Regulatory Updates on Medical Devices in Japan

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

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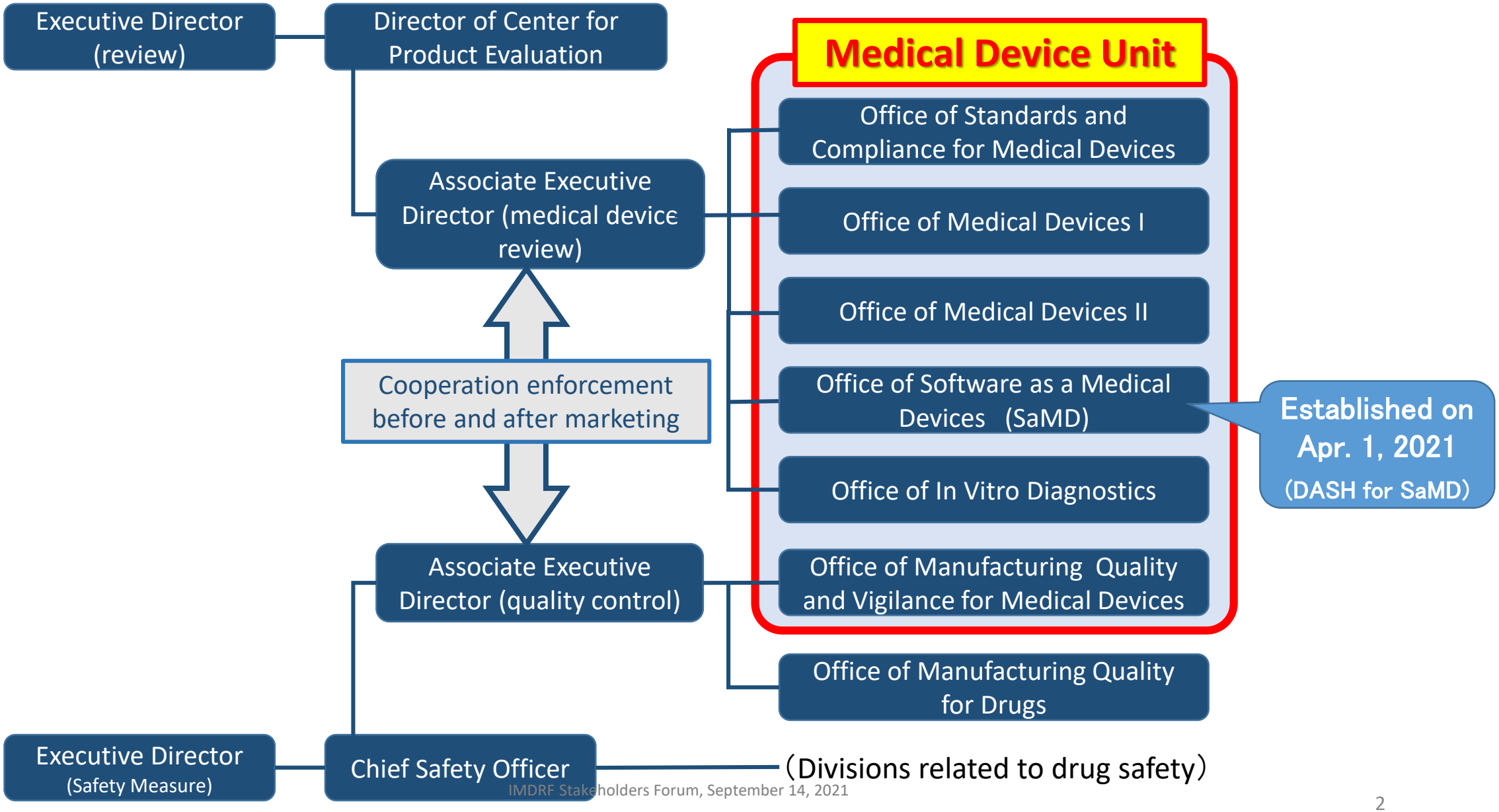
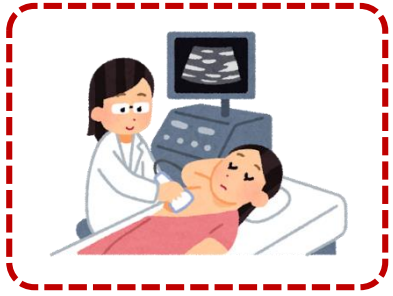


What is Software as Medical Device (SaMD) ?

