

US-JAPAN

HBD EAST Think Tank Meeting 2023

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# Points to Consider in the Application of AI for Medical Devices

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# Development of the Integrated Cancer Medical System Using Artificial Intelligence (JST CREST Project since 2016)



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The PRISM project “Development of Artificial Intelligence Accelerating Drug Discovery” was launched in 2018, and the BRIDGE project “Medical Digital Twin” has just started in June 2023.

Large-scale Data in NCC

Omics information

Clinical information

Medical images

PDX model

Pathology reports,  
Radiology reports

NCC Integrated Cancer Medical Information Database

AI Technology  
(Machine Learning ·  
Deep Learning)

Support system for  
personalized medicine

Precision Medicine **CANCER**

New cancer diagnostic  
system

Reduction of the medical insurance

New drug design system

Promoting the movement from  
R&D to industrialization

Application for healthcare industry

JST AIP Network Lab/CREST "Artificial Intelligence" Research Area



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Division of Medical AI Research and Development  
National Cancer Center Japan

# Overview of the Medical AI Project in NCC (Tsukiji Campus)

On the basis of the FY 2016 JST CREST project, the National Cancer Center, Preferred Networks, and Artificial Intelligence Research Center of AIST jointly launched the project.

## Participating Organizations

### National Cancer Center Japan

#### Research Institute

*Div. Medical AI Research and Development*  
*Div. Genome Biology*  
*Div. Cellular Signaling*

#### Center for Public Health Sciences

*Div. Bioethics and Healthcare Law*  
*Div. Biostatistical Research*

*Dep. Radiation Oncology*  
*Dep. Diagnostic Radiology*  
*Dep. Experimental Therapeutics*  
*Dep. Pathology and Clinical Laboratories*  
*Dep. Dermatologic Oncology*  
*Dep. Gastric Surgery*  
*Dep. Hepatobiliary and Pancreatic Oncology*  
*Dep. Radiological Technology*  
*Dep. Colorectal Surgery*  
*Dep. Esophageal Surgery*  
*Dep. Genetic Medicine and Services*  
*Innovation Center for Supportive, Palliative and Psychosocial Care*

#### Hospital

*Dep. Endoscopy*  
*Div. Medical Informatics*  
*Dep. Thoracic Oncology*  
*Dep. Thoracic Surgery*  
*Dep. Neurosurgery and Neuro-Oncology*  
*Dep. Gynecology*  
*Dep. Musculoskeletal Oncology and Rehabilitation*  
*Dep. Breast Surgery*  
*Dep. Gastrointestinal Medical Oncology*



