

OUTCOME STATEMENT
30th Session of the International Medical Device Regulators Forum
14-18 September 2026
SINGAPORE

The 30th Session of the International Medical Device Regulators Forum (IMDRF) was chaired and held in Singapore from 14 to 18 September 2026. Approximately 320 in-person attendees and 310 virtual attendees participated in the first two days of public meetings. Approximately 120 attendees participated on the third day, and about 80 attendees participated on the fourth and fifth days.

A regulator training session on N78 Conformity Assessment and N89 Reliance Playbook was also held on 13 September 2026 with 59 in-person attendees and 53 virtual attendees.

IMDRF Industry Joint Workshop on Shaping Global Regulatory Approaches for Medical Devices in Digital Health

The IMDRF Industry Joint Workshop on 14 September 2026 featured four sessions on digital medical devices regulatory topics, with speakers and panellists from regulatory authorities, industry, and WHO.

The workshop opened with scene-setting presentations covering the clinician and patient perspective on digital health technologies, followed by an overview of the global regulatory landscape including key IMDRF documents and frameworks in various jurisdictions.

The first session examined software characterisation and risk categorisation, focusing on IMDRF documents N12 and N81. Regulators and industry shared implementation experiences and case studies on managing classification differences across jurisdictions, with panel discussions exploring opportunities for convergence and supporting patient access.

The second session explored AI governance and good machine learning practices, including an overview of the IMDRF Artificial Intelligence/Machine Learning (AI/ML) lifecycle N93 document under public consultation. Regulatory perspectives were presented alongside industry's key themes from the N93 public consultation. Panel discussions covered lifecycle regulation, and alignment opportunities across jurisdictions.

The third session discussed IMDRF document N90 on Predetermined Change Control Plans (PCCPs) for software as a medical device (SaMD) and its role in enabling timely product updates. Regulators and industry shared implementation experiences, with discussions focusing on practical challenges and considerations for leveraging reliance frameworks in the context of PCCPs.

The fourth session focused on medical device cybersecurity, discussing practical and regulatory challenges and existing IMDRF documents N60, N70, and N73. Regulators and industry discussed emerging risks and possible solutions, as well as the importance of medical device regulators working closely with other relevant cybersecurity authorities.

IMDRF Stakeholder Forum

The IMDRF Stakeholder Forum took place on 15 September 2026.

The first session started off with a panel discussion on understanding the differences in regulatory controls across jurisdictions and emphasized the value of convergence through IMDRF.

In the second and third sessions, IMDRF MC members presented on recent regulatory updates. For the fourth session, Official Observers (OOs) and Regional Harmonisation Initiatives (RHIs) presented on their recent regulatory updates. In the fifth session, IMDRF Affiliate Members (AM) provided their regulatory updates.

The last session focused on updates from the following industry groups:

- Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
- Global Medical Technology Alliance (GMTA)
- IMDRF Industry Group
- Asia Pacific Medical Technology Association (APACMed)
- Singapore Manufacturing Federation - Medical Technology Industry Group (SMF-MTIG)

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 16 September 2026 with the MC, OOs, RHI, AMs, the industry group and invited observers.

The session covered six topics: reflections from the March meeting and June teleconference 2026; perspectives on digital health and AI in healthcare from academic, industry, and regulatory experts; an overview of the 2026 Implementation Table report; and a presentation on the IMDRF Strategic Plan 2026–2030. The session also included an update on IMDRF training initiatives from the Training Oversight Sub-Committee. The session concluded with sharing on AI/ML and SaMD regulatory approach from various MC members, OOs and AMs.

IMDRF MC Bilateral Meetings

IMDRF MC and OOs held bilateral meetings with AMs, and the IMDRF Industry Group on 16 September 2026.

The meetings among IMDRF MC, OOs, and AMs covered three topics: IMDRF governance structure reform, an update on the National Competent Authority Report (NCAR) Programme

and Safety Communications Survey outcomes, and an update from the African Medicines Agency (AMA).

The IMDRF MC and Industry Group Bilateral meeting covered IMDRF governance structure reform, and continued discussions from the March 2026 bilateral on the reliance dataset and change management. The Industry Group discussed regulatory topics including standards, digital labelling, and UDI. The meeting concluded with discussions on training and implementation support for IMDRF, and potential topics for the March 2027 workshop.

IMDRF MC Closed Session

The IMDRF MC Closed Session was held on 17 and 18 September with the MC and OOs. In accordance with the IMDRF Strategic Plan, the MC advanced on the topics of IMDRF training, governance reform and stakeholder engagement.

The MC discussed training and governance reform including membership, enhanced participation from AMs and RHs and geographical representation where appropriate. The MC agreed that increased involvement and participation of AMs should be facilitated through opportunities such as direct involvement in closed session discussions. These changes are expected to be rolled out in 2028 as part of broader governance updates under discussion.

In relation to stakeholder engagement, the MC has committed to focused stakeholder engagement with strategic partners. The MC held exchanges with the International Coalition of Medicines Regulatory Authorities (ICMRA), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), HealthAI and Scarlet Notified Body on the principles of AI, relevant work programmes, and potential opportunities for future engagement and exchanges of experience.

Following the updates from the Standards Liaison Programme, the MC reiterated the importance of engagement with Standards Bodies, particularly on software, AI and lifecycle-related standards.

The MC also recognised the need to ensure that IMDRF documents remain up to date and relevant with emerging technologies like AI.

All MC decisions are available in the Annex.

ANNEX
DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

17 to 18 September 2026
SINGAPORE

In summary:

- The MC approved the applications for IMDRF Affiliate membership submitted by:
 - Agency for Sanitary Regulation (ARSA), Honduras
 - Thai Food and Drug Administration (Thai FDA), Ministry of Public Health, Thailand
- The MC agreed:
 - To the posting of proposed document “IMDRF/GRRP WG/N52 DRAFT (Edition 3) Principles of Labelling for Medical Devices” for a 60-day public consultation period.
 - To the New Work Item Proposal from the Adverse Event Terminology (AET) Working Group on Remedial Action Codes (Annex H) to describe industry remedial actions.
 - To publish a synopsis of the recent Global IMDRF Unique Device Identification Workshop on the IMDRF website, and to convene further targeted workshops and topic-based discussions to support harmonised work and strategic priorities.
 - To pilot an IMDRF training programme in September 2027, delivered through an external organisation using materials reviewed and endorsed by IMDRF, alongside an expression of interest process and exploration of potential engagement with universities.