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

DITTA Update

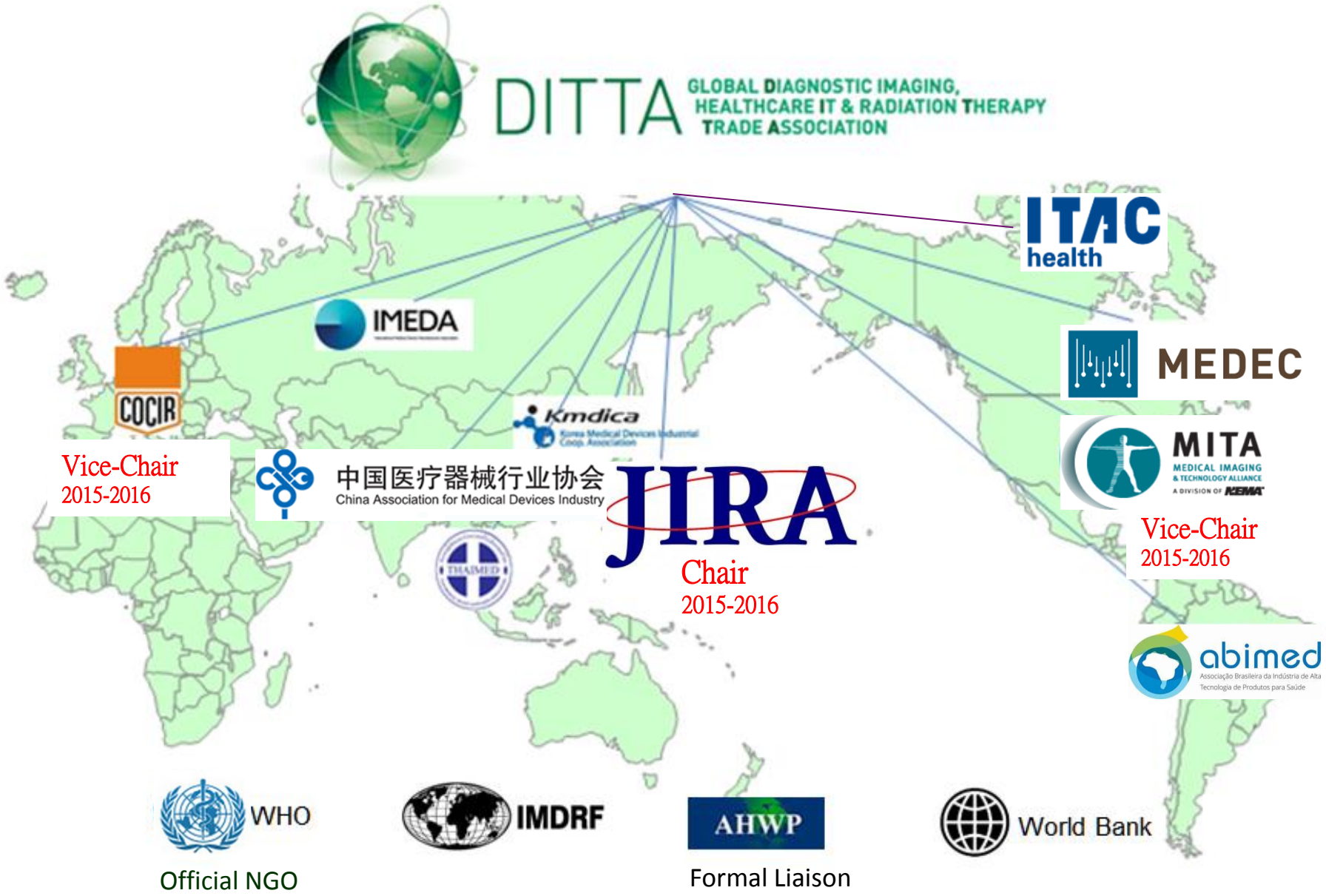
Susumu Uchiyama
Member of DITTA SC
International Committee Chair, JIRA

