Artificial Intelligence in Healthcare
Section 3: AI in Healthcare and regulatory developments: possibility and challenges (regulatory view)

# The development of policy measures on medical devices using AI technology in Japan

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September 16, 2019

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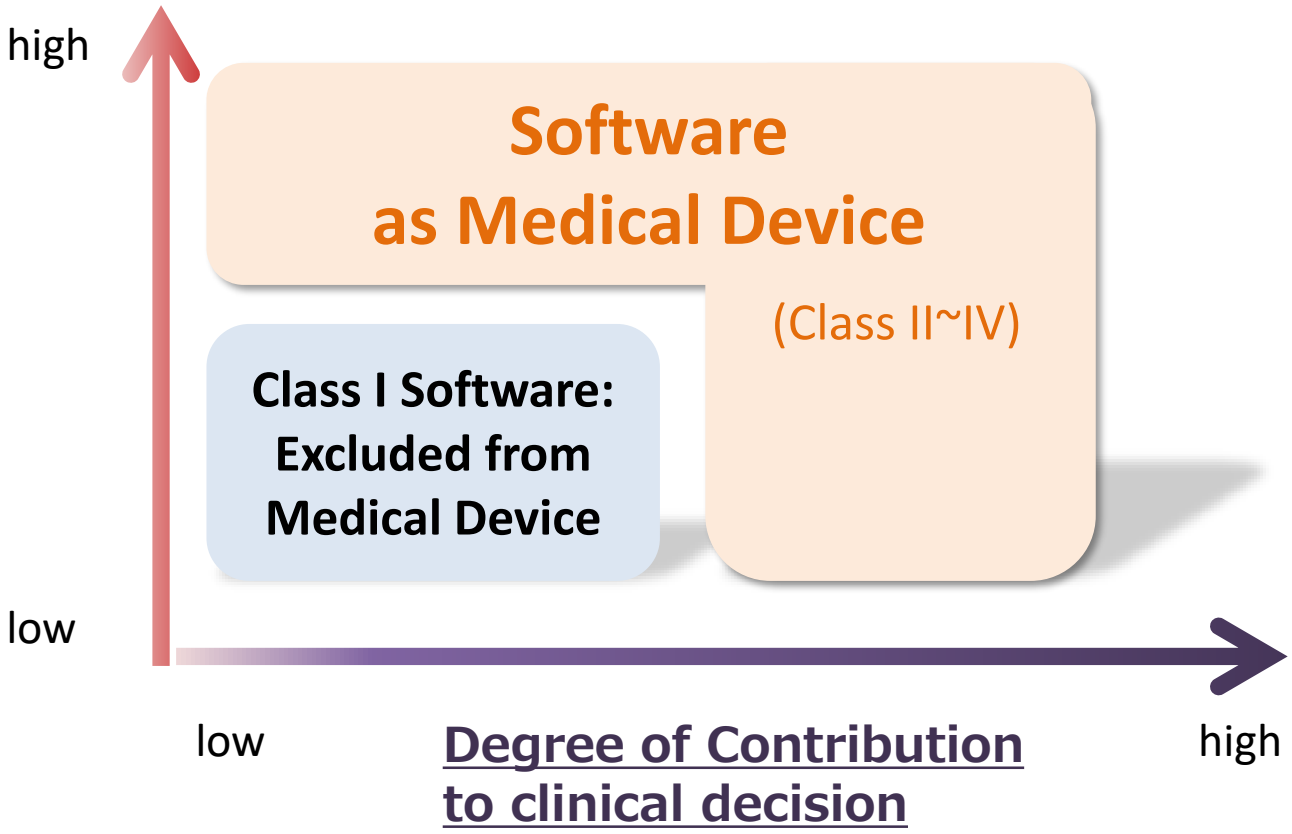
# What kind of Software is Medical Device?

**Not Medical Device**

**Not used for prevention, diagnosis or treatment of diseases**



# How “Artificial Intelligence” is defined?

Basic Act on the Advancement of Public and Private Sector Data Utilization (2016)

Article 2. Definitions

(2) The term "artificial intelligence-related technology" as used in this Act means technology for the realization of intelligent functions, such as learning, inference, and judgment, by artificial means, and utilization of the relevant functions realized by artificial means.

# Approval Review Principles (1)

Reasons of Approval Rejection are common to all types of medical device.

