IQVIA MEDTECH

White Paper

Regulations and Reimbursement of Software as a Medical Device in Europe

Part 1 — Definitions and regulatory challenges.

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Table of contents

Introduction

Over the past decades, the development in software used alone or together with a medical device has significantly increased. This is due to the increased adoption of smart technology such as smartphones, wireless connectivity, cheaper and better sensors, cloud computing, big data and Artificial Intelligence (AI) which are alerting healthcare delivery across the world.

With the advancement of these technologies leading to a shift in how healthcare is administered and delivered, software has become an essential component of the development of medical devices. Particularly "Stand alone" software or "Software as a Medical Device" has seen fast growth recently as there is no hardware involved, fewer constraints as well as the use of fast feedback loops for improvement.

Given the unique features of SaMD which extend beyond those of a traditional medical device or hardware, SaMD brings both, new opportunities and challenges, for device companies and regulators. It is an area where new regulatory models are being piloted to ensure effectiveness and patient safety without limiting innovation growth.

Even though reimbursement options for SaMD and digital care in general are not yet standardized, the development of reimbursement pathways is increasing globally as regulators recognize the role that digital health can play in patient care.

In this series, we provide a detailed overview of SaMD, with its definitions, regulations and reimbursement pathways in the European market.

In this Part 1 of the publication series, we explore SaMD definition, it's challenges and the ways the regulatory bodies try to address them, as well as the expected development of regulations related to Artificial Intelligence (AI) and Machine Learning (ML) in SaMD.

In Part 2, we discuss SaMD regulations under the EU MDR and the EU IVDR frameworks, and provide an overview on the key challenges for market entry.

In part 3, we discuss the current reimbursement pathways for SaMD in Europe as well as explore the expected advancement in the reimbursement of digital healthcare in the coming years, with European countries trying to adopt more systematic pathways for evaluation and reimbursement of digital health solutions.

Due to its unique features, SaMD brings both, new opportunities and challenges, for device companies and regulators.

What is SaMD

With the rise of the digital era, IT technologies, AI, and the abundant use of mobile applications and computers in healthcare, a question of what software should be considered as a medical device has emerged.

We believe that it is important for medical software providers to have a clear understanding on what software is considered a SaMD - to apply the same set of policies to such software as are used for hardware medical devices. This is necessary to improve accessibility for patients as well as formalize the control over this developing field. This topic should be especially interesting for companies or programs intending to participate in or benefit from the healthcare reimbursement regulations, e.g., for hospitals using and companies producing such software.

An International Medical Device Regulators Forum (IMDRF) defines Software as a Medical Device as a "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." A typical example of the SaMD usage is when it is installed on or connected to a non-medical computing platform working with traditional medical devices or other general-use hardware via a network.[1–3]

An important clarification is that SaMD does not refer to the physical location from where the software is running but to the regulatory status of the software. Location-wise, the software can run either on regular IT equipment, in 'the cloud' or be a software directly connected to the hardware medical device and still be SaMD.

For the latter case, however there are exclusions – e.g., if the hardware medical device requires the software to operate properly to serve its intended medical purpose (e.g., it is driving the hardware) - then the software is not considered SaMD in regulatory terms. In some cases the borderline is not very clear and depends on the manufacturer's claims, e.g., a software for an automatic organ detection, linked to an ultrasound device. A placement of this software on the market can be done as either a part of the ultrasound device or as a separate software, depending on the description and claimed purpose by the manufacturer. On the other hand, a software that does not fulfill a medical purpose on its own is not considered SaMD. For example, software intended to exclusively drive a part of an ultrasound device can be placed on the market as either an essential part of the ultrasound device or as an accessory of the ultrasound device (see table 1).[4]

To be able to clearly identify what is SaMD and what is not, it's important for digital healthcare manufacturers to understand what type of software is considered as SaMD and what is not.

WHAT IS CONSIDERED TO BE SaMD?

