IMDRF International Medical Device Regulators Forum

Final Document

IMDRF/MC/N91 FINAL: 2025

IMDRF Strategic Plan 2026-2030

AUTHORING GROUP

IMDRF Management Committee

19 December 2025

Preface

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1. IMDRF Mission, Goals and Objectives[1]

1.1. Mission

The mission of the International Medical Device Regulators Forum (IMDRF) is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

1.2. Goals

IMDRF addresses the common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies. IMDRF provides the structure where the strategic decisions and operational mandates are made by public health-missioned medical device regulators, based on appropriate, equitable and transparent input from stakeholders.

1.3. Objectives

The objectives underpinning the goals of IMDRF are to:

- Accelerate international medical device regulatory convergence[2];
- Support innovation and timely access to safe and effective medical devices globally;
- Promote open discussion and the sharing of best practices among regulatory authorities responsible for medical device regulation;
- Facilitate frequent exchange of policy and regulatory information of common interest to regulatory authorities;
- Provide opportunities to identify commonalities and develop approaches to overcome unnecessary regulatory barriers;
- Promote prospective convergence in areas of advanced and innovative technologies;
- Enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders; and
- Establish and develop dialogue with other relevant organizations.

[1] The IMDRF Strategic Plan is aligned with the following mission, goals and objectives defined in IMDRF Terms of Reference (IMDRF/MC/N1 FINAL: 2025) (ToR)

[2] "Regulatory convergence" (hereinafter "convergence") is meant to represent a voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.

2. Background

The period from 2021 to 2025 marked a transformative era in the global regulation of medical devices. The medical device sector experienced rapid technological innovation, shifts in global collaboration mechanisms, and continued responses to the COVID-19 pandemic, all while supporting the development of regulatory systems in countries with health systems in transition. IMDRF, in collaboration with national and regional authorities, manufacturers, auditing organizations, conformity assessment bodies, healthcare professionals and patients, played a pivotal role in addressing these multifaceted challenges and opportunities.

2.1. Rapid Advances in Innovative Technologies

Regulatory authorities increasingly needed to strike a balance between promoting innovation and patient safety. Between 2021 and 2025, the medical device industry witnessed unprecedented advancements in innovative technologies, including the rise of artificial intelligence (AI), machine learning (ML), digital therapeutics, and next-generation implantable devices. These innovations brought significant clinical promise but also posed complex regulatory questions regarding safety, effectiveness, and real-world performance. This provides a pivotal moment where the development of risk-based, resource appropriate harmonized approaches is possible since the advancements in technology may require new procedures to be developed.

IMDRF responded by continuing to address, develop and refine key guidance documents, such as those on Personalised Medical Devices, Software as a Medical Device (SaMD), AI-enabled medical devices, and cybersecurity. Beyond guidance documents, IMDRF continued to challenge itself in Stakeholder workshops to address emerging regulatory and scientific developments in the areas such as breakthrough technologies, paediatric devices, AI and real-world evidence (RWE).

2.2. Increased Use of Reliance Mechanisms

During this period, the concept of regulatory reliance - where one regulatory authority leverages the work or decisions of another - gained substantial traction. The COVID-19 pandemic catalyzed this trend by revealing the need for greater efficiency in assessing critical medical products. As regulators have learned more about reliance, they are embracing this tool for more than critical medical products or emergency use.

IMDRF responded by continuing to support convergence and by developing the Reliance Playbook, which provides considerations when creating a reliance framework through the total product lifecycle while maintaining jurisdictional autonomy.

2.3. The Continuing Impact of the Pandemic

Although the acute phase of the COVID-19 pandemic had receded around 2023, its long-term impact on medical device regulation remained evident through 2025. Regulatory systems were forced to adjust at a rapid pace to cope with challenges such as expedited approvals, derogations, emergency use authorizations, and disruptions in global supply chains.

The pandemic also spurred a shift toward remote inspections, remote and decentralized clinical trials/investigations, acceptance of global clinical trial data and RWE, reliance implementation and greater use of digital health technologies.

