



IMDRF International Medical Device
Regulators Forum

Final Document

IMDRF/MC/N78 FINAL:2023

IMDRF Strategic Plan 2021-2025 – Progress Report Card

AUTHORING GROUP

IMDRF Management Committee

Preface

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A handwritten signature in blue ink, appearing to be 'AR', is positioned above the name of the chair.

Andrzej Rys, IMDRF Chair

IMDRF Strategic Plan 2021-2025 - Progress Report Card – March 2023

This document provides a summary of progress made in implementing the [IMDRF Strategic Plan 2021-2025](#) including key actions and action status.

Complete ● Underway/on Track ● Off Track ● Yet to commence ●

IMDRF Strategic Plan Objectives - Objective 1: Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance; and



Objective 2: Strengthening post market surveillance for medical devices and innovative technologies and implement regulatory life cycle processes.

IMDRF Strategic Plan Priorities - There are 3 priorities identified that aim to meet the above objectives which are detailed below.

PRIORITY 1: PRE-MARKET

Develop a risk calibrated regulatory approach for innovations and promote harmonised pre-market review requirements for medical devices. The following topics are being progressed to achieve Priority 1.



| Description | Summary of Progress | Status of Planned Activities prior to March 2023 | Planned Activity for the period March 2023 to March 2024 |
|--|---|--|--|
| <p><u>Personalized Medical Devices (PMD) Working Group</u></p> <p>Purpose:</p> <ul style="list-style-type: none"> Develop guidance document which provide harmonized recommendation for the regulation of PMDs. Develop IMDRF Technical Document which will provide recommendations for production validation of PMDs. Consistent and harmonized requirements for PMDs across various jurisdictions will offer significant benefits to users, patients, manufacturers, and regulatory authorities. | <p>The following documents were published in 2023:</p> <ul style="list-style-type: none"> N58 <i>Personalized Medical Devices - Regulatory Pathways</i> consultation, September 2022. N74 <i>Personalized Medical Devices Production Verification and Validation</i> consultation, September 2022. N58 <i>Personalized Medical Devices - Regulatory Pathways</i>, as a Final Document in April 2023. N74 <i>Personalized Medical Devices Production Verification and Validation</i>, as a Final Document in April 2023. | ● | The PMD WG plans to monitor the implementation of N58 and N74. |
| <p><u>Good Regulatory Review Practices (GRRP) Working Group</u></p> <p>Purpose:</p> <ul style="list-style-type: none"> Develop guidance that establishes good regulatory review practices for regulatory authorities and/or their conformity assessment bodies. The GRRP WG aims to improve the effectiveness and efficiency of pre-market review. | <p>The following documents were published in 2021, 2022 and 2023:</p> <ul style="list-style-type: none"> N66 <i>Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews</i>, July 2021 N71 <i>Marketing Review Report Work Instruction</i> consultation, May 2022. N71 <i>Marketing Review Report Work Instruction</i> as a Final Document in February 2023. | ● | <p>The GRRP WG plans to undertake the following task:</p> <ul style="list-style-type: none"> The Working Group will review previously issued documents to identify any potential revisions to existing documents or the need to develop and submit a NWIP for additional documents. |
| <p><u>Regulated Product Submission (RPS) Working Group</u></p> <p>Purpose:</p> <ul style="list-style-type: none"> 'Early-stage' development of Table of Contents for non-IVD market authorization and IVD market authorization. Creation of a dynamic template that supports the electronic transmission of regulatory submissions. | <p>The following documents were published in February 2023 for public consultation:</p> <ul style="list-style-type: none"> N9 <i>Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)</i> N13 <i>In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC)</i> | ● | <p>The RPS WG plans to undertake the following tasks:</p> <ul style="list-style-type: none"> Analyze consultation comments and revise nIVD and IVD ToCs accordingly Create a dynamic submission template through eSTAR using the updated nIVD and IVD ToCs. |
| <p><u>Artificial Intelligence Medical Devices (AIMD) Working Group</u></p> <p>Purpose:</p> <ul style="list-style-type: none"> To achieve an aligned approach to the management of artificial intelligence (AI) based-medical devices. | <p>The following documents were published in 2021 and 2022:</p> <ul style="list-style-type: none"> N67 <i>Machine Learning-enabled Medical Devices - A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions</i> consultation, November 2021. N67 <i>Machine Learning-enabled Medical Devices - A subset of</i> | ● | The AIMD WG has completed the scope of their work. |

