



**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
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TRADE ASSOCIATION

# **DITTA Update**

**Keiichiro Ozawa**

*DITTA Medical Software Chair*

*JIRA International Committee*

*JIRA Oversea Medical Device Regulation Committee*

**AHWP 2016 Annual Meeting**

*Cebu, Philippines, Friday 25 November 2016*



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# Key Topics

1. Update on DITTA
2. Good Refurbishment Practices (GRP) Update
3. Outcomes from DITTA Workshop on Standards on 12 Sept
4. DITTA Views on Current IMDRF Work Items



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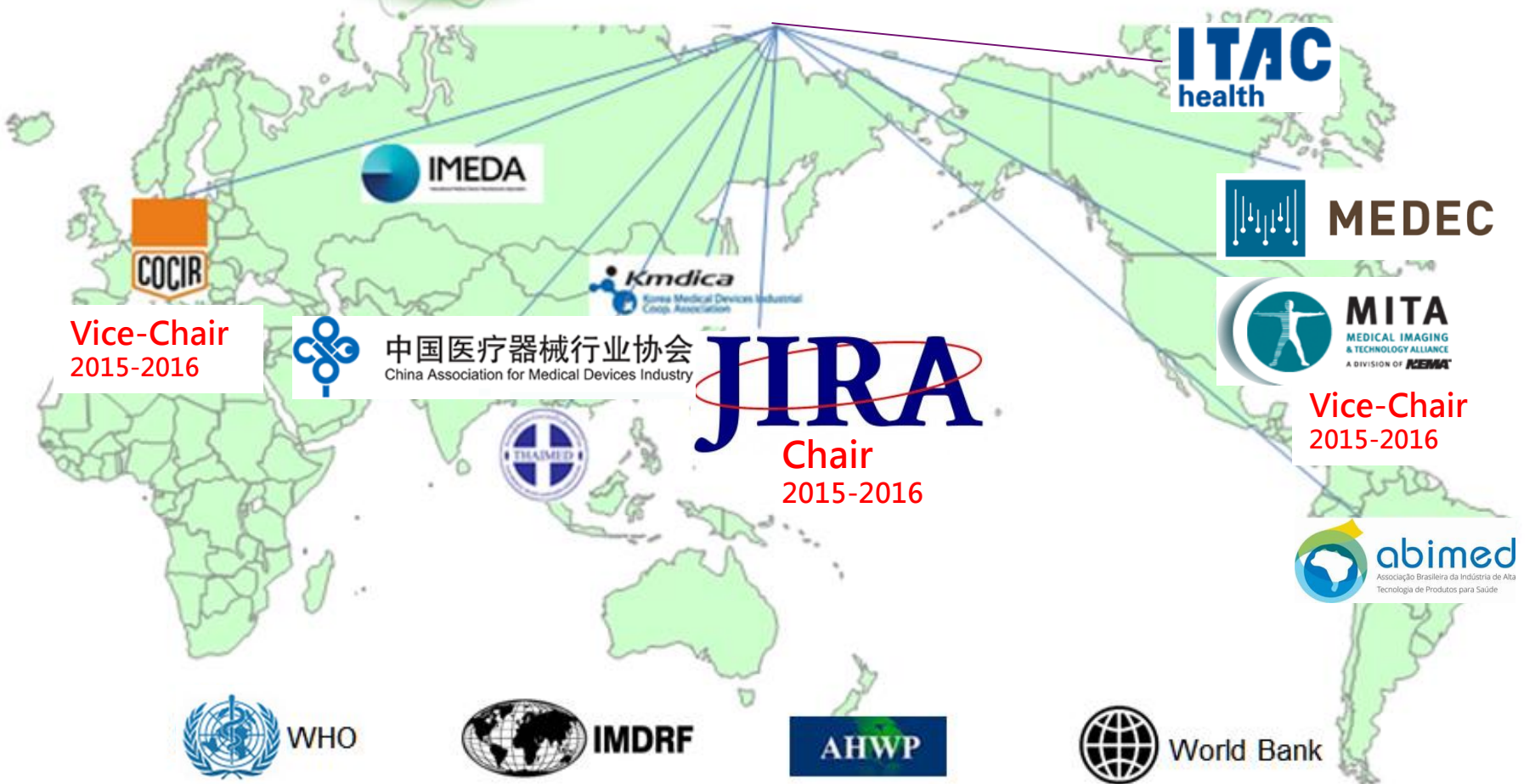


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# **1. UPDATE ON DITTA**



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**Vice-Chair**  
2015-2016



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Associação Brasileira da Indústria de Alta  
Tecnologia de Produtos para Saúde