AHWP
Bangkok, Friday 6 November. 2015

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

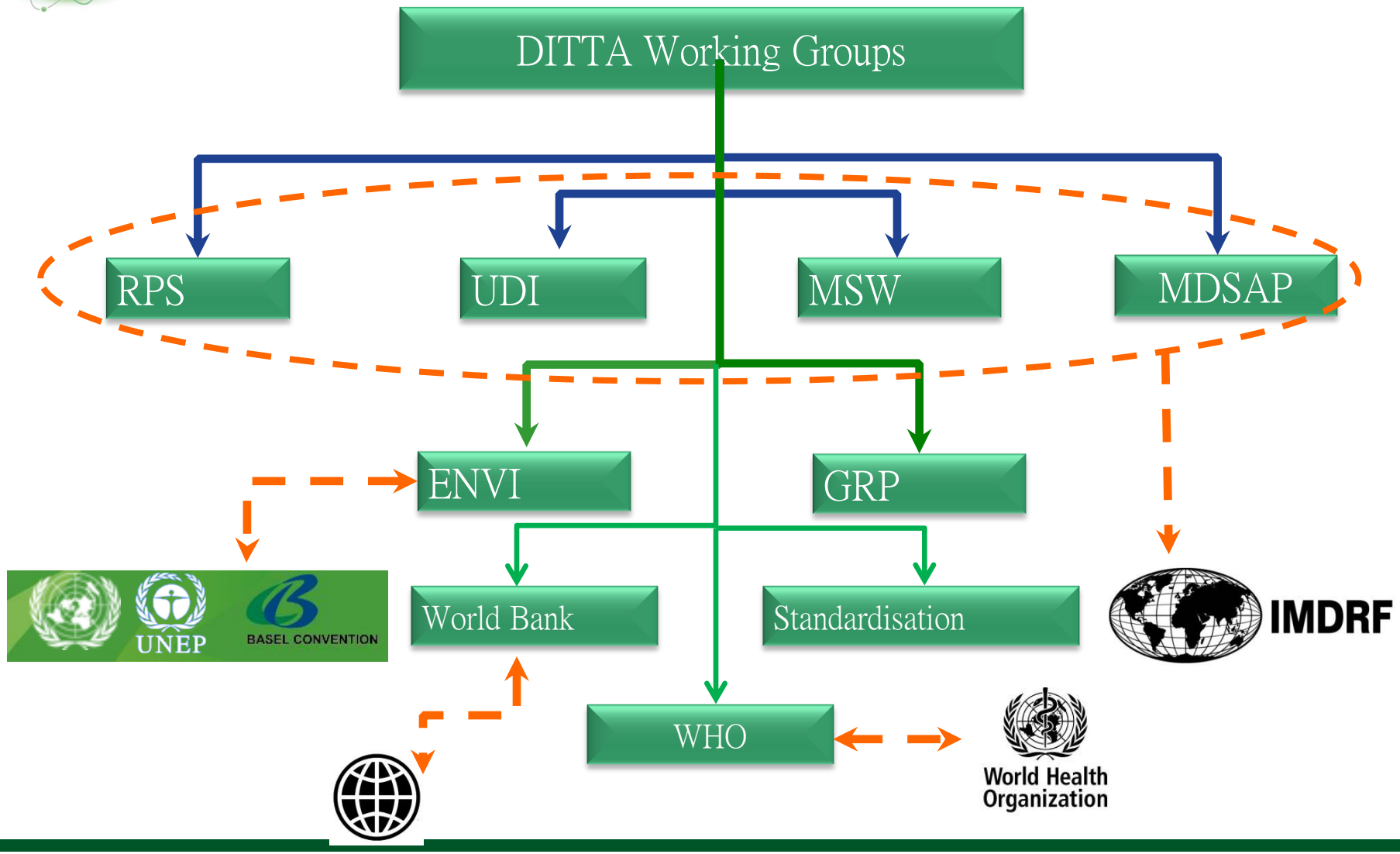
Key Topics

1. Update about DITTA
2. Outcomes of DITTA Kyoto Standards Workshop
3. Recommendations on standards to IMDRF
4. DITTA Views on Current IMDRF Work Items


DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION
ITAC health
IMEDA
MEDEC
COCIR
Vice-Chair
2015-2016
Kmdica
Korea Medical Devices Industrial Coop. Association
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
THAIMED
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 THAIMED 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

KEY ACHIEVEMENTS

- DITTA representatives in all IMDRF groups where industry can participate
- 2013 : DITTA work item on medical software proposed and accepted by IMDRF
- 2014 and 2015: DITTA workshops on standards during IMDRF meetings (Washington D.C. and Kyoto)
- 2014: DITTA official liaison with AHWP
- 2014: DITTA GRP presentation at AHWP
- 2015: DITTA as NGO in official relations with WHO (DITTA delegation of 15 people at WHA, issued statement on NCDs, on SDGs and initiative at UNGA)
- 2015: DITTA Brochure on Circular Economy (see next page)
- 2015: DITTA support Software Workshop at AHWP

COCIR JIRA MEDEC MITA THAIMED 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