SaMD has a wide range of applications, from enabling a smartphone to view and diagnostically analyze images obtained from a magnetic resonance imaging (MRI) medical device to Computer-Aided Detection (CAD) software that performs image post-processing.[2]

Other examples of SaMD include:

- SaMD interfacing with other medical devices, including hardware, SaMD, and general-purpose software. It may provide parameters as an input for a different hardware medical device or other SaMD, e.g., the FDA (U.S. Food and Drug Administration) gives an example of a treatment planning software that supplies information used in a linear accelerator is SaMD[2]
- Software with a medical purpose that operates on a general (non-medical) purpose computing platform, e.g., a software intended for diagnosis of a condition using the tri-axial accelerometer that operates on the embedded processor on a consumer's digital camera[2]
- Software that is connected to a hardware medical device but is not necessary for that device to fulfil its intended medical purpose. This is considered as SaMD and not an accessory to the hardware medical device

It is important to differentiate between the embedded software (SiMD) which is a part of a hardware (and is a key for the machinery to work properly) and Software as a Medical Device.

WHAT IS NOT CONSIDERED AS A SOFTWARE AS A MEDICAL DEVICE?

As already mentioned earlier, SaMD does neither include the software intended for clinical communication and workflow, nor the software that monitors performance or proper functioning of a medical device (e.g., X-ray tubes performance), nor the software that provides input parameters for SaMD (e.g., databases with a search function). Some examples from FDA and public sources to differentiate between SaMD and SiMD are:

Software controlling the mechanical parts:

- Software used by radiologists and clinicians to assess a cardiovascular condition by analyzing MRI scans is SaMD. However, the piece of software that controls the X-ray machine is SiMD[5]
- Software used to "drive or control" the motors and the pumping of medication in an infusion pump; or software used in closed loop control in an implantable pacemaker or other types of hardware medical devices. These types of software, sometimes referred to as "embedded software", "firmware", or "micro-code" are not Software as a Medical Device[6]
- Software required by a hardware medical device to perform the hardware's medical device intended use, even if sold separately from the hardware medical device[6]

Software assisting the medical devices, being a part of an accessory of that device:

- A mobile application analyzing blood glucose level (reading an input from a glucose meter) and patient food log to provide insulin dosage recommendations for diabetic patients is SaMD, if it can take input from multiple glucose meters or accepts manual inputs. If it requires input from a specific glucose meter, then it is an accessory to the glucose meter, and therefore, SiMD. If the mobile app is the primary display for the glucometer, then it is part of the glucometer rather than an accessory, and also SiMD[5]
- Software that monitors performance or proper functioning of a device for the purpose of servicing the device, (e.g., software that monitors x-ray tube performance to anticipate the need for replacement), or software that integrates and analyzes laboratory quality control data to identify increased random errors or trends in calibration on IVDs[6]
- Software that relies on data from a medical device, but does not have a medical purpose, e.g., software that encrypts data for transmission from a medical device[6]

General non-medical purpose software databases:

- Software that enables clinical communication and workflow including patient registration, scheduling visits, voice calling, and video calling[6]
- Software that provides parameters that become the input for software as a medical device is not software as a medical device if it does not have a medical purpose. For example, a database including search and query functions by itself or when used by Software as a Medical Device[6]

With no hardware involved, SaMD technology has been developing faster compared to medical devices "hardware", there are fewer constrains to innovation and with the ability to use fast feedback loops for improvement, SaMD has seen fast growth in recent years. Now SaMD software products serve various purposes, related to diagnosis, disease prevention, modernizing care, or treatment of an illness or injury.

