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

DITTA CONTRIBUTION TO IMDRF STAKEHOLDER FORUM

Satoshi Kimura
DITTA Chair
JIRA Executive Director

IMDRF Stakeholder Forum
Tokyo, 25 Mar. 2015

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

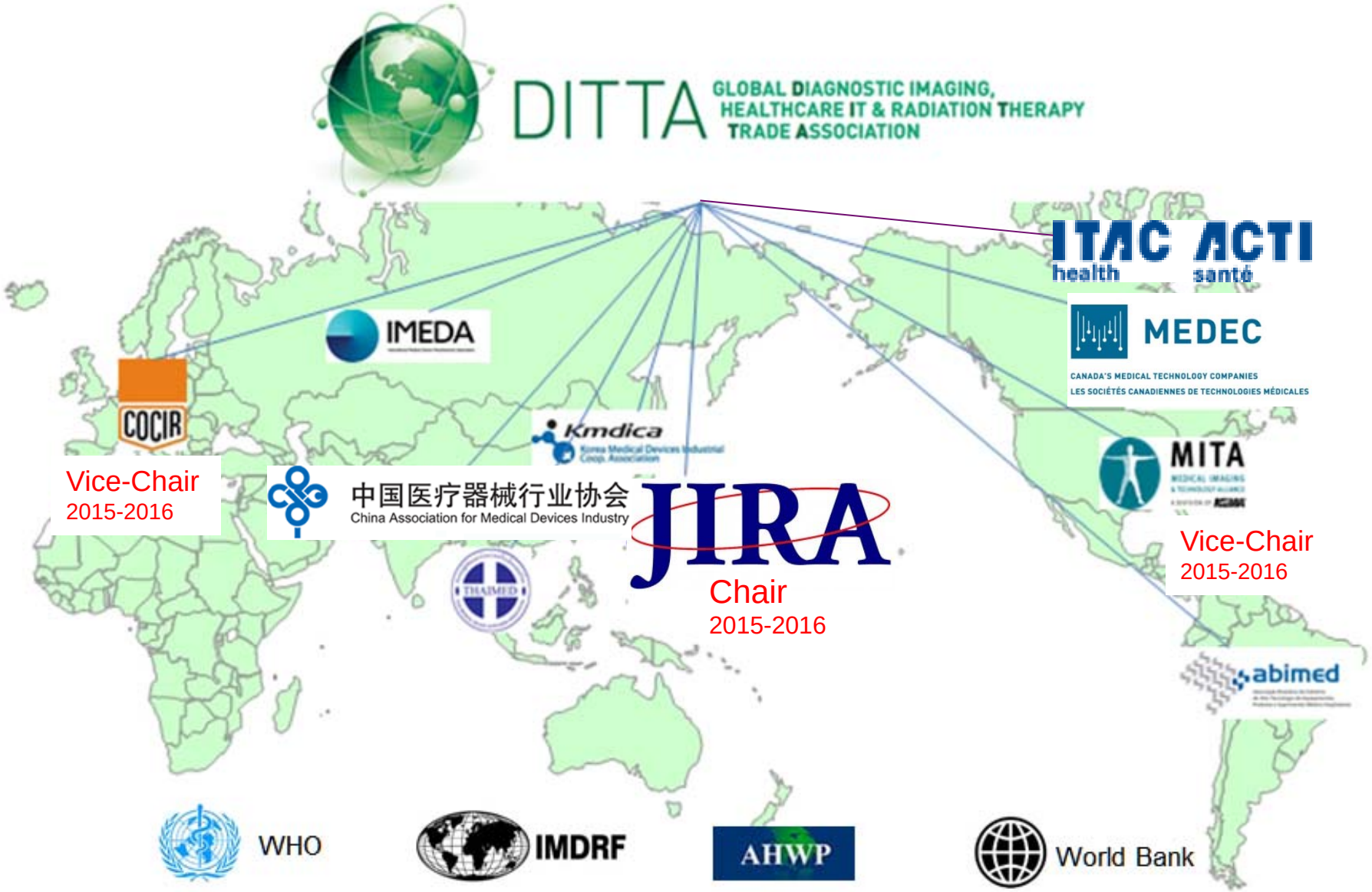
Key Topics

Updates about DITTA

DITTA views on current work items

DITTA views on standards

Outcomes on DITTA Workshop on RPS & SaMD


DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION
ITAC ACTI
health santé
IMEDA
MEDEC
CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES
COCIR
Vice-Chair
2015-2016
Kmdica
中国医疗器械行业协会
China Association for Medical Devices Industry
JIRA
Chair
2015-2016
MITA
Vice-Chair
2015-2016
abimed
WHO
IMDRF
AHWP
World Bank