**RIKEN Center for Advanced Intelligence Project**  
*Cancer Translational Research Team*

### Academic collaborators

#### The University of Tokyo

*Research Center for Advanced Science and Technology*

**National Institute of Advanced Industrial Science and Technology (AIST)**  
*Artificial Intelligence Research Center*



**Tokyo Medical and Dental University**  
*Dep. National Cancer Center Cancer Science*  
*Dep. Cardiovascular Medicine*

### Companies cooperating with us

**Preferred Networks Inc.**

**NEC Corporation**

**FUJIFILM Corporation**

**Fujitsu Limited**

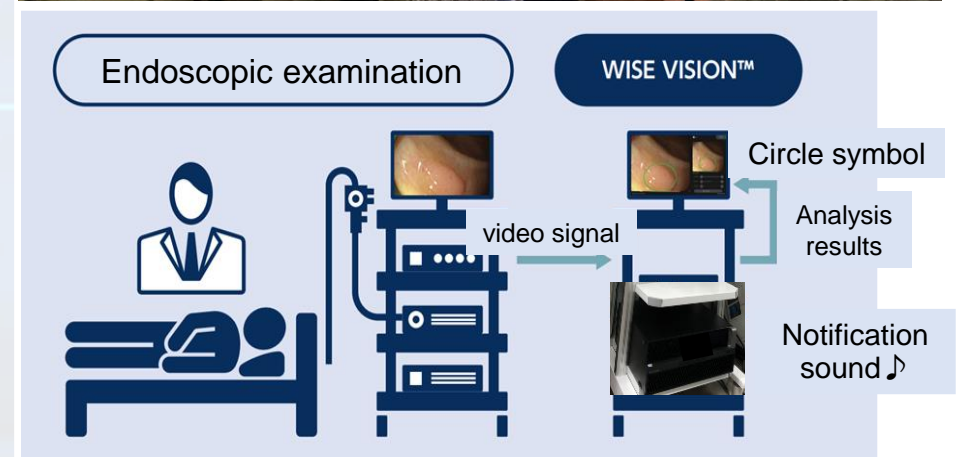
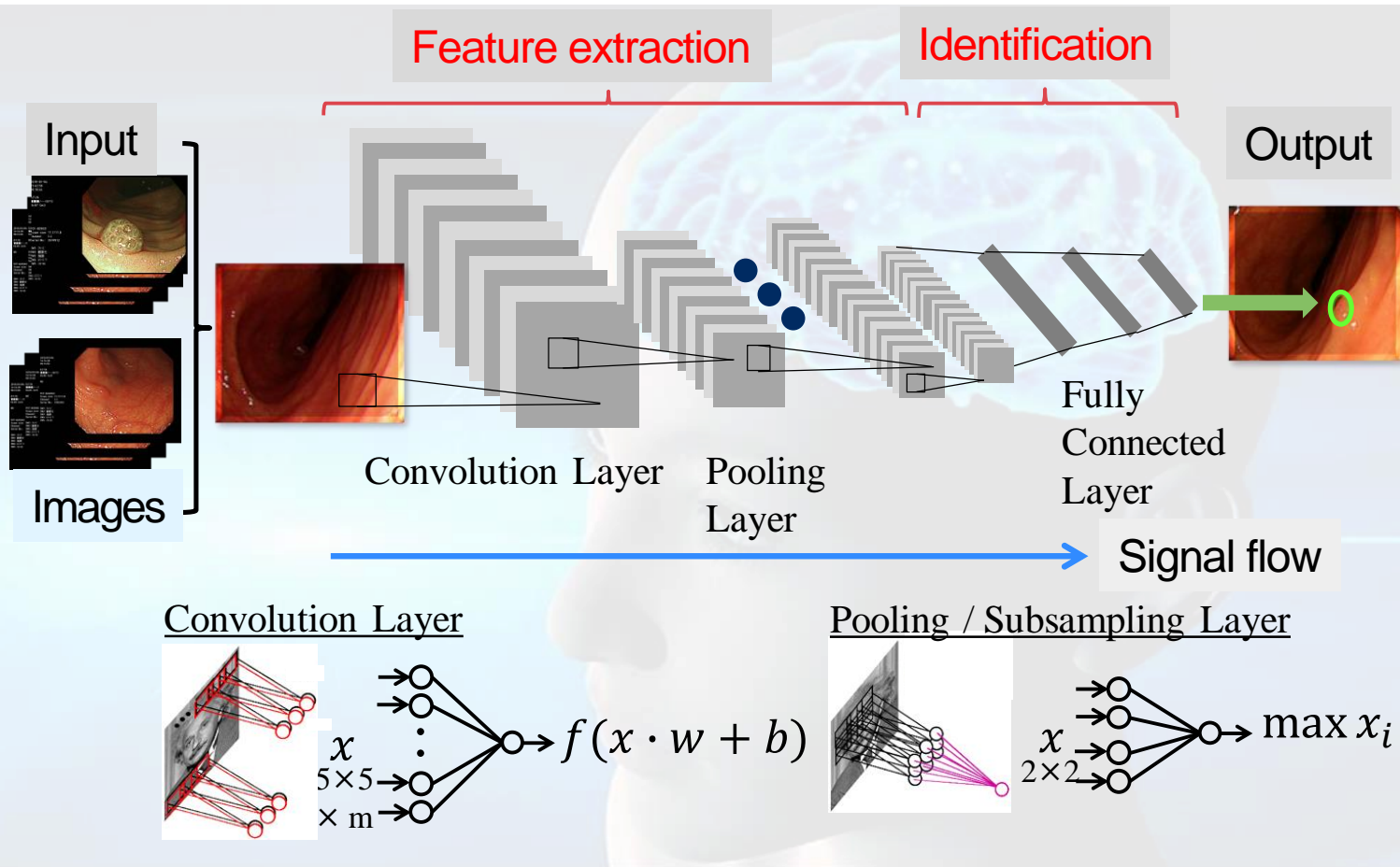
**Hitachi, Ltd.**

**Xcoo, limited**

**Humanome Lab., Inc.**

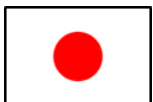
## WISE VISION™ : Endoscopic diagnosis support AI SaMD

The real-time endoscopic diagnostic support system we developed for the detection of colorectal cancer and precancerous lesions received regulatory approval in 2020 as a controlled medical device (Class II) and is CE Mark compliant. In addition, the product was also applied to Barrett's esophagus tumor detection, and was the first product in the world to conform to the CE Mark.