**WHO**

Official NGO



**IMDRF**

**AHWP**

Formal Liaison

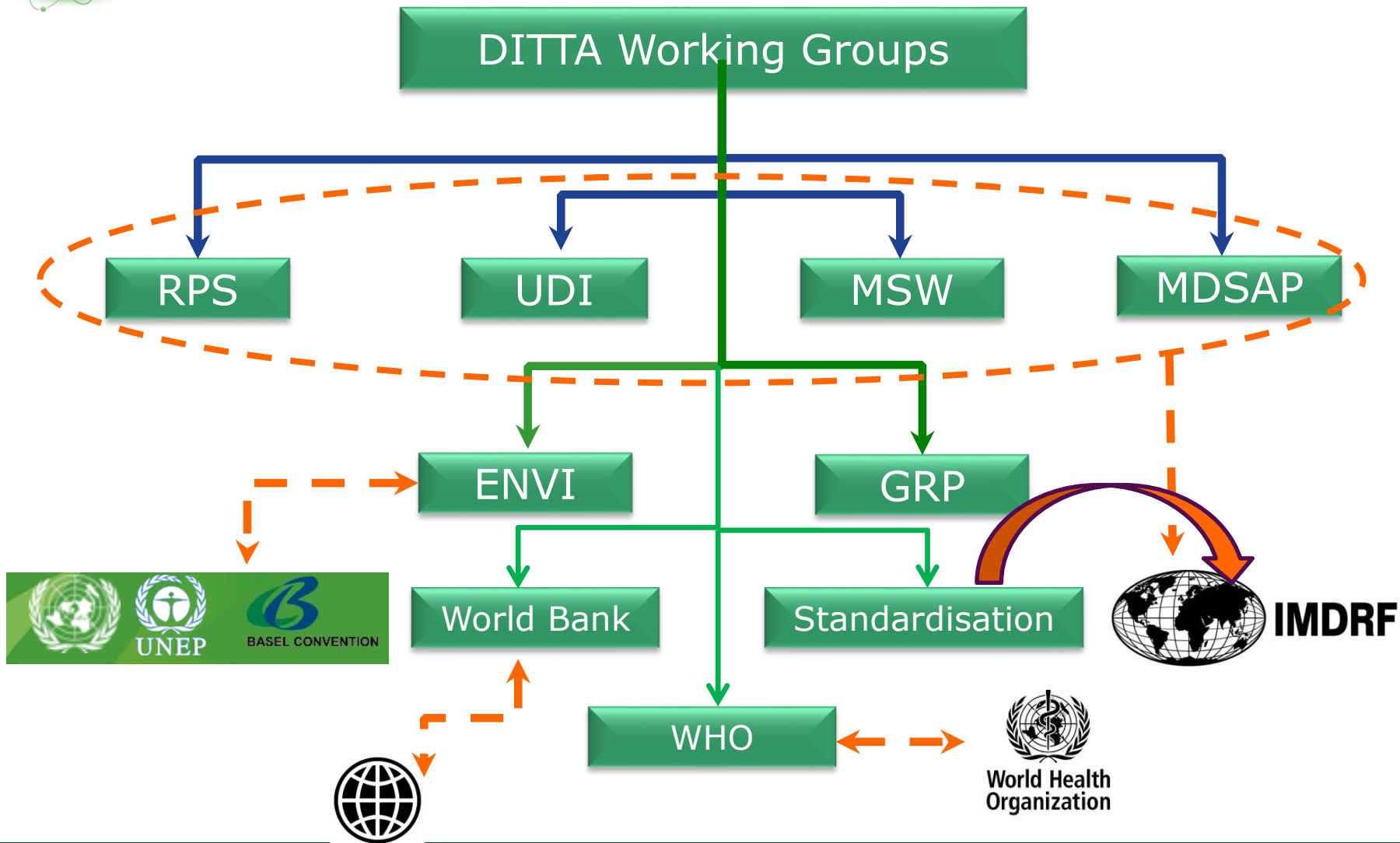


**World Bank**



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# DITTA: 9 WORKING GROUPS





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# DITTA 2016 UPDATES

- **Activities linked to IMDRF:**

- DITTA proposed work item on Int'l Standards adopted by IMDRF
- DITTA workshop on Medical Software in March
- DITTA workshop on Int'l Standards in Sept.

