



**IMDRF** International Medical Device  
Regulators Forum

# 29<sup>th</sup> IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026



# Japan Update



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### 【MHLW】

Ministry of Health, Labour and Welfare

#### Administrative Responsibilities

- PMD Act and related regulations
- Approval of pharmaceuticals, medical devices and regenerative medical products
- Safety-related notices and orders
- Oversight of PMDA

### 【PMDA】

Pharmaceuticals and Medical Devices Agency

#### Implementation of Scientific Reviews

- Scientific review and consultation
- GCP/GMP/QMS inspections
- Post-market safety information
- Relief compensation for adverse drug reactions (medical expense payments)



# Applicability of SaMD in Japan

## Medical Device and SaMD Definition

- Medical Device: used for diagnosis, treatment, or prevention, or affecting body structure/function
- SaMD consists of a program and a recording medium used for medical purposes.

### Non-medical Device (Non-SaMD)

#### Example:

- Patient-education tools
- Hospital business support
- Personal health record apps
- Sports/fitness management

### Software as a Medical Device (SaMD)

#### Example:

- Program to support cognitive behavioral therapy conducted by doctors (Digital therapeutics)
- Treatment-planning programs
- Diagnostic support (CADe/CADx)

Class I-equivalent  
processing programs

## Regulatory Support

- MHLW has issued guidance to support SaMD applicability decisions.
- MHLW offers consultations on the applicability of individual products.

# Overview of Approved SaMD (Japan)

Total: 618 products  
As of September 2025

Non-medical Device (Non-SaMD)	Medical Device (SaMD)	Class II	Class III	Class IV
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Example:  
Dietary Advice

Surgical Training

Electronic Medical Record

Class I-equivalent functions (e.g. Vision Test Program)

Home Use

Home Use for Diagnosis (9)

Diagnosis / Examination

Image Diagnosis Support (395)

Other Diagnosis Support (115)

Gene Mutation analysis (13)

Applicability of Drugs (1)

Treatment  
Decision of Treatment Strategy

Treatment Planning Support (73)

Support of Treatment

DTx (6)

Surgical Support (3)

Equipment Control (3)

CureApp AUD (Alcoholism Treatment)



ENDEAVOR RIDE(ADHD Treatment)



ステアリング：指定の経路に沿って運転する操作



タッピング：指定の対象物に反応する操作

Apple Sleep Apnea Notification



## 1. Early Identification of Emerging SaMD and Guideline Development

- (1) SaMD development support through PMDA videos and collaboration with other consultation services
- (2) Developing guidance and evaluation principles for SaMD development etc.

## 2. Promoting Practical Implementation Based on SaMD Characteristics

- (1) Two-step approval process specific to SaMD
- (2) Promoting the use of IDATEN change-plan system and streamlining procedures etc.

## 3. Strengthening Systems for Early Implementation

- (1) Enhanced PMDA review, consultation and post-market systems
- (2) Dedicated SaMD consultation category
- (3) Industry–academia–government collaboration forum and sub-forum etc.

## 4. Supporting Global Expansion of Japan-Origin SaMD

- (1) Analyses of overseas regulations
- (2) Collaboration via PMDA's Asia Office and IMDRF etc.

# Two-Step Approval Process Specific to SaMD

**Purpose:** To support **flexible development and timely patient access**, **two-step approval process** applies to **innovative SaMD** whose final clinical significance is not yet fully established, but which **show diagnostic value or early evidence suggesting a reasonable likelihood of effectiveness based on preliminary data**.

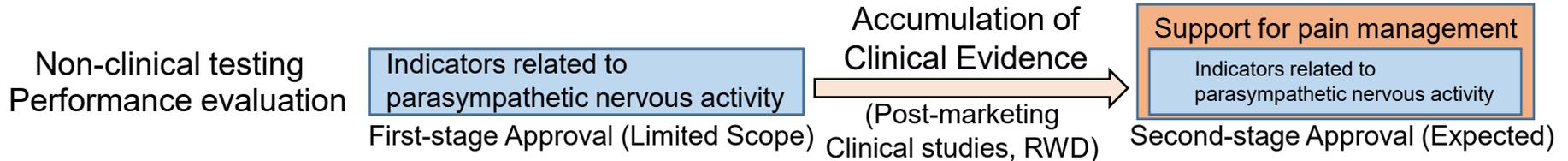
Reference (MHLW notification):

[https://www.mhlw.go.jp/web/t\\_doc?dataId=00tc8055&dataType=1&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=00tc8055&dataType=1&pageNo=1)

