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# Regulatory Prospective on Software as a Medical Device

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## Abstract

Software is becoming increasingly important in medical devices and digital adoption more broadly. It is becoming more important as a medical device in its own right. (1) Currently the use of software in medical market is growing exponentially and many countries have already set guidelines for quality control and clinical evaluation for SaMD. Millions of users use AI based medical device for the diagnosis & Management of diseases. Regulation for the SaMD, IMDRF published guidance document in 2013, in EU they are regulated by EMA, in Australia they are regulated by TGA and in Canada they are regulated by Health Canada. Regulations of these countries and IMDRF were reviewed and articles of challenges in artificial intelligence based medical devices reviewed. There are also many challenges like cybersecurity, safety, and decommissioning, high cost of device and also the design and development process. The objective is to focus on SaMD's regulations and Challenges.

**Keywords:** SaMD, MDSW, Medical Device, IMDRF, TGA, MDR, Health Canada, Challenges

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## 1. Introduction

Software is becoming increasingly important in medical devices and digital adoption more broadly. It is becoming more important as a medical device in its own right. Currently the use of software in medical market is growing exponentially and many countries have already set guidelines for quality control and clinical evaluation for SaMD. The objective is to focus on SaMD's regulations and Challenges. (1)

**What is Software as a Medical Device?** According to IMDRF, the term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms.
- "Without being part of" means software is not necessary for a hardware medical device to achieve its intended medical purpose;
- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.
- SaMD may be used in combination (e.g., as a module) with other products including medical devices;
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software.
- Mobile apps that meet the definition above are considered SaMD. (2)

### *Definitions of SaMD in Different Countries*

**Europe: (EU)**

In the EU, SaMD is termed as Medical Device Software (MDSW).

Medical Device Software for classification purposes is defined in MDR rule 11.

That rule applies to software-only devices and hardware devices that comprise MDSW as an integral part.

MDSW also applies to software that fulfills a medical device purpose on its own but is at the same time necessary for a medical device to achieve its medical purpose (SaMD). (3)

**Australia: (TGA)**

The term Software as a Medical Device (or SaMD) refers to software that can function on, for example, a laptop computer, smartphone or tablet, and has an intended purpose consistent with the definition of a medical device. This could be any kind of software, including but not limited to: computer programs and applications, mobile apps, software as a service (cloud based), websites and browser delivered products. Software would generally be a medical device if it is intended to be used for:

- Diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability compensation for an injury or disability
- Investigation of the anatomy or of a physiological process
- To control conception

Some SaMD may be an accessory to a medical device. Accessories are regulated as separate medical devices. (4)

**USA: (FDA)**

FDA released new draft guidance in July 2011 on "mobile medical applications", Test for determining whether a mobile application is a regulated mobile 'medical' application is the same test one would use to determine if any software is regulated.

According to the FDA, SaMD is a class of software that is designed to carry out one or more medical functions. This includes software or mobile apps intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions. (5,6)

**UK, Canada, ASEAN:**

The definition of SAMD in these countries is same as that given by IMDRF, "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

**2. Categorization of SaMD:**

Categorization of SaMD is according to IMDRF and it is followed by all regulatory agencies. (7)

**Table 1.** SaMD Risk Categorization (7)

| State of Healthcare situation or condition | Significance of information provided by SaMD to healthcare decision | | |
|---|---|---|---|
| | Treat or diagnose | Drive clinical Management | Inform clinical Management |
| **Critical** | IV | III | II |
| **Serious** | III | II | I |
| **Non-serious** | II | I | I |

**Table 2.** Comparison of IMDRF, EU, TGA & Health Canada Guidelines for SaMD

| PARAMETERS | IMDRF | EUROPEAN UNION | AUSTRALIA | CANADA |
|---|---|---|---|---|
| **Regulatory Agency** | - | EMA | TGA | Health Canada |
| **DEFINITION** | The term SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. | Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the MDR or IVDR, regardless of whether the software is independent or driving or influencing the use of a device. | The term SaMD refers to software that can function on, for example, a laptop computer, smartphone or tablet, and has an intended purpose consistent with the definition of a medical device. | Same as IMDRF |
| **Risk Categorization** | 9 types of risk category | Same as IMDRF | Same as IMDRF | Same as IMDRF |
| **Risk Categorization based on** | health care condition severity (urgent, serious, or critical) and information provided by the SaMD application to the health care decision | seriousness of the situation or condition | seriousness of the situation or condition | Same as IMDRF |
| **Classification** | Class A, B, C, & D | Class I, IIa, IIb, or III | Class I, IIa, IIb, or III | Class I, II, or III |

| PARAMETERS | IMDRF | EUROPEAN UNION | AUSTRALIA | CANADA |
|---|---|---|---|---|
| **Quality Standards** | ISO 13485<br>ISO 14971<br>IEC 62304 | EN ISO 13485<br>ISO27001<br>EN 14971<br>EN 62366<br>EN ISO 14155<br>EN ISO 15223-1<br>EN 62304<br>IEC 82304-1 | Same as EU | Same as IMDRF |
| **CER** | (1) the technology on which the device is based; (2) the intended use of the medical device and any claims made about its safety, clinical performance, and effectiveness; and (3) a description of the clinical data and how it demonstrates the safety, clinical performance, and effectiveness of the device | Same as IMDRF & also requires manufacturers to prepare and follow a post market follow-up plan | Same as EU | Same as IMDRF |
| **Registered in** | - | EUDAMED | ARTG | MDL |
| **For Registration** | - | CE mark required | CE mark required | MDEL/MDL |

