Regulation of SaMD in Japan

Pharmaceuticals and Medical Devices Agency
Office of Software as a Medical Device

Kazuhisa Koike

Outline

1. Regulation of SaMD in Japan

2. How to review SaMD in Japan

Definition of Medical Device (MD)

- International Medical Device Regulators Forum (IMDRF)
  - Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for vitro use, software, material or other similar or related article
    - ✓ intended by the manufacture to be used, alone or in combination, for human beings, for one or more of the specific medical purposes.

- Pharmaceutical and Medical Device Act (PMD Act) in Japan
  - Medical devices are instruments/apparatuses
    - ✓ intended for use in the diagnosis, treatment or prevention of disease in humans or animals

      or
    - ✓ intended to affect the bodily structures and functions of humans or animals.

Medical Device Classification and Regulation

MDs are classified into 4 categories (Class I to IV) according to risk level

Pre-market regulatory process for MDs differs depending on the classification

Risk Level	Low → High			
International Classification	Class I	Class II	Class III	Class IV
Classification under PMD Act	General Medical Devices	Controlled Medical Devices	Specially Controlled Medical Device	
Regulation	Notification to MHLW	Certification by registered certification bodies	Approval by the Minister of MHLW (based on scientific review by PMDA)	
Specific Description	Devices that may pose an extremely low risk to the human body in case of a malfunction Examples: ● In vitro diagnostic devices ● Steel made small devices (including a scalpel, tweezers) ● X-ray film ● Devices for dental technique	Devices that may pose a relatively low risk to the human body in case of a malfunction Examples: ● MRI system ● Electronic endoscope ● Ultrasonic system ● Dental alloy	Devices that may pose a relatively high risk to the human body in case of a malfunction Examples: ● Dialyzer ● Bone prosthesis ● Automated external defibrillator (AED) ● Mechanical ventilator	Devices that are highly invasive and thus may pose a life-threatening risk in case of a malfunction Example: ● Pacemaker ● Artificial cardiac valve ● Artificial breast ● Stent graft

* Classes I – IV correspond to GHTF categories (Class A – D)

What is SaMD

Definition of SaMD

IMDRF Document Title;
Software as a Medical Device: Key Definitions

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.


IMDRF/SaMD WG/N10FINAL:2013

IMDRF International Medical Device Regulators Forum

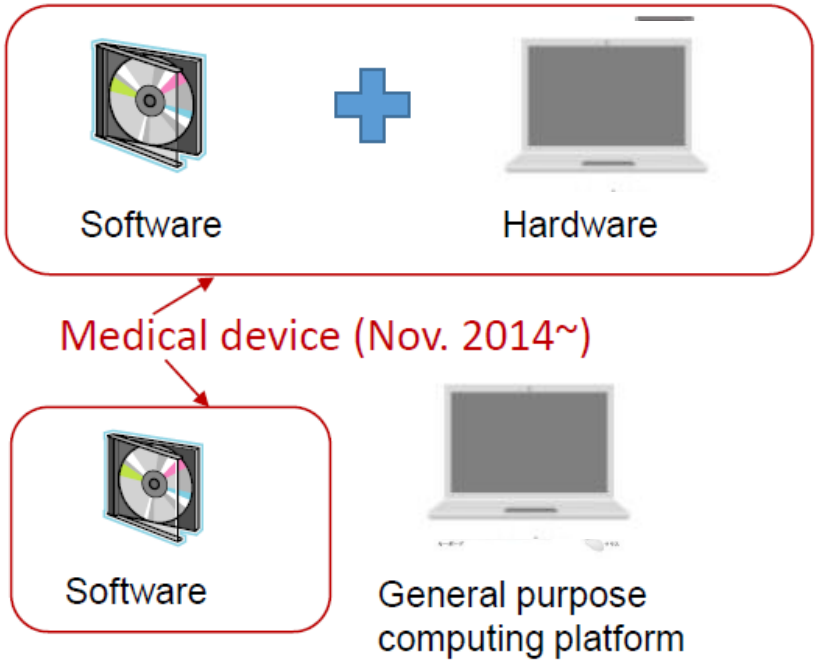
Final Document

Title:	Software as a Medical Device (SaMD): Key Definitions
Authoring Group:	IMDRF SaMD Working Group
Date:	9 December 2013

SaMD in Japan

Software products that have the intended purpose as a medical device such as contributing to the diagnosis, treatment, or prevention of diseases include the following:

- Those which are used in combination with tangible medical devices
- Those which are installed in general-purpose personal computers such as desktop personal computers or personal digital assistants such as smartphones



SaMD Classification and Regulation

Software products corresponding to class I are not regulated under PMD Act.

