# AI-based SaMD and medical systems in Japan: Towards social acceptance

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SaMD = Software as medical device：医療機器プログラム
PMD Act = Pharmaceutical and medical device Act：薬機法

# Today's Messages

- AI-based SaMD and medical systems in Japan
  - Approval cases
  - Regulatory requirements
- For social acceptance, more than just regulatory concerns
- Some are technical, some are legal.

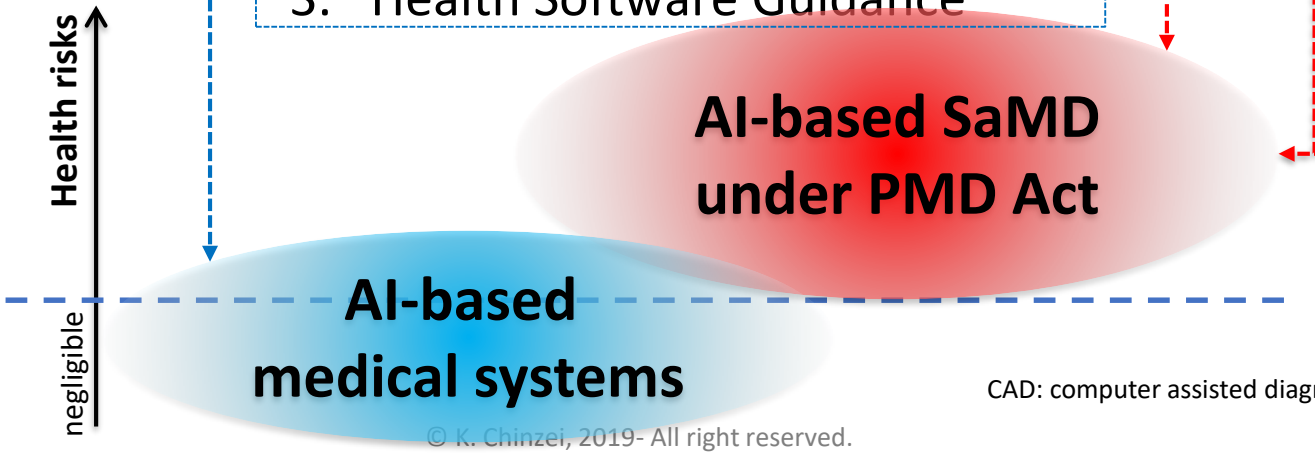
# Approved AI-based SaMD in Japan

- **ENDOBrain** (Cybernet / Olympus): 2018/12/6
  - Neoplasticity of colon polyps in microscopic endoscope image
  - Support vector machine
  - Accept Olympus “Endocyto” only
  - Class Ⅲ
- **EIRL aneurysm** (LPIXEL): 2019/09/17
  - Extract suspected anelysium in MRI
  - Deep learning
  - Accept DICOM format
  - Class Ⅱ

https://www.cybernet.co.jp/medical-imaging/products/endobrain/
https://lpixel.net/news/press-release/2019/9757/

# Related regulation and documents

- **PMD Act**
  - **SaMD related notices**
- Guidance
  1. AI-CAD Evaluation Indices
  2. AI-CAD R&D Guidelines
  3. Health Software Guidance




CAD: computer assisted diagnosis

# AI-CAD Evaluation Indices[1] / R&D Guidelines[2]

- Issued May 23, 2019
- **NOT Mandatory**
- **For PMDA reviewers, Manufacturers**
- Critical points to be considered in AI-CAD review process.
- **Data management**
- **Performance change by post-market training**

- Issued Dec 2019
- **NOT Mandatory**
- **For CAD developers, AI-CAD trainers**
- Implementation of the Evaluation Indices to IEC 62304 (Software lifecycle process)
- Statistical analysis methods

1. 人工知能技術を利用した医用画像診断支援システムに関する評価指標（薬生機審発0523第2号別添4 令和元年5月23日）
2. 医用画像診断支援システム（人工知能技術を利用するものを含む）開発ガイドライン（手引き）（2019年12月公表）

