



# Software as a Medical Device (SaMD)

## **Background**

The term Software as a Medical Device (SaMD) is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." IMDRF further defines "medical purpose" in the context of SaMD as:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body

SaMD are regulated by the Food and Drug Administration (FDA) and require IRB oversight.

## **Important notes on SaMD:**

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical devices.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms.
- In the definition of SaMD above, "without being part of" means software 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 applications that meet the definition above are considered SaMD.

## **Does your project meet the requirements for SaMD?**

To aid in determining if a project meets the requirements for SaMD, use this checklist:

1. The project uses software.  Yes  No
2. The software is being used for a medical purpose (check any that apply). If you select any of the boxes below, the answer to this statement will be "Yes":
  - Cure, treat, diagnose, mitigate, alleviate, prevent, detect, inform, monitor disease
  - Investigate, replace, modify physiological process
  - Aid in treatment or diagnoses (e.g., used as an aid to make a definitive diagnosis)
  - Used to triage or identify early signs of a disease or condition
  - Guide next diagnostics or next treatment interventions
  - Inform of options for treating, diagnosing, preventing, or mitigating a disease or condition
  - Provide clinical information by aggregating relevant information

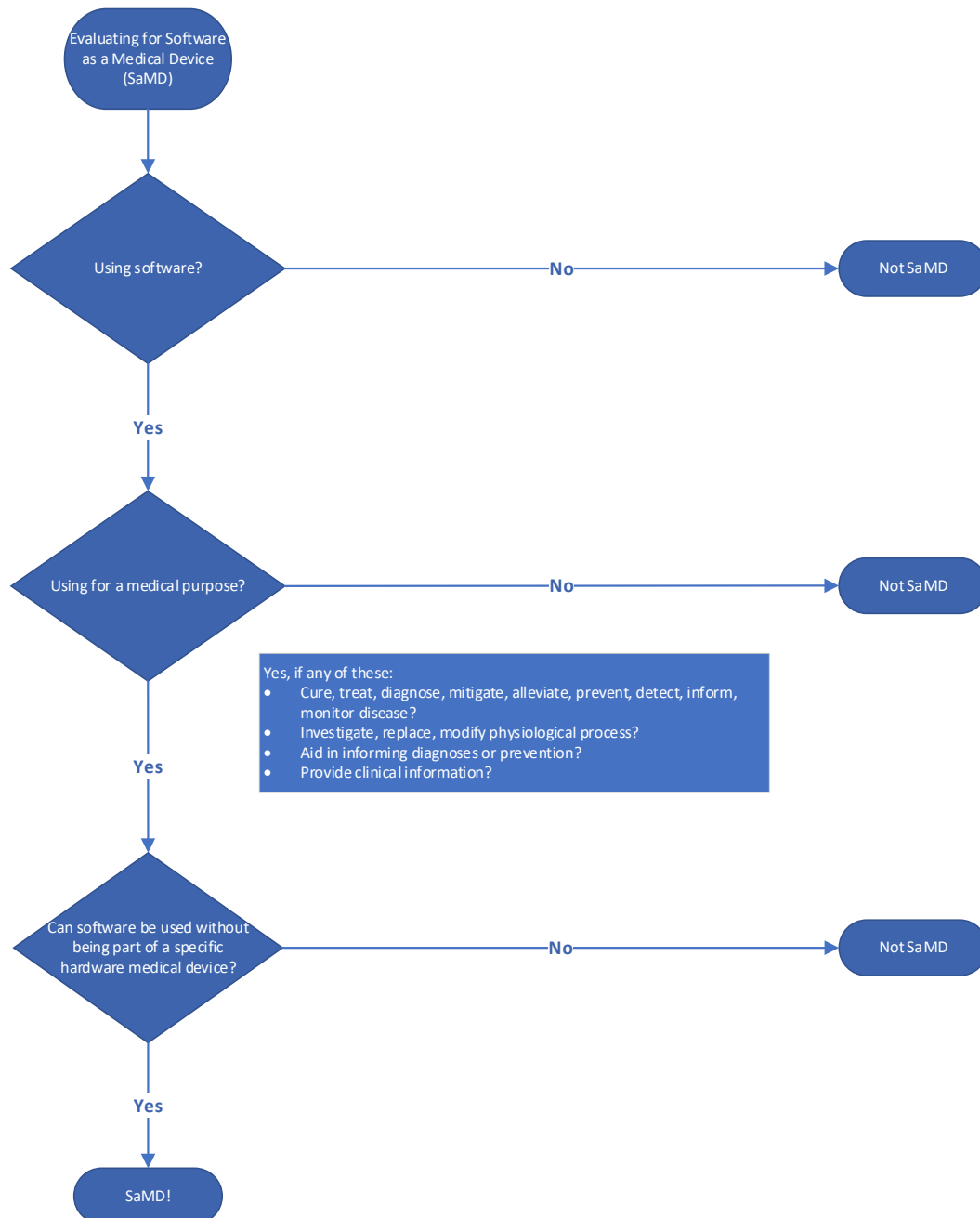


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3. The software can be used without being part of a specific hardware medical device.  Yes  No

If 1, 2, and 3 are all “Yes,” your project uses SaMD. If your project uses SaMD, submit the [Appendix for Devices](#) with your IRB application materials. The IRB will also need to review the device manual. If one does not exist, please provide a one-page document clearly explaining the device along with its purpose, description, risks, etc.

## SaMD Decision Tree





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## **Examples of Software that ARE SaMD**

“I am conducting a research study. I am testing whether subjects can use a mobile app to self-assess hearing loss. The mobile app uses hearing sensitivity, speech in noise, and answers to a questionnaire about common listening situations.”

*Did you know that this study is considered a medical device study, and is subject to FDA regulations?*

This example is considered a SaMD because it **provides clinical information** even though it will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

## **Other Examples:**

- SaMD that performs analysis of cerebrospinal fluid spectroscopy data to **diagnose** tuberculosis meningitis or viral meningitis in children.
- SaMD that uses the microphone of a smart device to **detect interrupted breathing** during sleep and sounds a tone to rouse the sleeper.
- SaMD that analyzes heart rate data intended for a clinician as an **aid in diagnosis** of arrhythmia.
- SaMD intended for use by elderly patients with multiple chronic conditions that receives data from wearable health sensors, transmits data to the monitoring server, and **identifies higher-level information** such as tachycardia and signs of respiratory infections based on established medical knowledge and communicates this information to caregivers.
- SaMD that collects data from peak-flow meter and symptom diaries to **provide information** to anticipate an occurrence of an asthma episode.

## **Examples of Software that are NOT Medical Devices**

- Software functions that are intended to provide access to electronic “copies” (e.g., e-books, audio books) of medical textbooks.
- Software functions that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received.
- Software functions that are intended for general patient education and facilitate patient access to commonly used reference information.
- Software functions that automate general office operations in a health care setting (e.g., analyze insurance claims for fraud or abuse).

## **Additional Resources Regarding SaMD**

- FDA: [Software as a Medical Device \(SaMD\)](#)
- FDA Guidance: [SaMD: Clinical Evaluation](#)
- FDA: [What are examples of Software as a Medical Device?](#)
- FDA: [International Medical Device Regulators Forum \(IMDRF\)](#)
- IMDRF Technical Document: [SaMD: Key Definitions](#)



## Software as a Medical Device (SaMD)

- IMDRF Technical Document: [SaMD: Possible Framework for Risk Categorization and Corresponding Considerations](#)
- IMDRF Technical Document: [SaMD: Application of Quality Management System](#)