

# Japan's Regulatory Updates

30 November, 2023  
27<sup>th</sup> GHWP Annual Meeting

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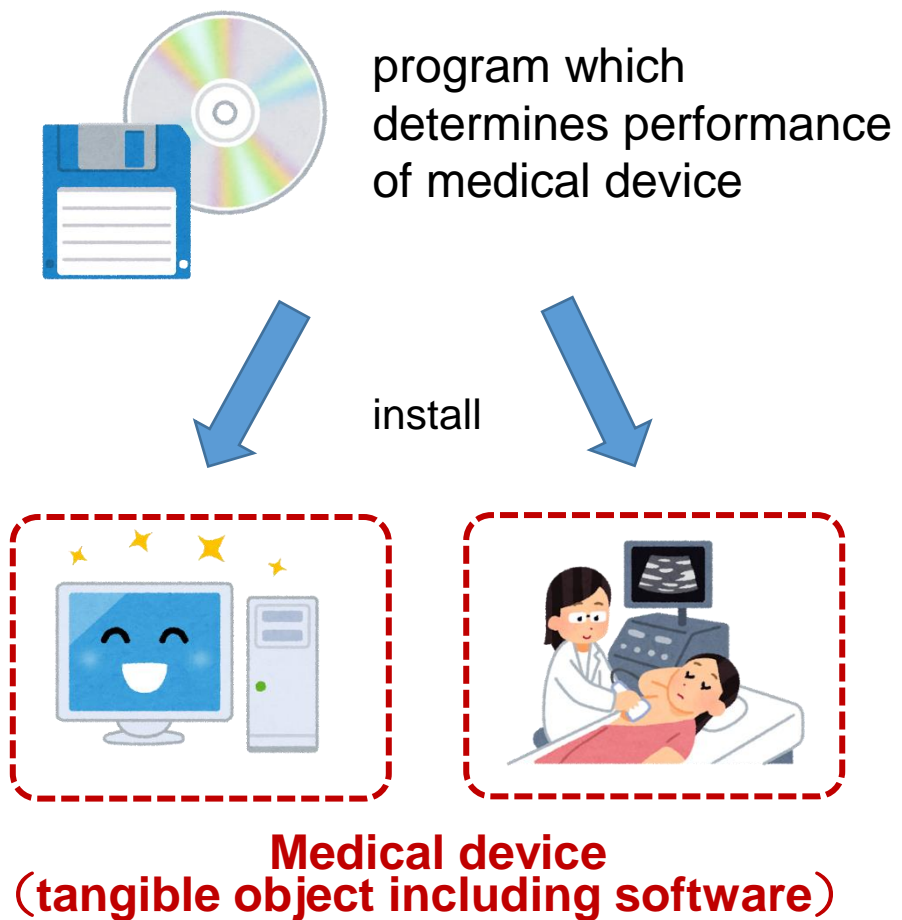
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