Previous legislation

program which determines performance of medical device

install



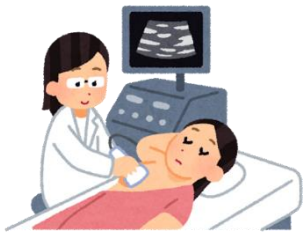
Medical device
（ tangible object including software ）

Current legislation

program which determines performance of medical device

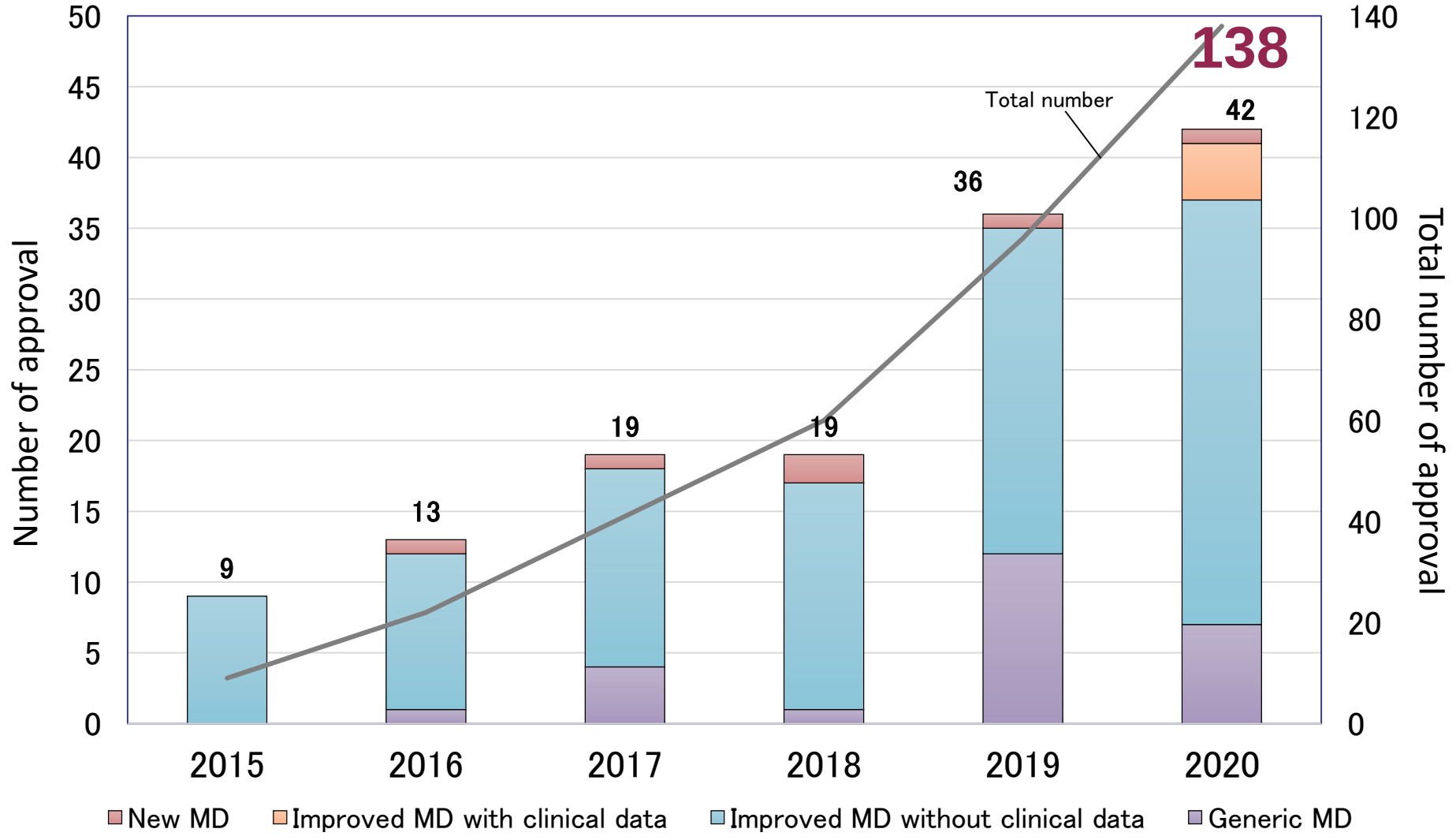
Medical device（ software only ）

install



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

2. Unification of the consulting contact point

a. Unify consultation service

b. Publish consultation case examples as many as possible

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

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!