IMDRF Stakeholders Meeting

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What Is DITTA?

• DITTA was created over 12 years ago to represent industries in diagnostic imaging, healthcare IT, radiation therapy, electromedical and radiopharmaceutical at the global level. This includes manufacturers ranging from small businesses to multinational companies.

• DITTA combines the knowledge and efforts of COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry; JIRA, the Japan Industries Association of Radiological Systems; MITA, the Medical Imaging and Technology Alliance; and MEDEC, Canada’s Medical Technology Companies.

• DITTA allows manufacturers to more effectively engage policymakers, organizations, professional associations and stakeholders at the international level, like IMDRF, as they propose policies that impact innovative technologies and patient access to life-saving medical procedures.
We Are

Associations of manufacturers of:

– 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.

With the aim to:

– Detect disease early;
– Improve the quality of care;
– Reduce the likelihood of medical errors; and
– Lower the long-term cost of health care.
We Do

• 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.
Website Launch
www.globalditta.org

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.

Join Us
For more information about joining DITTA click here

News

02.24.12
Nanoscale Magnetic Resonance Imaging, Quantum Computer Get Nudge from New Research

Magnetic resonance imaging (MRI) on the nanoscale and the ever-elusive quantum computer are among the advancements edging closer toward the realm of possibility, and a new study co-authored by a UC Santa Barbara researcher may give both an extra nudge.

Read More
DITTA on IMDRF Governance

• IMDRF Management Committee should be open to industry and other interested parties.

• Industry and other key stakeholders should be allowed to participate in IMDRF working groups.

• IMDRF should commit to the legacy of GHTF by keeping its documents up-to-date. The global regulatory model should continue to be the basis for future projects.

  • Establish a specific group to monitor this task, including industry experts who have participated to GHTF.

• Industry should be recognized as an important stakeholder, and be able to make recommendations in defining the overall IMDRF strategy and work plan.

• IMDRF meetings should start with a session open to industry and other interested parties, and should be concluded by an additional open session where decisions can be presented and discussed.
DITTA on IMDRF Membership

• Adequate provisions should be made to allow for expanded membership of the IMDRF beyond the five initial founding members for both regulators and other stakeholders.

• Regulators joining IMDRF should be subject to certain conditions, including a commitment to implement IMDRF decisions.

• IMDRF should clarify their relationship with and continue to liaise with relevant bodies (e.g. AHWP, IEC, ISO).

• IMDRF should be geographically balanced to facilitate inclusive and transparent dialogue for different cultures to be adequately represented and heard.
DITTA on IMDRF Activities

- The scope of IMDRF should foster innovation and global trade, work toward “Approved Once, Accepted Everywhere.”
- The importance international standards should be acknowledged with a strong commitment.
- Create a standards task force and assign a permanent seat for a standards expert on the IMDRF Management Committee.
- Ad Hoc working group and/or task forces should be established (e.g. medical software and remanufacturing).
- For pre-market approval/clearance, each member should encourage the implementation of a common data set.
- STED, essential principles check sheet, risk management evidence, clinical evaluation evidence and QMS without type testing or auditing for each registration.
- For QMS, each region should accept the audit certification or report for ISO 13485.
- Alternatively, encourage the multi-purpose audit by the third-party to confirm the requirement for each region (e.g. QSR, CAMDCAS, etc.)
- If IMDRF rejects an industry proposed activity, adequate motivation should be required.
Conclusion

• DITTA is committed to providing innovative technologies to improve quality, increase safety and enhance patient access while driving cost efficiency.

• DITTA looks forward to a strong relationship with IMDRF in the interest of patient safety, and patient access to advanced medical imaging, radiation therapy and health IT technology.

• DITTA expects IMDRF to clearly indicate its goals and ambitions, and have an open attitude for industry's proposals and proposed contributions to achieve them.