- **Other activities with other International Organisations:**

- **At UN level:**

- DITTA invited to UNAIDS Smart Cities in NY in June to present on innovative technologies
- DITTA has 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:**

- DITTA is a member of the GMNCD Group since last year
- DITTA provided comments during 2 consultations on priority medical devices in cancer
- DITTA provided comments during 2 consultations on Global Regulatory Framework
- DITTA speakers at CIPRaM in Spain in Oct. on Radiation Safety and Bonn Agreement

- **With IAEA:**

- DITTA representation in Training course on Brachytherapy (Vienna – Oct)



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## 2. GOOD REFURBISHMENT PRACTICES (GRP) UPDATE





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# 2. GRP (REFURBISHMENT) UPDATE

## Goal:

Have a globally recognised standard that supports optimised access to safe, effective refurbished medical imaging equipment that may be used in the future by regulators

## Update:

- NEMA has published NEMA/MITA 1-2015 Good Refurbishment Practices for Medical Imaging Equipment.
- In August 2016, DITTA submitted to IEC a Public Available Specification (62B/1022/PAS). This was approved in October and going to be “IEC/PAS 63077 Ed.1, Good refurbishment practice for medical imaging equipment”.

## Current status:

On going discussions with conformity assessment bodies to optimise the use of such NEMA standard and IEC PAS.



NEMA MITA 1-2015



IEC/PAS 63077 Ed. 1







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# **3. OUTCOMES FROM DITTA WORKSHOP ON STANDARDS 12 SEPT**



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## 3. OUTCOMES FROM DITTA WORKSHOP ON STANDARDS – 12 SEPT.

**Goal:** To provide the latest information on how regulators consider standards in their regulatory framework as well as how standards are used by industry at global level and to share information on standards development at IEC and ISO levels and latest updates on their work programs

**Attendance:** over 140 people registered

**Speakers:** from Regulators (EU, Brazil, USA and WHO), from industry (Brazil, Canada, Japan, EU and US)

### **Outcome Summary:**

- Full day meeting with latest information on various aspects
- Experts from industry, regulators and WHO shared importance of standards from a variety of perspectives
- Comprehensible outlook on standards process and latest update on new IMDRF WI
- Constructive interactions and exchange of ideas that we believe will be fruitful as we continue to work together through the IMDRF WI





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## **4. DITTA VIEWS ON CURRENT IMDRF WORK ITEMS**

- A. SaMD
- B. MDSAP
- C. RPS
- D. UDI
- E. STANDARDS



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# A. SOFTWARE AS A MEDICAL DEVICE (SaMD)

- DITTA has been actively engaged in this WI since the beginning in the current focus on Clinical Evaluation.
- DITTA appreciates IMDRF continuing efforts to address the current topic despite difficulties.
- DITTA supports the current working policy based on the previous 3 guidance documents.



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## B. MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

- DITTA applauds the efforts that have gone into developing MDSAP and thanks the jurisdictions that have joined the MDSAP program.
- DITTA is interested in the progress of MDSAP and in particular the intention for wider participation.
- DITTA continues to believe a survey could be helpful in understanding hesitations from some manufacturers (incl. SMEs) to participate in MDSAP and stands ready to help.



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## C. REGULATED PRODUCT SUBMISSIONS (RPS)

- DITTA appreciates the potential benefits of a single exchange format for product submissions to multiple regulatory jurisdictions. However, ROI remains key for DITTA.
- DITTA appreciates involvement of industry but is concerned about the limited resources for the successful continuation of this WI.
- DITTA suggests a careful assessment of the ToC and exchange format aspects.



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# D. UDI – A KEY ELEMENT FOR INDUSTRY

- US FDA implementation of UDI has progressed steadily but with adjustments made as lessons are learned.
- DITTA suggests that IMDRF takes steps (e.g. through additional guidance) so that lessons learned can also benefit other jurisdictions.
- DITTA recommends that regional databases are interoperable.



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## E. STANDARDS

- DITTA is very pleased with the shared ambition to improve the standards development process, aiming for a better uptake of international standards in regulatory compliance
- DITTA is keen to contribute to help improve the role of standards as platforms to enhance regulatory convergence at global level
- DITTA was encouraged with the 1<sup>st</sup> meeting of the IMDRF WG in Berlin:
  - 3 days meeting
  - Attendance: 11 regulators (US, EU, Brazil, Japan, Russia and Canada) and 6 industries and 1 from WHO
  - Regulators and industry shared similar motivations
  - Active interest from WHO to join efforts







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**DITTA REMAINS SUPPORTIVE OF  
IMDRF WORK & IS ALWAYS READY  
TO CONTRIBUTE!**

**THANK YOU FOR YOUR SUPPORT**

[www.globalditta.org](http://www.globalditta.org)