# AI SaMD for endoscopic imaging diagnostic support

No.	Brand name	Manufacturers	Functions	Year of approval
1	EndoBRAIN	Cybernet Systems Ltd.	Ultra-magnified endoscopic images assist in the determination of tumor/non-tumor colorectal lesions. Compatible with Olympus endoscopes.	2018
2	EndoBRAIN-UC	Cybernet Systems Ltd.	Software that uses AI to analyze images of the intestinal tract obtained by colonoscopy to assist in the diagnosis of the inflammatory state of ulcerative colitis. Compatible with endoscopes manufactured by Olympus.	2020
3	EndoBRAIN-EYE	Cybernet Systems Ltd.	Diagnosis support software for colonoscopy lesion detection using deep learning. Compatible with Olympus endoscopes.	2020
4	EndoBRAIN-Plus	Cybernet Systems Ltd.	Diagnostic support software for pathological diagnosis prediction (non-tumor, adenoma/intramucosal carcinoma, invasive carcinoma) for colonoscopic lesions. Compatible with Olympus endoscopes.	2020
5	CAD EYE (EW10-EC02)	Fujifilm Corporation	Endoscopic diagnosis support software that uses AI technology to assist in the detection of polyps and other lesions during colonoscopy and the differentiation of neoplastic or nonneoplastic lesions. Compatible with endoscopes manufactured by Fujifilm Corporation	2020
6	WISE VISION	NEC Corporation	Diagnostic support software that uses AI technology to automatically detect precancerous lesions and early-stage colorectal cancer in real time during colonoscopy. Compatible with endoscopes from Olympus, Fujifilm, and HOYA.	2020
7	CAD EYE (EW10-EG01)	Fujifilm Corporation	Endoscopic diagnosis support software that uses AI technology to extract and present to the examiner areas that may be esophageal squamous cell carcinoma or gastric neoplastic lesions during upper gastrointestinal endoscopy. Compatible with endoscopes manufactured by Fujifilm Corporation.	2022
8	EIRL Colon Polyp	LPIXEL Inc.	Endoscopy diagnosis support software that uses AI technology to assist in the detection of polyp candidate lesions during colonoscopy. Compatible with Olympus endoscopes.	2022



<https://www.pmda.go.jp/PmdaSearch/kikiSearch/>, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> (Accessed May 25, 2023)

Japanese endoscopes have the largest market share in the world (>90%), and Japan also leads the world in AI SaMD for endoscopic imaging diagnostic support.

