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2023年5月25日（木） 13:10-13:30
IMDRF活動報告会2023

IMDRF活動の概要解説

～IMDRF Strategic Plan、GHWPとの連携～

日下部 哲也
医療機器品質管理・安全対策部長/国際業務調整役
独立行政法人 医薬品医療機器総合機構

Pharmaceuticals and Medical Devices Agency

IMDRF Strategic Plan について

- **IMDRFとして優先的に対応する内容をまとめた5か年計画**
- **議長国がMCメンバーや産業界等の意見を聴取しとりまとめ**

＜IMDRF Strategic Plan 2020＞

- 2016年～2020年の５か年戦略計画
- 2015年10月2日作成、日本（議長国）がとりまとめ
- IMDRF設立後３年が経過。同活動の戦略的方向性を示し、限られたリソースの有効活用のため、戦略的優先事項（※）を設定

※ 戦略的優先事項

- ➢ 市販後調査（Post-Market Surveillance）の強化
- ➢ 市販前審査の効果・効率の改善

Strategic Plan 2021-2025 について

- 2020年9月25日作成
- 2021年～2025年の5か年戦略計画
- IMDRF　MC会合で議論の上、議長国（シンガポール）がとりまとめ

https://www.imdrf.org/documents/imdrf-strategic-plan-2021-2025

規制対応の策定

- テクノロジーが医療機器に新たな特徴・機能を組み込むことで、医療機器の性能が向上した一方、アクセス性、サイバーセキュリティ、相互運用性、データ保全性、データセキュリティ等、新たな規制上の課題が浮上
- ソフトウェアとデジタル技術は、安全性・有用性を継続的に改善可能であり、変更管理・リスク管理プロセス等、性能仕様が固定された従来型医療機器の規制アプローチに対する挑戦となる

規制対応の策定（つづき）

- 個別化医療機器は、臨床評価、リスクマネジメント、市販後調査過程等において、これらに適切に適合した規制要件が必要
- 革新的医療機器について、規制ガイダンスの作成・見直しが必要
- 新分野・技術の国際規制コンバージェンスの実現が重要
- IMDRFは、戦略計画2025の中で規制上の課題に注力し、医療機器の国際規制コンバージェンスを継続的に加速