Table 1: Medical software classification

NON-SaMD	SaMD				NON-SaMD
Universal software in a specific medical case, e.g.,: • Encrypting data for transmission from a medical device • Communication systems, enabling clinical communication and workflow (e.g., patient registration, visits scheduling, Laboratory Information Systems (LIS)) • Machines performing monitoring (e.g., signalling if an MD should be replaced) • Information systems, integrating and analyzing quality control data (e.g., in laboratories) • Home care monitoring, wired or mobile, applied to the results available, readable and understandable by the user without the intervention of the software • Generating import for SaMD (e.g., databases research and query functions)	**Type 1 – informs non-serious, serious conditions and drives non-serious conditions:** e.g., predictive apps, used to assess the overall health of a patient, heart rhythms, quality of sleep, reproductive cycle of women	**Type 2 – informs critical, drives serious and treats / diagnoses non-serious conditions:** e.g., an app, connected to a wrist detecting atrial fibrillation or myocardial ischemia, an app analyzing urea chemical composition for the detection of glucosuria	**Type 3 – drives critical and treats / diagnoses serious conditions** e.g., a software that can assess a rapid blood analysis and controls medication injectionsin the blood in the right moment	**Type 4 – treats / diagnoses critical condition:** e.g., AI – based app that can analyze mammo-graphy moles or histology images and determine a chance that a patient has cancer	**Software that is necessary for a proper functioning of medical devices:** Operating, modifying the state of, or controlling the device via an interface (e.g., software, hardware) or via the operator of this device Supplying output related to the functioning of that device
				IMPACT ON PATIENT	

Source: IQVIA analysis, www.imdrf.org.

SaMD opportunities and regulatory challenges

Among other factors leading to adoption of SaMD are automation of patient treatment and healthcare digitalization. In the recent past, usage of electronic health records (EHR) has led to creation of databases that connected healthcare across the globe, leading to various government actions aimed at encouraging hospitals to adopt EHR, boosting this trend even higher. Similarly, by driving automation and integrating with EHR, SaMD speeds up the detection, supervision and treatment of various medical conditions. Recognizing the importance of this trend, FDA together with IMDRF published the guidelines on regulations of the SaMD, promoting industry innovation, and usage of AI and ML with medical devices.[1,7–9]

SaMD'S KEY CHARACTERISTICS AND OPPORTUNITIES

The ability to collect and analyze large amounts of data quickly has enabled SaMD to open up the opportunity for fast diagnosis and better patient management which can lead to improved health outcomes through more accurate data, in addition to quicker production and fast feedback loops, which can support continuous innovation:

1. **Better health reports powered by data:** SaMD enables easy and fast collection of better-quality data, increasing the effectiveness and efficiency of medical devices and existing treatment plans
2. **Faster innovation and feedback:** SaMD enhances and builds on existing medical device functionality through fast software solutions, often cheaper to update than hardware. It also uses the latest technologies to share health data and integrate it across many platforms, including the smartphones, cloud, etc.
3. **Easy access to the user's feedback:** since SaMD can collect large amounts of data quickly. For organizations that are using or developing such software, this feedback loop can enable fast product iterations, shorten time to market, and drive fast innovation growth[7]

SaMD'S KEY REGULATORY CHALLENGES

Technological innovations in the field of medical software over the past years have led to substantial advancements in the field of digital health technology. However, in the highly regulated and safety-critical field of medical devices, there are certain challenges that come along with this digital transformation.

While SaMD's unique characteristics have led to better healthcare delivery and increased use in recent years, it also presented challenges to both developers and regulatory bodies related to how to integrate this ever changing technologies while at the same time ensure patient safety and regulatory compliance:

- SaMD can have frequent updates potentially changing safety and/or effectiveness of the software and Digital health manufacturers must also respond quickly to bugs, adverse events and other concerns which can result in continuous development and changes to the software
- A possibility to download the software via the internet presents a cyber security challenge to protect sensitive data, including intellectual property, financial data, and personal patient information
- Software as medical device makes patient sensitive data accessible over the internet. The challenge faced by regulators is how to align the safety of the data while maintaining the functionality and efficiency of the product
- The regulation of networked medical devices and mobile medical applications is also affected by compliance requirements. Network security, application security, Internet of Things security, and Data security are some elements of cyber security that help ensure coordinated compliance throughout entire information systems
- Artificial Intelligence allows for the enhancement of SaMD applications in image-based healthcare by continuously learning from the software's data. A regulator needs to know that there are no unintended consequences for the software's intended purpose when the software delivers the output

The challenge for regulators has been to adapt the rules to the constantly changing technology without hindering innovation and development while ensuring safety and effectiveness of these solutions. Consequently, it also presents a challenge for medical software providers who must meet compliance standards set by the EU, US, and other international regulatory requirements, for medical device software. As updates are released, companies using SaMD must continuously adhere to compliance standards set for digital health software.

