IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

14:30 – 14:45

Software as a Medical Device (USA / Canada)

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IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs

March 2023

Overview

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 the existing documents by publishing new document(s) related to:**
  - The granularity of the risk categorization matrix (N12)
  - Enhancing focus on better characterizing the device to inform downstream risk considerations
  - The location of where the software may be running (N10)
  - Other improvements as identified by working group members
- **Considering 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
- **August 2023: Planned submission of draft document to IMDRF MC**
- October 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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