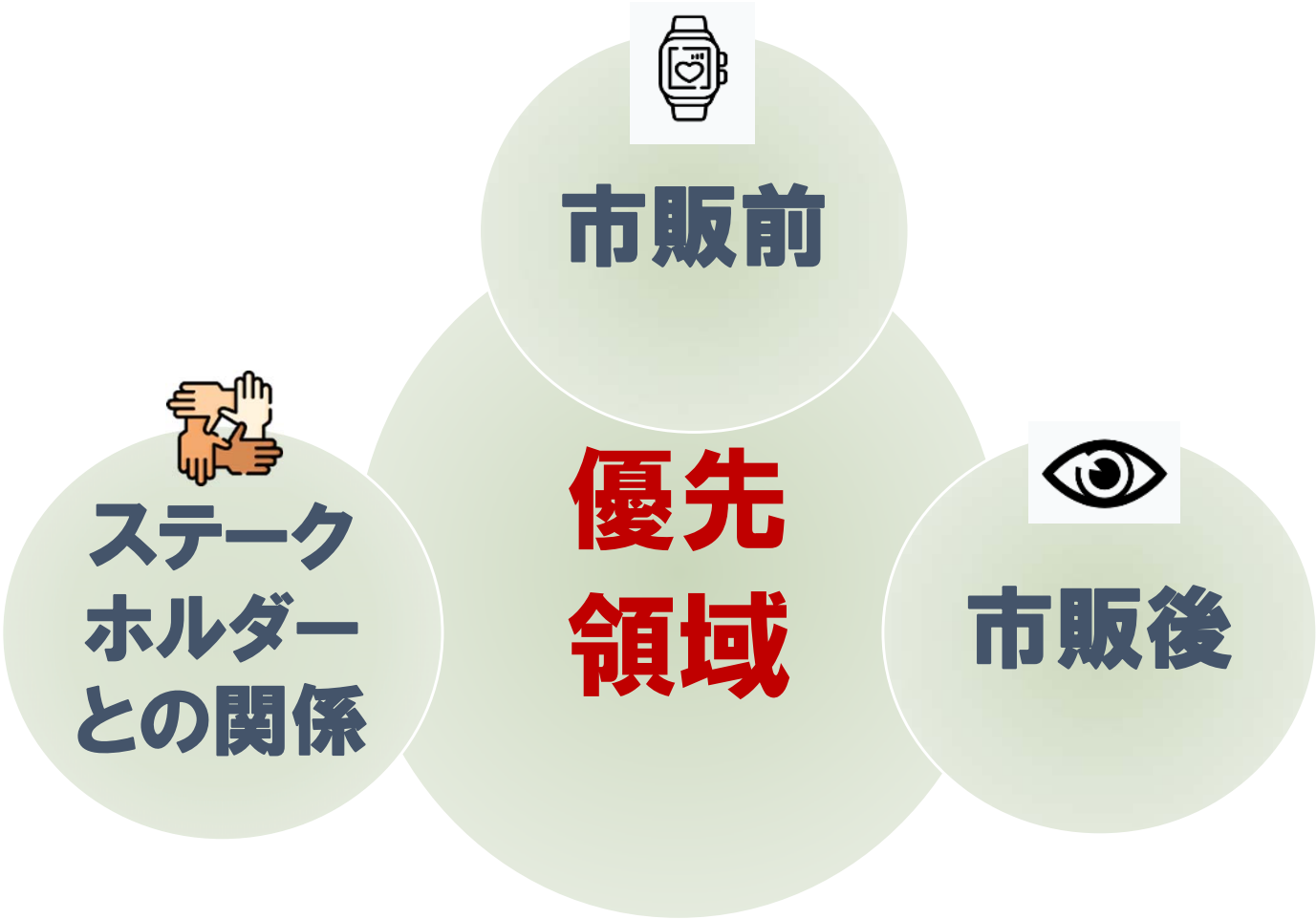
IMDRF 主要目的 2021-2025

- **今後５年間で、IMDRFは、以下の2つの主要目的に重点を置いて、戦略計画2020の成果をもとに継続的に活動する**

① タイムリーで適切なガイダンスの提供により、医療機器及び革新的技術の規制上の課題を管理

② 医療機器の市販後調査を強化し、規制ライフサイクルプロセスを実装

IMDRF 主要優先事項 2021-2025



IMDRF International Medical Device Regulators Forum

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Information document

IMDRF Strategic Plan 2021-2025 - Progress Report Card

IMDRF Code: IMDRF/MC/N78 FINAL:2023 **Published date:** 8 May 2023

IMDRF code: IMDRF/MC/N78 FINAL:2023 **Published date**: 8 May 2023

IMDRF Strategic Plan 2021-2025 Progress Report Card (N78)
DOCX (325.52 kb) PDF (393.47 kb)

https://www.imdrf.org/documents/imdrf-strategic-plan-2021-2025-progress-report-card

