IMDRF International Medical Device Regulators Forum

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IMDRF International Medical Device Regulators Forum

Strategic Plan

2021 - 2025

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IMDRF Mission

The mission[1] 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.

IMDRF was launched in 2012 and has delivered a number of significant work products:

- Continuation of the Global Harmonization Task Force (GHTF) work items,
- Updates to some of the GHTF documents
- New work items focusing on regulatory approaches for rapidly evolving technologies in medical devices.

IMDRF has focused its attention on developing a total product lifecycle approach to regulating medical devices while enabling timely access to safe and effective devices for the patients.

IMDRF[2] will pursue its goals by defining, implementing and evaluating strategic priorities so that objectives are met in an efficient and effective manner.

[1] The IMDRF Strategic Plan is aligned with the following mission defined in IMDRF Terms of Reference (IMDRF/MC/N1FINAL: 2014; updated 2018) (ToR)
[2] Stipulated Under "D. Scope of Activities of the ToR

Evolving Medical Device Landscape

The global medical device landscape is characterised by rapidly evolving technologies. New technologies including the Internet of Things (IoT), 3D printing and artificial intelligence/ machine learning with features such as connectivity, continuous or controlled learning and personalisation have reached the medical device sector. Remote monitoring devices, at-home diagnostic tests, portable imaging equipment and enhanced connectivity have extended the reach of healthcare delivery beyond hospitals and clinics in great parts of the world. Doctors and care givers are able to monitor their patients' health statuses remotely and are also able to receive alerts when their patient needs attention thus allowing patients to be effectively managed in the comfort of their homes. Patients can be discharged earlier from hospitals by leveraging such remote monitoring technologies thus reducing the burden on our stretched healthcare resources globally. To ensure safety and effectiveness of these new medical technologies and to utilise their great potential requires an appropriate regulatory response to challenges connected with those new technologies.

In the context of COVID pandemic, the adoption of telemedicine or virtual consultations was accelerated to enable more efficient use of limited medical resources and to prevent spreading of diseases. While these technologies have proven that significant improvements in healthcare delivery can be achieved even beyond the pandemic, it will be important to pay attention to their safety, effectiveness and data security related issues including securing patient personal information when using them. It is important for medical device manufacturers and regulators to incorporate the current learnings such as regulatory agility and harmonised regulatory principles to collaborate and better prepare for future pandemics or other crisis scenarios.

Digital technologies including wearable devices and software including mobile applications have transformed healthcare in many parts of the world to be patient-centric. Consumers are

increasingly using preventive monitoring and care to improve and maintain their health and to mitigate or avoid the onset of illness. In recent years, the scope of self-monitoring devices for consumers which used to be mainly blood glucose and blood pressure measurements, has expanded to include heart rate, blood oxygen saturation, ECG, arrhythmia and various other physiological parameters. This, together with the permanently increasing extent of available medical information in the Internet, has empowered patients to be more engaged in their healthcare decisions and even disagree with their doctors' diagnosis or prescribed treatments (e.g. choice of implants, health screening, surgery).

Developing a Regulatory Response

While technology has opened up opportunities to incorporate new features and functionalities in modern medical devices to enhance their performance, it has also posed additional regulatory challenges such as:

- accessibility,
- cybersecurity,
- interoperability,
- data integrity, and
- data security etc.

Software and digital technologies are capable of improving their safety and effectiveness continuously. For instance, artificial intelligence (AI) medical devices might continuously learn from training with more datasets and their performance specifications are not fixed unlike hardware medical devices. This is challenging the traditional regulatory approaches such as change management process, risk management process, clinical evaluation process, manufacturing facility and process controls, etc.

Personalised medical devices that deliver targeted or patient specific therapy for better clinical outcomes are gaining popularity. Personalised treatments including:

- personalised digital therapies (e.g. cognitive behaviour therapy software for treatment of insomnia) and
- personalised implants (e.g. orthopaedic implant designed and manufactured to fit an individual patient's anatomy)

These necessitate additional considerations to traditional clinical evaluation requirements and clinical study designs. Ensuring the safety, quality and efficacy of these devices without impeding innovation will require suitable adapted regulatory requirements at least on the design, clinical evaluation, risk management and post market surveillance processes.

The IMDRF Management Committee (MC) is aware of the regulatory challenges within its global regulatory model for innovative devices. In order to manage these challenges and to achieve greater global regulatory convergence and consistency, development and review of regulatory guidance will be necessary.

