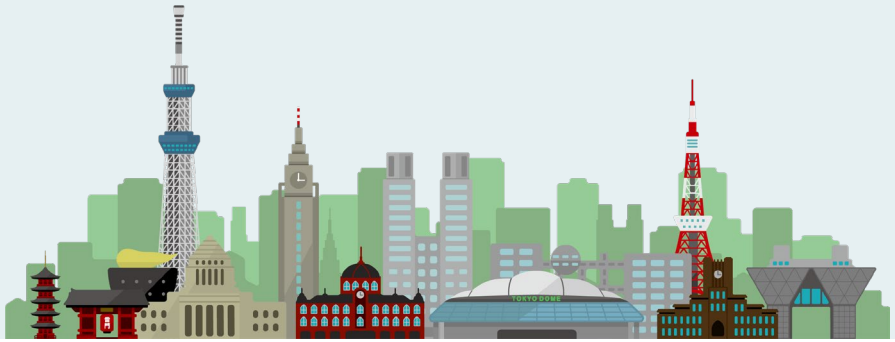
IMDRF International Medical Device Regulators Forum



SaMD Working Group Update

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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.

Established: 2013

WG Meeting Cadence: bi-weekly meetings

Co-chairs: Health Canada and US FDA

Group members: 13 jurisdictions, GMTA, DITTA

About Us

Alignment with the IMDRF Strategic Plan

- Previous work (N81) introduced a framework to enhance the characterization of medical device software, helping stakeholders ensure proper use and risk evaluation.
- Current work related to Predetermined Change Control Plans (PCCPs) aligns with the IMDRF 2021-2025 Strategic Plan as a mechanism to manage regulatory challenges associated with the rapid pace of software development while providing the necessary regulatory oversight.
- For patients, the authorization of PCCPs may support quicker access to improved medical devices, which can lead to better health outcomes.

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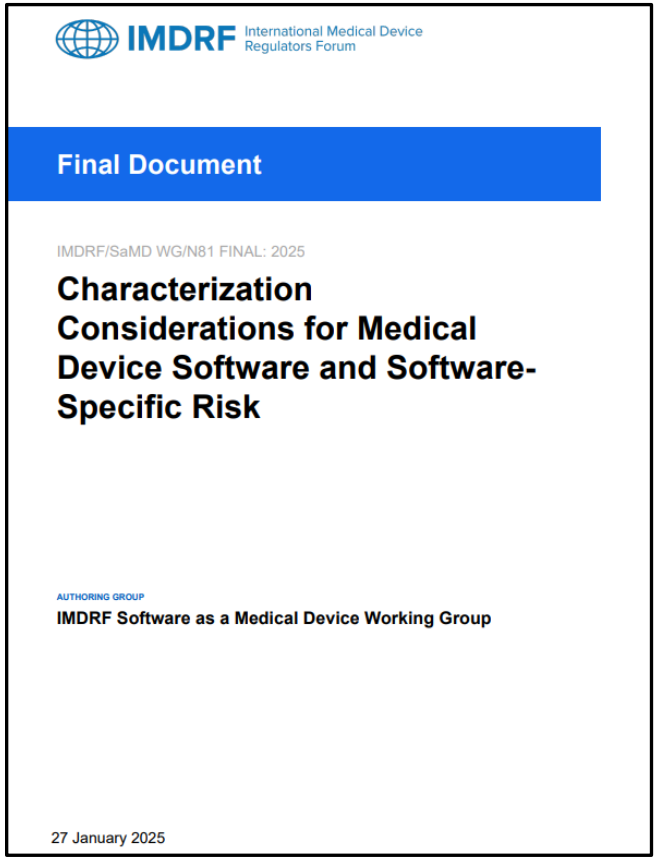
Recent Publication – N81: "Medical Device Software: Considerations for Device and Risk Characterization"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Final Document

IMDRF/SaMD WG/N81 FINAL: 2025

Characterization Considerations for Medical Device Software and Software-Specific Risk

AUTHORING GROUP

IMDRF Software as a Medical Device Working Group

27 January 2025

- The objective of N81 is to promote and inform clear and accurate characterizations of medical device software (including intended use/intended purpose statements and device descriptions).
- N81 introduces a general strategy for characterizing software-specific risks that leverages the key features of a comprehensive medical device software characterization.
- N81 applies to the subset of software that meets the definition of a medical device (referred to throughout as medical device software), including software that meets the definition of Software as a Medical Device (SaMD).

Current work – Essential Principles and Content of Predetermined Change Control Plans (PCCPs)

- PCCPs are one way to support iterative changes to software that may allow updates to occur at a pace that better aligns regulatory oversight with software development best practices, while providing continued assurance that devices are safe as they are modified.
- The purpose of this document is to
  - provide internationally harmonized high-level guidelines on what should be included in a PCCP and best practices for developing and documenting a PCCP
  - develop a broad but harmonized framework for PCCPs allowing each jurisdiction to apply the concepts within the scope of regulations applicable to their jurisdiction
- The Working group is targeting draft document submission to the Management Committee in late 2025.

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Opportunities for convergence

- PCCPs are an emerging concept, and their implementation may vary significantly across different regulatory jurisdictions.
- This document serves, in part, to facilitate international convergence and harmonized approaches across jurisdictions by describing essential principles for PCCPs.
- PCCPs have the potential to be applied beyond medical device software to other areas of medical technology. The evolution of PCCPs could lead to more flexible and responsive regulatory frameworks, better suited to the fast-paced nature of technological innovation in healthcare.

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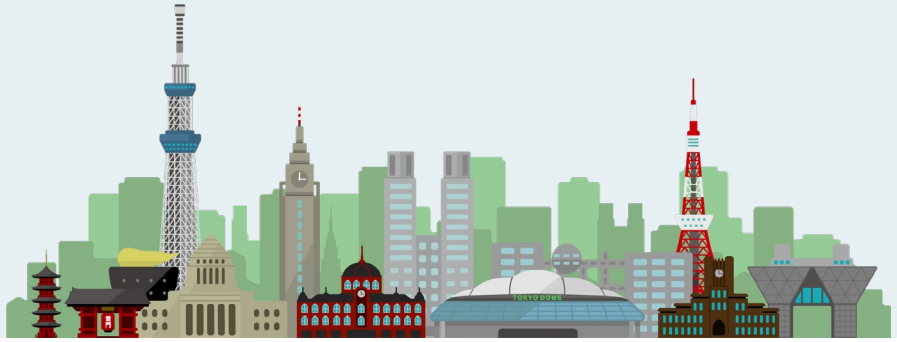

Thank you/Questions

Annex – SaMD Working Group Members

Co-Chairs: Health Canada and US Food and Drugs Administration (US FDA)

Group Members:

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