



**IMDRF** International Medical  
Device Regulators Forum

**OUTCOME STATEMENT**  
**of the IMDRF-10 MANAGEMENT COMMITTEE**  
*13 to 15 September 2016*

The tenth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Florianópolis - SC (Brazil), from 13 to 15 September 2016. The meeting was chaired by Brazil. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, and the United States of America. Representatives of the World Health Organization (WHO) as Official Observer and Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) as Affiliate Organizations also participated.

On the first day, the MC discussed the progress achieved on the current work items:

1. National Competent Authority Report (NCAR)
2. Software as a Medical Device (SaMD): Clinical Evaluation
3. Regulated Product Submission (RPS)
4. Medical Device Patient Registries
5. Medical Device Adverse Event Terminology
6. Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist
7. Improving the quality of international medical device standards for regulatory use

No New Work Item Proposal (NWIP) or New Work Item Extension Proposal (NWIEP) was presented to the MC.

In the afternoon, there was an open session including MC members, Official Observers, Affiliate Organizations and Invited Observers. Brief statements were provided by:

1. Official Observer
  - a. World Health Organization (WHO)
2. Affiliate Organizations
  - a. Asian Harmonization Working Party (AHWP)
  - b. Pan American Health Organization (PAHO)

### 3. Industry

- a. Global Medical Technology Alliance (GMTA)
- b. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
- c. Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios (ABIMO) / Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde (ABIMED)

A presentation was also provided by the Invited Observer:

1. Singapore

On the second day, an open Stakeholder Forum was held. The Forum included around 190 participants representing regulators, industry, healthcare professionals, and the research community members. Participants had in the morning an opportunity to hear updates on the regulatory situation in Brazil, Canada, China, European Union, Japan, Russia and United States and update reports on IMDRF's current work items. The morning was closed with a Questions & Answers Session.

In the afternoon of day two, Stakeholders and participants had an opportunity to hear updates about the work of:

1. DITTA
2. GMTA
3. WHO
4. AHWP
5. PAHO

Sessions also included presentations on:

1. UDI Implementation in the USA
2. ISO 14155:2011 "Clinical investigation of medical devices for human subjects – Good Clinical Practice"
3. Brazilian System for Conformities Evaluation (SBAC) on Medical Devices
4. ANVISA Good Regulatory Practices
5. RPS – Pilot ToC industry feedback and impression
6. MDSAP – Pilot Update

The second day was closed with an IMDRF General Questions and Answers Session and concluding remarks by the IMDRF Chair.

On the third day of the meeting, the MC discussed feedback from the public Stakeholder Forum, and made decisions regarding current Work Items (*see Annex*).

The MC also discussed about possible approaches to ensure all IMDRF documents are routinely reviewed and there is a process in place to keep documents current.

Singapore was unanimously accepted as a Member of the Management Committee of IMDRF, considering the fulfillment of the requirements described in article 2.1 of IMDRF/MC/N2 – IMDRF Standards Operating Procedures, including Singapore long standing contributions to the work of IMDRF.

IMDRF-11 will be held in Canada, (city to be determined), 14-16 March 2017. Details on the venue and on the Stakeholder Forum will be communicated on the IMDRF website.

# ANNEX

## DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the proposed document, “Software as a Medical Device (SaMD): Clinical Evaluation” (N41), of the SaMD working group for two-month public consultation.
- The MC approved the proposed document, “Methodological Principles in the Use of International Medical Device Registry Data” (N42), of the Medical Device Patient Registries working group for two-month public consultation.
- The MC approved the final document, “Principles of International System of Registries Linked to Other Data Sources and Tools” (N33), of the Medical Device Patient Registries working group.
- The MC approved the proposed document, “IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes” (N43), of the Medical Device Adverse Event Terminology working group for two-month public consultation.

*Florianópolis SC, Brazil  
15 September 2016*