# Social implementation of the AI development support platform "SYNAPSE Creative Space" (announced on April 5, 2022)

Data transfer/Anonymization

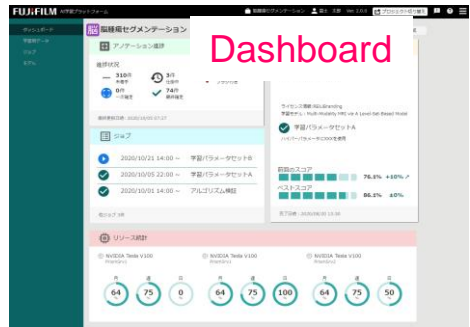
Annotation

Setting up learning models

Training

Application of AI

## Project Management



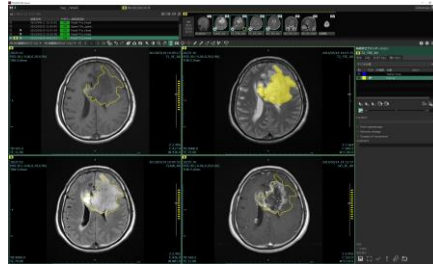
## Annotation worklist



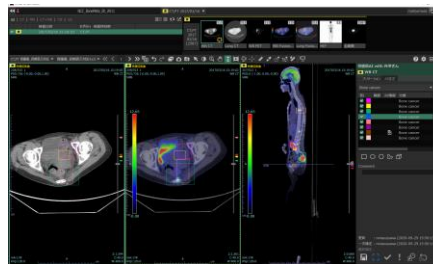
## Training status management



## Annotation

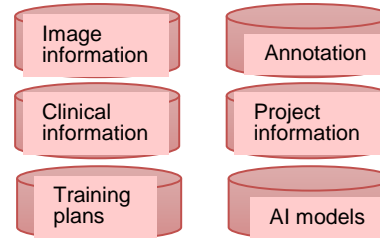


The image editing technology developed in SYNAPSE SAI viewer<sup>\*1</sup> and SYNAPSE VINCENT<sup>\*2</sup> can be used.



Advanced annotation using multiple series is also possible.

## Training management



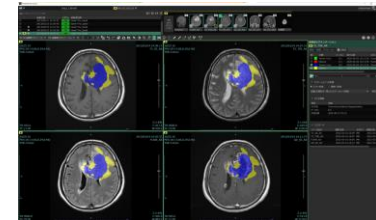
Centralized management of information required for AI development.



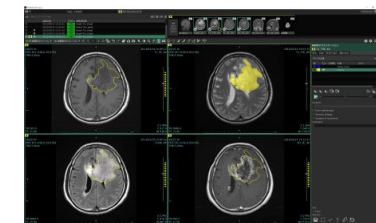
- \*Progress management of correct data
- \*PC schedule management for AI training
- \*Automatic execution of learning
- \*Learning model management

## AI execution

Training results can be displayed instantly.



Efficiently create additional training data using the trained model.



We provide an all-in-one platform to support AI development.



\*1 Trade name: Program for diagnostic imaging workstation FS-V686  
 Certification Number: 231ABBZX00028000

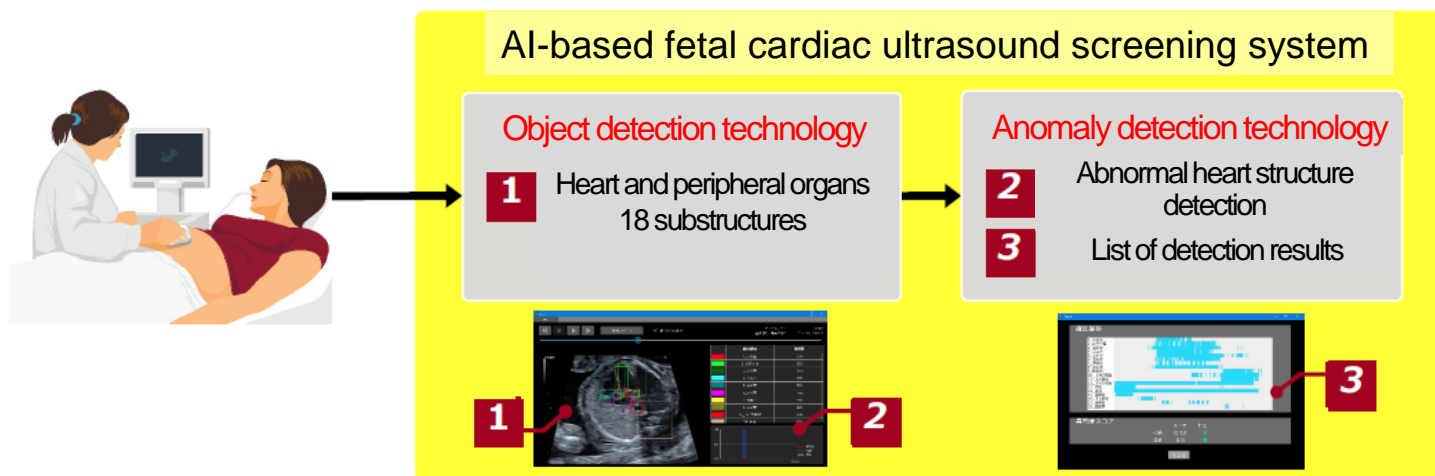
\*2 Trade name: Fuji Diagnostic Imaging Workstation FN-7941  
 Certification Number: 22000BZX00238000

