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
Kyoto, 16 Sep. 2015

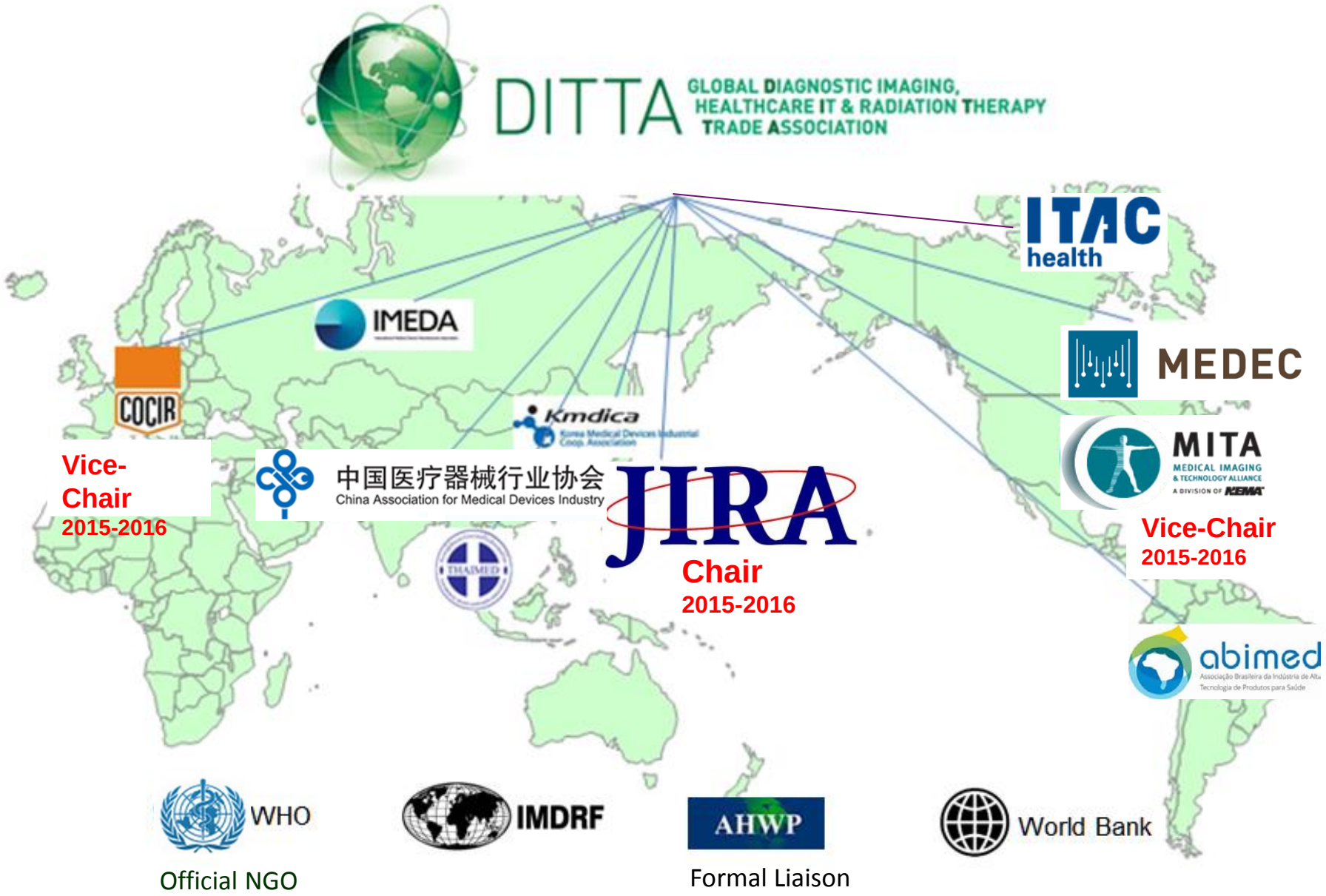
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Key Topics

