



COCIR



Sustainable Competence
in Advancing Healthcare



22nd Global GS1 Healthcare Conference

COCIR/DITTA perspective on UDI

Lisbon, 23-25 October 2012

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



Summary



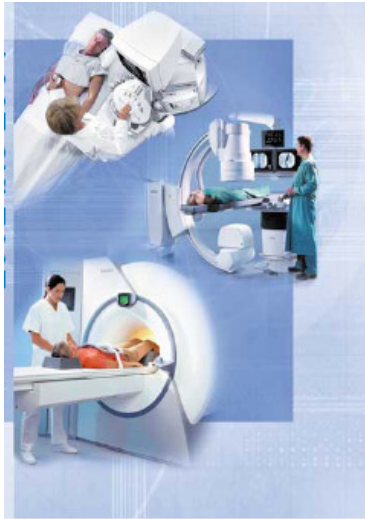
1. An innovative sector
2. Industry contributions on UDI
3. UDI-Status per geography
4. Industry recommendations



1. An innovative sector



What does COCIR do?



COCIR represents the Industry Voice in Medical Imaging, Electromedical and Healthcare IT



Our Industry leads in innovative healthcare technologies and provides solutions for the complete care cycle

Visit us at www.cocir.org





COCIR's Focus: improve market access

1. Provide COCIR's members with competence towards policy makers in Europe and outside
2. Contribute to sustainability of healthcare systems through integrated care approach
3. Promote Research and Innovation as a key enabler for economic growth
4. Drive global regulatory convergence (registered once, accepted everywhere)
5. Optimise use of International standards
6. Push for national and regional deployment (eHealth)
7. Pro-active in Green Technology (Eco-Design)



COCIR Member Companies





COCIR National Trade Associations Members



Belgium



Hungary



ASSOBIOMEDICA
Federazione nazionale per le tecnologie
biomediche, diagnostiche, apparecchiature
medicali e servizi, telemedicina

Italy



UK



Spain



Netherlands



Finland



Netherlands



France



Germany



Sweden



Turkey



Germany



What is DITTA?



- DITTA is the **Global Diagnostics Imaging, Healthcare IT, and Radiation Therapy Trade Association**
- DITTA is associations of manufacturers that represent medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers.
- 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 COCIR (Europe), JIRA (Japan), 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



IMEDA
International Medical Device Manufacturers Association



What does DITTA do?



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DITTA Member Goals:

- Detect 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
- Streamline clearance processes



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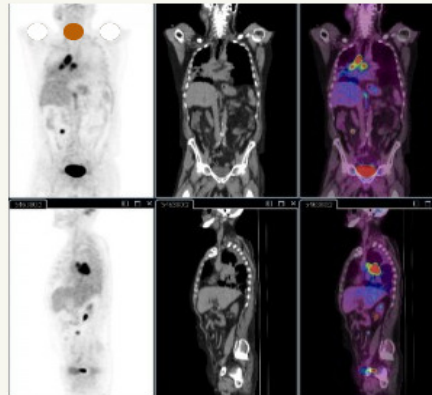
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DITTA is the global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers to better communicate, coordinate and collaborate on matters of common interest between participating associations and member companies. DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders. [Learn more.](#)



DITTA's members represent the world's medical imaging devices manufacturers.

Join Us

For more information about joining DITTA click [here](#)

UPDATE FROM DITTA

DITTA's response to IMDRF's open letter on March 22, 2012

[Read More](#)



2. Industry contributions on UDI



What DITTA is doing on UDI?



DITTA
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1. Created a DITTA UDI Task Force

In support of IMDRF UDI Work Team activities

2. Coordinated the IMDRF UDI consultation on “capital equipment”

3. Commented on the EC proposed recommendations on UDI

4. Reviewing EC proposed regulation on medical devices which include clauses on UDI

5. Reviewing US FDA proposed regulation



3. UDI – Status per geography

Our industry main concern



UDI – Status per geography (1/2)



- **European Union**

- Draft Recommendation on UDI requirements when EU Member States plan to implement a country specific system: Release expected by December 2012.
- Risk: EU Member States implement in the meantime different UDI systems.
- Risk: Country specific UDI systems could be incompatible.
- With the new Medical Device Regulation, a unique EU UDI system will be implemented by all 27 EU Member States and legally binding: Implementation expected by 2014.



UDI – Status per geography (2/2)



- USA

- Draft UDI Regulation from FDA is out for comments.
 - Deadline is November 07, 2012.
 - Final rule is likely to be issued in early 2013 (May 2013 is expected).
- DITTA is currently reviewing the draft UDI regulation.



Industry's main concern



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Our main concern at this time is the difference in progress and timelines between all these initiatives!



4. Industry recommendations



Industry recommendations (1/2)



1. Regulators to have a **concerted effort** to keep all jurisdictions drafting regulations with the same basic requirements, and have core elements in associated databases to ensure data exchange across the globe.
2. Regulators to take into consideration that many medical device manufactures have global markets. Regulators must recognize that how they implement UDI in their regions/countries will impact companies globally. **Regulators should implement UDI as consistently as possible across regions/countries.**
3. Need to accelerate the IMDRF UDI Work Team working groups activities to **finish recommendations and rules** in first half of 2013, and to suggest a clear timeline to understand a global adoption scheme.
4. IMDRF UDI road map to address the complexity of the medical device sector. **The IMDRF UDI roadmap must further define requirements in more detail.** Manufacturers need this level of detail to create their compliance action plan.



Industry recommendations (2/2)



5. IMDRF UDI road map timelines must take into consideration time needed by manufactures to develop and implement requirements prior to compliance deadlines. **IMDRF UDI to revised roadmap milestones in consideration of the required follow-on compliance activities of the manufacturers.**

6. Database development among different regions and with interconnectivity will be challenging given the current IMDRF UDI roadmap timelines. **Regulators to publish more detailed plan and roadmap (short term and long term database solutions) that is aligned with compliance deadlines.**



Thank you!

Questions?