**Table 3.** Summary of required parameters

| PARAMETERS | IMDRF | EU | TGA | Health Canada |
|---|---|---|---|---|
| Intended Use | √ | √ | √ | √ |
| Risk Classification | √ | √ | √ | √ |
| QMS std. | √ | √ | √ | √ |
| Risk Management Std. | ISO 14971 | EN ISO 14971 | ISO 14971 | ISO 14971 |
| V & V | √ | √ | √ | √ |
| Clinical Evaluation | √ | √ | √ | √ |
| Technical Documentation | √ | √ | √ | √ |
| Conformity Assessment | √ | √ | √ | √ |
| Product Company & registration | - | √ | √ | √ |
| PMS/ Follow up | √ | √ | √ | √ |

## 3. Challenges for SaMD (8)

- **Cost and Regulations**

  Speaking of rising costs, the already-high cost of healthcare continues to trend upward. For those who require medical devices to treat or manage a chronic condition, there's concern that these products will become unaffordable and out of reach. This is compounded by the fact that many medical devices exist outside traditional insurance coverage. Patients are left fighting for even partial coverage of new and innovative devices—or footing the bill themselves. For many, even some financial assistance form insurance isn't enough to bridge the gap between cost and need.

- **High Cost of Software design and development**

  It requires Needs elicitation, requirements gathering, and specification approval; Medical device software architecture design; UX/UI design of medical device software; Medical device software development; Quality Assurance; Integration with smart devices (wearable and non-wearable, medical or general-purpose); Medical device software support and evolution.

- **Decommissioning (Retirement or End-of-life Activity)**

  What minimum retention time periods are defined by each territory in which the devices are marketed; Will any data be migrated onto new/replacement devices/software systems and, if so, will any data conversion be needed and how will this be validated; Will the SaMD be withdrawn or will it be only a withdrawal of support for the device; What sensitive legacy data (patient information, etc.) will be securely stored; and How the users of the device that is to be decommissioned will be informed and supported. In this way both companies can make the appropriate decisions to effectively and gracefully plan the decommissioning of their devices.

- **Data Protection and Privacy Issues**

  Medical devices software Database Updating and Data storage: Healthcare data is not static, and most elements will require relatively frequent updates in

order to remain current and relevant. For some datasets, like patient vital signs, these updates may occur every few seconds. Other information, such a home address or marital status, might only change a few times during an individual's entire lifetime.

Understanding the volatility of big data, or how often and to what degree it changes, can be a challenge for organizations that do not consistently monitor their data assets.

Providers must have a clear idea of which datasets need manual updating, which can be automated, how to complete this process without downtime for end-users, and how to ensure that updates can be conducted without damaging the quality or integrity of the dataset.

Organizations should also ensure that they are not creating unnecessary duplicate records when attempting an update to a single element, which may make it difficult for clinicians to access necessary information for patient decision-making.

- **Cybersecurity**

Data security is the number one priority for healthcare organizations, especially in the wake of a rapid-fire series of high-profile breaches, hackings, and ransomware episodes. From phishing attacks to malware to laptops accidentally left in a cab, healthcare data is subject to a nearly infinite array of vulnerabilities. The HIPAA Security Rule includes a long list of technical safeguards for organizations storing protected health information (PHI), including transmission security, authentication protocols, and controls over access, integrity, and auditing. In practice, these safeguards translate into common-sense security procedures such as using up-to-date anti-virus software, setting up firewalls, encrypting sensitive data, and using multi-factor authentication. But even the most tightly secured data center can be taken down by the fallibility of human staff members, who tend to prioritize convenience over lengthy software updates and complicated constraints on their access to data or software. Healthcare organizations must frequently remind their staff members of the critical nature of data security protocols and consistently review who has access to high-value data assets to prevent malicious parties from causing damage.

- **Cost regulation and Product quality and high recall rate**

While connected medical devices clearly have numerous benefits, including the ability to reduce long-term costs of patient care, the initial cost of developing and maintaining a connected solution is a major concern. Connectivity infrastructure either is the medical device itself, or an extension of the medical device. Either way, all regulatory requirements must be met. Creating products that fall into the connective category and meet all regulatory requirements is a tough process. This is also one that requires an extensive expertise in the space and a highly specific skill set, both of which are hard to come by, making device development and regulation a great expense. (8)

## 4. Conclusion

IMDRF has published the guidance document for regulation of SaMD. However, the classification and nomenclature of SaMD varies from country to country. The guidelines published by Health Canada include exclusion criteria for SaMD. Placing SaMD on the market has become significantly difficult in the EU because of the complexity in the classification of SaMD. Moreover, TGA more or less, follows the rules and regulations set by the EU. According to the new rules, Australian classification of SaMD will be the same or lower than EU. The Certification is also to be used for lower risk devices in Australia.

The health care field is moving faster than it has in the past, and new applications might make us pause and go back to our fundamental goals of assuring safety and effectiveness and discovering alternative paths to reach those goals. The shift from a purely product focus to a product and process viewpoint for SaMD is a new pathway through which it converges towards the quality management system approach. Product developers are innovators.

With the explosion of wearables and objects that are part of the Internet of Things (IoT), health and wellness information and technology can be found everywhere. Technology surrounds us to the point that we suggest that humanity has entered an era of 'every whereables', and this technology will vastly improve our understanding of the human body. Most of these innovations will be driven by software, and most of that software will be SaMD. In this context, developing appropriate regulations for SaMDs and amending these regulations with time, to cope up with the evolution of technology will be a challenge to the regulatory agencies of all countries.

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## Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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