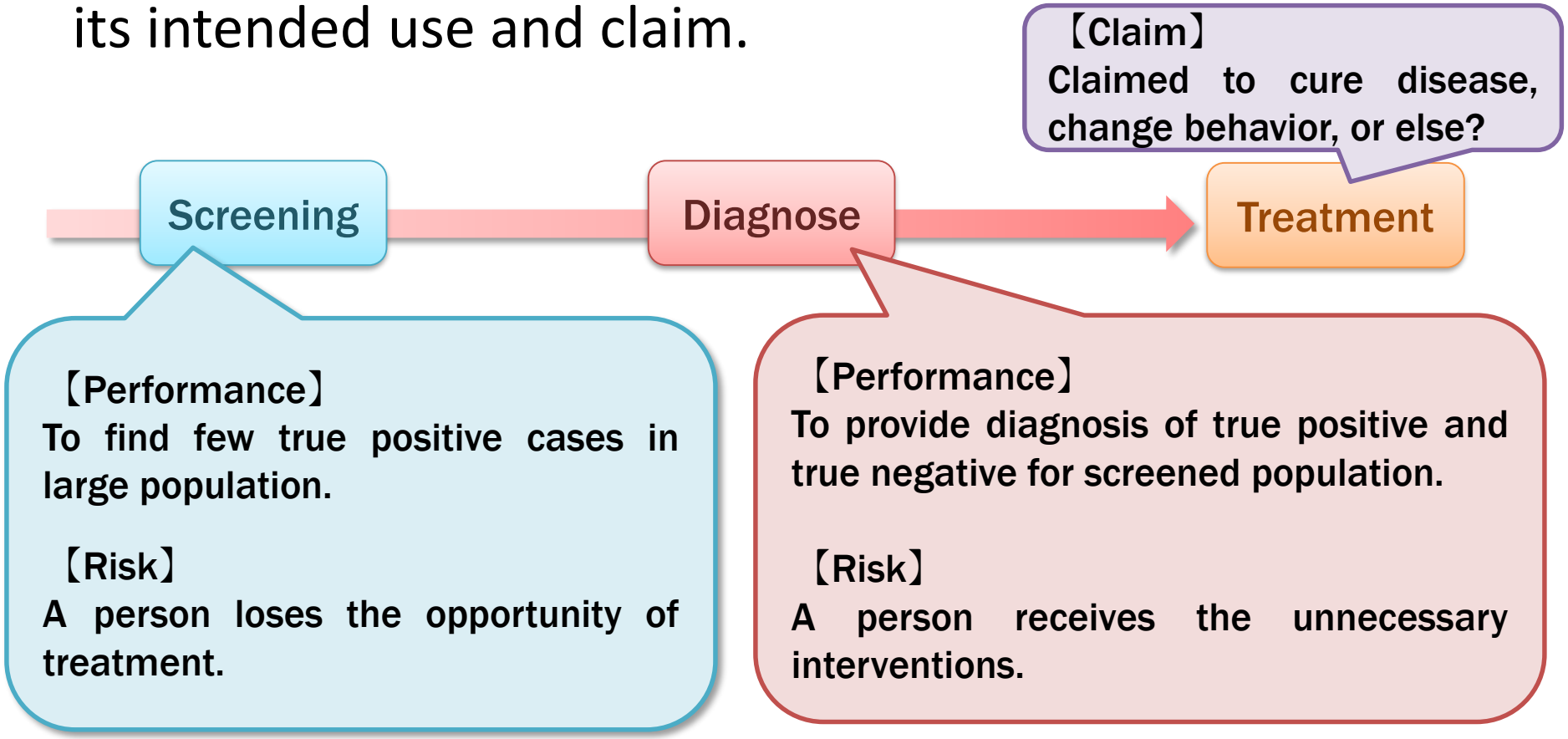
(a) The given device is judged that it does not have its own efficacy, effectiveness and/or performance as to be concerned in the application.

(b) The given device is judged of no value for medical use because its adverse effect(s) far exceed its efficacy, effectiveness and/or performance.


*PMD Act, Article 23-2-5 paragraph (2), item (iii), (a) & (b)*

# Approval Review Principles (2)

Risk/benefit balance and evidence level are variable by its intended use and claim.




**How much are false-positive and false-negative rates acceptable?**
**What sort of clinical evidence is needed to support its claim?**

# Approval Review Principles (3)

## Specific Considerations for Artificial Intelligence

### Unpredictability

Users cannot understand the reasoning of output

How do you figure out the difficult situation?