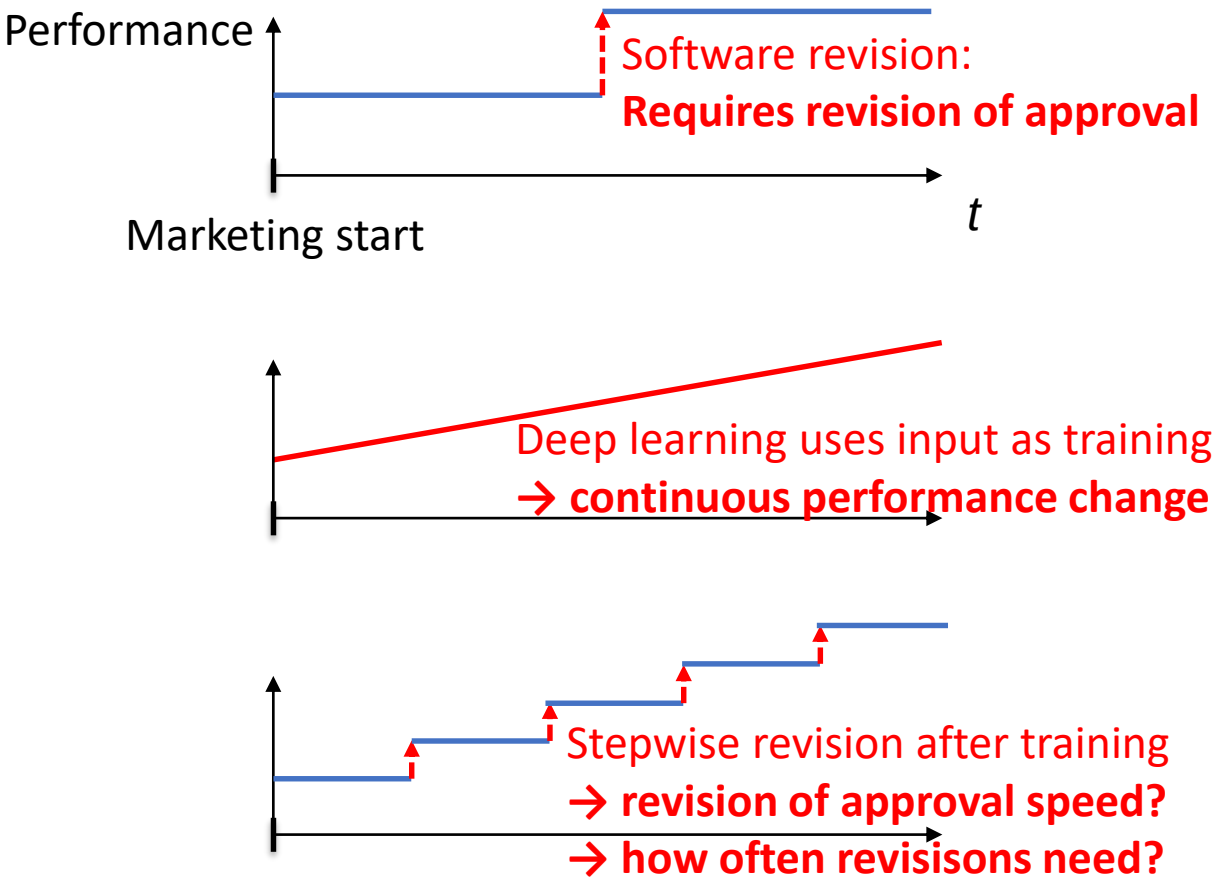
# Data management

- Quality
  - Data appropriately represent the patients population?
  - Cybersecurity
- Compliance
  - Privacy, ethics
- Data as "SOUP item[1]"

- Medical data in internet
- Annotation without good management record
- Synthesized data
- Network model trained by others

[1] SOUP item (off-the-shelf software) : IEC 62304 term refers to 1) generally available software (e.g. operating system), or 2) software missing adequate records of the development process (e.g., old software you wrote 10 years ago)

# Performance change by post-market training




- Conventional software is static.
- Deep learning can continuously train.
- Improvement not guaranteed
- Who / how to keep quality assurance?
- PMA Act will be revised for this.