2.4. Progress in the Establishment of Medical Device Regulatory Systems

The 2021-2025 period also saw significant strides in the development and strengthening of medical device regulatory systems. Many countries worked to implement harmonized regulatory frameworks using IMDRF and Global Harmonization Task Force (GHTF) documents as well as international standards.

IMDRF has supported the development and strengthening of national regulatory systems by providing training based on IMDRF guidance documents. Key areas of focus have included implementation of conformity assessment based on essential principles of safety and performance, post-market surveillance (PMS) systems utilizing harmonized adverse event terminology, and the application of international standards. The Total Product Life Cycle approach advocated by IMDRF has emphasized the importance of comprehensive regulatory oversight across the entire life cycle of medical devices, rather than focusing solely on premarket review. This has provided valuable guidance for regulators and key stakeholders (e.g., regulatory authorities and industry).

The utilization of reliance mechanisms has also contributed to both strengthening regulatory capacity and ensuring timely access to safe and effective medical devices for patients. Continued efforts are necessary to promote innovative regulatory models, build regulatory capacity, and enhance international cooperation.

To realize a future in which patients around the world have timely access to safe and effective medical devices, IMDRF will continue playing its central and foundational role in driving the harmonization and advancement of global medical device regulation, providing leadership, and sharing best practices.

3. IMDRF Focus Areas

Over the next five years, IMDRF will continue to collaborate with stakeholders (e.g., the IMDRF Industry Group) to advance global harmonization in the following five focus areas. Each focus area is supported by at least one priority activity (see Section 4) and requires a shared responsibility to achieve a shared success.

3.1. Fostering sustainable leadership and growth of IMDRF

IMDRF (and its predecessor, GHTF) has long been the leading global forum for medical device regulatory harmonization. With the introduction of Affiliate membership in 2023, IMDRF greatly expanded the opportunities for regulatory authorities to participate and contribute directly to its work. During the timeframe of the 2021-2025 strategic plan, IMDRF membership grew from 17 members to 47. IMDRF membership includes medical device regulators responsible for contributing to positive public health outcomes that benefit almost 5 billion people worldwide.

IMDRF is committed to sustaining its strong global leadership while continuing to meet the needs of and engage with its growing number of members and stakeholders. In recent years, IMDRF has led globally in expanding its offerings, now conducting training and bilateral meetings with specific stakeholder types (e.g., the IMDRF Industry Group) in addition to leading publication of technical documents on novel and innovative medical device regulatory topics.

IMDRF recognizes the challenges that growing membership and expanding activities present. Therefore, during the timeframe of this strategic plan, IMDRF will focus on fostering sustainable leadership and growth of IMDRF.

> **Priority Activity #1:** Modernize IMDRF governance to support sustainable, transparent growth and operations

3.2. Reinforcing foundational principles that support implementation of harmonized regulatory frameworks globally

One of the focus areas for IMDRF is to maintain a robust regulatory foundation while promoting a comprehensive approach that spans the entire product life cycle. From manufacturing to PMS, consistent oversight is essential to ensuring the quality, safety and effectiveness of medical devices across jurisdictions. A harmonized baseline provides the necessary stability to reduce variability and support confidence in regulatory outcomes.

The GHTF established these principles through an open, globally collaborative process, both within its own framework and through related standardization initiatives. These principles remain the pillars of every modern regulatory system, and it is IMDRF's responsibility to ensure that these principles remain relevant, reliable, and effective through continuously updating them in light of evolving technologies and global needs. By reinforcing and refining this shared foundation, IMDRF safeguards the coherence of the global regulatory framework and continues to promote convergence, trust and enhances the reliability of regulatory systems worldwide.

Priority Activity #2: Convert GHTF documents to updated IMDRF documents

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

Treatment delayed could be treatment denied especially for critically ill patients. Therefore, in addition to ensuring the quality, safety and effectiveness of medical devices, regulators should also be facilitators ensuring patients have timely access to essential medical devices. Fostering a transparent, well-defined, risk-based regulatory process to demonstrate safety and effectiveness could significantly speed up the total time taken for safe and priority medical device innovations to reach patients. IMDRF will continue to work together with all relevant stakeholders to proactively identify useful innovative areas and set up Working Groups (WGs) to develop clear guidance to support prospective regulatory convergence in these areas.