Risk Level	Low → High			
International Classification	Class I	Class II	Class III	Class IV
Classification under PMD Act		Controlled Medical Devices	Specially Controlled Medical Device	
Regulation		Certification by registered certification bodies	Approval by the Minister of MHLW (based on scientific review by PMDA)	
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DASH for SaMD

DASH for SaMD 2（2023/9/6）

- Organize and publicize the two-step approval scheme for SaMD
- Develop guidelines for approval review and marketing procedures for SaMD for the general public
- Promotion of overseas acceptance of our review results (such as English translation of review reports)
- Subsidies for development funds for SaMD developers
- Support for SaMD developers to actively business overseas

DASH for SaMD（2020/11/24）

- Setup an office to review SaMD in MHLW and PMDA
- Establishment of SaMD centralized consultation service
- Next-generation medical device evaluation index, development guidance, audit points, and certification criteria formulation
- Trial implementation of priority review, etc. for innovative SaMD
- Promote the use of IDATEN (Improvement Design within Approval for Timely Evaluation and Notice) and streamline procedures, etc.

<Expand and continue>

- Upgrade from office to Department for reviewing SaMD in PMDA
- Establishment of SaMD-specific consultation service
- (Continue)
- (Continue)
- (Continue)

Review point for;

- Software for Peritoneal Dialysis Treatment
- Supporting Software for Dental Implant Treatment
- Software for Ophthalmic Surgery Treatment Planning
- Supporting Software for Detecting Lesion with Endoscopic Imaging
- Computer-Aided Diagnosis Program to Support Interpretation of Medical Images

DASH for SaMD: DX(Digital Transformation)Action Strategies in Healthcare for SaMD(Software as a Medical Device)

New Consultation for SaMD

Comprehensive consultation for SaMD

Determine whether the product is MD or non-MD

MHLW, Compliance and Narcotics Division

Consultation regarding the determination of whether or not software under development is classified as a medical device under the PMDA Act.

Review the developed product

PMDA, Office of SaMD

Pre-consultation before each consultation (pre-development consultation, clinical trial protocol consultation, etc.) conducted by PMDA.

Consult the reimbursement prices

Various consultations regarding medical insurance.

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Review of Software Products

In principle, it is not different from the review of hardware medical devices.

Concept of development

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Intended use of SaMD

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Non-clinical evaluation
- Performance
- Safety

Clinical evaluation
- Clinical trials
- Literature investigation

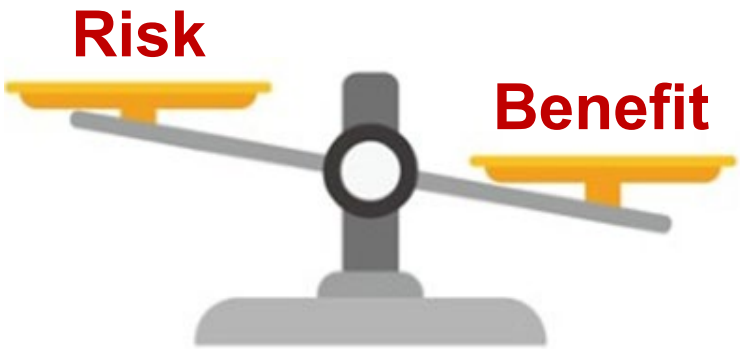
Essential principle

General review points

To understand the concepts, intended use and claim of the product.

To assess whether the benefits outweigh the risks based on the following information:

- Data supporting its clinical performance and safety
- Clinical evaluation



Reasons of Approval Rejection

(a) The given device is judged that it does **NOT** have its own effectiveness and/or performance as to be concerned in the application.

(b) The given device is judged of **NO** value for medical use because its adverse effect(s) far exceed its effectiveness and/or performance.

PMD Act, Article 23-2-5 paragraph (2), item (iii), (a) & (b)

Checking Role of SaMD is important

What kind of issues in clinical practice were you trying to solve?
What kind of "medical devices" are you trying to evaluate?

Development concept

What is the role of SaMD in clinical practice?
What kind of clinical needs were you trying to meet?

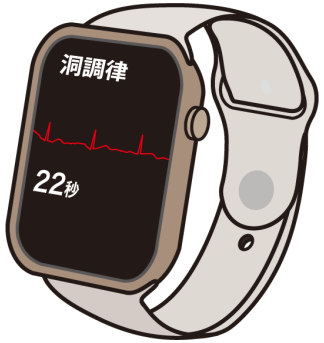
Design concept

What kind of product specifications were realized in order to achieve the development concept?

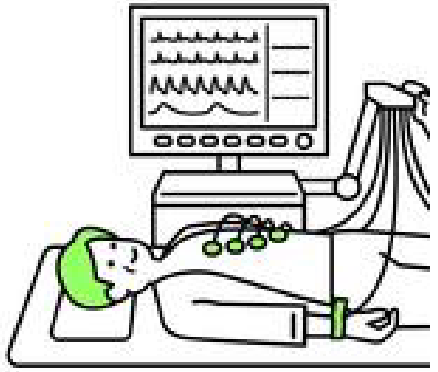
Role of SaMD

Examples of the matters which determine the role of SaMD (or medical devices) in clinical practice

- What kind of medical practice is the medical device used for ?
- What is the indication of the medical device ?
- What does the medical device bring to the patients ?



