Points to consider in the review of SaMD and action plan of accelerating the review process ~ Japanese regulatory view

Pharmaceuticals and Medical Devices Agency (PMDA)

Medical Devices Unit, Office of Software as a Medical Device, Reviewer

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Agenda

1. Overview of review on SaMD
2. Action plan of accelerating the review process for SaMD

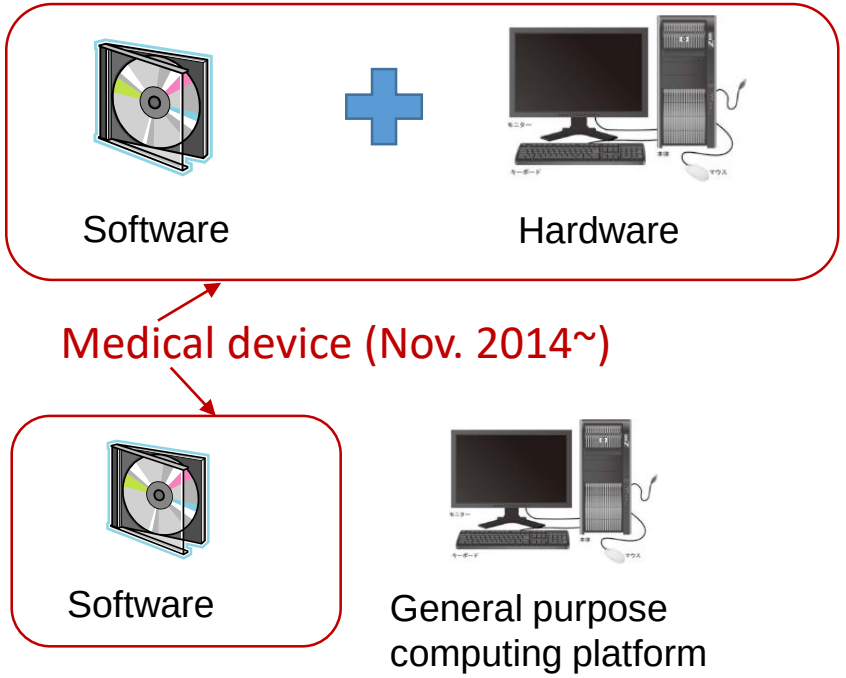
Overview of review on SaMD

Definition of SaMD in Japan

- Software products that have the intended purpose as a medical device such as contributing to the diagnosis, treatment, or prevention of diseases include as follows;

  - Those which are used in combination with tangible medical devices.

  - Those which are installed in general-purpose personal computers such as desktop personal computers or personal digital assistants such as smartphones.



The importance of determining the role of the SaMD in clinical practice

Height, weight, age

Amount of exercise

Calories in daily meals

Software

Overeating

Appropriate

Little eating

For those who are concerned about their weight!

- Non-medical device

Prevention of lifestyle-related diseases

- Medical device?
- Would this product help prevent lifestyle-related diseases?

Improvement of HbA1c for patients with diabetes

- Medical device
- Evaluate the ability to improve HbA1c

Action plan of accelerating the review process for SaMD

“DASH for SaMD”

November 2020

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

c. Centralize consultation service (April 1, 2021)
d. Marshal and publish consultation case examples

https://www.mhlw.go.jp/content/11120000/000836443.xlsx

3. Review system applicable to unique characteristics of SaMD

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

4. Enhancement of structure for early realization

h. Establish new office specialized in SaMD in MHLW and PMDA (April 1, 2021)
i. Establish Expert Examination Committee for SaMD in the Pharmaceutical Affairs and Food Sanitation Council (April 1, 2021)
j. Establish collaborative forum among regulator, academia and industry

(February 4, 2022)

k. Enrich published database of approval cases

https://www.pmda.go.jp/PmdaSearch/kikiSearch/

New consultation for SaMD

Comprehensive consultation for SaMD

Determine whether the product is MD or Non MD

MHLW, Compliance and Narcotics Division

Consultation regarding the determination of whether or not software under development is classified as a medical device under the PMDA Act.

