IMDRF International Medical Device Regulators Forum

SaMD Working Group Update

Co-chairs: US FDA and Health Canada

IMDRF Meeting – Seattle, Washington

IMDRF SaMD Working Group Update: N81

"Medical Device Software: Considerations for Device and Risk Characterization"

- **Objective**: 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.
- **Status**: The SaMD WG is currently resolving comments from public consultation and plans to submit the revised version to the Management Committee prior to the December 2024 MC Meeting. Pending approval by Management Committee later this year, final N81 publication would be early in 2025.
- **Scope**:
  - 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).
  - N81 is separate from the IMDRF SaMD N12 2014 document, though the concepts within N81 are compatible with the principles described in that document.
- **Next steps:**
  - (1) facilitate alignment of these concepts with the IMDRF AI and Cybersecurity working group activities as applicable
  - (2) monitoring stakeholder responses to the publication and operationalizing of N81 as feedback for review and consideration.

IMDRF SaMD Working Group Update: Proposed Work Item

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

- The SaMD WG submitted an NWIP for this draft document in July 2024
- The purpose of this document is to –
  - provide internationally harmonized high-level guidelines on what should be included in a PCCP for software 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
- Predetermined Change Control Plans 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

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Thank you/ Questions

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