UPDATES ABOUT DITTA

. DITTA Chair for 2015 – 2016 under JIRA
  Vice-chairs under COCIR and MITA

. DITTA was granted a NGO status at WHO
  with work programme covering 2014 -2017

. DITTA has a Formal Liaison with AHWP

. DITTA Working Groups expansion:

RPS, UDI, MDSAP and SaMD WG; 4 groups mirroring IMDRF activities
Environment WG; working for Basel Convention
World Bank WG; for World Bank on Procurement
Refurbishment WG; for future refurbishment standard
New! 2 groups created recently: 1 on standards + 1 on WHO activities

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

DITTA VIEWS ON CURRENT WORK ITEMS

1. SaMD

DITTA initially proposed this IMDRF work item, appreciates the active engagement with industry and publication of IMDRF guidance (definitions & risk categorization).

- DITTA believes that the IMDRF QMS paper can benefit from further discussion on risk and severity assessments and post-market monitoring:

  - DITTA appreciates the link between QMS draft and ISO 13485. Additional references to ISO 14971, IEC 62304 and ISO 12207 should be considered.

  - DITTA believes QMS process measures are critical to software development.

2. MDSAP

Industry remains committed to MDSAP & favors further QMS convergence.

Current Status

- Implementation of IMDRF MDSAP in member jurisdictions is not formalized and DITTA would like to raise the adoption in member jurisdictions.
- It is unclear how to expand the MDSAP Guidance Documents into non IMDRF member countries.

Harmonized Requirements for QMS & ISO 13485 Revision.

- Current MDSAP covers multilateral audit, Industry expects convergence with QMS requirements.
- DITTA has the following concerns regarding ISO 13485 draft:
  - Concern regarding current and future differences to ISO 9001.
  - Concern regarding the adoption and use of a significantly different ISO 13485 in the marketplace (including impact on MDSAP).

3. RPS

- DITTA appreciates the recent engagement with industry.
- **RPS Table of Contents (TOC)**
  - DITTA recognizes the benefits of the ToC to provide manufacturers with the common dossier structure for regulators in the IMDRF RPS WG.
  - For next step of ToC, DITTA suggests to develop the guidance documents for the Common Technical Documents (e.g. Validation Report, Risk assessment report, Clinical Evaluation Report, etc. Including Software Documents) in order to reduce the reviewing time in Regulatory.
- **RPS Electronic Submission Format**
  - DITTA recognizes benefits of a harmonized electronic submission format.
  - The RPS standard is one possible format. The chosen harmonized format must make business sense for both regulators and industry, e.g. cost/risk benefit, ease of use, infrastructure required to set up, process, and maintain, etc.
  - DITTA believes the business case should involve the objective evaluation of multiple electronic options from both regulator and industry perspectives.

4. REVIEW OF NCAR

DITTA appreciated the opportunity to comment on the Exchange Criteria and Report Form, and hope that next steps address:

- Clarify terms and definitions

- Increase of industry engagement in further development of NCAR

DITTA

GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

DITTA VIEWS ON STANDARDS

DITTA VIEWS ON STANDARDS

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

Strategic Policy

- DITTA supports convergence on the use of standards which will lead to convergence of technical dossiers regardless of regulatory scheme.
- DITTA emphasizes role of standards and their link to regulation (as mechanism for streamlining market access while maintain safety).

Possible Short term & Mid term Action

- IMDRF engage with international standards bodies. (e.g. ISO, IEC through type A liaison)
- IMDRF countries to agree on common transition timeline and mechanism for revised International Standards. (e.g. IEC60601-1 Ed2 and Ed3)

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

OUTCOMES ON DITTA WORKSHOP ON RPS & SAMD ON 23RD MARCH 2015

OUTCOMES ON DITTA WORKSHOPS ON RPS & SAMD

Attendance: 100 participants

Summary on RPS:

2 Presentations:

- MC including principles of ToC , file exchange and reference to subgroup evaluating 4 technical options
- and industry perspective with concerns on complexity and resource demand

Sept.: Pilot planned with US, Canada, EU, Brazil and Australia targeting 20 to 30 industry participants

Questions on complexity, resource demands, broadening outside IMDRF members

Summary on SaMD:

2 Presentations:

- US FDA Project leader update on achievements on Phase 1 and 2 and progress for Phase 3
- Industry perspective with emphasis on external developments calling for IMDRF leadership

Questions on clinical investigations for SaMD, embedded software, data privacy and security

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

DITTA REMAINS SUPPORTIVE OF IMDRF WORK AND ALWAYS READY TO CONTRIBUTE!

THANK YOU FOR YOUR SUPPORT

www.globalditta.org