

# DASH for SaMD

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

Drastic reform of review system for innovative medical device  
including Software as a Medical Device

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Pharmaceutical Safety and Environmental Health Bureau  
Ministry of Health, Labour and Welfare (MHLW), Japan

# General Concept

To Promote early realization of practical use of innovative SaMDs;

- Assess the seeds of cutting-edge technology for SaMDs in early stage and provide points to consider for premarket evaluation of such devices
- Centralize the consultation contact desk and establish the scheme and organizational structure in consideration of characteristics of SaMD

# Policies and Challenges

**Early recognition of seed technologies**

- Need more thorough research

**Guidelines/  
case examples**

- Taking long time to disclose relevant information

**Prompt review**

**Timely approval of cutting-edge medical devices**

**Proactive guide for development regarding medical device realization**

- Unclear whether the products are subject to the PMD act
- Unclear what kind of evaluation will be required for review

**Consultation/  
Guidance**

- Unclear whom to consult with
- Need for applicable organizational system for review/consultation

# “DASH for SaMD”

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

## 1. Early recognition of research seeds and publication of the review guide

- a. Assess seeds of technology in the early stage of research.
- b. Organize and publish the review guide regarding characteristics of SaMD.

## 2. Centralization of the consultation contact desk

- a. Centralize consultation service
- b. Marshal and publish consultation case examples

## 3. Review system applicable to unique characteristics of SaMD

- a. Carry out efficient review based on characteristics of SaMD
- b. Utilize the Post-Approval Change Management Protocol (PACMP) scheme
- c. Consider establishing the innovative SaMD designation program

## 4. Enhancement of structure for early realization

- a. Establish new office specialized in reviewing SaMD in MHLW and PMDA
- b. Establish Expert Examination Committee for SaMD in the Pharmaceutical Affairs and Food Sanitation Council
- c. Establish collaborative forum among regulator, academia and industry.
- d. Enrich published database of approval cases