



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

IMDRF Stakeholders Meeting

Nicole Denjoy

DITTA Chair

COCIR Secretary General

IMDRF Open Stakeholders Forum

Sophia Antipolis, France

March 20, 2013

- 1. What is DITTA**
- 2. DITTA achievements since IMDRF meetings in Sydney**
- 3. DITTA proposed NWIP on medical software**
- 4. DITTA priorities**

1. What is DITTA?

- DITTA is the **Global Diagnostics Imaging, Healthcare IT, and Radiation Therapy Trade Association**
- DITTA is a global organization representing Industry Associations of Manufacturers around the world.
- Member companies manufacture: medical x-ray equipment; computed tomography (CT) scanners; ultrasound; nuclear imaging; radiation therapy equipment; magnetic resonance imaging (MRI); imaging information systems; medical software and health IT; and radiopharmaceuticals.
- DITTA was officially incorporated in 2012 as a non-profit trade association in the United States after more than 12 years of existence.
- DITTA's membership currently includes Abimed (Brazil), COCIR (Europe), JIRA (Japan), KMDICA (Korea), MEDEC (Canada), MITA (United States), THAIMED (Thailand), CAMDI (China) and IMEDA (Russia).



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



What does DITTA do?

DITTA Member Goals:

- Enhance the detection of disease early
- Improve the quality of care
- Reduce the likelihood of medical errors
- Lower the long-term cost of health care

DITTA Activities:

- Communicate, cooperate and coordinate between associations
- Identify topics and trends with global industry impact
- Develop and submit joint industry positions
- Promote ethical conduct and practices
- Leverage the benefits of international standards

- Build and improve public awareness and relevance of industry products in healthcare and its benefits for patients and users
- Advocate for efficient and appropriate regulation that promotes innovation
- Enhance the global competitiveness of member companies
- Identify unnecessary regulatory burdens
- Promote and pro-actively provide solutions to harmonize regulatory frameworks as much as possible (approved once, accepted everywhere)
- Expand market access for member companies

2. Since the last meeting in Sydney, DITTA has...

1. **Delivered** a presentation to the World Health Organization (WHO) consultation on ageing population in Kobe, Japan (20-21 February 2013)
2. **Started** the process to be recognized as NGO to WHO
3. **Submitted** a NWIP on medical software to IMDRF
4. **Been actively contributing** to the IMDRF RPS and UDI working groups activities
5. **Added** two new member associations: ABIMED (Brazil) and KMDICA (Korea)
6. **Organized** an event with the World Bank that took place in Washington DC on 27 September 2012 on procurement of medical technology. Leading global medical technology industry engagement with the World Bank to increase understanding of new equipment and improve the procurement process to improve access and reduce waste in the system
7. **Co-organized** with AHWP a medical software workshop during their November conference in Taipei, Taiwan (03 November 2012)
8. **Started** the process to be recognized as official partner with AHWP
9. **Created** a new DITTA task force bringing experts from its constituency on Environmental policies
10. **Held** our first DITTA Board of Directors meeting in Chicago



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

www.globalditta.org

DITTA remains committed to...

1. Continue our active participation to the IMDRF Management Committee.

➡ *We thank you for continuing to invite Industry to attend the special session of the Management Committee and ask that Industry gain a permanent seat on it*

2. Contribute to IMDRF working groups.

➡ *DITTA is actively participating in the IMDRF RPS and UDI Working Groups and has dedicated mirror groups within DITTA to support IMDRF activities*

3. An opportunity to provide industry perspectives in defining a global regulatory strategy.

➡ *DITTA is ready to contribute if invited to do so*

4. Supporting the use of international standards.

➡ *Shortly a DITTA working group on standards will be set up and will be ready to support IMDRF efforts*

5. Provide industry view on the Medical Device Single Audit Program (MDSAP).

➡ *A DITTA working group on MDSAP has been set up, and we welcome the opportunity to actively contribute to the work being done*



More specifically on transition of GHTF documents into IMDRF documents, DITTA recommends...

- IMDRF create documents that are based upon and expand on the spirit of GHTF documents
- IMDRF clarify its position on GHTF documents
- GHTF and IMDRF documents be kept updated

➔ DITTA is ready to contribute to the maintenance of relevant GHTF and IMDRF documents



3. DITTA proposed NWIP on medical software

- 1st draft submitted to IMDRF on 27 April 2012
- Feed-back from IMDRF on 12 October 2012
- 2nd amended draft submitted on 05 February 2013

DITTA NWIP on Medical Software (1/2)

1. Goal

- To agree on a common terminology
- To advance global regulatory harmonization on standalone medical software
- To define key criteria that qualify software as a medical device

Having a harmonized Medical Software regulatory framework will benefit the public, healthcare providers and industry.

2. Proposed Working Group

- Regulator Chair: to be decided by IMDRF Management Committee
- Industry Vice-Chairs: DITTA MSW TF Chair and Deputy-Chair (Catherine Bahr and Eva-Maria Reiter)
- Working group membership:
 - Regulators: at a minimum: USA, Japan, China, Europe (including regulators from Sweden and the UK), Canada
 - Healthcare providers: *to be identified*
 - *Industry: Healthcare and ICT manufacturers*

DITTA NWIP on MSW (2/2)

IMDRF MC approval
of DITTA NWIP

International proposal
on **terminology and
qualification** of
standalone MSW

International proposal
on **classification** of
standalone MSW

International proposal
for a **regulatory
framework** for
standalone MSW

March
2013

July
2013

Nov.
2013

July
2014



4. DITTA priorities



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

www.globalditta.org

In summary...

1. Complete the IMDRF UDI Guidance document
2. Finalize the single audit process
3. Complete RPS Beta Testing and finalize general elements of the Table of Contents **after coordination with industry**
4. Include Industry in establishment of a framework for internationally recognized standards
5. Maintain relevant GHTF documents
6. Define common data set for pre-market approval and post-market activities

DITTA's vision remains to provide products and services that are of...

- 1. Highest quality**
- 2. Maximum safety**
- 3. Easily accessible**
- 4. Cost efficient**

We all need a global regulatory framework which foster innovation and facilitate global trade

Thank you

*... and please join us at the DITTA / GMTA cocktail at
Hotel PLAGES BEAU RIVAGE at 18.30*



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