## ■ Diagnostic Programs

**First-stage approval:** based on non-clinical data, performance evaluation

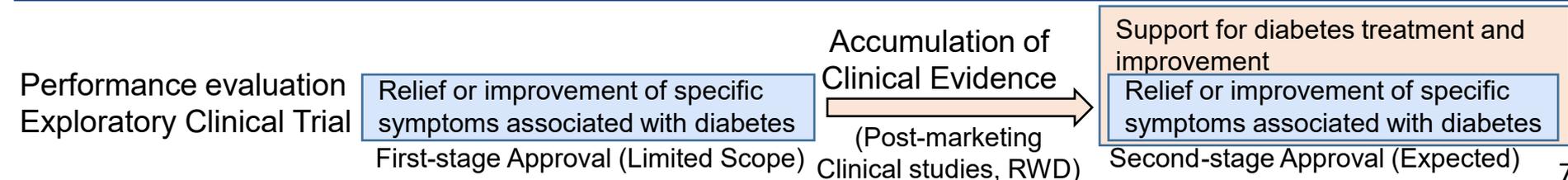
**Second-stage approval:** after accumulation of clinical evidence (post-marketing clinical studies, real-world data (RWD))



## ■ Therapeutic Programs

**First-stage approval:** based on preliminary effectiveness data (exploratory clinical trials etc.)

**Second-stage approval:** confirmed effectiveness after real-world evidence accumulation



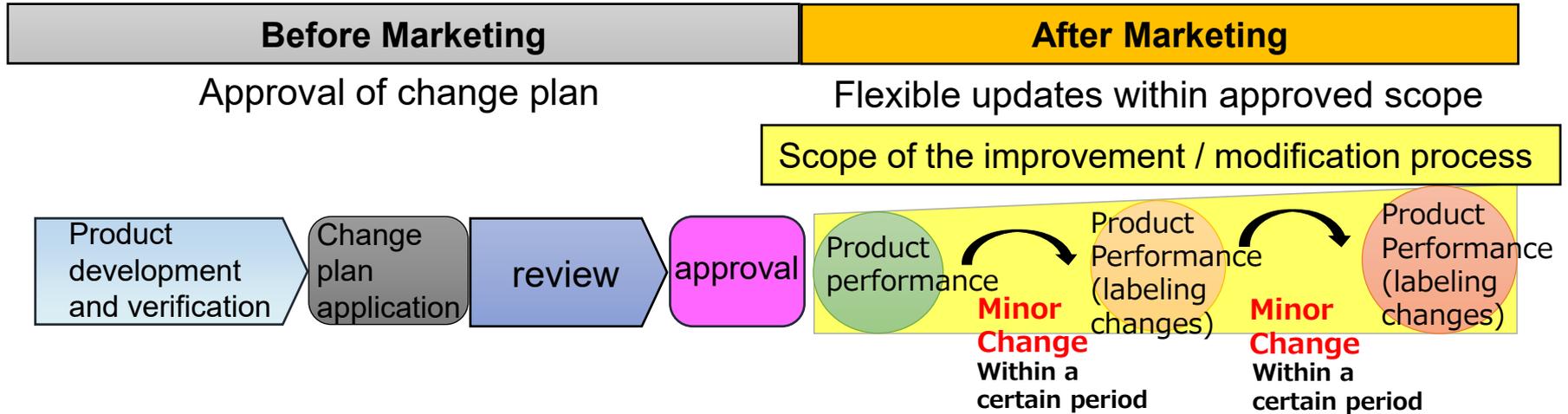
# IDATEN Change-Plan System

## Purpose

- Pre-approved plan for expected modifications
- Enables rapid and flexible updates after marketing

## Key Feature

- Suitable for evolving products (e.g., AI-based software)
- Ensures safety via pre-reviewed change processes



# Examples of AI/ML-based SaMD

## Examples:

### Diagnosis/Examination

- Endoscopic diagnostic support
- MR aneurysm detection
- Surgical image-recognition
- Microbial classification

### Home-Use/Monitoring

- Heart-rate monitoring

### Dental/Other

- Bone-morphology assessment

**51** products approved

(as of September 30, 2025)

All products use machine-learning techniques (not generative AI).

PMDA's count includes only approved AI-based medical device programs intended to improve patient outcomes or reduce workload. Certified products and non-clinical-purpose functions are excluded.

Therefore, this list does not represent all AI-based medical device programs.

# Regulatory Discussions for AI/ML-based SaMD

Discussed through an industry–academia–government sub-forum:

- Evaluation of medical devices using **adaptive AI**
  - Data quality and quantity
  - Appropriate training/evaluation databases
  - Domain shift across facilities
  - Regulatory updates
- Application of **generative AI** to medical devices
  - Medical-device use cases
  - Potential contributions to healthcare
  - Risks (e.g., hallucination)
  - Need for evaluation methods

# AI Characteristics and Regulatory Implications

## Plasticity

Performance may change after approval



Traditional regulations assume fixed performance

Static frameworks do not fit evolving models.

