



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

# INTRODUCTION TO DITTA

IMDRF Open Forum

March 15 2017 Vancouver, Canada

DITTA Chair Patrick Hope

*Executive Director, MITA*





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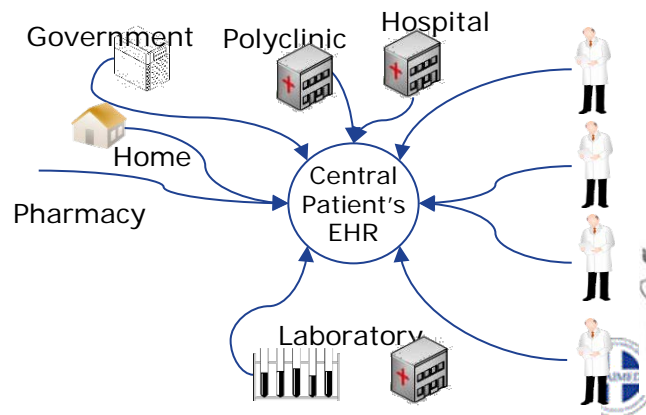
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe



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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# ACTIVITIES WITH INTERNATIONAL ORGANISATIONS

## Activities linked to IMDRF:

- Proposed work item on Int'l Standards adopted by IMDRF
- Workshop on Medical Software in March
- Workshop on Int'l Standards in Sept.

## At UN level:

- Invited to UNAIDS Smart Cities in NY in June to present on innovative technologies
- Published a statement on importance of technologies linked to discussions on SDGs for UN General Assembly in New York

## With World Bank:

- Partnership agreement between DITTA and WB signed in May in Geneva

## With WHO:

- Member of the GMNCD Group since last year
- Provided comments during 2 consultations on priority medical devices in cancer
- Provided comments during 2 consultations on Global Regulatory Framework
- Speakers at CIPRaM in Spain in Oct. on Radiation Safety and Bonn Agreement

## With IAEA:

- Representation in Training course on Brachytherapy (Vienna – Oct)





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# GENERAL FEEDBACK

## **DITTA continues strong support of IMDRF and its many accomplishments to be proud of:**

- RPS ToC & CDEs
- MDSAP/MDSAP pilot
- SaMD definitions and QMS
- UDI guidance

## **There is still work to be completed:**

- RPS data exchange
- MDSAP implementation
- UDI global implementation and next steps
- Standards WI deliverables

## **Looking to the future:**

- NWIP for Good Regulatory Review Practices - Status?
- Additional NWIPs, i.e. UDI – Status?





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# UPDATE REPORT: MDSAP WG

## DITTA MDSAP seminar:

- 150 registered; 100 attendees. All stakeholders well-represented

## Takeaways:

- MDSAP is here to stay
- Effectively reduced number of inspections
- Pilot participants report positive experience

## Issues to address:

- AO's – need to increase capacity and knowledge
- Cost – especially difficult for SMEs
- Timely issuance of audit reports

## Program concerns:

- Current number of country-specific requirements makes expansion unwieldy. Regulators must align and converge requirements.





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# UPDATE REPORT: RPS WG

- Regulators and industry agree there are benefits to a single submission ToC format for product submissions to multiple jurisdictions
- Creation of a specific program for entry requires additional improvements and DITTA is concerned about the limited resources available
- IMDRF plans for RPS remain unclear to industry

## **Open Questions:**

- What is each IMDRF regulator's commitment to adopting ToC and RPS?
- When will IMDRF provide estimated savings or added cost (\$ or time) and how it will effect industry?
- When will IMDRF release the ToC roadmap?
- Which regulators are accepting electronic submissions today?
- What are the different formats/gateways today for each regulator?
- Do any of those formats accommodate ToC?
- If so what work is being done to investigate their utility?

## **Industry Request:**

- A joint focused Q&A session to discuss Regulator perspective on the pilot and format of ToC.





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# UPDATE REPORT: SAMD WG

- DITTA believes the 1,400+ comments received during the latest consultation will improve the proposed document on clinical evaluation
  - Given the volume of comments submitted, a synopsis of major themes would be helpful
- DITTA supports the 6 month extension; the current WI requires careful consideration due to its importance
- DITTA suggests that terms be referenced and defined in the IMDRF documents, e.g. “real-world evidence” and “real-world data”
- DITTA believes it is important for future SaMD documents to build on the framework established in GHTF documents, e.g. SG 5





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# UPDATE REPORT: STA WG

- Based on recent meeting in Geneva last month:
  - DITTA appreciates the progress this group has made
  - DITTA supports creation of a strategic plan for Standards WG
  - Request: timeline + deliverables from MC perspective
- DITTA suggests better feedback within the IMDRF WG on
  - Communication to ISO and IEC leadership
  - strategic plan as it develops
- Industry suggests IMDRF refrain from developing separate IMDRF standards and to rely rather on the process of international standards development



**JIRA**

**MEDEC**



**IMEDA**



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

**abimed**  
Asociación Brasileira de Indústria de  
Tecnologia de Produtos para Saúde

**Kmdica**  
Korea Medical Devices Industrial  
Coop. Association

**ITAC**  
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## Request for the next IMDRF

- Provide more clear content and targets for Strategic Plan 2020, and
- Share information with stakeholders regarding implementation and challenges in IMDRF Open Stakeholder meeting.





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ABOUT DITTA OUR INDUSTRY ACTIVITIES LIAISONS MEDIA CENTRE MEMBERSHIP



**WELCOME TO THE NEW DITTA WEBSITE!.....**



We are very happy to share with you our newly designed website and are sure you will enjoy the information shared and posted here.

**DITTA is the global industry united voice** of the medical imaging, radiation therapy, and health IT industry. Our technologies have revolutionized healthcare, and are integral to patient care and health

**Learn about our innovative technologies:** how it leads to better health while reducing costs; and what we're doing to bring access to imaging to more people in more places.

**Why DITTA matters to industry:** In today's increasingly global world, DITTA is leading the way to help ensure medical imaging and device technologies are seamlessly interacting, cybersecurity threats are mitigated and patient safety is protected through the adoption of global





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**THANK YOU!**

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