In order to facilitate timely access to safe medical devices for patients, achieving global regulatory convergence for these emerging areas is critical. IMDRF established the Software as a Medical Device (SaMD) working group that developed guidance on the appropriate regulatory controls for SaMDs. The guidance has promoted international regulatory convergence as many countries who have finalised their SaMD regulatory approaches after this work item, have adopted or aligned with these IMDRF guidance. Some of the current IMDRF work items such as Medical Device Cybersecurity and Personalised Medical Devices are intended to promote convergence in regulatory requirements, support safe innovation and ensure better clinical outcomes for patients.

IMDRF has identified regulatory challenges in the existing regulatory models, in particular for new technologies. To continue with acceleration of the international medical device regulatory convergence, the IMDRF will focus its work on those regulatory challenges as part of the strategic plan 2025, while keeping the IMDRF Mission in mind.

IMDRF Key Objectives 2021-2025

Over the next five years IMDRF will continue to build on its achievements from the 2020 Strategic Plan, with an emphasis on the two key objectives below:

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*

1. 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 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 proactively identify useful innovative areas and set up working groups to develop clear guidance to support prospective regulatory convergence in these areas.

IMDRF will continue to work collaboratively within the MC and also with various external stakeholders[3] and partners to share information and knowledge on an on-going basis. This includes working with standards setting bodies to play an active role in ensuring that international standards continue to be effective tools in conforming to essential principles for safety and performance for medical devices.

[3] medical devices industries, other regulators, international organizations, standards development organizations, patient and professional associations, and academia, in IMDRF working groups, as appropriate.

IMDRF also seeks to promote further development of useful and relevant international standards for innovative technologies in medical devices to enhance their safety and effectiveness.

In addition, IMDRF has also embarked on a challenging journey towards achieving a single pre-market review process for medical devices. We are currently developing the building blocks and working towards all MC members receiving the same set of information in the pre-market submissions.

IMDRF Key Objectives 2021-2025

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

Medical devices have a relatively short development phase and controlled clinical studies may not adequately reflect the real-world safety and effectiveness. Various factors come into play once the medical device is on the market which includes training and skill set of the users, user facility and infrastructure, environmental interference, diverse patient profiles and clinical practice differences. An effective post-market surveillance system is critical to continuously monitor feedback and implement improvements in a controlled manner under the manufacturer's quality management system to make the medical device better in its future versions or iterations. In order to collect post-marketing information efficiently, it is important to standardize information collected by regulators via post-market surveillance activities, such as via utilization of the Unique Device Identifier (UDI) System to precisely identify the implicated device and harmonized terminology for medical device reporting.Where a defect or failure of a device is identified, appropriate actions to correct the issues identified and also measures to prevent recurrence of the defect is important in the interest of patient health and safety.

Post-market regulatory controls complement pre-market requirements for medical devices. While pre-market requirements can address known and foreseeable risks, an effective post-market surveillance is necessary to manage evolving and new risks effectively. In pursuing the strategic priorities, IMDRF would seek to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

IMDRF Key Priorities 2021-2025

To improve accessibility to safe medical devices, key areas of opportunity arise in achieving greater global convergence of pre- and post-market requirements and regulatory reviews.

Priority areas

To deliver our key objectives, IMDRF will prioritise work on:

1. Pre-market
2. Post-market
3. Relationships with stakeholders

The priority areas are interdependent. Success will require concerted action across all these areas.