## Unpredictability

- Hidden biases in machine-learning models
- Images may be interpreted differently by AI



Addressing bias in evaluation data and limitations of single-institution or narrowly scoped datasets.

Need diverse data reflecting real clinical variation

## 1. Lifecycle-based regulatory framework for SaMD

- Two-step approval process
- *IDATEN* – post-market improvements

## 2. Strengthening systems and global alignment

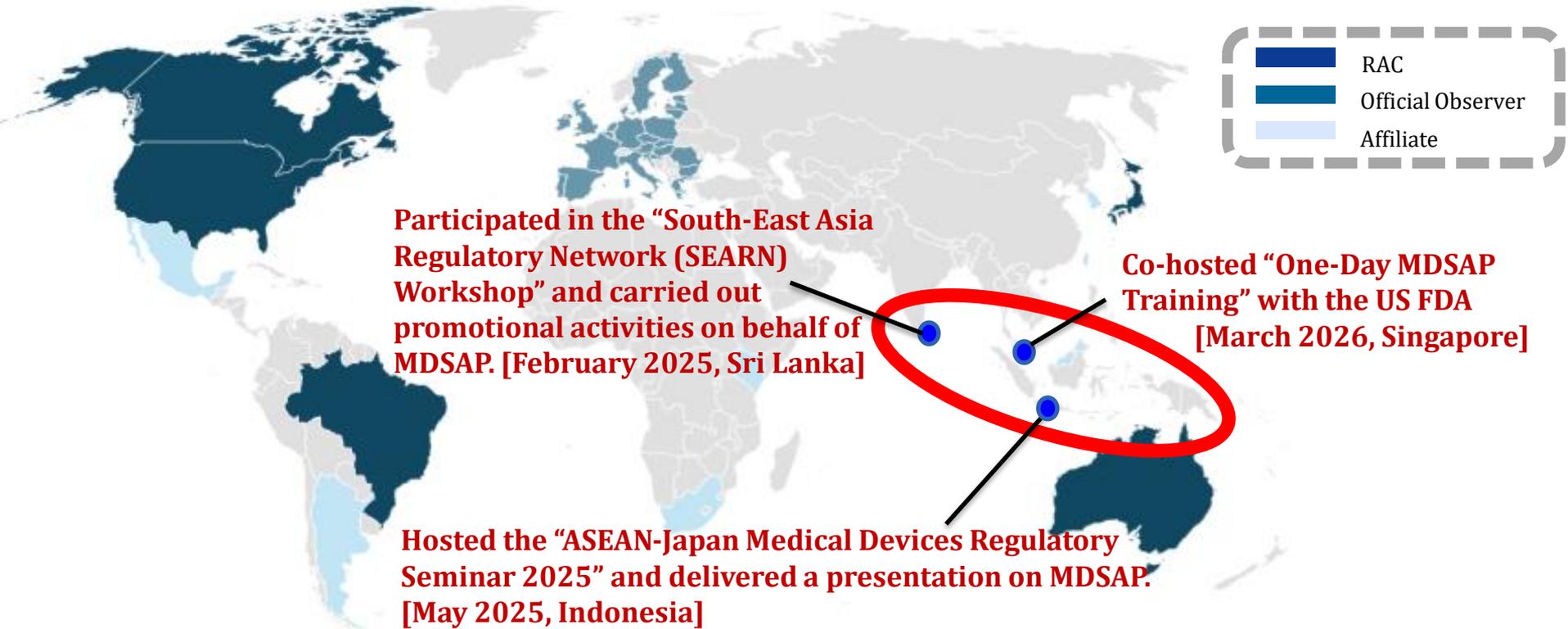
- Specialized SaMD review/consultation (PMDA)
- International collaboration (PMDA's Asia Office and IMDRF)

## 3. Regulatory discussions for AI/ML-based SaMD

- Evaluation of adaptive AI, bias and domain shift
- Emerging considerations for generative AI



# Japan's Outreach Initiatives on MDSAP



Since 2025, Japan has been conducting outreach activities on MDSAP in the Asian region.



# 2026 MDSAP Forum

## Kyoto, Japan

**June 15–19, 2026**

**International Conference Center Kyoto (ICC Kyoto)**

**Register:** <https://2026mdsapforum.omcst.org/registration/>

**Contact:** [mdsapforum2026\\_secretariat@pmda.go.jp](mailto:mdsapforum2026_secretariat@pmda.go.jp)

# Thank You!