# Overview (Update for SaMD regulations in Japan)

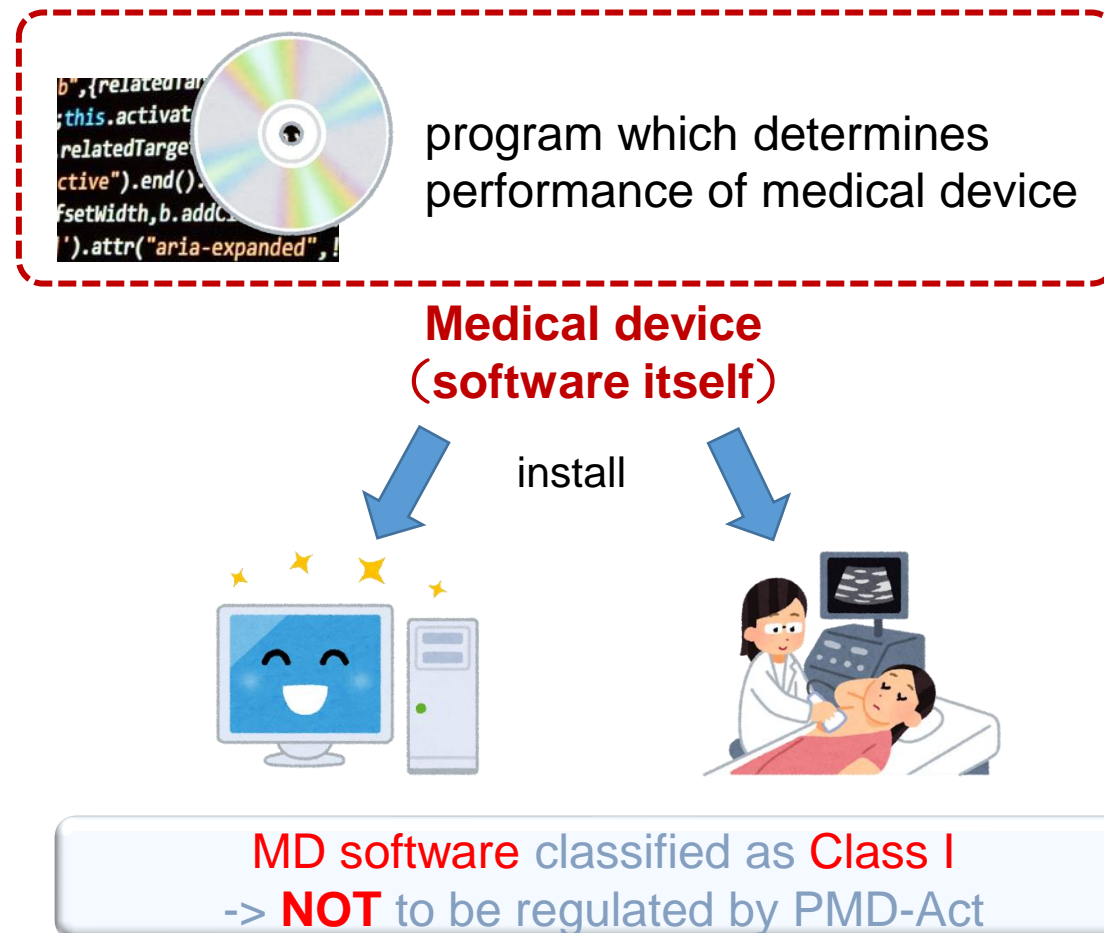
- ❑ Transition of regulations for SaMD in Japan
- ❑ Toward Further Practical Application and International Development of SaMD in Japan
- ❑ Contents of “DASH for SaMD 2”
- ❑ Development status of SaMD in Japan
- ❑ Two-step Approval scheme for SaMD

# Transition of regulations for SaMD in Japan

before November 2014



after November 2014



# Toward Further Practical Application and International Development of SaMD in Japan

- **High expectations: utilization of SaMD** (Software as a Medical Device)

- ➔ Need to make direction: efficient development of SaMD

- (A new field for all stakeholders in Japan)

- November 24, 2020

- MHLW: - **“DASH for SaMD”** (Package Strategy for Accelerating the Commercialization of SaMD)

- Established Institutional infrastructure

- (efficiently obtain an approval under the PMD Act)

# Toward Further Practical Application and International Development of SaMD in Japan

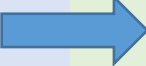
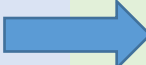

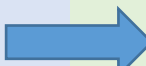
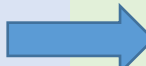
- Need to explore further
  - ✓ Clarify various paths to commercialization  
(two-step approval scheme for SaMD, SaMD for the general public)
    - Cooperation bw regulatory / insurance authorities to ensure predictability  
(approval to insurance)
  - ✓ Accelerate R&D of Japan-originated SaMD, promote expansion into int'l markets
- MHLW: Launched a new strategy **“DASH for SaMD 2”** (September 6, 2023)  
for the next five years

## DASH for SaMD 2 (6 Sep., 2023)

- ◆ 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** (ex English translation of review reports)
- ◆ **Subsidies for development funds** for SaMD developers
- ◆ **Support for SaMD developers** to actively business overseas

