify draft

Face to face meeting – Brussels (Feb. 12-15, 2018)

- International Workshop on Global Use & Application of UDI; joint presentation GMTA/DITTA
- IMDRF UDI Working Group meeting – discussion and revision of draft guidance
- Teleconferences ongoing through April to develop final draft
- Anticipated second face-to-face meeting at fall IMDRF conference, Beijing

Outcomes & Recommendations

- Good synergy and mutual understanding of opportunities
- Strong desire for consistent UDI implementation 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.)
- DITTA needs to remain involved in this effort as well and other opportunities such as development of EC UDI guidances to present DITTA member's interests





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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