IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

European Commission

European Union

IMDRF Status Update

Dr. Andrzej Rys

IMDRF Chair 2023

Directorate-General for Health and Food Safety (DG SANTE)

European Commission

16 February 2023 – 26th GHWP Annual Meeting

IMDRF
International Medical Device Regulators Forum

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Governance

The International Medical Device Regulators Forum (IMDRF)

Mission: Accelerate international medical device regulatory convergence - whereby the requirements and approaches become more similar or aligned as a result of the adoption of the same technical documents, standards and scientific principles and similar regulatory practices and procedures.

Result: the EU MDR/IVDR take onboard a substantial amount of IMDRF/GHTF principles

Management Committee members: 

Official Observers: 

Affiliate Members: Regional Harmonisation Initiatives (GHWP, ARF, APEC, PAHO)

***New membership*: Affiliate Members**

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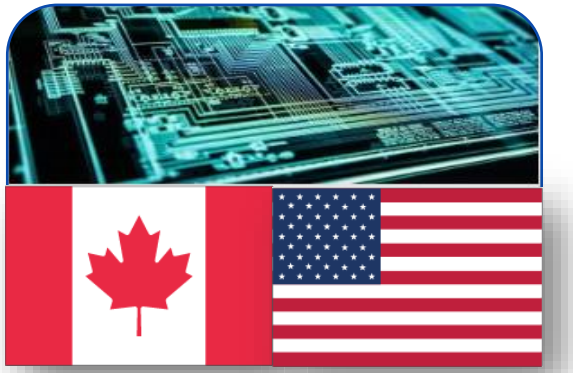
Working Groups

Adverse Event Terminology

Cybersecurity



Good Regulatory Review Practice

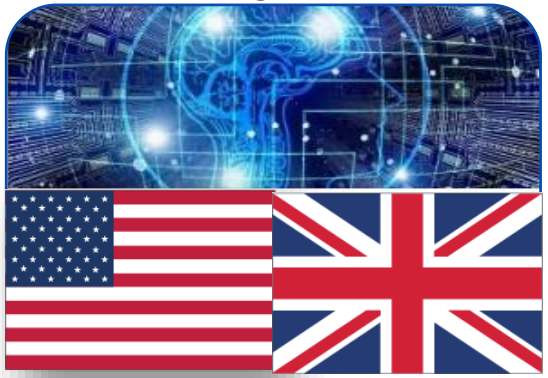
Personalised Medical Devices

Quality Management Systems

Regulated Product Submission

Software as a Medical Device

New group = Good Machine Learning Practices



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IMDRF Strategic plan 2021-2025

Our objectives

1. **Managing** regulatory **challenges** for medical devices and innovative technologies by providing **timely and appropriate** guidance

2. **Strengthening post-market surveillance** for medical devices and implement regulatory life cycle processes

Key priorities

Pre-market

Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices

Post-market

Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients

Relationship building

IMDRF will seek opportunities to develop stronger relationships with organizations that help international medical device regulatory convergence

Key priorities – status February 2023

1. Pre-market

- **Artificial Intelligence enabled Medical Device: 1** guidance finalised (published)
- **Good Regulatory Review Practices (GRRP): 2** guidance finalised (1 published, 1 under publication)
- **Personalised Medical Devices (PMD): 2** guidance with an estimated finalisation in Q2 2023
- **Regulated Product Submissions (RPS):** public consultation (being launched)
- **SaMD:** public consultation estimated in Q2 2023

2. Post-market

- **Cybersecurity: 2** new guidance with an estimated finalisation in Q2 2023
- **Adverse Event Terminology (AET):** review in 2021, 2022 and most recently in Jan 2023 (currently under publication)
- **Quality Management System (QMS):** new group

Key priorities – status February 2023

Relationship with actors

- Improved IMDRF operational transparency, tracking and accountability practices.
- Regional harmonization initiatives delegates invited to the IMDRF MC Open Session.
- **New Affiliate membership!**

New membership: Affiliate member

Regulatory Authorities who:

- ✓ would like to engage with IMDRF (who are not Official Observers),
- ✓ are using IMDRF documents in part or in whole as the basis for their own regulatory framework.

Are invited to:

- ✓ participate in IMDRF by attending “open” meetings,
- ✓ participate in open Working Groups,
- ✓ provide input to open consultations.

Areas for further work

- ✓ Ensuring timely availability of necessary guidance whilst facilitating open and transparent public consultations,
- ✓ Development of trainings with interested partners to ensure appropriate dissemination to all actors,
- ✓ Technical capacity building and regulatory knowledge transfer.

IMDRF planning for 2023

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SAVE THE DATE!

BRUSSELS, BELGIUM
27-31 MARCH 2023

BERLIN, GERMANY
25-29 SEPTEMBER 2023

Stay informed
by registering here:
bit.ly/3ARW6U1

Register at www.imdrf2023.com

European Commission

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BRUSSELS, BELGIUM
27-28 MARCH 2023

European Commission

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Joint IMDRF / Industry Workshop – 27 March 2023

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

Session 1: Safety notices and vigilance

- Regulators, industry and healthcare professional perspectives.

Session 2: Real World Evidence

- Gathering and uses of RWE.

Sessions 3, 4 and 5: Post-market considerations for software including AI: opportunities and challenges

- How to distinguish between safety signals and noise,
- Changes requiring post-market validation,
- Monitoring of endpoints, bias, change management.

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IMDRF Stakeholder Forum – 28 March 2023

Session 1: Opening remarks and welcome

Session 2: Regulatory updates from IMDRF Management Committee and Official Observers

- Australia, Brazil, Canada, China, EU, Japan, Singapore, South Korea, United Kingdom, United States of America.
- Argentina and WHO

Session 3: Progress overview of IMDRF work items

- Adverse Event Terminology (USA/EU), Good Regulatory Review Practices (USA), Cybersecurity (USA/Canada), Personalized Medical Devices (Australia), Quality Management Systems (USA/EU), Regulated Product Submission (Canada/USA), Software as a Medical Device (USA/Canada).

Sessions 4: Stakeholder session

- African Medical Device Forum, Global Harmonization Working Party, Pan American Health Organization, the Global Diagnostic Imaging, Healthcare ICT and Radiation Therapy Trade Association (DITTA) and the Global Medical Technology Alliance (GMTA).

THANK YOU / QUESTIONS

IMDRF 2023 Secretariat

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