Software as a Medical Device: Current Regulations in North America and Europe

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INTRODUCTION

- Software intended to be used for a medical function can be regarded as a medical device. These devices can include monitoring apps, diagnostic software, and interruptive devices. The most common software as a medical device (SaMD) therapeutic areas approved by the United States (U.S.) Food and Drug Administration (FDA) are radiology (64.3%), cardiovascular (12.9%), and general hospital (4.4%).[1]
- The FDA and Health Canada (HC) have available guidance on SaMD. These regulatory bodies rely on the International Medical Device Regulations Forum (IMDRF) to define SaMD, which mention that qualified SaMD perform medical purposes without being part of hardware.[2,3] Since the inception of its regulatory classification, HC has approved over 1,000 SaMDs.[4] Meanwhile, in 2023, the FDA had approved 135, increasing from an average of 59 over the previous five years.[1]
- On the other hand, the European Commission (EC) defines software used for medical purposes as medical device software (MDSW) which is intended to be used alone or in combination for a medical function.[5] For the purpose of this poster, MDSW will be included under SaMD.
- As increasingly more SaMD is being developed due to technological advancements, it is crucial for medical device developers to understand whether their devices are regarded as SaMD or MDSW, as well as the different processes required for approval depending on the device functionality.

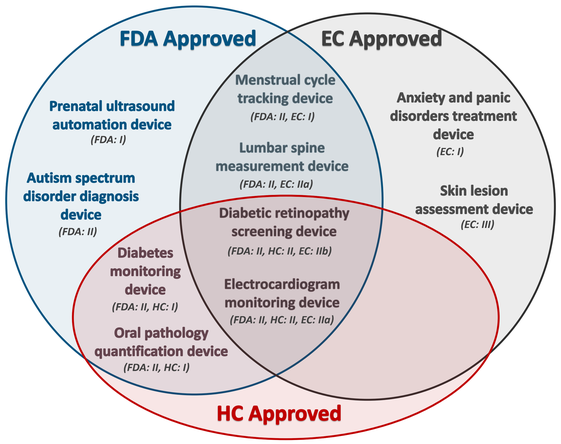
OBJECTIVE

- The objective of this scoping review was to investigate the guidelines by the FDA, HC, and the EC to determine the different definitions of a SaMD as well as the varied classifications and their respective pathways to approval.
- SaMD approved by the different regulatory bodies was also investigated to illustrate successful examples to guide medical device developers in future medical device endeavors.
- SaMD and MDSW both include in in-vitro diagnostic (IVD) medical devices, although regulations vary compared to non-IVD SaMD. This poster focuses on non-IVD SaMD.

METHODS

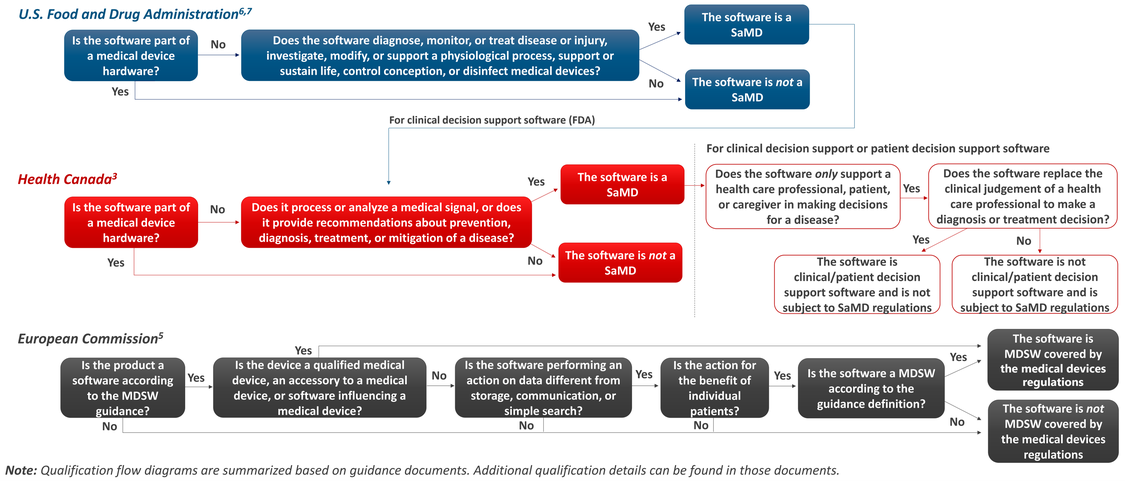
- Official guidance from the FDA, HC, and EC was collected, followed by the gathering of other grey literature articles.
- Guidance documents and other literature were reviewed, and data was extracted based on definition and qualification of SaMD, classification, approval processes, post-market surveillance, and examples of SaMD which have been approved. The data was then summarized.

FIGURE 1. SaMD EXAMPLES



Approval of SaMD is based on data available at the time of poster presentation; classification of the SaMD is in parentheses.

