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, including by promoting greater convergence of pre- and post-market regulatory review requirements in areas of advanced and innovative technologies.

Established: 2013, and reinvigorated with new members in 2022

WG Meeting Cadence: Bi-weekly meetings

About US

Group Members:

- Argentina National Administration of Drugs, Food and Medical Devices (ANMAT)
- Australia Therapeutic Goods Administration (TGA)
- Brazil Health Regulatory Agency (ANVISA)
- Health Canada (HC)
- 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)
- US Food and Drug Administration (FDA)

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 and aligning with the goal of harmonizing pre-market regulatory approaches.
- Current work related to Predetermined Change Control Plans (PCCPs) aligns with the IMDRF 2021-2025 Strategic Plan because PCCPs are one way to manage regulatory challenges associated with the rapid pace of software development while still providing the necessary regulatory oversight across both the pre- and post- market.
- For patients, the authorization of PCCPs may support quicker access to improved medical devices, which can lead to better health outcomes.

Publications

- **N81: Characterization Considerations for Medical Device Software and Software-Specific Risk**
  - The SaMD WG published the final N81 document in January 2025, following approval from the Management Committee at the January 2025 meeting. 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.
- **N41: Software as a Medical Device (SaMD): Clinical Evaluation**
- **N23: Software as a Medical Device (SaMD): Application of Quality Management System**
- **N12: Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations**
- **N10: Software a s a Medical Device (SaMD): Key Definitions**

Ongoing work

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

- The draft document has been submitted to Management Committee
- PCCPs are one way to support iterative changes to software that may allow such 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

Opportunities and Challenges

- 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.

Thank you/Questions