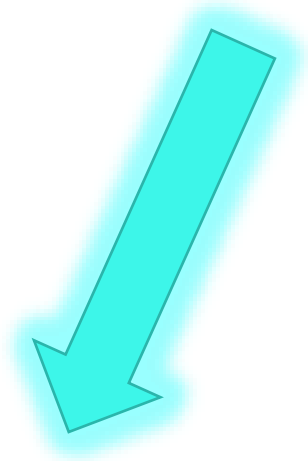
IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs



Provide your feedback on this Working Group!

Follow this link and let us know:

https://forms.office.com/e/Xqap73btKc

September 2023

About US

- The SaMD Working Group published 4 technical documents from 2013-2017
- Working group membership:
  - Argentina National Administration of Drugs, Food and Medical Devices (ANMAT): Bioing. Carolina Magnatti, Bioing. José Médico Orellano, Dr. José Atilio Méndez
  - Australia Therapeutic Goods Administration (TGA): Dr David Hau, Lesley-Anne Farmer
  - Brazilian Health Regulatory Agency (ANVISA): Mr Francisco Iran Cartaxo Barbosa, Mr Helio Bomfim de Macedo Filho, Mr Jangley Bahia Costa
  - Health Canada: Marc Lamoureux, Janet Hendry, Martina Buljan
  - European Union: Matthias Neumann, Nada Alkhayat, Rolf Oberlin Hansen, Valerie Soumet
  - Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA): Camille Vidal, Hyun-Bae Park, Koen Cobbaert, Tomohisa Fukunaga
  - Global Medical Technology Alliance (GMTA): Cassie Scherer, Diane Johnson, Kees Maquelin, Mr Toshiaki Nakazato
  - Japan: Dr Kentaro Kato, Dr Madoka Murakami, Mr Kuniki Imagawa, Yuhei Fukuta
  - Singapore Health Sciences Authority (HSA): Mr Ong Ming Hao, Ms Siew Jie Yee
  - South Korea Ministry of Food and Drug Safety (MFDS): Byung-Gwan Kim (Mr), Rosa Da-yeong Ryoo (Ms)
  - Switzerland Swissmedic: Rudolf Waelti
  - United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA): David Grainger, Russell Pearson
  - United States of America Food and Drug Administration (FDA): Sonja Fulmer, Catherine Bahr, Wil Vargas, MiRa Jacobs
- The SaMD Working Group meets bi-weekly

About Us

The SaMD Working Group's activities align directly with 2021-2025 IMDRF Strategic Priority 1: Pre-Market – specifically the SaMD Topic Area. Ongoing work aims to bring clarity to how device descriptions are provided and considerations necessary to understand SaMD risk, which are in alignment with furthering a harmonized risk category framework. Future opportunities will further this objective and the development and refinement of SaMD-related international definitions.

- 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/considerations in areas of advanced and innovative technologies.

Ongoing Work

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

- **Publishing a new document related to:**
  - Enhancing focus on better characterizing the device to inform downstream risk considerations
    - Drafted document includes discussion of how to clearly characterize medical device software to improve consistent understanding of these devices by regulators globally
    - Drafted document includes considerations for identifying and understanding medical devices software risks based upon information-based hazards

Opportunities and Challenges

- **Opportunity for future improvements to the existing documents by publishing new document(s) 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 working group members
- **Additional opportunities for international alignment related to:**
  - 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, meeting every two weeks
- April 2023: 3 x half-day virtual WG meeting
- **November 2023: Planned submission of draft document to IMDRF MC**
- December 2023: Public consultation of document(s)*
- January 2024: 3/4-day WG meeting
- March 2024: Final document(s) submitted to IMDRF MC
- **May 2024: Publish final technical document(s)***

* Pending IMDRF MC Approval

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Thank you/Questions

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