FIGURE 2. QUALIFICATION



Note: *Qualification flow diagrams are summarized based on guidance documents. Additional qualification details can be found in those documents.*

TABLE 1. REGULATORY BODY CLASSIFICATION

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decisions		
	Treat or diagnose	Drive clinical/patient management	Inform clinical/patient management
Critical	IV III III	III III IIb	I I or II[b] IIa
Serious	III II or III[a] IIb	II II or III[a] IIa	I I or II[b] IIa
Non-serious	II I or II[b] IIa	I I or II[b] IIa	I I or II[b] IIa

FDA SaMD Categories for Classification[8]

HC Non-IVD SAMD Classification[3]: *[a]Class III if an erroneous result could lead to immediate danger; [b]Class II if the software is intended to image or monitor a physiological process or condition; Class IV was mentioned in HC guidance as pertaining to regular medical devices and was not included in the HC classification table*

EC Medical Device Regulation (MDR) Classification (in vitro diagnostic medical devices regulation (IVDR)), is not included[5]

TABLE 2. SUMMARY TABLE

Criteria	U.S. Food and Drug Administration	Health Canada	European Commission
Definition	Software intended to be used for one or more medical purposes that perform a qualified purposes without being part of a hardware medical device[6]	Software intended to be used for one or more medical purposes that perform a qualified purposes without being part of a hardware medical device[3]	Software that is intended to be used alone or in combination, for a qualified medical device purpose[5]
Classification	Class I, II, III, IV[8]	Class I, II, III[3]	Class I, IIa, IIb, III[5]
Approval process	Self-registration (Class I, some Class II), 510(k) submission (Class II, some Class I), pre-market approval (PMA) submission (Class III), De Novo classification request (novel devices which are low-to-moderate risk)[9]	Medical Device Establishment License (Class I), Medical Device License (Class II-III)[12]	Medical devices overall: Self-registration (Class I without a measuring function or those that are non-sterile), conformity assessment & Conformité Européenne (CE) mark (some Class I & Class II-III)[16]
Clinical investigation requirement	Required for Class III/IV, sometimes Class II[9,10]	Required for Class III[12]	Required for Class III, sometimes Class IIa & IIb[17]
Approval time	90 days (501(k)), 150 days (De Novo), and 180 days (PMA)[9]	120 days (Class I), 15 days (Class II), 75 days (Class III)[13,14]	Medical devices overall: 3-6 months (some Class I & Class IIa and IIb), 6-9 months (Class III)[18]
Post-market surveillance	Mandatory reporting of adverse events, post-market studies, manufacturing plant inspections, user feedback, recall oversight[11]	Medical device incidence and adverse reactions reports, complaint handling, recall provisions, discontinuance and shortage reporting[15]	Medical devices overall: Monitoring performance and safety, periodic safety update report, vigilance reporting, post-market clinical data collection, quality management system[19]

RESULTS

- Numerous SaMDs have been approved by each regulatory body, several of which utilize artificial intelligence (AI) (**Figure 1**). These range from electrocardiogram monitoring to diabetic retinopathy screening to lumbar spine structure measurements. Other examples include devices which support the diagnosis of autism spectrum disorder, oral pathology detection and quantification, and cognitive-behavioral treatment of anxiety and panic disorders.
- The qualification of medical device as software is similar for the FDA and HC, whereas differences exist for the EC (**Figure 2**). The FDA and HC SaMD qualification depend on being a software and not part of hardware, as well as appropriate intended use. Clinical decision support software qualification is also the same for the FDA and HC. For the EC, qualification depends on being a software and an accessory of or influencing a medical device. If the medical device does not meet this criteria, then it must perform a non-simple action on data, it must benefit patients, and it must meet the definition of medical devices under the MDSW guidance.
- Classification of SaMD is risk-based for all regulatory bodies which depends on the significance of information provided for the healthcare decision and the state of the healthcare condition (**Table 1**). The classification for the FDA depends on the IMDRF, and HC has adapted the IMDRF classification to align with Canadian regulatory processes.
- The classification numbers differ which lead to differences in regulatory approval, as different classes have different pathways and timelines (**Table 2**). The FDA requires self-registration for class I (sometimes class II), 510(k) submission for class II (sometimes class I), and a premarket approval for class III/IV devices. HC requires a medical device establishment license for class I and a medical device license for class II and III devices. For the EC, self-certification can be conducted for some class I devices and a conformity assessment and CE mark is required for some class I devices as well as class II-III devices.

LIMITATIONS

- Only three regulatory bodies (FDA, HC, and EC) were investigated for guidance on SaMD/MDSW, although other regulatory bodies exist and may have official guidance, which may or may not differ from those investigated in this study.
- Official guidance documents were written with technical vocabulary.
- IVDs were not separately investigated in this poster. Regulatory differences for the FDA, HC, and EC can be found below:
  - For the FDA, the IMDRF framework for SaMD applies to any software that performs a medical function independently of hardware, regardless of whether it relates to IVDs or not. As a result, both IVD and non-IVD SaMDs adhere to the same general principles outlined by IMDRF. However, the FDA makes a distinction between IVD devices, which are regulated separately.[6]
  - For HC, IVD is considered under the IMDRF framework similar to the FDA, although classification rules are dependent on Schedule 1, Part 2 of the Medical Device Regulation that are applicable to IVD devices. All IVD device classification rules apply to IVD SaMD besides Rule 6.[3]
  - The EC also provides MDSW guidance for in vitro diagnostic medical devices regulation (IVDR), although this was not included in the classification. The definition is the same as the medical device regulation (MDR) for qualified IVDR purposes, although they are regulated differently.[5]

CONCLUSIONS

- SaMD qualification and classification determines the regulatory pathway for approval and marketing capabilities in different regions. Understanding the regulation of SaMD, and the differences between regulatory bodies, is essential for successful approval, specifically as guidance continues to evolve with advances to AI and machine learning (ML).
- To balance safety requirements with technological innovation in healthcare, regulators and industry stakeholders must collaborate continuously to develop appropriate recognition standards for evidence and documentation.

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DISCLOSURES

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