# Regulation is not the solo problem

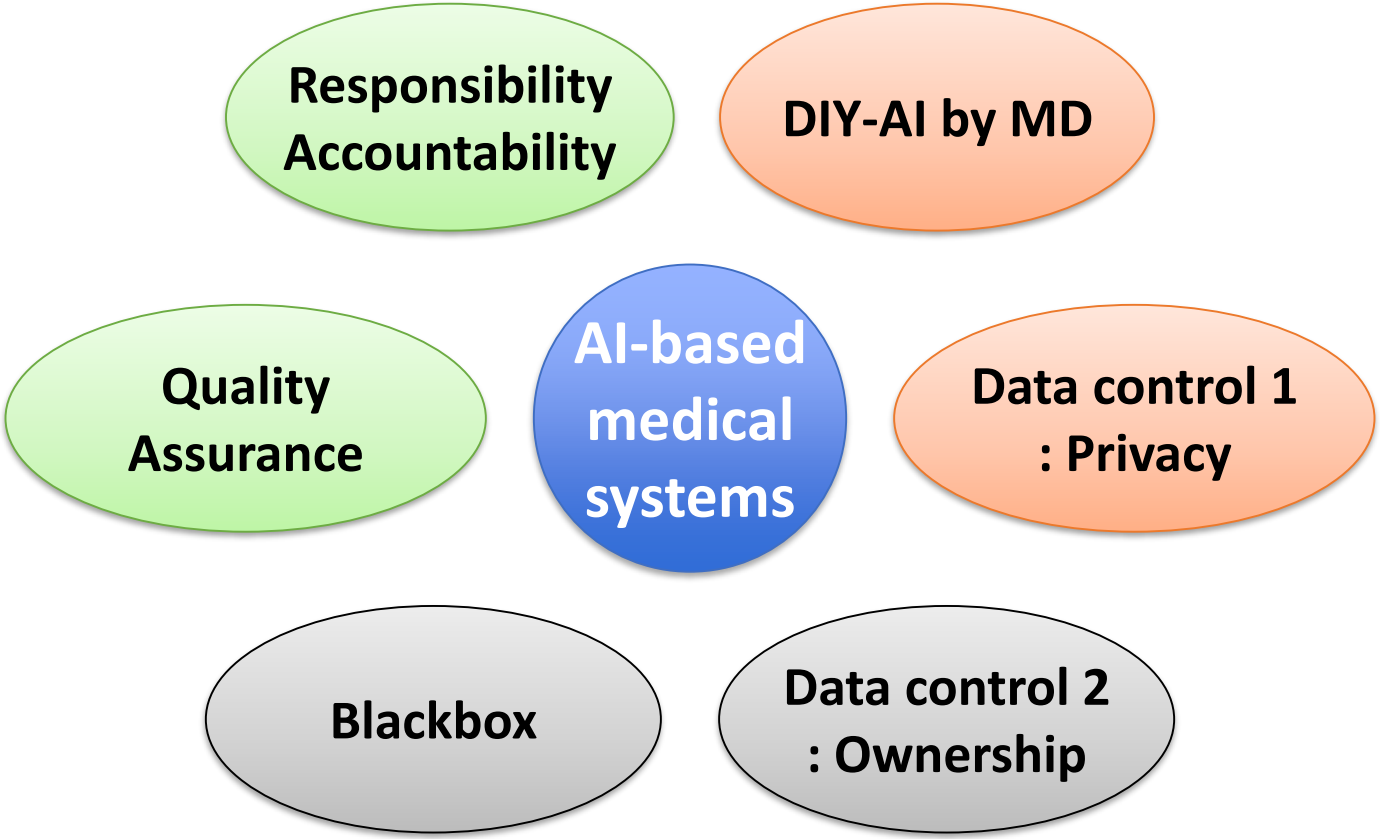
# CAD is not the only AI-based SaMD.

| Replacing existing medical practice? | Replacing existing (non-AI) software? | Examples |
|---|---|---|
| Y | Y | • Radiology CAD incl. EIRL aneurysm |
| Y | N | • ENDOBrain<br>• Pathology CAD<br>• CAD for fru visual exam [1] |
| N | N | • AF detection using smart watch [2]<br>• Early detection of pandemic from SNS [3] |

[1] Detection of follicles in pharyngeal wall https://aillis.jp

[2] Wasserlauf et.al., *Circulation: Arrhythmia and Electrophysiology*. 2019 doi: 10.1161/CIRCEP.118.006834
[3] Wakamiya, et.al., *JMIR Public Health and Surveillance*. 2018 doi: 10.2196/publichealth.8627

# AI-based medical systems: barriers



# Responsibility & accountability

***In medical practice using AI for diagnosis and/or therapy, MD shall play the main role to conduct the medical practice. The MD shall hold the final accountability to the decision making of the medical practice, as Article 17 of Medical Practitioners' Act[1].***

– [2] MHLW Notice 1219 No.1 on Dec 19, 2018.
(Translation by Chinzei)

*Ah, doctors take every responsibility... **NO!***

**MD accountability** assumes **consensus on sharing responsibility** between MD and manufacturer.

[1] Medical Practitioners' Act. = 医師法
[2] 厚生労働省医政局医事課長通知「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」（医政医発1219第1号平成30年12月19日）

# DIY-AI by MD

- **What rules apply to DIY-AI by MD?**

✓ **PMD Act** : lawful, as far as used at own clinic.