IMDRF will continue to work collaboratively within its membership and also with various external stakeholders and partners to share information and knowledge on an on-going basis. This includes playing an active role in ensuring that international standards and guidance documents continue to be effective tools used to conform to essential principles for safety and performance for medical devices.

Priority Activity #3: Continue to publish new technical documents on innovative technologies

Priority Activity #4: Continue to hold joint workshops with the IMDRF Industry Group

3.4. Expanding engagement with stakeholders

Stakeholder collaboration and engagement is a critical and necessary requirement to support the principles and aims of IMDRF and its membership. Essential input from stakeholders at various stages of IMDRF’s activities including perspectives from regulatory authorities, industry (e.g., the IMDRF Industry Group), patients, healthcare professionals, and other partners ensures that IMDRF’s work reflects the diversity and relevancy across jurisdictions. It also supports feasible implementation considerations of the principles and documents published by IMDRF.

Fast-paced emerging technologies and blurring of boundaries between various sectors requires proactive and strategic expansion of engagement activities by IMDRF with a broader group of stakeholders and interested parties to foster global awareness and harmonization while making better use of shared resource.

IMDRF continuously evaluates the effectiveness of its stakeholder engagements. As an example, during the timeframe of the 2021-2025 strategic plan, IMDRF established the IMDRF Industry Group and the Standards Liaison Program to create specific dialogue with and identify opportunities for efficiencies and collaboration with the medical device industry and standards development organizations, respectively.

During the timeframe of this strategic plan, IMDRF will continue to evaluate stakeholder engagements. Specifically, IMDRF will identify and engage with new stakeholders with shared interests and regulatory responsibilities. IMDRF will also enhance opportunities for all stakeholders, new and old, large and small, representing different perspectives, and across the jurisdictions of its membership, to engage with and contribute to IMDRF activities.

Priority Activity #5: Identify and engage with new stakeholders

Priority Activity #6: Enhance opportunities for all stakeholders to engage with and contribute to IMDRF activities

3.5. Supporting IMDRF members and stakeholders in their implementation of IMDRF documents and principles

IMDRF documents and principles are only as effective as their implementation. IMDRF is committed not only to publishing documents, but also in supporting their consistent implementation worldwide. During the timeframe of this strategic plan, IMDRF will place greater emphasis on supporting IMDRF members and stakeholders to implement IMDRF documents and principles in their regulatory systems. This includes clarifying the intent of documents and sharing practical approaches to support consistent use across jurisdictions.

Consequently, IMDRF aims to foster greater alignment among members and reduce unnecessary differences in regulation. This will reinforce the reliability of regulatory systems and contribute to better global patient safety and access.

Priority Activity #7: Develop a list of foundational IMDRF documents

Priority Activity #8: Enhance IMDRF trainings

4. IMDRF Priority Activities

4.1. Modernize IMDRF governance to support sustainable, transparent growth and operations

IMDRF will strengthen its leadership and long-term sustainability by reforming its governance structure to ensure transparency, inclusiveness, and effectiveness in decision-making.

IMDRF will, through the IMDRF Governance Subcommittee,

- Review and assess the current IMDRF governance model, membership criteria, and operational processes;
- Develop and propose a revised governance structure that supports IMDRF's strategic growth, global representation, and operational sustainability; and
- Make operational decisions, as authorized by the Management Committee, on the design and implementation of the future governance model.

The Governance Subcommittee will report its progress to the Management Committee and present recommendations for endorsement.

The reform will also encompass a comprehensive revision of the IMDRF Standard Operating Procedures (SOPs) to clarify roles, improve transparency, and enhance coordination between the Management Committee, Secretariat, Subcommittees, and WGs.

4.2. Convert GHTF documents to updated IMDRF documents

IMDRF will convert GHTF documents (e.g. definition, PMS, risk classification) that still serve as the foundation of medical device regulation, into updated IMDRF documents, and ensure that these documents represent current best practices and that they can be adopted by a wide range of regulatory authorities. This conversion will ensure that foundational principles are aligned with current needs, supporting consistent international practices.

