Use of AI in Medical Devices and Challenges in Market Authorization of Machine Learning-enabled Medical Devices (MLMD)

PS 3.1 "*Geopolitical Landscape*"

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Examples of AI ML-enabled MDs approved in Japan

SaMD＋Recording medium
=Programmed Medical Device

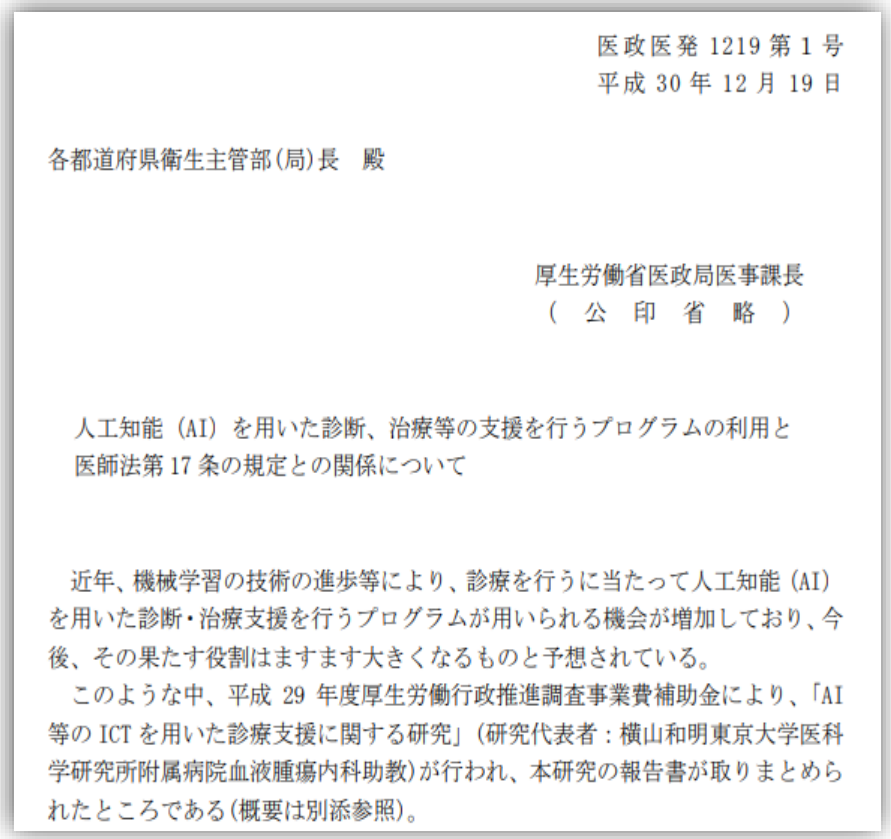
Software As Medical Device(SaMD)

Nodoca
disease characteristic finding detection support software for endoscope
(influenza virus infection)

Aillis, Inc.

Responsibility of Medical Practitioner to use AI

Physician has responsibility for the final decision



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各都道府県衛生主管部(局)長　殿

厚生労働省医政局医事課長
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人工知能（AI）を用いた診断、治療等の支援を行うプログラムの利用と医師法第 17 条の規定との関係について

近年、機械学習の技術の進歩等により、診療を行うに当たって人工知能（AI）を用いた診断・治療支援を行うプログラムが用いられる機会が増加しており、今後、その果たす役割はますます大きくなるものと予想されている。

このような中、平成 29 年度厚生労働行政推進調査事業費補助金により、「AI 等の ICT を用いた診療支援に関する研究」（研究代表者：横山和明東京大学医科学研究所附属病院血液腫瘍内科助教）が行われ、本研究の報告書が取りまとめられたところである（概要は別添参照）。

- In Japan, even when AI is used to provide support for diagnosis and medical treatment,
  - Physician has responsibility for the final decision.

- This medical diagnosis/treatment is regarded as a medical practice under Article 17 of the Medical Practitioners Act (Act No. 201 of 1948).

Market Authorization Review of Medical Devices using AI

Points to consider for the pre-market review for AI is basically the same as that of other medical devices.

Challenges in premarket review for MLMD

- Plasticity
- Unpredictability

Plasticity

Performance can change in the post market phase

Unpredictability

- Bias of data could affect the performance of the software
- Independence and completeness of data is critical

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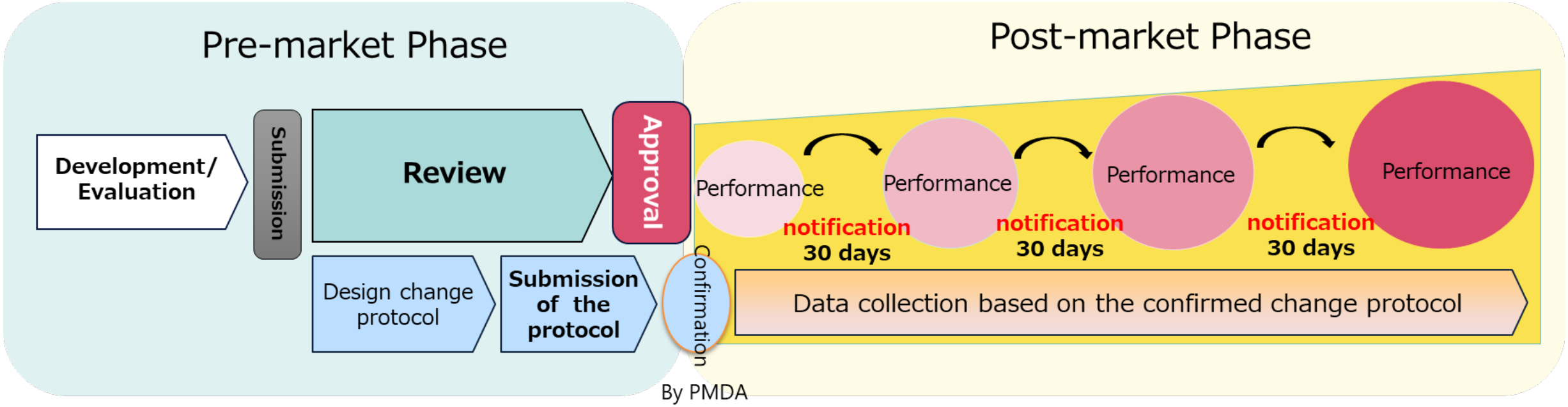
Post-Approval Change Management Protocol (PACMP/IDATEN) for Medical Devices