Progress Report Card

優先1：市販前

- **革新的医療機器のリスクに応じた規制アプローチの開発と医療機器の市販前審査要件の調和促進**

（Strategic Plan 2021–2025より）

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
Personalized Medical Devices (PMD) Working Group Purpose: • 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.	The following documents were published in 2023: • N58 *Personalized Medical Devices - Regulatory Pathways* consultation, September 2022. • N74 *Personalized Medical Devices Production Verification and Validation* consultation, September 2022. • N58 *Personalized Medical Devices - Regulatory Pathways*, as a Final Document in April 2023. • N74 *Personalized Medical Devices Production Verification and Validation*, as a Final Document in April 2023.		The PMD WG plans to monitor the implementation of N58 and N74.
Good Regulatory Review Practices (GRRP) Working Group Purpose: • 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.	The following documents were published in 2021, 2022 and 2023: • N66 *Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews*, July 2021 • N71 *Marketing Review Report Work Instruction* consultation, May 2022. • N71 *Marketing Review Report Work Instruction* as a Final Document in February 2023.		The GRRP WG plans to undertake the following task: • 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.
Regulated Product Submission (RPS) Working Group Purpose: • '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.	The following documents were published in February 2023 for public consultation: • *N9 Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)* • *N13 In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC)*		The RPS WG plans to undertake the following tasks: • Analyze consultation comments and revise nIVD and IVD ToCs accordingly • Create a dynamic submission template through eSTAR using the updated nIVD and IVD ToCs.
Artificial Intelligence Medical Devices (AIMD) Working Group Purpose: • To achieve an aligned approach to the management of artificial intelligence (AI) based-medical devices.	The following documents were published in 2021 and 2022: • N67 *Machine Learning-enabled Medical Devices - A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions* consultation, November 2021. • N67 *Machine Learning-enabled Medical Devices - A subset of*		The AIMD WG has completed the scope of their work.

https://www.imdrf.org/sites/default/files/2023-05/IMDRF%20Strategic%20Plan%202021-2025%20Progress%20Report%20Card%20%28N78%29.pdf

Progress Report Card

優先2：市販後

- 患者にとって安全で効果的な革新的医療機器へのアクセス性を確保するため、市販後モニタリングと市販後調査を活用

（Strategic Plan 2021−2025より）

Softw Purpose: • 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.	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.		• 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.
Artificial Intelligence – Machine Learning Working Group	The AI-ML WG was recently approved by the IMDRF MC. There is no progress to report to date.		The AI-MLWG is being established.

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
Medical Device Cybersecurity Guide (MDCG) Working Group Purpose: • A life cycle approach to effectively manage cybersecurity risks in medical devices. Striking the right balance between pre-market and post-market requirements.	The following documents were published in 2022 and 2023: • 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.		The MDCG WG plan to undertake the following tasks: • 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.

https://www.imdrf.org/sites/default/files/2023-05/IMDRF%20Strategic%20Plan%202021-2025%20Progress%20Report%20Card%20%28N78%29.pdf

Progress Report Card

優先3：ステークホルダーとの関係

- ステークホルダーとの緊密なコミュニケーションを継続的に促進
- 地域調和イニシアティブや他の規制当局との協働と対話を引き続き奨励
- 規格作成機関など、IMDRFの使命を発展させるのに役立つ組織とのより強固な関係性を構築する機会を模索
- 一貫したトレーニングプログラムの開発によって、規制コンバージェンスの促進に向けた取り組みを推進
- 新規メンバーの加入申請を検討

（Strategic Plan 2021–2025より）

		Activities prior to March 2023	
Promotion of IMDRF activities and transparency of progress of implementation.	• 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.		The following tasks are planned: • 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.

https://www.imdrf.org/sites/default/files/2023-05/IMDRF%20Strategic%20Plan%202021-2025%20Progress%20Report%20Card%20%28N78%29.pdf

Progress Report Card

	• 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.	• 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.		The following tasks are planned: • 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	• *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.		The following tasks are planned: • 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	• The IMDRF MC agreed on a set of high-level strategic principles for IMDRF trainings.		The following tasks are planned: • 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	• 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.		The following tasks are planned: • 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.

https://www.imdrf.org/sites/default/files/2023-05/IMDRF%20Strategic%20Plan%202021-2025%20Progress%20Report%20Card%20%28N78%29.pdf