Updates about DITTA

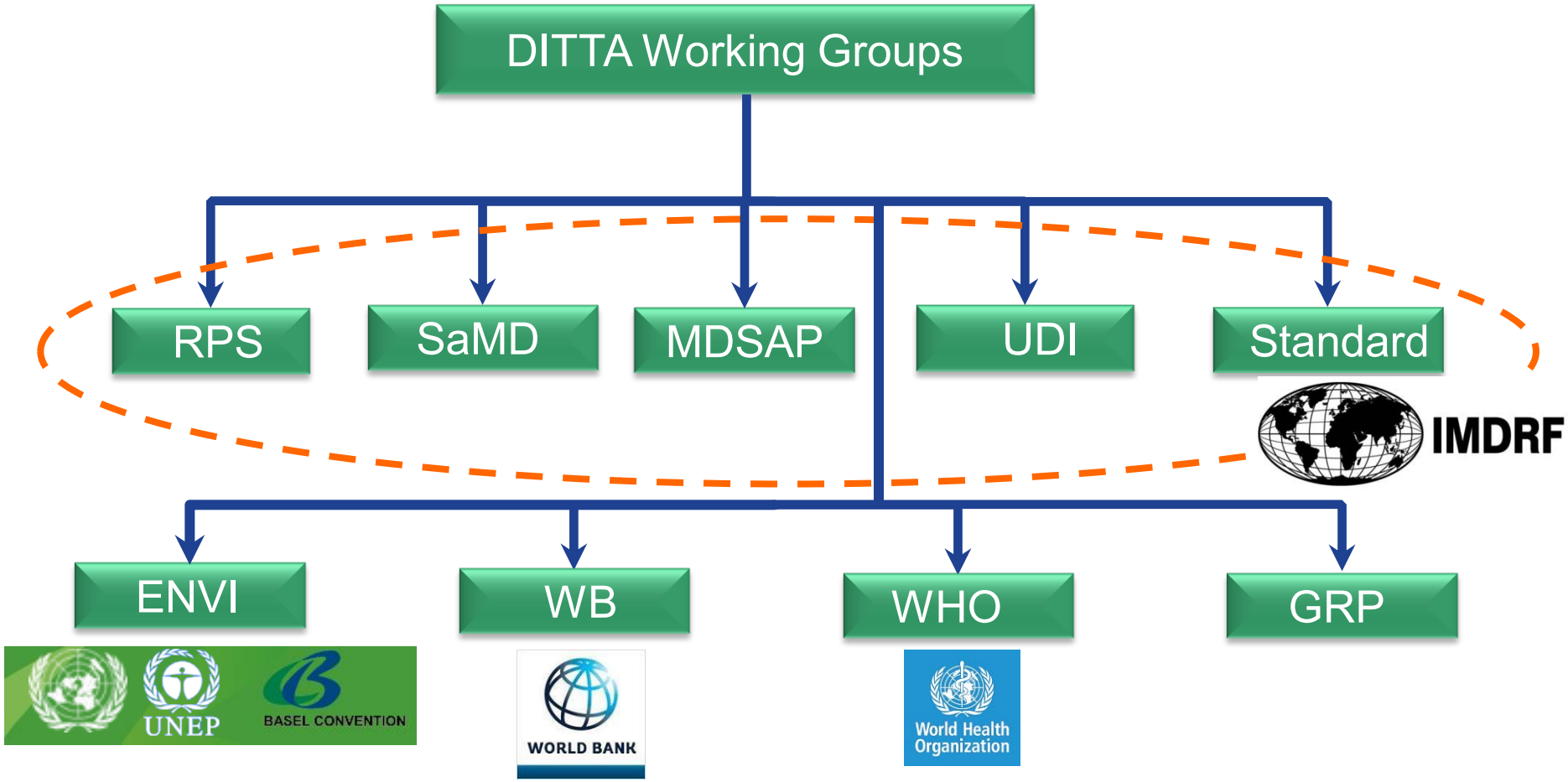
DITTA views on current work items

Outcomes on DITTA Workshop on Standard


DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION
ITAC health
IMEDA
MEDEC
COCIR
Kmdica
Korea Medical Devices Industrial Coop. Association
Vice-Chair
2015-2016
中国医疗器械行业协会
China Association for Medical Devices Industry
JIRA
Chair
2015-2016
MITA
MEDICAL IMAGING & TECHNOLOGY ALLIANCE
A DIVISION OF NEMA
Vice-Chair
2015-2016
abimed
Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde
WHO
IMDRF
AHWP
World Bank
Official NGO
Formal Liaison