Regulations of hardware-based medical devices do not fit the rapid, iterative nature of software, that's why recently the regulations regarding digital health solutions and medical software are changing in many areas of the world.

HOW ARE REGULATORS ADDRESSING THE CHALLENGES WITH SaMD

Given the unique characteristics of SaMD that are way different from any traditional medical device or hardware, regulators across the world recognized the need to converge on a common framework and principles for SaMD that enables all stakeholders, including regulators, to promote safe innovation and protect patient safety.

The major concern is how to ensure effectiveness and patient safety without limiting faster innovation growth. The International Medical Device Regulators Forum (IMDRF), a voluntary association of several medical device regulatory authorities, have developed a set of guidelines, including those for the categorization of SaMD, which aim to provide harmonization across regulatory bodies.

With the continued development and increased use of SaMD in everyday healthcare, the IMDRF, have divided SaMD into four categories, I – IV, based on their functionality and how they impact patient care (See Table 1). There are two dimensions through which SaMDs are characterized[10] :

1. **Information provided by SaMD**
    - To diagnose or treat patients
    - To inform clinical management
    - To drive clinical management
2. **Healthcare condition**
    - Critical condition
    - Serious condition
    - Non-serious condition

Building on the IMDRF guidelines, nearly a decade ago, the Food & Drug Administration (FDA) recognized the need to adapt to a changing technological landscape. Through its Software Pre-Certification Program, the FDA has begun laying the groundwork to promote faster innovation, without losing its stringent focus on patient safety.

The FDA has launched the Software Pre-Certification Pilot Program to test the safety and efficacy of pre-certifying software developers as a streamlined pathway for regulatory review.

The major concern is how to ensure effectiveness and patient safety when using SaMD without limiting innovation growth.

Pre-Certification Pilot program

Due to the tremendous potential of software (and in particular, SaMD) to increase both the quality and effectiveness of care, as well as the growth of general computing platforms and connectivity, there should be a certification process that could keep up with the speed of software innovation.