- **Expect developing AI technology?, or**
- **Run exhaustive situation ?**

### Plasticity

Post market learning may be worsen the performance of AI products

How do you keep the performance of it?

- **Review learning process (how, who, when, what data… etc)**

# Guidance for evaluation on AI medical imaging systems (1)

**Guidance for evaluation of artificial intelligence–assisted medical imaging systems for clinical diagnosis**

Annex 4 of MHLW MDED Notification No.2 May 23, 2019

English translation is available on the NIHS website (bottom of the page):
http://dmd.nihs.go.jp/jisedai/tsuuchi/index.html

## Section 1. Introduction

Issues:

- Algorithm for calculating output is “black box” nature in AI based on deep learning.
- Its performance, especially after post-market training, can only be evaluated by verification of the output.
- How to consider the source or type of the data, authenticity and bias in the learning data?

This guidance summarizes the issues and points to consider on evaluating the efficacy and safety of the medical imaging system for CAD utilizing AI technology in the approval review.

# Guidance for evaluation on AI medical imaging systems (2)

## Section 5. Open Problems and direction of their solutions:

### (1) Black box

- Approval review process should focus on the performance evaluation by confirming if the input yields the required output.
- Manufacturers should guarantee the performance by indicating that the systems always meet the specifications on performance.
- Functions that inform any unexpected outputs of the system to the users should be also required.

### (2) Changes in performance

1. **Continuous verification of performance:**
   The assistance systems should be validated every time when their performance changes to ensure their quality, safety, and efficacy.
2. **Quality assurance associated with performance changes:**
   Training algorithm and training data should be clarified.
3. **Principles on post-market approval process:**
   Necessity of taking the approval process should be determined in accordance with the magnitude of the associated changes in performance and risks.

# Guidance for evaluation on AI medical imaging systems (3)

## Section 5. Open Problems and direction of their solutions: (3) Assigning responsibility

- Manufacturers are responsible for the maintenance and troubleshooting of systems, and clarifying the use method of the system including by training for users
- Referring to the MHLW Health Policy Bureau notification that medical doctors are responsible for the final decision in diagnosis and treatment

Further technical considerations on the development and evaluation are discussed in **Section 6. Points to consider in evaluation**.

The potential type of AI for which users can perform post-market training to change their performance is discussed in **Annex**.

