

# Regulatory Updates on Medical Devices in Japan

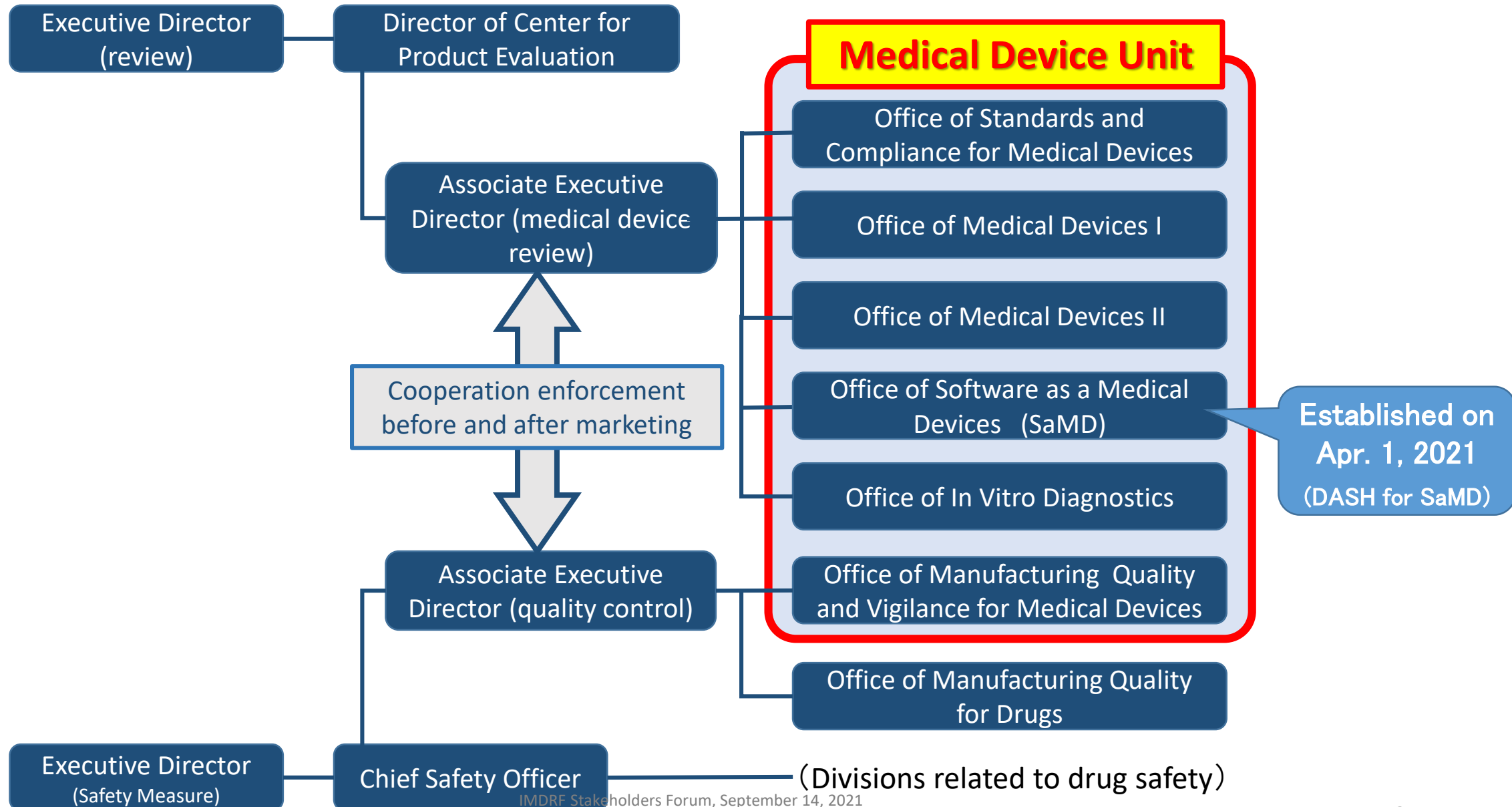
- DX (Digital Transformation) Action Strategies in Healthcare for SaMD “DASH for SaMD” -

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# PMDA's Medical Device Unit