| Description | Summary of Progress | Status of Planned Activities prior to March 2023 | Planned Activity for the period March 2023 to March 2024 |
|---|---|---|--|
| <ul style="list-style-type: none"> This will cover machine learning-based medical devices representing AI technology applied to medical devices and further standardize terminology for machine learning-based medical devices among member jurisdictions. | <p><i>Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions, May 2022.</i></p> | | |
| <p><u>Software as a Medical Device (SaMD) Working Group</u></p> <p>Purpose:</p> <ul style="list-style-type: none"> Review and refine, as needed, the previously published documents on SaMD to ensure ongoing consistency, predictability, transparency, and quality of premarket regulatory programs and criteria for assessing premarket technical documentation for SaMD. The review will also pay attention to post-market activities, recognizing the speed with which digital health technology develops and the value of taking a total product life cycle approach aligned with the principles of IMDRF. | <p>The SaMD WG has conducted an internal survey to identify areas of focus for revision of N12 Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations and N10 Software as a Medical Device (SaMD): Key Definitions and is analyzing the results.</p> |  | <p>The SaMD WG plans to continue:</p> <ul style="list-style-type: none"> Exploring WG use cases to better understand the challenges of the current risk categorization framework. Revising N12 and N10 to offer additional clarity of concepts and better reflect current experiences. |
| <p>Artificial Intelligence – Machine Learning Working Group</p> | <p>The AI-ML WG was recently approved by the IMDRF MC. There is no progress to report to date.</p> |  | <p>The AI-MLWG is being established.</p> |

PRIORITY 2: POST MARKET

Leverage post market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients. The following topics are being progressed to achieve Priority 2:

| Description | Summary of Progress | Status of Planned Activities prior to March 2023 | Planned Activity for the period March 2023 to March 2024 |
|--|--|---|--|
| <p><u>Medical Device Cybersecurity Guide (MDCG) Working Group</u></p> <p>Purpose:</p> <ul style="list-style-type: none"> A life cycle approach to effectively manage cybersecurity risks in medical devices. Striking the right balance between pre-market and post-market requirements. | <p>The following documents were published in 2022 and 2023:</p> <ul style="list-style-type: none"> N70 Principles and Practices for the Cybersecurity of Legacy Medical Devices consultation in May 2022. N73 Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity consultation in July 2022. N70 Principles and Practices for the Cybersecurity of Legacy Medical Device in April 2023. N73 Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity in April 2023. |  | <p>The MDCG WG plan to undertake the following tasks:</p> <ul style="list-style-type: none"> Working Group will review previously issued documents to identify any potential revisions to existing documents or the need to develop and submit a NWIP for additional documents. |

| Description | Summary of Progress | Status of Planned Activities prior to March 2023 | Planned Activity for the period March 2023 to March 2024 |
|--|---|---|---|
| <p>Adverse Event Terminology (AET) Working Group</p> <p>Purpose:</p> <ul style="list-style-type: none"> Harmonize adverse event terminology to expand terminology and systems being used to code information relating to medical device adverse events. | <p>The following documents were published in 2021, 2022 and 2023:</p> <ul style="list-style-type: none"> Harmonization of the terminology used to describe the essential aspects of an adverse event / incidents has been completed. The goal of this effort is to reduce the reporting burden, allow for the sharing of adverse event data, maximize post-market surveillance and provide a foundation for the future development of signal detection tools. The review of more than 258 change requests submitted in 2021 and updating Annexes A-G. This work was approved by the MC in January 2022 and published in March 2022. The review of more than 149 change requests submitted in 2022 and updating Annexes A-G has been completed. This work was approved by the IMDRF MC at the January 2023 meeting and the updated annexes were published in February 2023. <p>Additionally, the WG has developed a list of core adverse event reporting fields that should be collected and used when sharing data among IMDRF participants.</p> |  | <p>The AET WG plan to undertake the following tasks:</p> <ul style="list-style-type: none"> Yearly maintenance to update the terminology based on industry feedback will occur in 2023. Additionally, the WG has developed a list of core adverse event reporting fields that should be collected and used when sharing data among IMDRF participants. The goal of this effort is to reduce the reporting burden, allow for the sharing of adverse event data, maximize post-market surveillance and provide a foundation for the future development of signal detection tools. The WG is also working on harmonizing the data collected in certain fields and working on ways to share this standardized data. The WG is currently on track for completing work by March 2024. |
| <p>Quality Management System (QMS) Working Group</p> | <p>The QMS WG was recently approved by the IMDRF MC. There is no progress to report to date.</p> |  | <p>The QMS WG is being established.</p> |

