

Artificial Intelligence/ Machine Learning Working Group Update

Working Group Chair(s):

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Updates from the IMDRF AI/ML Working Group

- “Technical Framework for Artificial Intelligence Life Cycle Management” document was submitted to the Management Committee on January 16th 2026 as a proposed document for public comment.
 - This document describes an internationally harmonized technical framework to help promote responsible innovation and patient-centricity by facilitating the secure, safe, ethical, and effective design, development, deployment, maintenance, use, and decommission of AI-enabled medical devices.
 - Proposed public comment duration – 90 days
- The WG also plans to begin exploring topics for new work items later this Spring to bring to MC later in the year



About the Working Group

- Co-chaired by Health Canada and the US FDA
- Members: Argentina, Australia, Brazil, Canada, EU, Japan, Singapore, South Korea, Switzerland, UK, US, DITTA, GMATA
- Published five documents
 - N10: Software as a Medical Device (SaMD): Key Definitions (2013)
 - N12: SaMD: Possible Framework for Risk Categorization and Corresponding Considerations (2014)
 - N23: SaMD: Application of Quality Management System (2015)
 - N41: SaMD: Clinical Evaluation (2017)
 - N81: Characterization Considerations for Medical Device Software and Software-Specific Risk (2025)



2025 Public Consultation

- Public consultation held October – December 2025 on the draft document N90: Essential Principles and Content of Predetermined Change Control Plans
- 143 comments from 10 stakeholders
- In general, the comments reflected thoughtful suggestions addressing
 - The future application of PCCPs to a broader scope
 - Clarification around the authorization of modified PCCPs
 - Additional benefits and challenges of PCCPs for both industry and regulators
- The WG is considering these comments and expects to submit the final draft for MC consideration at the September 2026 meeting