Review the developed product

PMDA, Office of SaMD

Pre-consultation before each consultation (pre-development consultation, clinical trial protocol consultation, etc.) conducted by PMDA.

Consult the reimbursement prices

MHLW, Economic Affairs Division

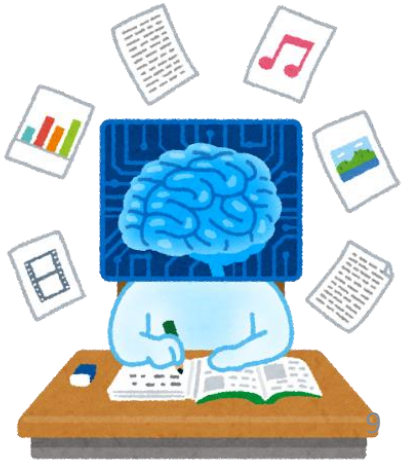
Various consultations regarding medical insurance.

Uniqueness of AI products -Plasticity-

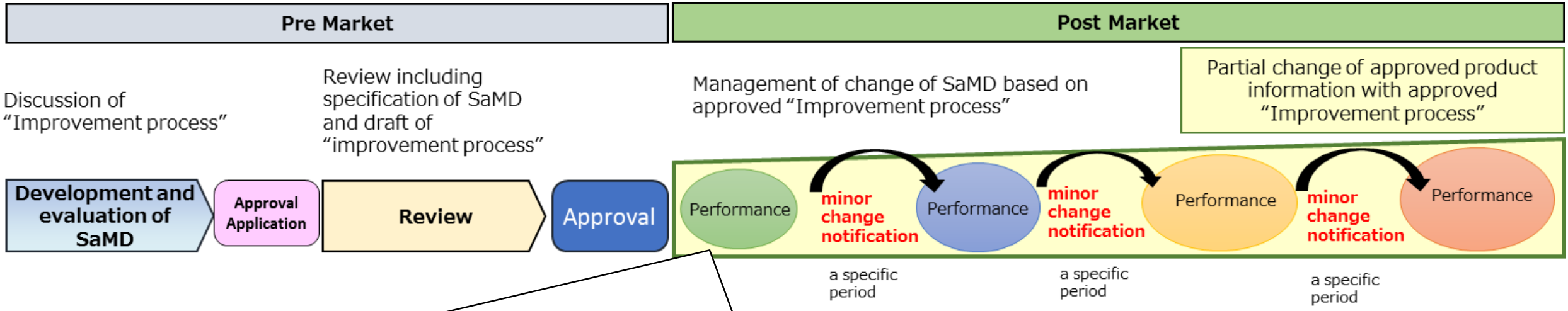
Post market learning may be worsen
the performance of AI products.

It is difficult to understand the appropriateness of input; especially reviewing in pre market phase cannot accurately predict the appropriateness of process to change characteristics in post market phase.

How are performance of SaMD that
used AI maintained?



Challenge to accept “Plasticity” in medical device regulation -Conceptual sketch of PACMP for SaMD using AI technologies -



QMS teams of PMDA regularly conduct on-site inspection and confirm the appropriateness of improvements and submissions of minor change notification.

Approvals of SaMD are withdrawn **in the case that change is out of approved “Improvement process”; the case includes that the performance of SaMD does not improve as approved “Improvement process”.**

Conclusion

<Overview of review on SaMD>

To review SaMD, the importance of determining the role of the SaMD in clinical practice; the role of the software affects whether the software is medical device or not, and how we review.

<Action plan of accelerating the review process for SaMD>

Challenging methods are requested to realize effective regulation of SaMD; effective regulatory pathway (including PACMP for SaMD), consultation service for good communications with applicants and discussion with experts are necessary for regulators.

Thank you for your kind attention!