## DASH for SaMD (24 Nov., 2020)

<Expand and continue>

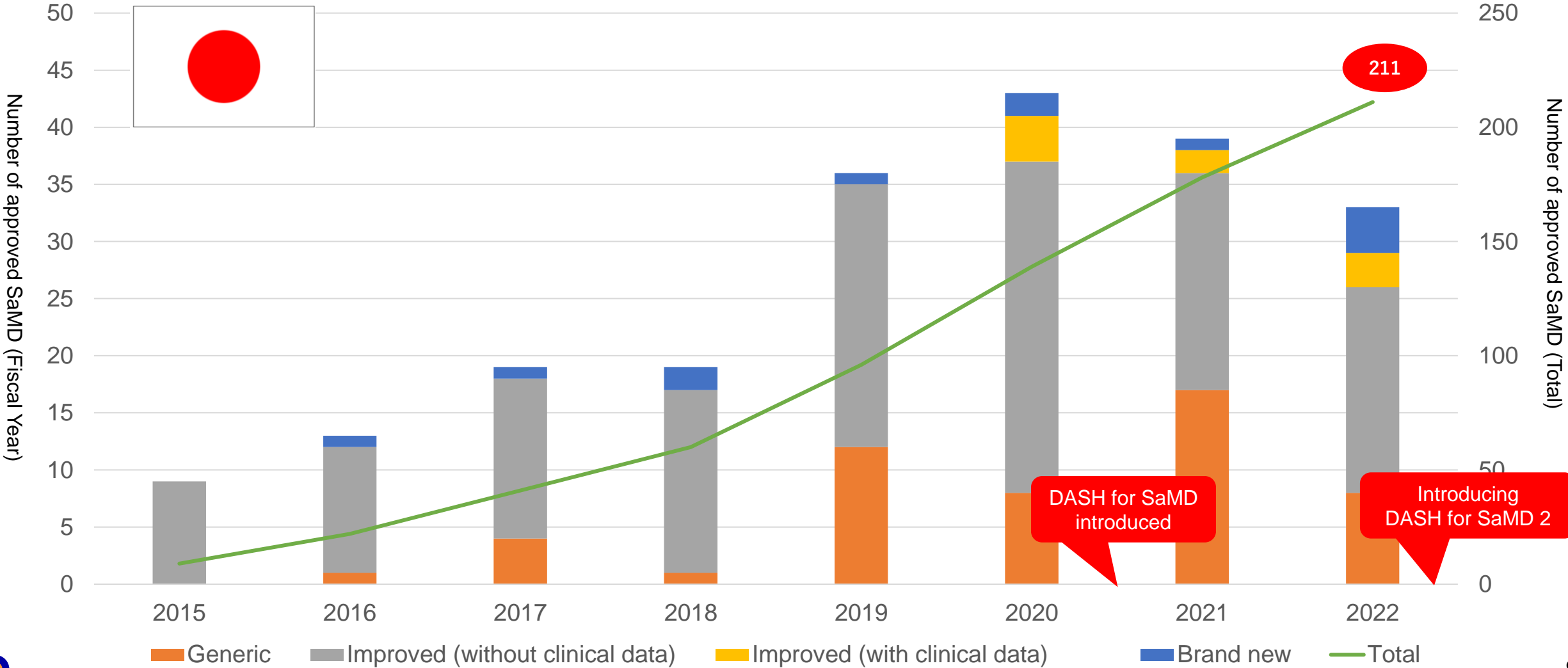
- ◆ **Setup an office to review SaMD** in MHLW and PMDA  ◆ Upgrade from office to Department for reviewing SaMD in PMDA
- ◆ Establishment of **SaMD centralized consultation service**  ◆ Establishment of SaMD-specific consultation service
- ◆ Next-generation medical device evaluation index, development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

# Goals for the next 5 years under DASH for SaMD 2

- ◆ Expansion of **more enhanced self-care options**
- ◆ Promotion of **better health for the public**
- ◆ **Exporting more and market acquisition** of innovative SaMD developed in Japan
- ◆ **Shorten the development cycle time of SaMD** by contributing to a smooth and efficient market introduction
- ◆ Realization of **efficient commercialization** of SaMD
- ◆ **Creation and early commercialization** of innovative SaMD
- ◆ **Smooth and efficient post-marketing performance improvement** of SaMD