PACMP is introduced for medical devices to enable continuous and timely improvements through product lifecycle.



Published in 2019, in force in 2020

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International Regulatory Hamonization

IMDRF (International Medical Device Regulators Forum)

[OUTCOME Documents]

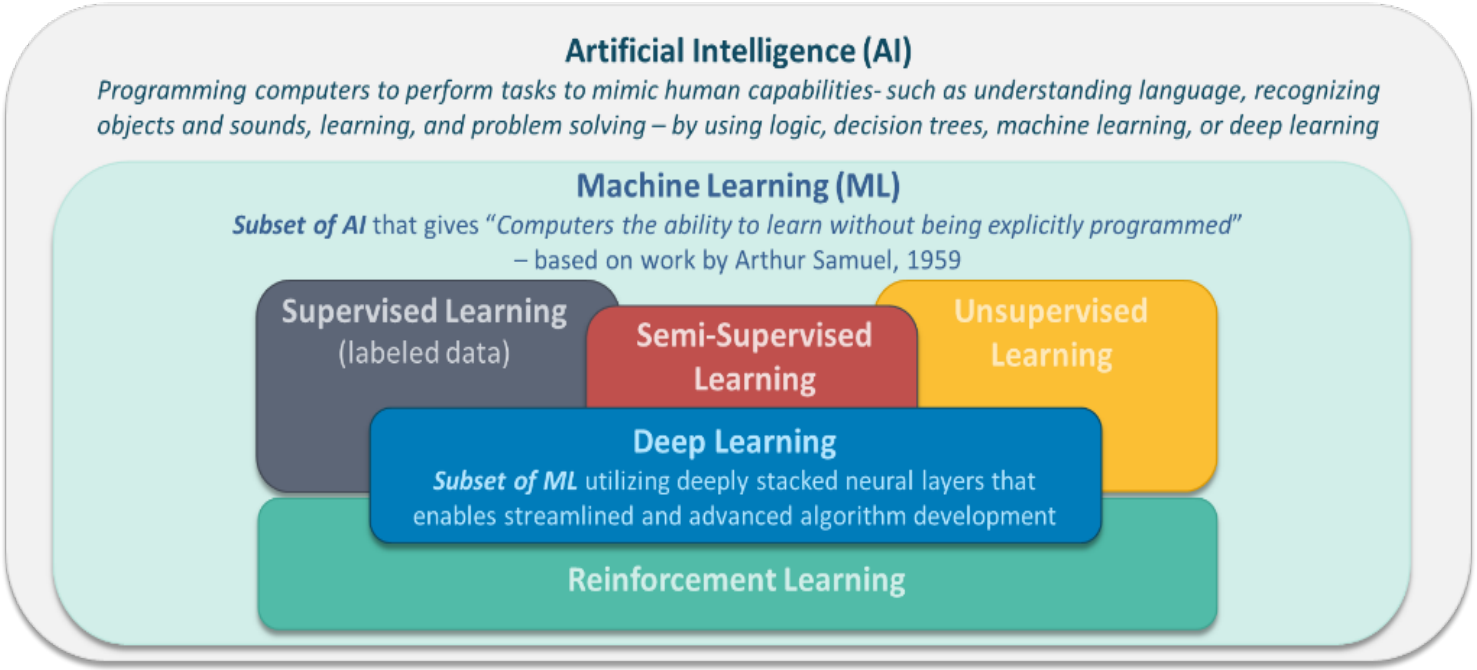
1. Machine Learning-enabled Medical Devices: Key Terms and Definitions
   finalized in 9 May 2022

2. Good machine learning practice for medical device development – Guiding Principles
   finished public consultation

3. Technical Framework for AI Lifecycle Management
   Start discussion

MLMD (Machine Learning-enabled Medical Device)

A medical device that uses machine learning, in part or in whole, to achieve its intended medical purpose.



※ The descriptions within the diagram are not definitions, and are included to convey a general sense of the technology.

- Collaboration with FDA/EC

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Call for Action

- Development may rapidly advance
  - If guidance documents covering usage and learning methods can be formulated and success stories emerge.

- Regulations may also be necessary
  - There are also issues regarding how to respond when AI learning is misused.
  - AI learning can also result in degradation intentionally.

- Useful to share the same concerns to come together and work toward a common measures as a best practices
  - Regulators face common challenges
  - Discussion is ongoing in the international harmonization of medical device regulations.

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Thank you very much!!

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Please visit the PMDA website

https://www.pmda.go.jp/english/index.l