



IMDRF International Medical
Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-6 MANAGEMENT COMMITTEE
16 to 18 September 2014

The sixth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Washington, DC (United States of America), from 16 to 18 September 2014. The meeting was chaired by the United States of America. 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 Asia-Pacific Economic Cooperation (APEC) as an Affiliate Organization also participated.

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

1. Medical Device Single Audit Program (MDSAP)
2. National Competent Authority Report (NCAR)
3. Recognized Standards
4. Regulated Product Submission (RPS)
5. Software as a Medical Device (SaMD)

A Revised New Work Item Proposal (NWIPs) and two NWIPs were also presented to the MC:

1. Medical Device Patient Registries - MDEpiNet
2. Development of common terminology and code related to adverse events of medical devices – Japan MC Delegation
3. Harmonization of Good Clinical Practices - GMTA

In the afternoon, an open session was held that included MC members, Official Observers, and Invited Observers. Brief statements were provided by the WHO as an Official Observer, as well as the following Invited Observers:

- a. Asia-Pacific Economic Cooperation (APEC), Life Science Innovation Forum (LSIF), Regulatory Harmonization Steering Committee (RHSC)
- b. Pan Africa Harmonization Working Party (PAHWP)
- c. Pan American Health Organization (PAHO)
- d. Argentina
- e. Cuba
- f. Colombia

- g. Ecuador
- h. Kazakhstan
- i. Malaysia
- j. Mexico
- k. Nigeria
- l. Peru
- m. Tanzania
- n. Uruguay
- o. US FDA Center for Biologics
- p. Global Medical Technology Alliance (GMTA)
- q. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

On the second day, an open Stakeholder Forum was held. The Forum included more than 200 participants representing regulators, industry, healthcare professionals, and the research community members. Participants had an opportunity to hear updates on the regulatory situation in the eight jurisdictions of the MC members. In addition, update reports were provided on IMDRF's current work items, presentations were made on New Work Item Proposals (NWIPs), and stakeholders had an opportunity to share their views and ideas on the work of IMDRF.

In the afternoon on day two, stakeholders held three interactive workshops that focused on Regulated Product Submission, Unique Device Identification, and Patient Registries.

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

IMDRF-7 will be held in Tokyo, Japan, 24-26 March 2015. Details on the Stakeholder Forum will be communicated on the IMDRF website, including a theme for possible presentations by stakeholders on that occasion.

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the final N11 document, “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization,” of the MDSAP Working Group. The MC approved the MDSAP overview flowchart to be posted on the IMDRF website as an Information Document. The MC also approved a Work Item Extension to develop an Audit Report Guidance.
- The MC approved the proposed N14 document, “Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form,” for two-month public consultation.
- The MC agreed to post the final Standards Report presentation on the IMDRF website as an Information Document. In addition, the MC agreed to post eight worksheets outlining recognized international standards in each of the IMDRF MC jurisdictions, listing the date to which the worksheet is current.
- The MC approved the final N12 document, “Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations,” of the SaMD WG. The MC also approved the Work Item Extension, “Applicability of Existing Quality Management System Requirements as a Risk Control Measure.” The WG is continuing the development of risk control measures under the Work Item Extension, and welcomes comments from the public on the final N12 document.
- The MC accepted the revised MDEpiNet New Work Item Proposal, “Integrating Patient Registries and Innovative Tools for Enhanced Medical Device Evaluation and Tracking.” This WG will be open to Stakeholders.
- The MC decided that a subcommittee would be formed to further explore and refine the New Work Item Proposal on Adverse Event Terminology and Coding.
- With regard to the New Work Item Proposal, “Harmonization of Good Clinical Practices (GCP) for Medical Device Trials” (presented by GMTA), the MC agreed to draft an Information Document on the use of international standard ISO 14155, “Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice,” in each of the respective IMDRF MC jurisdictions. The MC declined to progress with other parts of the New Work Item Proposal.
- The MC reviewed and revised the IMDRF Terms of Reference to include two categories of Affiliate Organizations: Official Observer and Invited Observer. The MC also reviewed and revised the IMDRF Standard Operating Procedure to include this change, and clarified the terms “New Work Item Proposal,” and “Work Item Extension”.

- Upon request, the MC unanimously accepted the Affiliate Organization Asia-Pacific Economic Cooperation (APEC), Life Science Innovation Forum (LSIF), Regulatory Harmonization Steering Committee (RHSC), as an IMDRF Official Observer.
- Upon request, the MC unanimously accepted the Pan American Health Organization (PAHO) as an IMDRF Affiliate Organization, Invited Observer.

*Washington DC, United States of America
18 September 2014*