OUTCOME STATEMENT
IMDRF Management Committee
Closed Session: 21 April 2022

The 21st meeting of the Management Committee (MC) of the International Medical Regulators Forum (IMDRF) and Official Observers was held on 21 April 2022.

The MC discussed and made decisions regarding the documents presented by Working Groups, New Work Item Proposals and Extensions proposed, the scheduling of future meetings and other procedural matters. A summary of the decisions and outcomes are listed below.

In summary, the MC approved:

- publishing of *Machine Learning-enabled Medical Devices: Key Terms and Definitions* document from the Artificial Intelligence Medical Devices (AIMD) Working Group.
- publishing of the document *Principles and Practices for the Cybersecurity of Legacy Medical Devices* for a 60-day consultation period. The consultation can be found here.
- publishing of the document *Marketing Review Report Work Instruction* for a 60-day consultation period. The consultation can be found here.
- an expanded scope of the document *Personalized Medical Devices – Regulatory Pathways.*
- publishing of the document IMDRF Standards Liaison Program Framework from the Standards Working Group.

In addition, the MC agreed:

- that the UK (MHRA) become an IMDRF MC Member.
- to establish a Software as a Medical Device Working Group with the USA and Canada as Co-chairs.
- a 24-month extension of the timeline for the NWIE, *Expanding the Harmonization of Adverse Event Terminology* to March 2024. The MC also agreed that the USA and the EU (Germany) take up the role of Co-chairs for the Adverse Event Terminology (AET) Working Group.
- that the IMDRF September 2022 meetings be held in Australia, through a hybrid format of face-to-face and use of a virtual platform. Details will be published on the IMDRF website, including the topics for the joint IMDRF/industry workshops.