Recognizing the critical role GHTF foundational documents have and the impact on regulatory frameworks and international standards worldwide, IMDRF aims to publish a workplan with timelines related to those planned revisions.

Once GHTF documents are converted to IMDRF documents, they will be maintained through periodic review, consistent with all other IMDRF documents.

4.3. Continue to publish technical documents on innovative technologies

IMDRF will continue to publish technical documents on innovative technologies and practices through a transparent and inclusive process. New documents will be developed by WGs in accordance with the IMDRF SOPs. Topics are selected based on strategic priorities, regulatory needs, and resources. Prior to finalization, proposed documents are published for public consultation for stakeholder input.

All IMDRF members and stakeholders are encouraged to identify potential new work and participate where they are able in IMDRF WGs and, in all cases, to contribute to the public consultation of IMDRF technical documents.

4.4. Continue to hold joint workshops with the IMDRF Industry Group

IMDRF will continue to conduct joint workshops with the IMDRF Industry Group to advance meaningful dialogue on the complex, evolving challenges facing all IMDRF members and stakeholders. Workshops are open to all members and stakeholders, including the public, and provide an opportunity for those impacted by global medical device regulation to engage in the important conversations and identify appropriate, feasible next steps to advance the foremost issues in global medical device regulation.

To this end, IMDRF and the IMDRF Industry Group will continue to operate in accordance with the IMDRF Industry Group Terms of Reference in identifying, developing, and executing joint workshops.

4.5. Identify and engage with new stakeholders

The work of IMDRF cannot be done by regulators alone. Additional perspectives and insights are critical to ensuring IMDRF outputs are harmonized, implementable, and effective.

During the timeframe of this strategic plan, IMDRF will identify and engage with stakeholders (new and existing) that are critical to the work of IMDRF, including where there are shared interests or intersections between regulatory responsibilities.

4.6. Enhance opportunities for all stakeholders to engage with and contribute to IMDRF activities

IMDRF will enhance opportunities for all stakeholders to engage with and contribute to IMDRF activities. In addition to hosting public meetings, inviting speakers to open meetings, posting statements on the outcomes of closed meetings, and conducting public consultations, during the timeframe of this strategic plan, IMDRF will also:

- publish approved New Work Item Proposals (NWIPs),
- clarify how and when individuals may participate directly in WG activities,
- explore mechanisms to increase the accessibility and outreach of its previous and future events (e.g., digitalization of meetings and availability of materials), and
- facilitate opportunities for interested groups to present and have strategic dialogue with IMDRF on shared matters of interest.

IMDRF looks forward to working with members and stakeholders to implement these and other measures to foster trust and build strong foundations for continued regulatory harmonization efforts.

4.7. Develop a list of foundational IMDRF documents

IMDRF will work with its members and stakeholders (e.g., the IMDRF Industry Group) to develop and publish a list of foundational documents to support navigation of IMDRF documents and prioritization of implementation by regulators.

4.8. Enhance IMDRF trainings

IMDRF will enhance IMDRF trainings to support members and stakeholders in consistent implementation of IMDRF documents and principles. IMDRF will work with its members and stakeholders (e.g., the IMDRF Industry Group) to identify the need for, develop, and conduct trainings in a consistent, systemic approach that includes topics ranging from foundational to more advanced in subject matter and addresses the needs and interests of attendees. IMDRF intends to “right-size” trainings to the intended audience, considering different modalities and supporting materials as appropriate.

IMDRF will develop a consistent, systematic approach to working with members and stakeholders in the identification, development, and execution of trainings. Upon agreement by the Management Committee, the approach will be published and implemented.

5. Progress Evaluation

Delivery on our Strategic Plan will be governed by the IMDRF Management Committee and monitored by the IMDRF Secretariat. Successful execution of the priority activities described in this plan requires the commitment and engagement of all IMDRF members and stakeholders.

Our Strategic Plan will be a document that is referred to and reported against to provide strong direction and focus over the next five years.

Activities and progress of IMDRF will be discussed and monitored by the Management Committee at each physical (face to face) meeting and published as a part of Meeting Outcome Statement.

Please visit our website for more details.

www.imdrf.org