DITTA INITIATIVE ON CIRCULAR ECONOMY

ENGLISH

FRENCH

SPANISH

CHINESE

JAPANESE

COCIR JIRA MEDEC MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE THAIMED 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

2. OUTCOMES OF DITTA KYOTO STANDARDS WORKSHOP

(14 September, 2015)

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

OUTCOME OF DITTA KYOTO STANDARDS WORKSHOP

Goal: *To openly discuss the best way to develop and use standards to support regulatory needs*

Attendance: over 100 participants

Speakers: 4 from regulators (Japan, EU, Brazil and US), 5 from industry (Brazil, EU, Japan, Canada)

Key topics discussed:

- *status of standards today around the globe*
- *Regulators involvement in standards development*
- *Opportunities and challenges for industry and regulators*

Outcome: *significant common perspectives between industry and regulators*

Recommendations: *seek opportunities and define way forward together*

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

ISSUES RAISED @ DITTA WORKSHOP

Arbitrary selection of some issues raised on 14 Sept Workshop

1. Too many standards projects / priority setting
2. "Optimum community benefit" not always obvious at NWIP
3. Design requirement specification + rationale is essential at NWIP
4. IMDRF should be involved at standard design stage
5. Too long development time; 2 year should be workable
6. Different expectation level across jurisdictions re. safety
7. Standards too long & difficult: should be simple, short & sharp
8. Better handling of multi-part standards (e.g., IEC 60601-1 ++)
9. Attitude of convener is critical and not always optimum
10. Project transparency must be improved
11. Make change log + rationale mandatory with revisions
12. Enforcement of IEC/ISO directives (e.g., WGs live forever)
13. Standards development is NOT for a scientific debating club

COCIR JIRA MEDEC MITA THAIMED 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

ISSUES RAISED @ DITTA WORKSHOP

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

Industry and regulators shared common concerns

Design "adequacy for regulatory use" into development process

- Ensure by design of development process that standards are suitable for regulatory needs

<u>Some</u> Implications

- Involve regulators at design requirement specification drafting
- SDOs need to amend processes (perhaps only for medical technology)
- Key stakeholders (including regulators and industry) need to communicate about relevance of standards for priority setting

COCIR JIRA MEDEC MITA THAIMED 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

3. RECOMMENDATIONS ON STANDARDS TO IMDRF

STANDARDS: LIFE AFTER DITTA WORKSHOP …

Proposals :

- Elaborate further on the issues, concerns, complaints, …
- Define potential solutions & discuss with stakeholders including SDO's
- Develop General Guidance for projects intended to deliver useful medical technology standards for regulatory purposes

Industry is ready to <u>jointly</u> work with IMDRF to shape the future

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

4. DITTA VIEWS ON CURRENT IMDRF WORK ITEMS

(September 2015)

1. SOFTWARE AS A MEDICAL DEVICE (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).

- The IMDRF QMS guidance can provide greater benefit by considering the following:
  - The guidance should carefully keep the scope of ISO 13485.
  - Global implementation should be actively considered.

- The next activity of the IMDRF SaMD work group is very important to regulatory convergence:
  - In future IMDRF SaMD work, risk management should embrace the goals of security and networking of medical devices.
  - Clarify when and what clinical data may be needed in the next future work

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

2. MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

DITTA applauds the MDSAP efforts

DITTA welcomes inclusion of Japan in the MDSAP pilot and has general positive feed-back from DITTA companies involved

DITTA supports having more companies involved in the pilot

DITTA looks forward to the expansion of the pilot to other IMDRF jurisdictions

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

3. REGULATED PRODUCT SUBMISSIONS (RPS)

DITTA appreciates the potential that RPS represents, and engagement with industry. To be viable, RPS should make business sense for both industry and regulators.

- The 'Strategic Analysis' recommendation from the IMDRF RPS WG to the MC is based on technical assessment only, it does not take into account costs:
  - It has not been fully determined that HL7 RPS is the best option.
  - Cost assessment for each technology option should be done for industry and participating regulators prior to the MC making an endorsement.
- Stakeholders should contribute to cost assessment in the future.
- DITTA is looking forward to hearing more information on the TOC pilot and getting a better understanding of milestones for implementation

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

4. UDI – A KEY ELEMENT FOR INDUSTRY

- IMDRF should build on US implementation
- DITTA would be happy for IMDRF to continue its efforts towards convergence of UDI systems from various jurisdictions
- IMDRF need to ensure database(s) established in the various geographies can communicate and use common basic architectures

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

DITTA APPRECIATES THE LIAISON WITH AHWP

THANK YOU FOR YOUR ATTENTION

www.globalditta.org