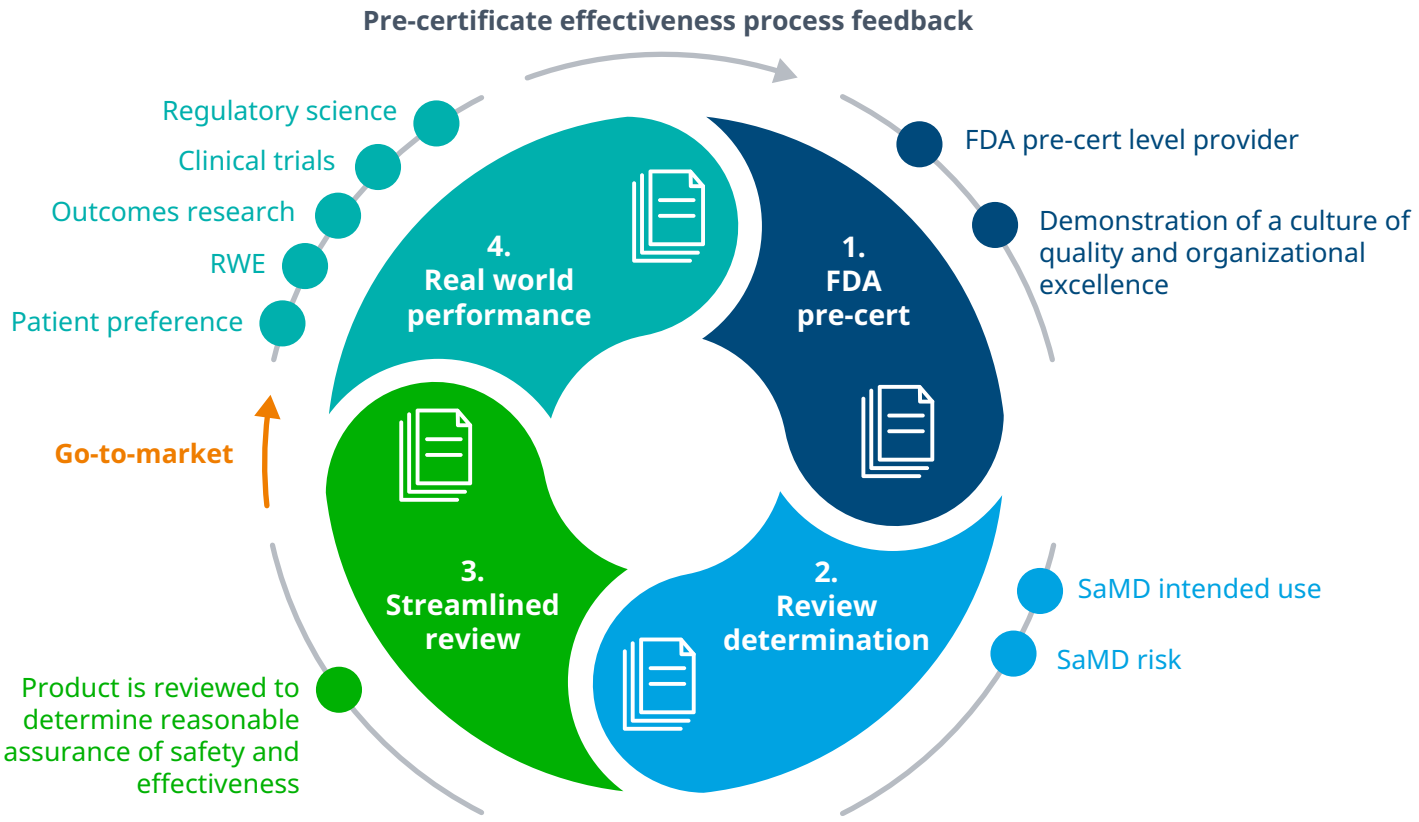
To adapt to the everchanging medical software solutions that are developing and upgrading through multiple iterations, the FDA developed its Software Pre-Certification Program. It includes a pre-certification of the SaMD developer first, rather than the product, lowering the burden of ongoing monitoring of these digital MedTech companies, reducing the content needed for submission and speeding up the review process.

The Pre-Cert program approach throughout the Total Product Life Cycle (TPLC) is aimed for the creation of an agile regulatory model that supports the faster innovation rate of software-based products, while still ensuring high standards of safety and efficacy.
The Software Pre-Cert Program aims to achieve this by certifying a company and its software products based on "Excellence Appraisal Elements"[11] :

- **Product quality:** Assessing the organization's documented quality metrics and models, particularly around mitigation of defects that affect device safety and effectiveness
- **Cybersecurity responsibility:** Assessing the organization's process to identify potential threats and vulnerabilities, communicate them, and develop countermeasures
- **Patient safety:** Verifying device compliance and established quality and risk management processes
- **Proactive culture:** Verifying quality data collection and analysis for qualitative and quantitative reporting
- **Clinical responsibility:** Understanding the clinical staff's role in an organization and learning about the interrelationships and communication between data elements, testing, reporting, and external linked devices/software (interoperability)

Once a company is certified, it can go through multiple product iterations without having to undergo the entire certification process again, and can instead participate in "streamlined reviews" as long as the product is determined to be low-risk.

Figure 1: Pre-certification Program TPLC approach



Source: IQVIA analysis, www.fda.gov.

The software pre-cert program has 4 main components:

1. **Excellence Appraisal:** Adherence to the 5 excellence principles iagnose or treat patients
2. **Review Determination:** Risk classification
3. **Streamlined Review:** Accelerated review process
4. **Real-World Performance:** Post-market product evaluation (See Figure 1)

In 2017, the FDA selected nine companies to participate in its Pre-Cert Pilot Program:

- Big players in tech (Apple, Samsung and FitBit)
- Traditional large, multiline medical device firms (Johnson & Johnson, Roche)
- Digital therapeutic companies (Pear Therapeutics, Phosphorus, Verily)
- Not-for-profit startup Tidepool, developing free software for the diabetes community

The Pre-Cert Pilot was completed in September 2022. This Pilot was fundamental in the development of a new adaptive regulatory approach. The FDA has concluded that there is a high necessity in a legislative change in order to regulate and accelerate the development of the fast-developing Med-Tech technologies.[7]

Similarly, many European countries have adopted or in the development stages of more streamlined regulations for digital healthcare, e.g., the DiGA fast track in Germany (will be explored in detail in Part 2). This is to ease market access for digital healthcare entrepreneurs and support early access for patients into new development in healthcare while ensuring safe and effective delivery.

