OUTCOME STATEMENT
28th Session of the International Medical Device Regulators Forum
15-19 September 2025
Sapporo, Hokkaido, JAPAN

The 28th Session of the International Medical Device Regulators Forum (the IMDRF) was chaired by Japan and held in-person in Sapporo, Hokkaido, Japan from 15 to 19 September 2025. Approximately 190 in-person attendees and 200 virtual attendees participated in the first two days of public meetings. Approximately 80 attendees participated in-person on the third day, and 50 participated on the fourth and fifth days.

IMDRF/Industry Joint Workshop on Modernizing Conformity Assessment Through Innovative Processes

The IMDRF/Industry Joint Workshop took place on 15 September 2025 as a public meeting. The agenda included four sessions on modernizing conformity assessment through innovative processes with speakers and panellists from regulatory authorities, industry, and the World Health Organization (WHO).

The first session featured discussion by regulatory authorities, industry and WHO on the role of conformity assessment procedures for medical devices and in vitro diagnostic devices (IVDs). Speakers from regulatory authorities and industry set the scene by providing an overview on the procedures of conformity assessment throughout the product life cycle. Discussions focused on 3 topics: classification approaches, post-market surveillance (PMS), and real-world evidence (RWE).

In the second session, regulatory authorities and industry discussed risk-based classification approaches. Some challenges were shared related to different risk-based classification interpretations across jurisdictions, with a focus on digital health and IVDs.

In the third session, the focus was on PMS. Speakers from regulatory authorities and industry provided background on the current PMS practices and discussed how modernized tools and harmonized approaches could lead to a more efficient post-market regulatory system.

The final session featured a moderated discussion by regulators and industry on the best practices of developing evidence using RWE. Speakers provided an overview of the foundational concepts related to RWE, identified key lessons from a landscape analysis of current regulatory policies, and shared examples of how RWE can fill gaps for clinical evidence. Panellists shared case studies of pre- and post-market applications using RWE, regulatory guidance documents, the barriers for the use of RWE in regulatory decision-making, and how the IMDRF could contribute to advancing the adoption of emerging technologies.

IMDRF Stakeholder Forum

The IMDRF Stakeholder Forum took place on 16 September 2025. In the first session, representatives from the IMDRF Management Committee (MC) and Official Observers (OO) briefed attendees on recent regulatory updates for their jurisdictions and answered questions.

In the second session, the IMDRF Secretariat provided updates on recent working group activities.

The third session featured presentations from IMDRF Regional Harmonization Initiatives (RHIs), including:

- Africa Medical Devices Forum (AMDF)
- Asia-Pacific Economic Cooperation (APEC), and
- Pan American Health Organization (PAHO).

Representatives from the IMDRF RHIs highlighted their recent achievements and harmonization efforts.

The fourth session focused on jurisdiction updates from the following IMDRF Affiliate Members:

- Egyptian Drug Authority (EDA), Egypt
- Dirección Nacional de Vigilancia Sanitaria (DINAVISA), Paraguay
- Drug Safety Center, Ministry of Health, Oman, and
- Medical Device Authority (MDA), Malaysia

In the final session of the Stakeholder Forum, regulators and industry gathered in a panel to discuss some implementation challenges of Unique Device Identification (UDI) systems. Panellists discussed practical insights and tips to consider for UDI implementation. The session also outlined the benefits of introducing UDI systems and how it can play a role in global medical device safety.

All presentation materials for the IMDRF/Industry Joint Workshop and the IMDRF Stakeholder Forum are available *here*.

IMDRF MC Open Session

The MC Open Session was held on 17 September 2025 with the MC, OOs, RHIs, Affiliate Members, and the IMDRF Industry Group.

In the first session, the IMDRF Secretariat provided reflections on the March 2025 Closed Session and June 2025 teleconference.

In the second session, external experts were invited to present on In Silico Trials and Computational Modelling and Simulation.

The IMDRF Secretariat also provided updates and moderated discussion on:

- The recently published IMDRF Document Implementation Report
- The draft IMDRF Strategic Plan 2026-2030

IMDRF MC Bilateral Meetings

IMDRF MC and OOs held individual bilateral meetings with Affiliate Members, RHIs, and the IMDRF Industry Group on 17 September 2025.

In the bilateral meeting with the IMDRF Industry Group, topics included standards, product changes and UDI, as well as possible themes for the IMDRF/Industry Joint Workshop in March 2026.

IMDRF MC Closed Session

The IMDRF MC Closed Session was held on 18 and 19 September 2025 with the MC and OOs. The MC discussed and took decisions on membership applications and publication of documents for consultation.

All MC decisions are available in the Annex.

ANNEX
DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

18 and 19 September 2025
Sapporo, Hokkaido, JAPAN

In summary:

- The MC agreed to accept the applications for IMDRF Affiliate Membership submitted by:
    - Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) - Colombia
    - Food and Drugs Authority (FDA) - Ghana
    - Ministry of Health (MoH) - Indonesia
    - Food and Drug Administration (FDA) - Philippines

- The MC agreed to:
    - Approve the draft document "Essential Principles and Content of Predetermined Change Control Plans" from the Software as a Medical Device (SaMD) WG for a 60-day public consultation.

    - Approve the New Work Item Proposal (NWIP) to develop a new guidance document on Cybersecurity Controls and Testing Considerations.

    - Approve in principle the NWIP to revise IMDRF/GRRP WG/N52.

- The MC agreed to close the Regulated Product Submission WG, but to continue refining and piloting the dynamic template with a small group of regulatory authorities, and to update the N9 and N13 documents, as necessary.

- The MC agreed for a training page to be created on the IMDRF website for central access to IMDRF training materials.