Congenius

Congenius Whitepaper

How to develop SaMD | 10 steps

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What is SaMD?

As health care advances, software has become integrated widely into digital ecosystems that serve both medical and non-medical purposes.

There are three types of software utilised within medical devices:

1. Software **as** a Medical Device (SaMD): Software which **is a medical device**
2. Software **in** a medical device: Software which **is integrated into a medical device**
3. Software used in the **manufacture or maintenance of a medical device**

This whitepaper focusses on type 1 - SaMD.

Step 1 | Determine whether your Health Software is SaMD

The International Medical Device Regulators Forum (IMDRF) defines Software as a Medical Device (SaMD) as:

> *"Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."*

In contrast, software that is driving or influencing the use of a medical device is Software **in** a Medical Device (SiMD) and is covered by the regulations either as a part/component of a device or as an accessory for a medical device. We will not cover SiMD or supporting software in this paper.

Here are some useful notes to help with clarification of the IMDRF definition:

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical devices
- SaMD can run on general purpose (non-medical purpose) computing platforms
- "…without being part of" means software that does not need 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 (accessory to a 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 also considered SaMD

Put plainly, think of SaMD as software which is a medical device on its own. For instance, the medical software used to view images from diagnostic equipment on your phone would be SaMD. But the software that enables the diagnostic to run its test would not be. To be considered SaMD, software must not principally drive a hardware device.

Sources:
IMDRF: Software as a Medical Device (SaMD): Key Definitions

Step 1 | Determine whether your Health Software is SaMD

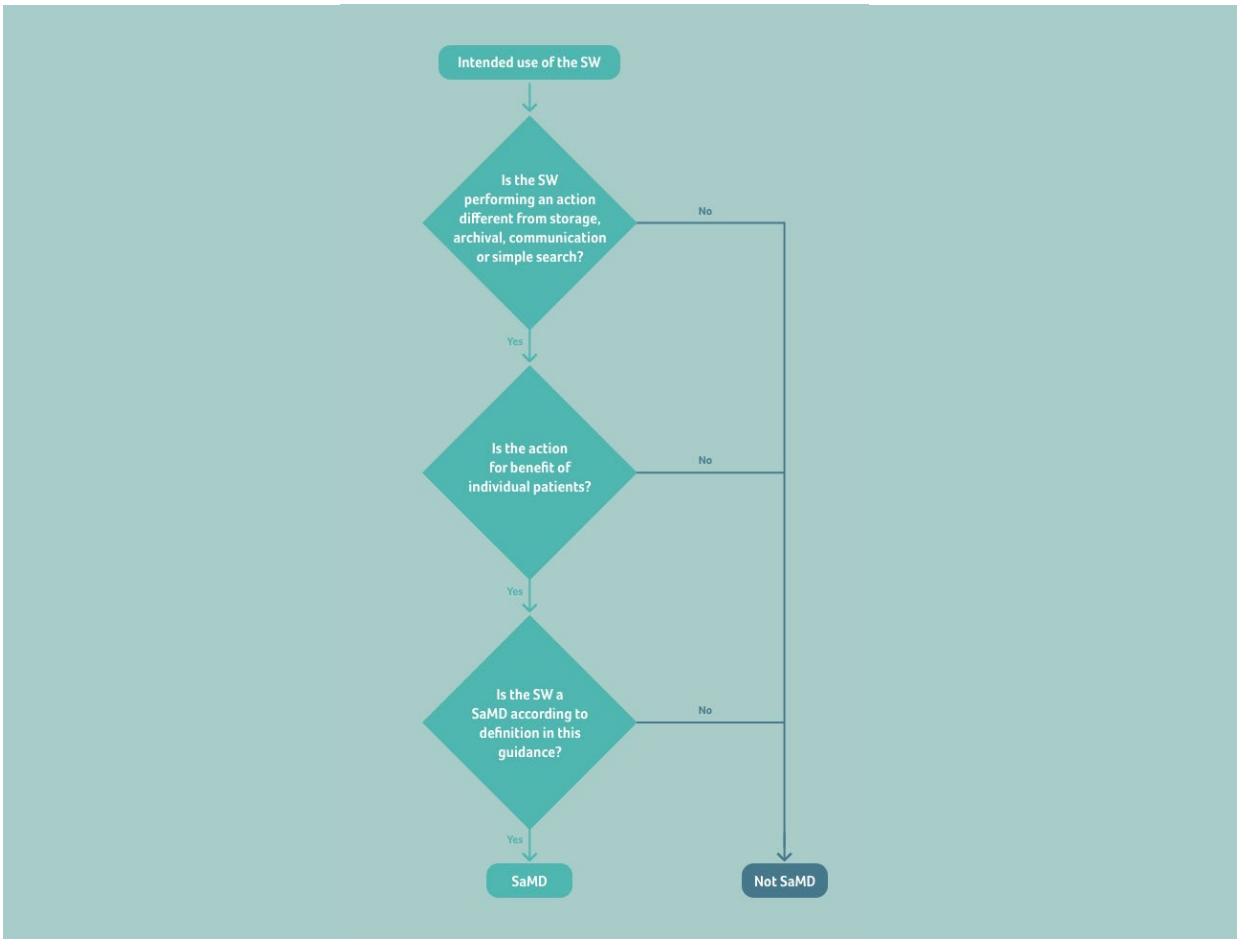
Should my software be classified as a Medical Device?

Software which is intended to process, analyse, create, or modify medical information is qualified as **medical device software,** if the creation or modification of that information is governed by a medical intended purpose.

The software which alters the representation of data for a medical purpose would qualify as a medical device software, e.g., software that searches an image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy, or software which locally amplifies the contrast of the finding on an image display so that it serves as a decision support or suggests an action to be taken by the user.

However, altering the representation of data for embellishment/cosmetic or compatibility purposes does not readily qualify the software as medical device software.

Furthermore, software intended for non-medical purposes, such as invoicing or staff planning, does not qualify as a medical device software.



Sources:
FDA: Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act
EU: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745

Step 1 | Determine whether your Health Software is SaMD

My software isn't SaMD, what do I do now?

Where a given product does not fall under the definition of SaMD or is excluded by the scope of the applicable Regulations, other Community and/or national legislation may be applicable. In any case, it is recommended that best practice software development is followed suitable to the risk the software would pose should it fail.

My software is SaMD – what next?

For the EU, you need to classify your SaMD according to MDR 2017/745:

Rule 11 of Annex VIII was introduced into the MDR and is intended to address the risks related to the information provided by an active device, such as SaMD. Rule 11 describes and categorises the significance of the information provided by the active device *(as software is defined as an active device)* to the healthcare decision *(patient management)* in combination with the healthcare situation *(patient condition)*.

For the US, you must classify your SaMD according to IMDRF (FDA) Guidance:

In 2013, IMDRF formed the Software as a Medical Device Working Group (WG) to develop guidance supporting innovation and timely access to safe and effective Software as a Medical Device globally. Chaired by the FDA, the Software as a Medical Device WG agreed upon the framework for risk categorization and subsequent classification for Software as a Medical Devices.

Sources:
EU: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
IMDRF (FDA): Framework for risk categorization for Software as a Medical Device

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If you would like to access the full whitepaper, or have a challenge that you think our team could help with, simply get in touch via our website form.

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