It's well known that the regulatory processes around SaMD are evolving globally, same as with medical device regulations that largely depend on the country. This is why we believe that it's important for manufacturers aiming to access the European market: 1. to understand the regulatory landscape in Europe, how is it different from the U.S, and what to expect when coming into the market; 2. to examine the specific definitions and regulations regarding SaMD in Europe. This is what we discuss in detail in Part 2 of this series.

Artificial Intelligence (AI) and Machine Learning (ML) in SaMD

Another important aspect of software growth in healthcare is the rising use of Artificial Intelligence and Machine Learning (AI/ML). The ability to learn and improve themselves over time and to adapt their performance as they collect and analyse real-world data about their past performance presents new challenges regarding regulating, classification and monitoring of these types of software.

Artificial intelligence (AI) and machine learning (ML) based technologies have the potential to transform healthcare by deriving new and important insights from the vast amount of data generated during the delivery of healthcare on an everyday basis. One of the greatest benefits of AI/ML in software is its ability to learn from the real-world use-cases and experience, and its capability to improve its performance. These technologies uniquely situated among software as a medical device (SaMD) and presents a challenge to regulatory bodies.[12]

The ability of AI/ML software to train on the real-world data and improve its performance makes it uniquely situated among SaMD.

The FDA has published a list of nearly 350 AI/ML-enabled medical devices that have received regulatory approval since 1997.[8] According to The Lancet Digital Health publication in 2021 there are 240 AI/ML medical devices approved in Europe.[13] And while the use-cases and companies developing such technologies have been increasing rapidly, regulatory bodies, such as the FDA and the European Medicine Agency (EMA), have tried to tackle its regulation and implementation.

REGULATORY ADAPTATIONS AROUND AI AND SaMD USING AI

AI is a powerful, yet difficult to control, tool that can lead to a big potential benefit as well as harm to the patients. Globally, the transformative power of AI is starting to be acknowledged, however, it is difficult to make regulatory rules around AI in medicine in the same way as to other medical devices.

Both of the US and the EU recognize the importance of AI / ML in healthcare development, to transform healthcare. Regulatory bodies have been trying to approach the regulatory side for AI in the best possible way. There are, however, several difficulties as the regulatory systems are not designed to such an adaptive and unpredictable technology.

The level of unpredictability of AI is driven by the non-exhaustive list of the next factors:

- **Adaptability:** AI is an adaptive system, changing in time, meaning if the regulations are in place they should be applied to both: the initial state and the final state of the system, after AI and ML were applied
- **Trust:** AI may lead a device or a course of treatment in the direction that is difficult to predict; there should be a regulatory consideration for the decision-making algorithms, provider consideration of the safety and efficacy validation and patient consideration of the adverse effects, benefits, minimized complexity and easy-to-understand logic
- **Usability:** both, guidelines, approval process and reimbursement depend largely on the intended use case of the enabled device, not on the software alone
- **Accountability:** in some cases, it may be hard to assign accountability. This can be overcome by the controlled access, education on the logic behind the algorithms, usability of the device
- **Equity:** as the training selection group for AI largely influence the consecutive decisions made by AI, the training group should account for gender, race, age, income, etc.

To face such challenges, both the United States and EU introduce the possibility of predetermining changes to AI and their performance at the initial authorization step.

