SaMD Working Group Update

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Co-Chairs: US FDA and Health Canada

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IMDRF International Medical Device Regulators Forum

About Us

SaMD WG Goals/ Objectives: support innovation and timely access to safe and effective SaMD globally while promoting greater global convergence of pre- and post-market regulatory review requirements in areas of advanced and innovative technologies.

SaMD WG Purpose and Rationale:

To supplement the previously published SaMD documents to improve international alignment and ensure ongoing consistency, predictability, and transparency by:

Developing a new document related to:

- Enhancing focus on better characterizing the device to inform downstream risk considerations
  - Drafted document includes discussion of how to clearly characterize medical device software to improve consistent understanding of these devices by regulators globally
  - Drafted document includes considerations for identifying and understanding medical devices software risks based upon information-based hazards

About Us

Established NWIP: Fall 2022; new WG members identified

WG Meeting Cadence: bi-weekly meetings

Group Members:

- Argentina National Administration of Drugs, Food and Medical Devices (ANMAT)
- Australia Therapeutic Goods Administration (TGA)
- Brazilian Health Regulatory Agency (ANVISA)
- Health Canada (HC)
- European Union
- Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
- Global Medical Technology Alliance (GMTA)
- Japan Pharmaceuticals and Medical Device Agency (PMDA)
- Singapore Health Sciences Authority (HAS)
- South Korea Ministry of Food and Drug Safety (MFDS)
- Switzerland Swissmedic
- United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA)
- United States of America Food and Drug Administration (FDA)

About Us – Alignment with IMDRF Strategic Plan

The SaMD Working Group's activities align directly with 2021-2025 IMDRF Strategic Priority 1:

Pre-Market – specifically the SaMD Topic Area. Recently completed work intends to bring clarity to how device descriptions are provided and considerations necessary to understand SaMD risk, which are in alignment with furthering a harmonized risk category framework. Future opportunities will further this objective and the development and refinement of SaMD-related international definitions.

About Us – Alignment with IMDRF Strategic Plan

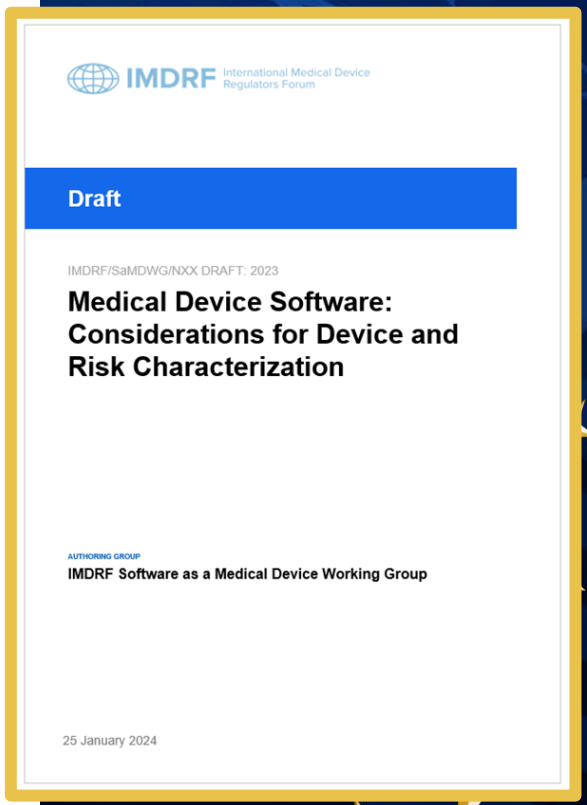
- **IMDRF/SaMD WG/N10: Software as a Medical Device (SaMD): Key Definitions 18 December 2013**
- **IMDRF/SaMD WG/N23: SaMD: Application of Quality Management System 2 October 2015**
- **IMDRF/SaMD WG/N12: SaMD: Possible Framework for Risk Categorization and Corresponding Considerations 18 September 2014**
- **IMDRF/SaMD WG/N41 SaMD: Clinical Evaluation 21 September 2017**

- The rapid pace of technological advancement in SaMD has tested these documents and refinements are needed to improve consistency, predictability, and transparency of pre- and post- market regulatory programs.
- Refining these documents supports innovation and timely access to safe and effective SaMD globally while promoting global convergence of review requirements/considerations in areas of advanced and innovative technologies.

Publication – N81: *Medical Device Software: Considerations for Device and Risk Characterization*

Objective: Add to concepts included in IMDRF/SaMD WG/N12 FINAL:2014 to **promote and inform clear and accurate characterizations** of medical device software (including intended use/intended purpose statements) and **introduce a general strategy for characterizing software-specific risks that leverages the key features of a comprehensive medical device software characterization.** This document is intended to:

- Highlight the importance of comprehensive characterizations for medical device software;
- Establish key features of and common vocabulary for the characterization of medical device software;
- Identify fundamental elements of an intended use/intended purpose statement for medical device software;
- Establish links between characterization features and risk for medical device software;
- Provide information for consideration during the identification and assessment of medical device software risks



Publication – N81: *Medical Device Software: Considerations for Device and Risk Characterization* – Main Content

4.0 Device Characterization Considerations	5.0 Medical Device SW Risk Characterization	Appendices
4.1 Intended Use/Intended Purpose Statement 4.2 Description of Medical Device Software	5.1 Identification and Analysis 5.2 Estimation 5.3 Approaches for Risk Categorization	Appendix A: Sample Intended Use/ Intended Purpose Statement Appendix B: Characterization Feature Summary Table Appendix C: Considerations to Understand Software Hazards Associated with Device Design and Intended Use Appendix D: Example of Discussing Information Risk in Application to Risk Characterizations

Publication – N81: *Medical Device Software: Considerations for Device and Risk Characterization* – Key Messaging

Why is it important?

This document is intended to help stakeholders (manufacturers, regulators, healthcare providers, patients, etc.) clearly and accurately characterize medical device software to enable proper use, to properly evaluate risks and benefits, and to help support risk classifications.

Does this replace the previous risk categorization framework?

No, this document is intended to build from the initial concepts of N12 and is not intended to replace the current framework.

Publication – N81: *Medical Device Software: Considerations for Device and Risk Characterization* – Timeline

- **January 2024 –**IMDRF Management Committee approval to post draft
- **February - May 2024** – Open for Public Comment (QR Code)
- **Final Publication –** Late 2024

Publication – N81: *Medical Device Software: Considerations for Device and Risk Characterization* – Future

Opportunity for future improvements to the existing documents by publishing new document(s) related to:

- Developing a new risk framework, building on the concepts in N81, to keep pace with technological advancements and improve consistency among regulatory agencies
- Other improvements as identified by working group members

Opportunities for international alignment related to:

- Alignment and coordination with other IMDRF WGs and technical documents (e.g., AI, Cybersecurity, SaMD risk categorization)

Thank you/ Questions

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