IMDRF International Medical Device Regulators Forum

OUTCOME STATEMENT

of the IMDRF-15 MANAGEMENT COMMITTEE

18 to 21 March 2019

The fifteenth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Moscow, Russia, from 18 to 21 March 2019. The meeting was chaired by Russia. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, Russia, Singapore, South Korea and the United States of America (USA). Representatives of the World Health Organization (WHO) participated as Official Observers and the Asian Harmonization Working Party (AHWP), Pan American Health Organization (PAHO) and Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC) participated as Regional Harmonization Initiatives.

On Monday, March 18th, IMDRF/DITTA Joint Workshop on "Optimization of Standards for Regulatory Use" in the frame of IMDRF with about 200 participants has been successfully held. Industry representatives and the regulators presented their view on the Standards development, improvements, and guidance. A panel discussion finalized the Workshop.

On the first day March 19th, an Open Stakeholder Forum was held. The Forum included approximately 300 participants representing regulators, industry, and the research community. In the morning, participants had an opportunity to hear regulatory updates from Australia, Brazil, Canada, China, EU, Japan, Russia, Singapore, South Korea and the USA and update reports on IMDRF's eight current working groups. A Question & Answers Session was held after each presentation.

The IMDRF's eight current working groups are:

a. Regulated Product Submission (RPS) - Canada
b. Medical Device Adverse Event Terminology - Japan
c. Good Regulatory Review Practices - USA
d. Standards - USA
e. Personalized Medical Devices-Australia
f. Unique Device Identification - EU
g. Medical device clinical evaluation - China
h. Medical device Cybersecurity – Canada/USA

In the afternoon, there was a Stakeholder session including Official Observers, RHIs and Invited Observers. Brief updates were provided by:

1. Official Observers
   a. WHO

2. RHIs
   a. APEC LSIF RHSC represented by Taiwan Food and Drug Administration
   b. AHWP represented by Saudi Food and Drug Authority
   c. PAHO

3. Invited Observers
   a. Eurasian Economic Commission
   a. DITTA
   b. GMTA
   c. IMEDA
   d. International association of developers, producers and users of medical technique (IAMT).

At the end of the Day 1, a special session on the regulatory approach for NGS testing has been performed, which was followed by a panel discussion on regulatory approaches for this new technology. The panel discussion explored the challenges, opportunities and the complexity of medical device validation and verification in the context of the current trends in New Generation Sequencing technology.

On the second day, the MC firstly held an open session to hear regulatory updates on the progress achieved by Invited Observers:

a. Saudi Arabia
b. Cuba
c. Republic of Kazakhstan
d. Kyrgyz Republic

After that, the MC heard a presentation from Argentina ANMAT.
The MC received feedback with respect to the progression of each IMDRF work item from DITTA and GMTA.

a. DITTA presented results of discussion of IMDRF/DITTA Joint Workshop and suggested discussion on forthcoming IMDRF-16 Workshop in September
b. GMTA presented a Pilot training proposal for IMDRF guidance documents.

In the afternoon MC open session, Medical Device Nomenclatures issues were presented and discussed by the Global Medical Device Nomenclature (GMDN) Agency, WHO and the EU.
The afternoon Closed session of the Day 2 MC members and Official Observers started with discussions of matters arising around the documents put forward from the current working groups.

Following this discussion, the MC discussed the matters arising from the Open Stakeholder Forum and the session with invited observers and industry.

On the third day, the MC discussed and made decisions regarding the documents put forward from current working groups, the New Work Item Proposals and New Work Item Extensions proposed by MC members, as well as some procedural issues (See Annex).

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the proposed documents, "Clinical Evaluation – Key Definitions and Concepts", "Clinical Investigation" and "Clinical Evaluation", of the Medical Device Clinical Evaluation Working Group, for a two-month public consultation period.
- The MC approved the proposed document, with necessary revisions "Personalized Medical Devices – Regulatory Pathways of the Personalized Medical Devices Working Group, for a two-month public consultation period.
- The MC approved the revised Final N9 document, "Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents (nIVD MA ToC)" of the Regulated Product Submission (RPS) Working Group.
- The MC approved the revised Final N13 document, "In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)" of the Regulated Product Submission (RPS) Working Group.
- The MC approved the Final N43 document "Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Annex E-F)" of the Medical Device Adverse Event Terminology Working Group.
- The MC approved the Final N52 document "Principles of Labeling for Medical Devices and IVD Medical Devices" of the Good Regulatory Review Practices Working Group.
- The MC approved the Final N48 document "Unique Device Identification System (UDI system) Application Guide", with the necessary revisions of the Unique Device Identification System (UDI) Working Group and decided to close the Unique Device Identification System (UDI) Working Group at this time.
- The MC agreed to post the Final N53 document "Use of UDI Data Elements Across IMDRF Jurisdictions" and the Final N54 document "System Requirements related to the use of UDI in healthcare including selected use cases" of the Unique Device Identification System (UDI) Working Group on the IMDRF website as information documents.
- The MC approved the NWIP: Review and Update of the GHTF Principles of In-Vitro Diagnostic (IVD) Medical Devices Classification (GHTF/SG1/N45:2008).
- The MC approved the NWIP: IMDRF Standard Developing Organizations (SDO) Liaison Program.
- The MC discussed the proposed changes to SOP which includes the New Work Item Proposal (NWIP) adoption process, updating the IMDRF Membership Criteria to provide additional clarity to become an Official Observer and a Management

Committee Member of IMDRF and finalizing a Record of Discussion process and format. These were approved and the SOP will be revised accordingly.

- The MC continued their discussions on a document which indicates the implementation of IMDRF documents by member jurisdictions, and will be further discussed in IMDRF-16
- South Korea has volunteered to serve as the 2021 Chair of the IMDRF

Moscow, Russia

March 21, 2019