THE FDA PROPOSED REGULATORY FRAMEWORK FOR AI/ML BASED SaMD

In April 2019 the FDA published a discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback" that describes the FDA's foundation for a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications.[12]

The new Proposed Regulatory Framework is closely related to:

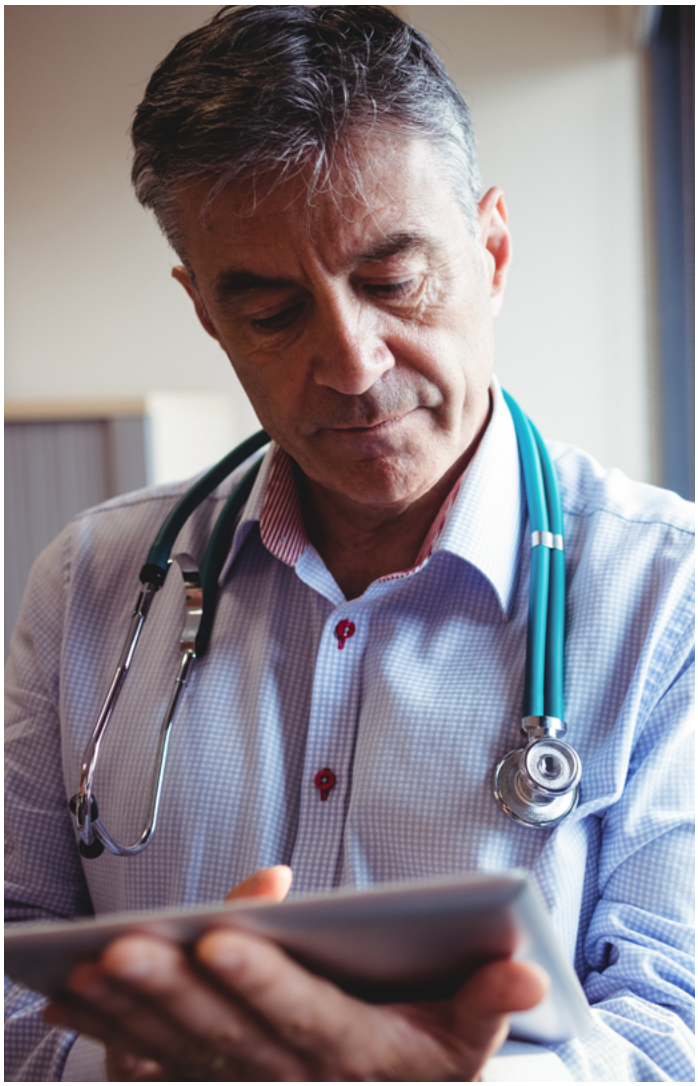
- The current US digital health regulatory pathways (e.g., the premarket programs)
- IMDRF's risk categorization principles for SaMDs
- The FDA's benefit-risk framework, risk management principles described in the software modifications guidance, and the organization-based total product lifecycle approach (also envisioned in the Digital Health Software Precertification (Pre-Cert) Program)[9]

In this protocol the FDA[12] foresees a "predetermined change control plan" in premarket submissions. This plan would include 1. the types of anticipated adjustments, or "Software as a Medical Device Pre-Specifications" and 2. the approach used to implement those changes in a controlled manner to minimize the risks for patients, or "Algorithm Change Protocol."

For this potential approach to work, certain commitments from manufacturers to FDA will be necessary:

- Transparency and real-world performance monitoring for AI- and ML-based SaMD
- Periodic updates on what changes were implemented as part of the approved "Pre-specifications" and the "Algorithm change protocol"

Such a close interaction within the regulatory framework could enable evaluation and monitoring of novel software products from its premarket development to post-market performance, as well for the FDA to control the iterative improvement power of AI- and ML-based SaMD, protecting patient safety.



ARTIFICIAL INTELLIGENCE ACT IN THE EU

Following in the footsteps of the US, in April 2021 the European Commission introduced first complex regulatory framework for artificial intelligence - The proposal for a regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act, AIA), which sets forth harmonized rules for the placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the European Union.[14]

Under the European regime, and similar to the FDA framework, the establishment of a quality management system is also mandatory. Manufacturers would be required to document, among other things, their strategy for managing modifications in their AI systems, techniques for quality control or testing, and validation procedures.[15]

This system shall actively and systemically collect, document and analyze relevant data provided by users or collected through other sources on the performance of AI systems throughout their lifetime, with the goal that the possible risks emerging from AI system can be addressed more efficiently. Furthermore, AI systems have to perform consistently throughout their lifecycle and meet an appropriate level of accuracy and robustness in accordance with the acknowledged state of the art.