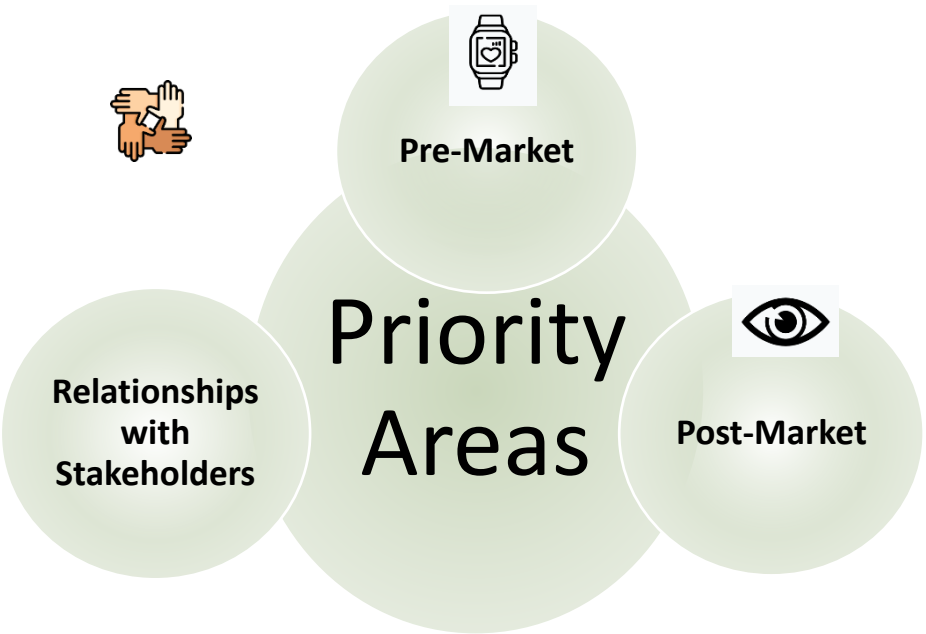
Plan of Action

In this section we describe each of our priority areas and the initiatives that will support their achievement. The initiatives provide an ambitious but achievable program of work. However, they are not intended as a prescriptive roadmap and are not an exhaustive list of everything we will do. We know that constant change is part of our environment and we will be ready to adapt and respond to new opportunities and challenges that emerge over the next five years.

Measures of success

For our Strategic Plan to be successful the outcomes must also be measurable.

The IMDRF MC will monitor and report on the progress of its work and implementation of IMDRF outputs.



Priority 1: Pre-Market 

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

The innovation landscape is rapidly evolving and this calls for more tailored and fit for purpose regulatory requirements. Promoting harmonized pre-market review requirements will improve transparency and predictability to stakeholders enabling timely access to safe and effective medical devices for patients.

For each topic, the following steps will occur to deliver IMDRF outputs:

- ✓ Consultation undertaken with stakeholders
- ✓ Drafting of a proposal for MC consideration
- ✓ MC agreement and publishing of IMDRF outputs
- ✓ Implementation considerations and adoption by IMDRF members

PRIORITY AREA: Pre-market
Topic: Personalized Medical Devices *A tailored regulatory approach that takes into consideration the unique characteristics and risks of each of these types of devices, which is significantly different from other standard mass-produced medical devices has been proposed.*
Topic: Software as a Medical Device *Develop international definitions, risk category framework, and quality management system.*
Topic: Regulated Product Submissions *'Early-stage' development of Regulatory Product Submissions including, ToC for non-IVD market authorization and IVD market authorization.*
Topic: Medical Device Evidence Evaluation *Improve Quantity and Quality of Clinical Data.*
Topic: Good Regulatory Review Practice *Develop Good Review Practices for pre-market reviews/evaluations.*
Topic: Artificial Intelligence Medical Devices (AIMDs) *Develop a harmonised approach to the management of artificial intelligence (AI) medical devices.*

Priority 2: Post-Market 

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

Post-market regulatory controls complement pre-market requirements for medical devices. While pre-market requirements can address known and foreseeable risks, an effective post-market surveillance is necessary to manage evolving and new risks effectively. In pursuing the strategic priorities, IMDRF would seek to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

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PRIORITY AREA: Post-Market
Topic: Cyber Security *A life cycle approach to effectively manage cybersecurity risks in medical devices. Striking the right balance between pre-market and post-market requirements.*
Topic: Adverse Event Terminology *Harmonize adverse event terminology to expand terminology and systems being used to code information relating to medical device adverse events.*
Topic: Unique Device Identifiers *Development of non-binding rules for creating, using, and maintaining unique device identifiers and related activities.*

Priority 3: Relationships with Stakeholders 

IMDRF values transparency and inclusiveness. IMDRF will continue to promote close communication about IMDRF activities and outputs with stakeholders, such as:

- medical devices industries,
- other regulators,
- international organizations,
- standards development organizations,
- patient and professional associations, and
- academia, in IMDRF working groups, as appropriate.

IMDRF will continue to encourage collaboration and outreach with Regional Harmonisation Initiatives and other interested regulatory authorities. IMDRF will seek opportunities to develop stronger relationships with organizations that help advance our mission, such as standards development organizations. IMDRF will work towards promoting regulatory convergence by developing consistent training programs to facilitate harmonised regulatory approaches and consistent implementation among various jurisdictions. In addition, IMDRF will consider new membership requests based on the established IMDRF ToR and Standard Operating Procedures.

Implementing our Strategic Plan

Delivery of our Strategic Plan will be governed by the IMDRF Management Committee.

Delivery of our Strategic Plan will be monitored by the IMDRF Secretariat, led by the IMDRF Management Committee and require the commitment of all members.

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. It will be updated as appropriate.

Tools to track our implementation:

1. An Implementation Table of IMDRF outputs will be published and updated by IMDRF members periodically.

2. The priority tables in this document, which lists priority areas will track progress of individual work items and be discussed and monitored by the MC at each meeting.