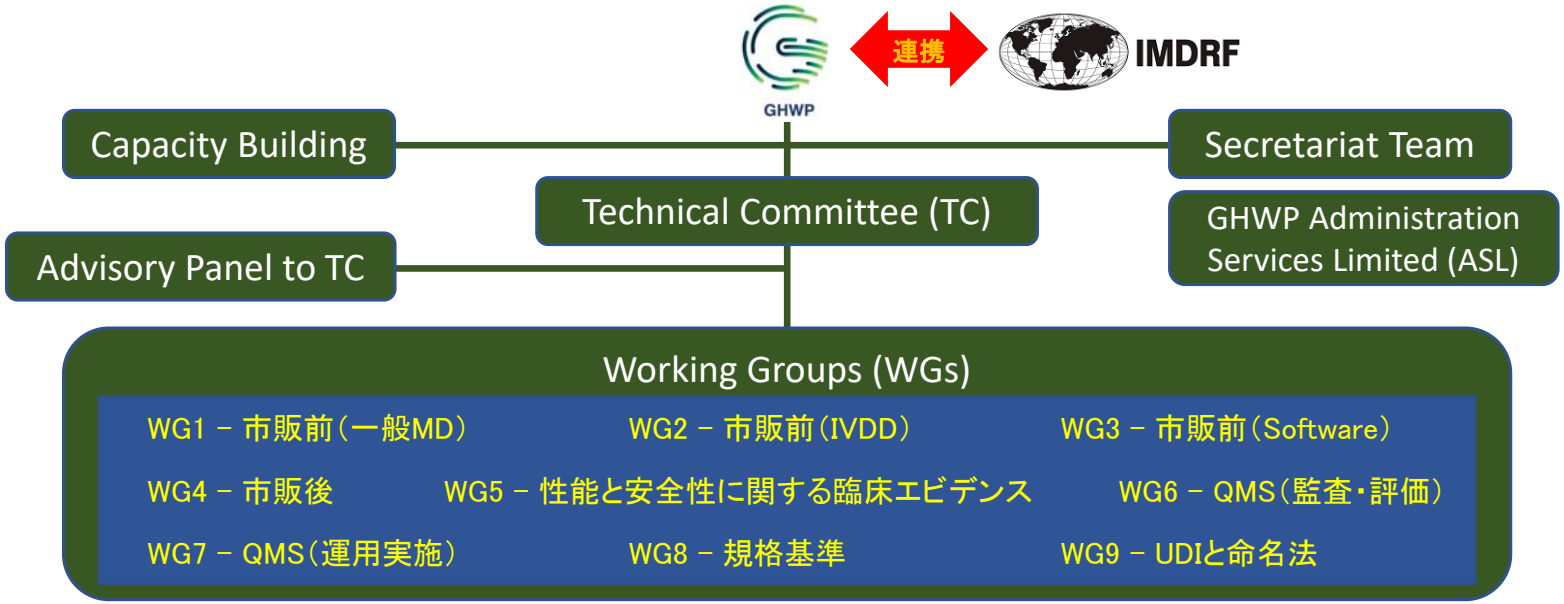
GHWP (Global Harmonization Working Party)

【概要】

- GHWPは、1996年に設立されたAHWP（Asian Harmonization Working Party）を前身とする組織
- 医療機器の国際規制調和を目的として、テーマごとに9つのWGが活動を実施
- アジアのみならず、世界の医療機器規制当局及び業界に門戸を開放し、2021年12月、GHWPへ名称変更
- 議長国は3年で改選（2023年～、中国NMPA）

【メンバー】

- アジア、アフリカ、中東、南米等、世界33ヶ国・地域（2023年5月現在）の規制当局と業界　（参考）日本は2023年2月に加盟



http://www.ahwp.info

GHWP Members

26th GHWP Annual Meeting Photos, Riyadh, The Kingdom of Saudi Arabia 2023

Brunei Darussalam
Cambodia
Chile
Chinese Taipei
Hong Kong SAR, China
India
Indonesia
Japan
Jordan
Kazakhstan
Kingdom of Bahrain
Kingdom of Saudi Arabia
Kyrgyz Republic
Laos
Malaysia
Mongolia
Myanmar
Pakistan
People's Republic of China
Philippines
Republic of Kenya
Republic of Korea
Singapore
South Africa
State of Kuwait
Sultanate of Oman
Tanzania
Thailand
United Arab Emirates
United States of America
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Zimbabwe

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参考資料

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ご清聴ありがとうございました