



IMDRF International Medical Device
Regulators Forum

IMDRF Stakeholders Forum – Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs

September 2022

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New Work Item Proposal

- The SaMD Working Group published 4 technical documents from 2013-2017
- The rapid pace of technological advancement in SaMD has tested these documents and refinements are needed to improve consistency, predictability, and transparency of pre- and post- market regulatory programs
- Refining these documents would support innovation and timely access to safe and effective SaMD globally while promoting global convergence of review requirements in areas of advanced and innovative technologies.

New Work Item Proposal

Goal: To refine the previously published SaMD documents to improve international alignment and ensure ongoing consistency, predictability, and transparency by:

- **Considering improvements to existing documents related to:**
 - The granularity of the risk categorization matrix (N12)
 - The location of where the software may be running (N10)
 - Other improvements as identified by survey results
- **Considering additional opportunities for international alignment related to:**
 - Harmonized SaMD labelling
 - Harmonized guidance for post-market SaMD activities
 - Alignment and coordination with other IMDRF WGs and technical documents (e.g. AI, Cybersecurity)

Progress and Planned Milestones

- June-July 2022: Identification of WG members and co-chair coordination meeting
- August 2022: Survey to WG members re: proposals for changes to existing documents
- September 2022: WG kick-off meeting, meet every two weeks (frequency to be confirmed)
- March 2023: 3/4-day WG meeting
- **May 2023: Submission of draft document(s) to IMDRF MC**
- July 2023: Public consultation of document(s)*
- November 2023: 3/4-day WG meeting
- January 2024: Final document(s) submitted to IMDRF MC
- **March/April 2024: Publish final technical document(s)***



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Thank you/Questions

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