IMDRF 2023

23rd session

27-28 March 2023 | Brussels, Belgium

The IMDRF Management Committee (MC) welcomed 350+ professionals to Brussels who participated to the EU chaired sessions as follows:

Day 1 - Joint IMDRF / Stakeholder (DITTA-GMTA) Workshop - 27 March 2023

The life cycle of medical devices: the importance of post-market-related activities

Opening Remarks

Welcome addresses by the IMDRF, DITTA and GMTA chairs

Andrzej Ryś, **Patrick Hope**, **Janet Trunzo**

Scene Setter

Thomas Linders, Adrien Guenego

Post-market surveillance and RWE

Lifecycle approach to medical devices

Philippe Auclair, Matthias Neumann

Session 1 : Safety notices and Vigilance

This is a session to discuss how we can improve "Safety Notice & Vigilance" to be more efficient and effective for manufacturers, regulators and healthcare providers. Each stakeholder will present concerns and propose ideas to improve current situation and discuss at the panel session.

- Opportunities and challenges: Regulator's perspective - Melissa Torres and Christophe Driesmans
- Opportunities and challenges: Industry perspective - Nicole Smith and Miang Tanakasemsub
- Opportunities and challenges: Healthcare professional perspective - You-kyoung Lee and Timothy Wilton
- Panel discussion: Opportunities for improvement - moderated by Paul Piscoi

Session 2: Real World Evidence

This is a session on real world evidence aims to describe the means through which real world evidence can be gathered and validated and which are the appropriate uses of real-world evidence within a regulatory context.

- Status of Global Acceptance of RWD/RWE in regulatory activities and lessons learned from various regions - Heather M. Colvin
- RIVD perspective and examples of RWD/RWE - Elodie Baumfeld Andre
- How to incorporate real-world data sources into regulatory decision-making processes? - Tom Melvin
- Uses of real-world evidence - Erin Cutts, Sabina Hoekstra and Lyu Yunfeng
- Panel Discussion - moderated by Heather M. Colvin and Donal O'Connor

Session 3: Criteria, methods, and strategies to monitor safety and performance of software

- PMS for software: apped if you do, apped if you don't - Kees Maquelin
- Challenges and opportunities in collecting or generating data for digital MDs - Pat Baird
- Common post-market issues faced with software and how to address them? - Rolf Oberlin Hansen
- Panel discussion moderated by Nada Alkhayat and Jesús Rueda Rodríguez

Session 4: Specific post-market considerations for AI MDs

- Monitoring of endpoints (surrogate and non-surrogate) - Leo Hovestadt
- Bias in the post-market phase - Anindita Saha and Pat Baird

- Change management - Rama Sethuraman and Melissa Finocchio
- PMS for AI software - Lesley-Anne Farmer and Hae Ung Lee
- Panel Discussion moderated by Matthias Neumann and Jesús Rueda Rodríguez

Closing Remarks

Day 2 - 28 March 2023

IMDRF Stakeholder Forum

Opening Remarks

Welcome and Introduction

Commissioner Stella Kyriakides

Regulatory Updates from IMDRF Management Committee and Official Observers

- Australia - Tracey Duffy
- Brazil - Augusto Bencke Geyer
- Canada - David Boudreau
- China - Yuang Peng
- European Union - Nada Alkhayat
- Japan - Masahiro Takahata
- Singapore - Rama Sethuraman

Regulatory Updates from IMDRF Management Committee and Official Observers

- South Korea - Gyuhan Chae
- United Kingdom - Harriet Teare
- United States of America - Melissa Torres
- Argentina (Official Observer) - Mariela Aranda and Carolina Magnatti
- World Health Organization (Official Observer) - Irena Prat

Progress Overview of IMDRF Work Items

- Adverse Event Terminology (USA / EU) - Andrea Hanson
- Good Regulatory Review Practices (USA / Singapore) - Erin Cutts
- Medical Device Cybersecurity Guide (USA / Canada) - Daniel Yoon
- Personalized Medical Devices (Australia) - Tracey Duffy
- Quality Management Systems (USA / EU) - Melissa Torres
- Regulated Product Submission (Canada / USA) - Daniel Yoon
- Software as a Medical Device (USA / Canada) - Daniel Yoon
- Good Machine Learning Practice (USA / UK) - Melissa Torres

Stakeholders Session

- African Medical Devices Forum (AMDF) - Paulyne Wairimu
- Asia-Pacific Economic Cooperation (APEC) - Cheng-Ning Wu
- Global Harmonization Working Party (GHWP) - Xu Jinghe
- Pan American Health Organization (PAHO) - Alexandre Lemgruber
- The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA) - Patrick Hope
- Global Medical Technology Alliance (GMTA) - Janet Trunzo

Closing Remarks

Andrzej Ryś