・People who have not been diagnosed yet.
・Detect the possibility of atrial fibrillation and recommend a clinical consultation.



・Patients in hospital
・Detect arrhythmias that are immediately dangerous and give alerts.

What to Evaluate Based on Role of SaMD

What is "concept of development"?

Clinical utility

Contribute to clinical outcome

e.g.
Evaluate whether CAD can improve reader performance:
- Reading with CAD
- Reading without CAD

Clinical performance

Perform appropriately for clinical data

e.g.
Evaluate the sensitivity and specificity for clinical image data

What is "concept of design"?

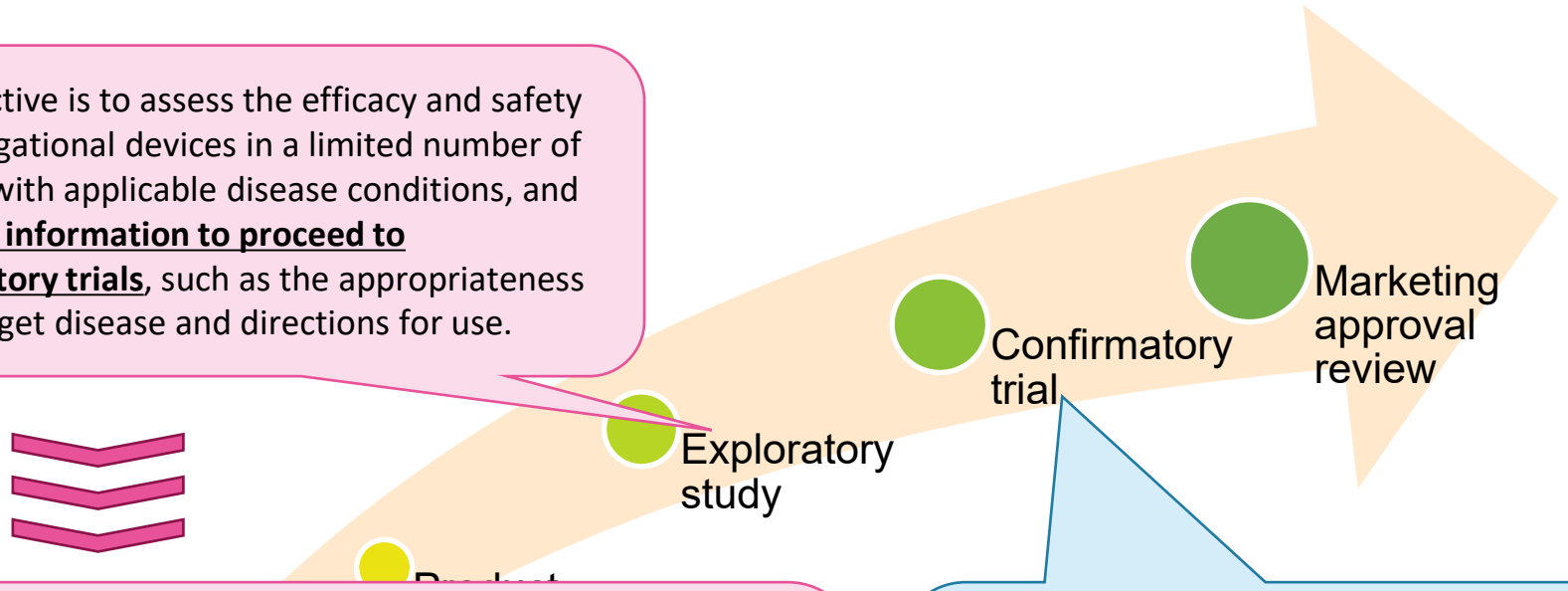
Basic Performance

Verify to work appropriately as designed

e.g.
Conduct the bench test for the verification of implemented functions

2 step Approval Based on the Characteristics of SaMD

The objective is to assess the efficacy and safety of investigational devices in a limited number of patients with applicable disease conditions, and to **gather information to proceed to confirmatory trials**, such as the appropriateness of the target disease and directions for use.



- Exploratory studies are conducted to inform the design of confirmatory trials, and the sufficiency of these exploratory studies depends on the nature of the confirmatory trials.
- The primary objective of the Stage 1 Approval is not to demonstrate expected outcomes for the approval, but rather, to **approve findings, if any, based on the collected information required for conducting a confirmatory trial.**

The purpose is to objectively and precisely clarify the efficacy and safety of the investigational device for the target disease, and to assess and position its clinical usefulness for target diseases of the investigational devices.

Thank you/Questions