IMDRF International Medical Device Regulators Forum

Regulatory Updates on Medical Devices in Japan

MIYASAKA Tomoyuki
Deputy Director,
Medical Device Evaluation Division, Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare Japan (MHLW)
Japan

Day2 – 26 September 2023

Overview

Update for SaMD regulations in Japan

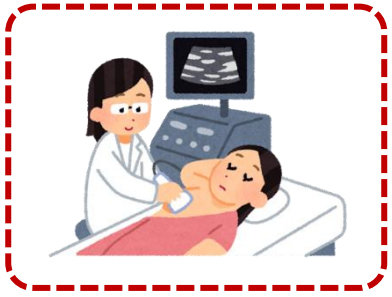
IMDRF International Medical Device Regulators Forum

Transition of regulations for SaMD in Japan

before November 2014

program which determines performance of medical device

install



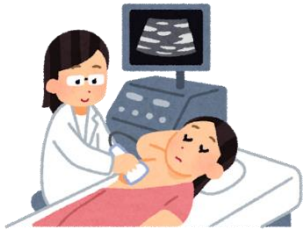
Medical device
（tangible object including software）

after November 2014

program which determines performance of medical device

Medical device
（software itself）

install



MD software classified as Class I is **NOT** subjected to regulations on PMD-Act

IMDRF International Medical Device Regulators Forum

Toward Further Practical Application and International Development of SaMD in Japan

- While there were high expectations for the utilization of SaMD (Software as a Medical Device), there were issues regarding the direction of efficient development of SaMD because it is still a new field for all stakeholders in Japan.

- To tackle the issues, on November 24, 2020, MHLW launched **"DASH for SaMD"** (Package Strategy for Accelerating the Commercialization of SaMD) , and the institutional infrastructure was established mainly to efficiently obtain pharmaceutical approval under the PMD Act.

IMDRF International Medical Device Regulators Forum

Toward Further Practical Application and International Development of SaMD in Japan

- However, in order to further promote the practical application of SaMD in the future, we need to do more, such as the following.
  - ✓ **Clarify various paths to commercialization (two-step approval scheme for SaMD, SaMD for the general public)** in cooperation between the regulatory and insurance authorities to ensure predictability from approval to insurance coverage.
  - ✓ **Accelerate research and development of Japan-originated SaMD and promote their expansion into international markets.**
- Based on the above, MHLW have just compiled a new strategy, namely **"DASH for SaMD 2"** on September 6, 2023, **with some goals for the next five years.**

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)

IMDRF International Medical Device Regulators Forum

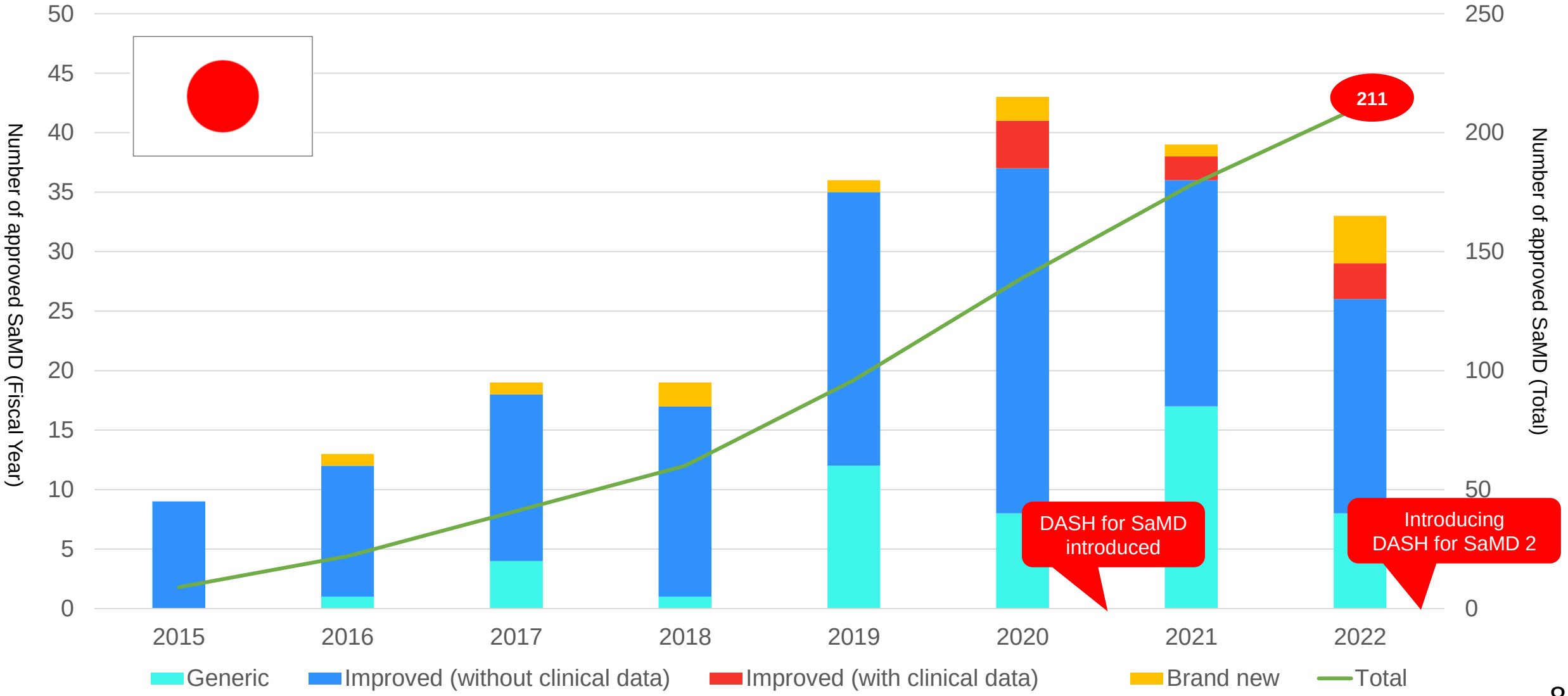
Goals for the next 5 years under DASH for SaMD 2