PRIORITY 3: RELATIONSHIPS WITH STAKEHOLDERS

Promote communication about IMDRF activities and outputs with stakeholders. The following topics are being progressed to achieve Priority 3:

| Description | Summary of Progress | Status of Planned Activities prior to March 2023 | Planned Activity for the period March 2023 to March 2024 |
|--|---|---|---|
| <p>Promotion of IMDRF activities and transparency of progress of implementation.</p> | <ul style="list-style-type: none"> IMDRF MC hybrid meeting in Sydney Australia on 12 to 16 September 2022. Improved virtual connection and collaboration methods such as IMDRF website modernization and re- relaunch; virtual IMDRF event platform developed for use; internal IMDRF resource hub for use. Improved IMDRF operational transparency, tracking and accountability practices. New operational/secretariat models under consideration. Development of IMDRF Strategic Plan 2021-2025 - Progress Report Card. N14 Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form published May 2022. |  | <p>The following tasks are planned:</p> <ul style="list-style-type: none"> Development of a White Paper after the 23rd IMDRF Joint Workshop on the life cycle of medical devices: the importance of post-market related activities. Publication of the IMDRF Chair and Secretariat rotation. |

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|--|--|---|---|
| | <ul style="list-style-type: none"> • N14 Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form updated and published April 2022. • IMDRF MC Meeting in Brussels on 27 to 31 March 2023. • Official Observers to provide input to the draft Implementation Table was agreed by the IMDRF MC. • The IMDRF Strategic Plan 2021-2025 – Progress Report Card published in April 2023. | | |
| Collaboration and outreach to Regional Harmonization Initiatives and other regulatory authorities. | <ul style="list-style-type: none"> • Regional harmonization initiatives (RHI) delegates and additional relevant stakeholders included in the IMDRF Management Committee Open Session. • Engagement with other interested countries occurring and invitations to attend IMDRF meetings. | ● | <p>The following tasks are planned:</p> <ul style="list-style-type: none"> • Work with other organizations such as GMTA, DITTA, GHWP and RHIs to establish points of alignment to facilitate co-operation. • Encourage IMDRF working group participation as appropriate. • Development of Collaboration Agreements between IMDRF and RHIs. |
| Strengthening relationships with other stakeholders including standards development organisations | <ul style="list-style-type: none"> • IMDRF Standards Liaison Program Framework published May 2022 to improve engagement with Standards Development Organisations. • Held joint IMDRF and Industry Stakeholder Workshop on Standards for Health Software in September 2022. • Appointment of interim IMDRF Standards Liaison Officer. | ● | <p>The following tasks are planned:</p> <ul style="list-style-type: none"> • Appointment of permanent IMDRF Standards Liaison Officer. • Liaise with standards development organisations including working group participation. • A stocktake of standards committee participation by IMDRF MC members. |
| Development of consistent training programs for IMDRF documents | <ul style="list-style-type: none"> • The IMDRF MC agreed on a set of high-level strategic principles for IMDRF trainings. | ● | <p>The following tasks are planned:</p> <ul style="list-style-type: none"> • A pilot training project will be identified. • An IMDRF MC sub-group for oversight on the trainings will be set up. |
| Consider new membership requests | <ul style="list-style-type: none"> • Welcomed UK, MHRA as a MC Member. • Welcomed Switzerland (Swissmedic) as a MC Official Observer • Review of IMDRF Standard Operating Procedures relating to IMDRF Memberships. • Welcomed a number of regulatory authorities on IMDRF Working Groups. • New membership category created as Affiliate Member. • Regulatory authorities have been advised that a new membership category has been created – Affiliate Member. • Welcomed South African Health Products Regulatory Authority (SAHPRA) as an Affiliate Member. | ● | <p>The following tasks are planned:</p> <ul style="list-style-type: none"> • Encourage new IMDRF Members as appropriate. |

A number of IMDRF Working Groups have been closed as the scope of work for these working groups has been completed. Please refer to [Closed working groups | International Medical Device Regulators Forum \(imdrf.org\)](#) for further info.

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