# Software as a Medical Device Working Group Update

**Working Group Chair(s):**
Health Canada, Canada
Food and Drug Administration, USA

# 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, GMTA
- 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