- 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

IMDRF International Medical Device Regulators Forum

Number of Approved SaMD (not including the certificated SaMD)

As of March 2023



IMDRF International Medical Device Regulators Forum

As of May 2023

Non-SaMD	SaMD		
	Class II	Class III	Class IV
● For health control (ex: programs which give patients advice on meal or exercise for health maintainance and promotion) ● Educational program (ex: training programs for health care professionals) ● In-hospital business support program (ex: medical appointment system, electronic medical record) ● Programs corresponded to class I (ex: eye test, programs for color perception test)	**For treatment at home** for used exclusively at home: 2		
	For diagnostics for computer assisted Imaging diagnostics: 322 for computer assisted diagnostics other than imaging: 89 for gene mutation analysis: 11		
	For treatment Application for behavioral therapy: 3	for therapy planning support: 58 for Surgical Support: 1 for controlling MD: 3	

IMDRF International Medical Device Regulators Forum

Examples of approved SaMD

（Ex.1）

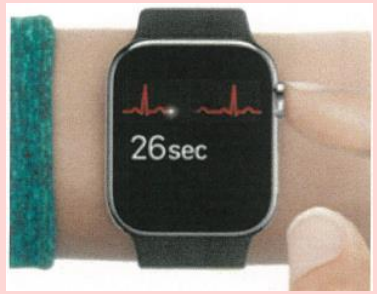
Digital Therapeutic App for Hypertension（approved in Apr. 2022）

→ Behavioral Approaches to Lifestyle Modification

（Ex. 2）

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

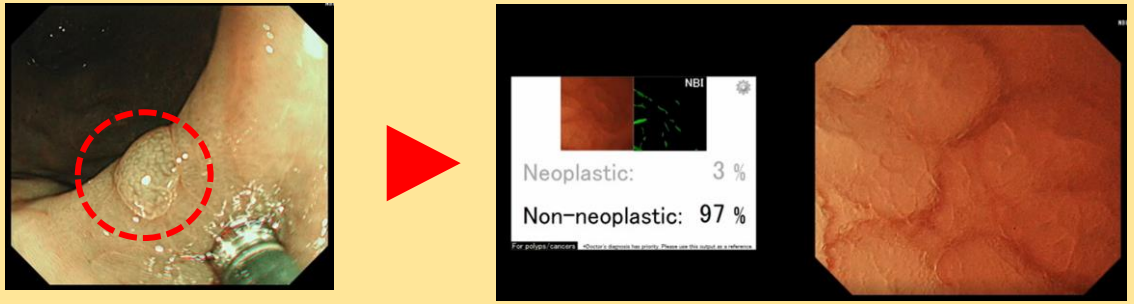
→ can provide information for identifying cardiac arrhythmias and encourage medical examination



（Ex.3）

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

→ Support for detection and differentiation of lesions in colonoscopy



IMDRF International Medical Device Regulators Forum

Two-step Approval scheme for SaMD *(draft)*

- Two-step Approval scheme was introduced in 2017.
- This scheme is mainly used for diagnostic MD, and is used when the analytical performance is reliable but the clinical benefit of the analyte is not sufficient. By using this scheme, it is possible to claim that “physiologic parameter “A” can be measured" in the First-step Approval, and, after concreting the clinical benefit, claim that "measuring A will lead to diagnose of specific disease B" in the Second-step Approval.
- MHLW is currently considering that **the scheme will expand to SaMD for the treatment** such as the next slide image. 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, the First-step Approval will be granted at that point. Then, after concreting the clinical benefit, the Second-step Approval will be granted to claim the final clinical benefit.

※ *This scheme is under consideration, but is being studied with the aim of introducing it by the end of 2023.*

IMDRF International Medical Device Regulators Forum

Two-step Approval scheme for SaMD *(draft)*

SaMD for diagnosis

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

Reliable performance for analyzing physiologic parameter “A”

First-step Approval

Diagnosis of disease “B” by analyzing physiologic parameter “A”

Second-step Approval

SaMD for treatment

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

Alleviation and improvement of specific symptoms caused by disease “C”

First-step Approval

Treatment support and improvement of disease “C”

Second-step Approval

IMDRF International Medical Device Regulators Forum

Thank you/Questions

MHLW Website
https://www.mhlw.go.jp/english/

PMDA Website
https://www.pmda.go.jp/english/index.html

If you have any questions, please contact me via email (miyasaka-tomoyuki@mhlw.go.jp) or visit our website as above.