DITTA: 9 WORKING GROUPS

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



COCIR JIRA MEDEC MITA IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

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

RECOMMENDATIONS FROM DITTA TO IMDRF

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

RECOMMENDATIONS FROM DITTA TO IMDRF

DITTA stated Recommendations on IMDRF MC at Tokyo meeting

- DITTA believes the time is right to set longer-term goals to guide the organization.
  - The MC also discussed IMDRF strategic plan to identify its direction for the coming years to better coordinate its activities and allocate its limited resources. The MC will finalize the plan in Kyoto meeting in September 2015.
- DITTA would appreciate the MCs openness in discussing your vision with industry.
  - Look forward to constructive and substantive discussions with IMDRF
- DITTA requests that the MC create a formal opportunity for industry to contribute to MC decision-making prior to final decision .
  - Look forward to constructive and substantive discussions with IMDRF

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 and appreciates the current active engagement in the IMDRF QMS guidance as well as the previous publications (definitions & risk categorization).

– DITTA believes that the IMDRF QMS guidance can benefit much more by the following consideration:

- DITTA believes the guidance should carefully keep the scope of ISO 13485.
- DITTA appreciates it if its global implementation will actively be considered.

– DITTA believes that the next activity of the IMDRF SaMD work group is very important for the upcoming worldwide regulatory convergence:

- DITTA believes that IMDRF should follow the results of the most recent stakeholders survey.
- In future IMDRF SaMD work items, risk management should embrace the goals of security and networking of medical devices!

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.
  - We still have the same concerns from the past – that a particular country won't "accept" the results and will do their own audit.

Harmonized Requirements for QMS & ISO 13485 Revision.

- Current MDSAP covers multilateral audit, Industry expects convergence with QMS requirements.
- Continue to ensure that MDSAP complements the ISO 13485 revision process as originally intended to achieve a harmonized standard among IMDRF members.

3. RPS

DITTA appreciates the recent engagement with industry.

For Business Case analyzing;

- Technology Option Scoring
  - The Management Committee should understand that the scoring exercise is based on technical assessment, not cost. It was made very clear that implementation considerations, e.g. cost are out of scope of the current scoring. Industry assumes that there will be a final scoring that incorporates cost, infrastructure, required, etc. Thus, one solution scoring well, e.g. HL7 RPS, does not mean it makes sense from a cost/benefit perspective.
- Cost Consideration
  - Cost considerations are a significant aspect of the assessment in addition to scoring the technology options. Cost for each of the solutions should be determined prior to the MC making their decision. The MC making a decision without fully understanding the cost of each technology option makes no sense.
- Implementation Guide
  - The RPS WG should be tasked with developing an implementation guide after the MC has made their decision, which should include high-level milestones for implementation work.

4. IMPACT OF NCAR'S OUTCOME

DITTA appreciated the opportunity to comment on the Exchange Criteria and Report Form.

Outcome of NCAR has very big impact to industries activities in post market phase, because the differences of reportable criteria or contents of incident report are existing in each jurisdiction, we need to support them in each jurisdiction.

- The NCAR WG needs to share more information on the activities that have taken place to date and future plans.
- Increase of industry engagement in further development of NCAR

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

OUTCOMES ON DITTA WORKSHOP ON STANDARD ON 14TH SEPTEMBER 2015

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

OUTCOMES ON DITTA WORKSHOPS ON STANDARD

Attendance: **XXX participants**

Summary :

Presentations:

Questions on

To be completed post workshop

COCIR JIRA MEDEC MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA THAIMED 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 REMAINS SUPPORTIVE OF IMDRF WORK AND ALWAYS READY TO CONTRIBUTE!

THANK YOU FOR YOUR SUPPORT

www.globalditta.org