✓ **Demonstration of efficacy and safety** : mandatory
- **Clinical Research Act** : applicable
- **Ethical Guidelines**[1] : applicable
- **Quality assurance** : in clinical research grade

- **Clinical research grade QA by MD?**

[1] Ethical Guidelines for Medical and Health Research Involving Human Subjects = 人を対象とする医学系研究に関する倫理指針

# Act on the Protection of Personal Information[1]

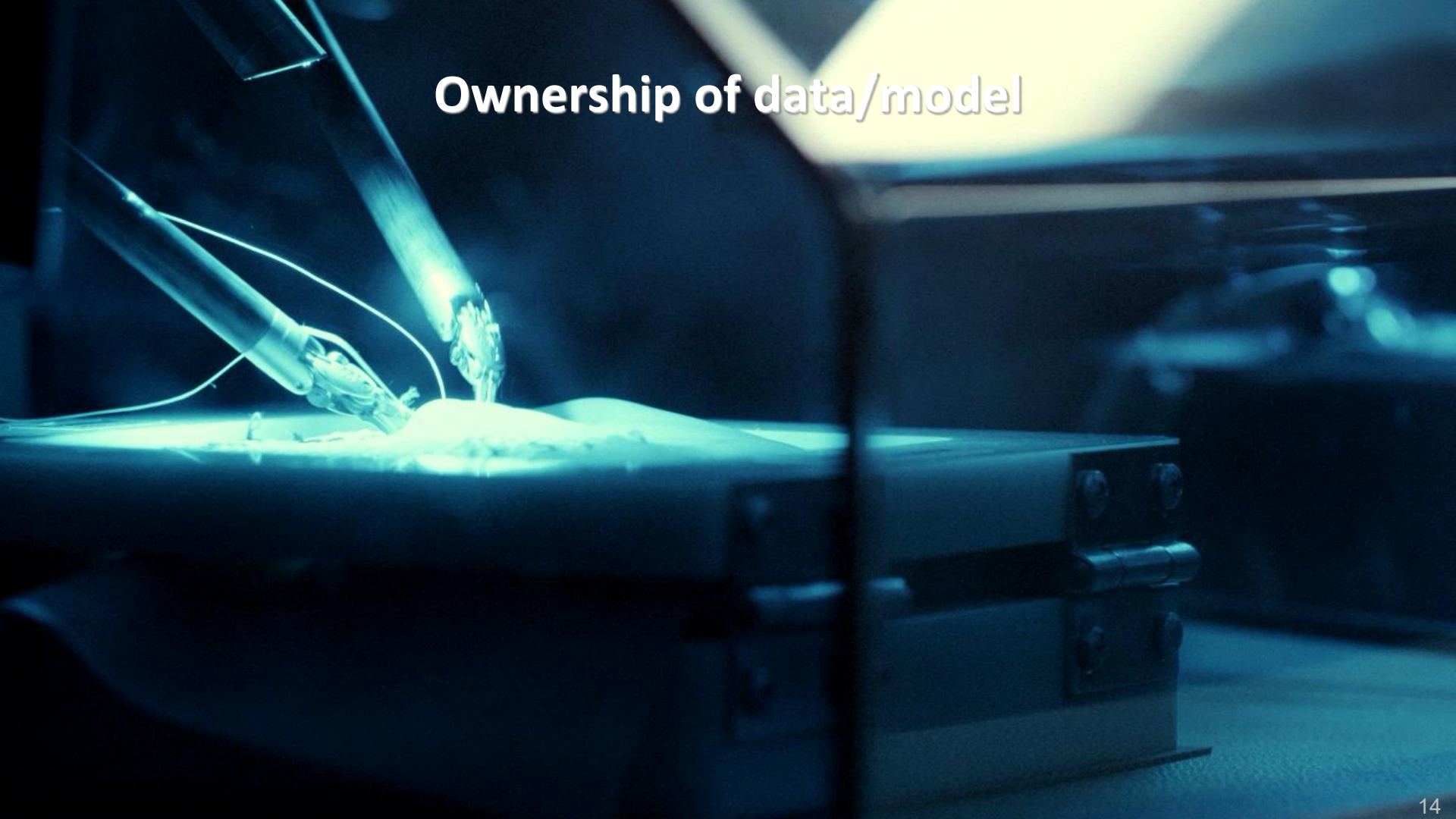
- Clinical data is a “critical personal info”
  → patient’s consent is essential
  – Cinical Research Act, Ethical Guidelines also

- If a patient cancelled the consent...
  – Anonymized dataset not necessary to delete this data. (You can’t)
  – Outcome from such dataset (e.g., network model) not necessary to delete or suspend using it.

  (Confirmed by Personal Information Protection Commission[2])

[1] Act on the Protection of Personal Information = 個人情報保護法
[2] Personal Information Protection Commission = 個人情報保護委員会

# Ownership of data/model



# AI-based medical systems: barriers

Need society agreement

Responsibility
Accountability

DIY-AI by MD

They do.
Need more tools.

Quality
Assurance

AI-based
medical
systems

Data control 1
: Privacy

Need technology for continuous QA

Nations/regions do
differently.

Blackbox

Data control 2
: Ownership

Explainable AI

???