The Artificial Intelligence Act draft combines a risk-based approach based on the pyramid of criticality, with a modern, layered enforcement mechanism. This means that a lighter legal regime applies to AI applications with a negligible risk, and that applications with an unacceptable risk are banned. Stricter regulations apply as risk increases, ranging from soft non-binding self-regulatory assessments accompanied by codes of conduct to heavy, externally audited, compliance requirements throughout the life cycle of the application.[16]

Conclusions

Challenges exist for healthcare innovators to best demonstrate solution impacts and to ensure compliance with standards, including uncertainty .. and keeping up to date with the evolving compliance landscapes.

The SaMD regulatory landscape is likely to continue evolving, as part of wider evolution in the regulation of medical devices. And the rapidly evolving nature of SaMD represents challenges for both providers as well as policy makers.

In this Part 1 of the publication series on SaMD, we equip the reader with the knowledge on how to define the new software, whether it can be called SaMD or not, what opportunities for the healthcare SaMD unravels. In addition we shed light onto the regulatory challenges present to the regulatory bodies related to ever-changing and adapting qualities of SaMD, especially AI and ML-based. We explain the solutions found in US and Europe to overcome these challenges. This is through the Pre-Certification programs, which are built on the mutual cooperation and data evaluation of the performance of the SaMD as well as its post-market access follow-up.

In addition, we are outlining the regulatory adaptations to the AI- and ML-based SaMD and proposed regulatory frameworks in US and Europe.

We believe that it's important for medical software providers to explore related regulatory pathways and how it's different form one part of the world to another. It's vital to explore the current reimbursement routes as well as reimbursement maturity for digital health solutions (DHS) in the different European markets, to be able to develop a winning market access strategy and to achieve funding, which can lead to successful launch and wide uptake of their products by healthcare providers as well as patients.

Parts 2 and 3 of this series will explore in detail the regulatory landscape of SaMD in Europe. We cover medical device software regulations under the EU MDR and the EU IVD how is it different from the SaMD definition and we also highlight the key challenges for market entry of digital health solutions into the European markets. We highlight the current reimbursement pathways for SaMD solutions in Europe e.g. the DiGA fast track in Germany, level of reimbursement process maturity within the different European markets and how reimbursement is expected to develop in the coming years in countries such as the UK and France.

The SaMD regulatory landscape is likely to continue evolving, as a part of wider evolution in the regulation of medical devices.

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Huda is a MedTech consultant who oversees management and insights generation of diverse MedTech studies across various therapeutic areas and geographies.

As a part of the Business Development unit, she drives proposal preparation work as well as play a role in thought leadership activities. She is also the liaison toward the Clinical and Real-World evidence activities, working together to generate business opportunities.

Huda holds a bachelorette degree in Biomedical engineering from Cairo university, which makes her well positioned in execution of MedTech studies as well as exploring innovation in new areas of the MedTech industry.

DR. ANASTASIA CHERNYATINA

Senior Consultant
IQVIA MedTech

Anastasia is a Senior Consultant at IQVIA MedTech Device practice, responsible for projects delivery and business development globally.

Using her experience in both fields, scientific research in molecular biology and business consulting, she helped clients with various types of projects: market landscaping, voice-of-customer, go-to-market and partnership strategies, due diligence, M&S, Lean business transformation.

Anastasia holds a doctorate from the KULeuven in Belgium and is an author of scientific publications.

JAN PIELAT

Business Analyst
IQVIA MedTech

Jan is a business analyst in IQVIA Global MedTech Device Consulting team and specializes in data analysis, innovations creation, secondary research, and market assessments.

Having background in economics, he contributed to top-down and bottom-up market sizing in various areas from diabetes care to ECLS pumps, market prioritizations for international expansions of innovative products.

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