# What is Software as Medical Device (SaMD) ?

## Previous legislation



program which  
determines performance  
of medical device

install



**Medical device**  
( tangible object including software )



## Current legislation



program which  
determines performance  
of medical device

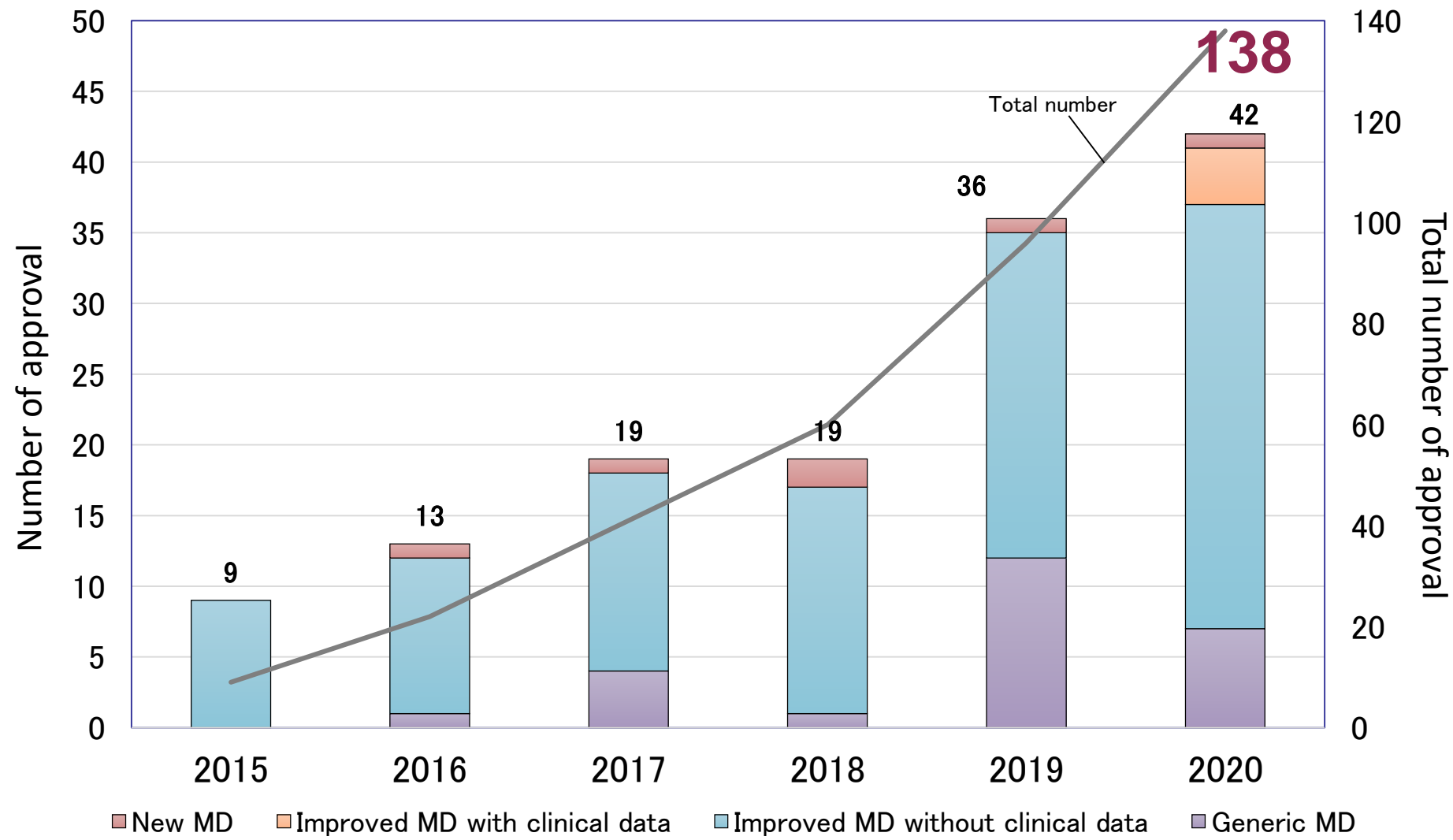
install



**Medical device ( software only )**

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

# Number of approved SaMD



# DX (Digital Transformation) Action Strategies in Healthcare for SaMD “DASH for SaMD”

## 1. Early grasp of research seeds and publication of the review policy

- a. Grasp research seeds in the early stage of development
- b. Organize and Publish the review policy based on characteristics of SaMD

## 3. Review system based on characteristics of SaMD

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

## 2. Unification of the consulting contact point

- a. Unify consultation service
- b. Publish consultation case examples as many as possible

## 4. Enhanced structure for early realization

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

**Thank you for your attention!**