# Number of Approved SaMD (not including the certificated SaMD)

As of March 2023





Non-SaMD	SaMD			
<ul style="list-style-type: none"> <li>● <b>For health control</b> (ex: programs which give patients advice on meal or exercise for health maintenance and promotion)</li> <li>● <b>Educational program</b> (ex: training programs for health care professionals)</li> <li>● <b>In-hospital business support program</b> (ex: medical appointment system, electronic medical record)</li> <li>● <b>Programs corresponded to class I</b> (ex: eye test, programs for color perception test)</li> </ul>		Class II	Class III	Class IV
	<b><u>For treatment at home</u></b>	<div data-bbox="868 315 1549 425">for used exclusively at home <b>2</b></div>		
	<b><u>For diagnostics</u></b>		<div data-bbox="868 496 2186 576">for computer assisted Imaging diagnostics <b>322</b></div>	
	<b><u>For treatment</u></b>	<div data-bbox="868 853 1549 1033">Application for behavioral therapy <b>3</b></div>	<div data-bbox="1582 853 2186 976">for therapy planning support <b>58</b></div>	
		<div data-bbox="1582 1005 2186 1130">for Surgical Support <b>1</b></div>		
		<div data-bbox="1582 1159 2186 1282">for controlling MD <b>3</b></div>		

# Examples of approved SaMD

(Ex.1)

Digital Therapeutic App for Hypertension (approved in Apr. 2022)  
→ *Behavioral Approaches to Lifestyle Modification*



(Ex. 2)

ELECTROCARDIOGRAPH SOFTWARE FOR OVER-THE-COUNTER USE (approved in Sep. 2022)

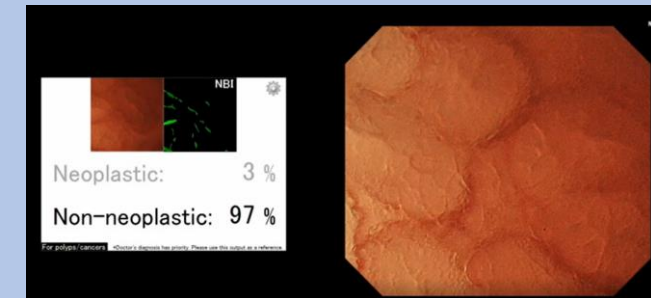
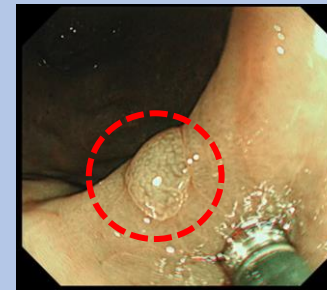
→ *can provide information for identifying cardiac arrhythmias and encourage medical examination*



(Ex.3)

AI-powered Colorectal Endoscopy Diagnosis Support Software  
(approved in Apr. 2022)

→ *Support for detection and differentiation of lesions in colonoscopy*



# Two-step Approval scheme for SaMD

- Introduced in 2017.

- Mainly used for diagnostic MD

**When analytical performance is reliable, but clinical benefit of the analyte is not sufficient.**

➔ possible to claim that

- First-step Approval "physiologic parameter "A" can be measured"
- Second-step Approval "measuring A will lead to diagnose of specific disease B"

- **Expand to SaMD for the treatment by MHLW**

In the case of SaMD for the treatment, if safety and a certain level of efficacy based on some evidences (including non-clinical trial) for Alleviation and improvement of specific symptoms caused by disease "C" can be confirmed

- First-step Approval : granted at that point.
- Second-step Approval: granted to claim the final clinical benefit.

# Two-step Approval scheme for SaMD

## SaMD for diagnosis

After clinical benefit concreted  
(Post-marketing CT, RWE)

Diagnosis of disease "B" by  
analyzing physiologic parameter "A"

Reliable performance for analyzing  
physiologic parameter "A"

First-step Approval

Second-step Approval

## SaMD for treatment

After clinical benefit concreted  
(Post-marketing CT, RWE)

Treatment support and  
improvement of disease "C"

Alleviation and improvement of  
specific symptoms caused by  
disease "C"

First-step Approval

Second-step Approval

# Thank you for your attention



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みらいのために

MHLW Website

<https://www.mhlw.go.jp/english/>



PMDA Website

<https://www.pmda.go.jp/english/index.html>