English translation is available on the NIHS website (bottom of the page):
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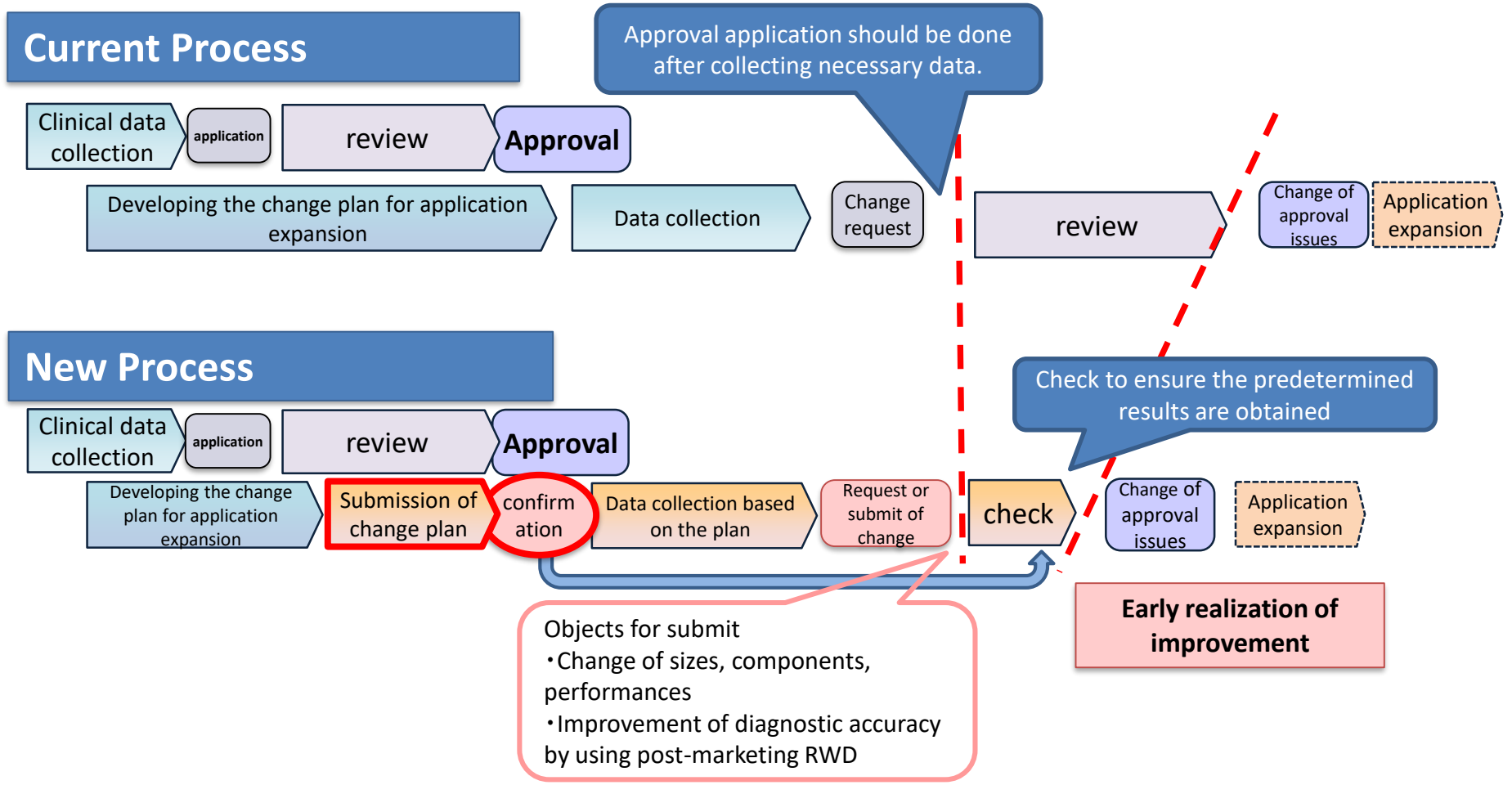
# Legal Amendment for medical devices using AI (1)

*Revision of Pharmaceutical and Medical Device Act is currently under discussion in the Diet.

Post-Approval Change Management Protocol will be introduced for medical devices including with AI to make continuous improvement possible.

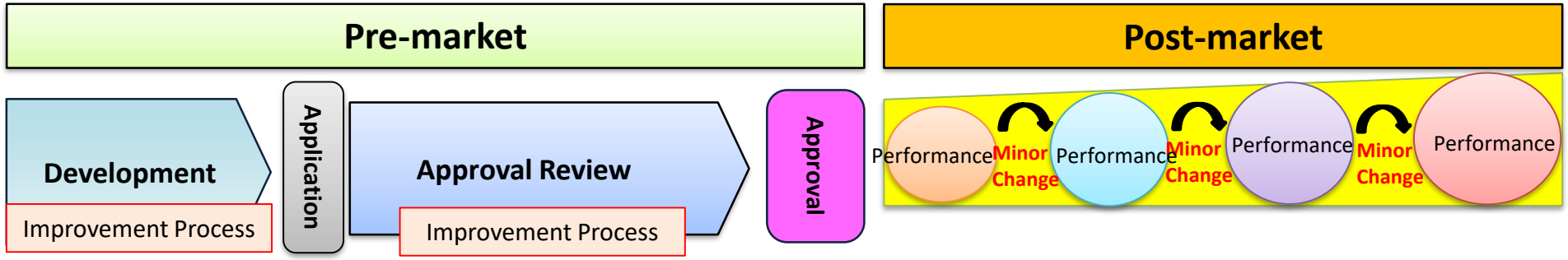


# Legal Amendment for medical devices using AI (2)

*Revision of Pharmaceutical and Medical Device Act is currently under discussion in the Diet.

Approval review process which enables continuous improvement of performance of SaMD using AI will be introduced.

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes “Improvement Process”, and submit to the approval review process.




“Improvement Process” is developed and reviewed in the approval review process.

Post-market changes in line with the Improvement Process can be made by minor change notification, which does not require approval process.

*Compliance is checked in the audit.

# Summary

The situation in Japan:

1. There are some specific consideration in the definitions and review principles of AI devices.

2. Evaluation guidance summarizes the issues and points to consider on evaluating AI devices.

3. Approval review process for AI device will be introduced by the legal amendment proposed.