## Purpose of this research

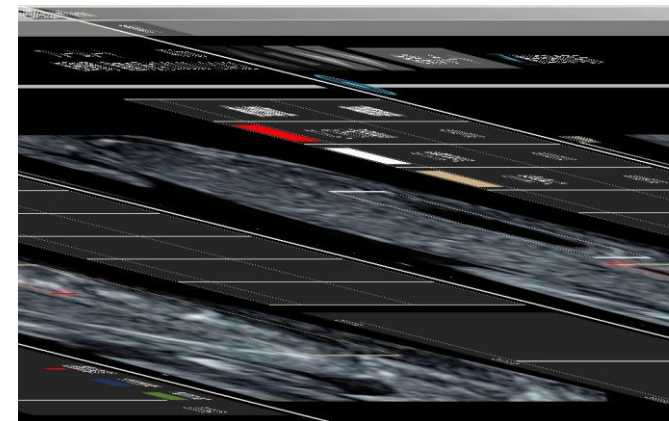
We develop fundamental technologies for a fetal cardiac ultrasound screening system.

\*Development of a technology to detect abnormalities in the fetal heart structure.

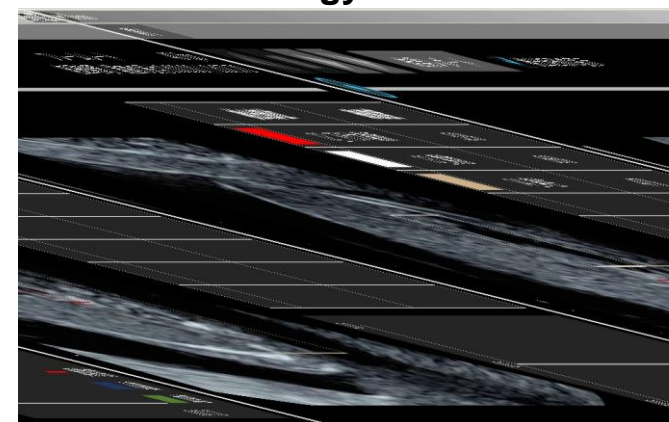
\*Development of a method for displaying detection results that improves the efficiency of diagnosis.



Normal fetus



Congenital heart disease  
(Tetralogy of Fallot)



## References

1. *Biomolecules*. 2020 Nov 8;10(11):1526.
2. *Biomolecules*. 2020 Dec 17;10(12):1691.
3. *Applied Sciences*. 2021 Jan 2;11(1):371.
4. *Applied Sciences*. 2021 Jan 26;11(3):1127.
5. *Biomedicines*. 2021 Jun 23;9(7):720.

We are currently preparing an application for regulatory approval.

# Difficulties in Utilizing Data Containing Personal Information and The Need for Measures to Resolve These Difficulties

## Development of AI SaMD

### Companies



Huge amounts of medical images and patient data are needed for training and validation data for development of AI SaMD, as well as for test data.

### Medical institutions



**X** Data containing personal information

- In order for a company to acquire such medical information and use it for research and development purposes, it is necessary to obtain consent from the individual patient regarding any change from the original purpose of use and provision to a third party.
- However, it is practically difficult to obtain consent for a huge number of patients going back in time

Newly established in April 2022

To accelerate the development of AI medical devices, measures to smoothly utilize "anonymous processed information" and "pseudonymized processed information" stipulated in the Personal Information Protection Law are necessary.

Data utilization

Protection of human subjects and proper promotion of research

Quality, safety and efficacy

Personal Information Protection Law

Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects

Pharmaceuticals and Medical Devices Act

To clarify measures that can be taken under the current system and issues that need to be resolved in the future, and improve the environment to further promote utilization in the future.



# A Guideline to Be Prepared; Procedures that Allow Medical Institutions to Process Appropriately in Accordance with The Standards



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厚生労働省

Ministry of Health, Labour and Welfare

## Research Grants for Research on Labor Sciences and Policy Sciences Research Project on Ethical, Legal and Social Issues (FY4 - FY5)

Preparation of a Guideline for The Use of Digital Data for Medical Research and Development, including Medical AI Research and Development  
Coordinating Researcher: Dr. Ryuji Hamamoto (National Cancer Center Japan)

### Required outcomes

Outcome 1: Preparation of a guideline for the utilization of digital data for AI research and development, including digital data processing methods and processing standards.

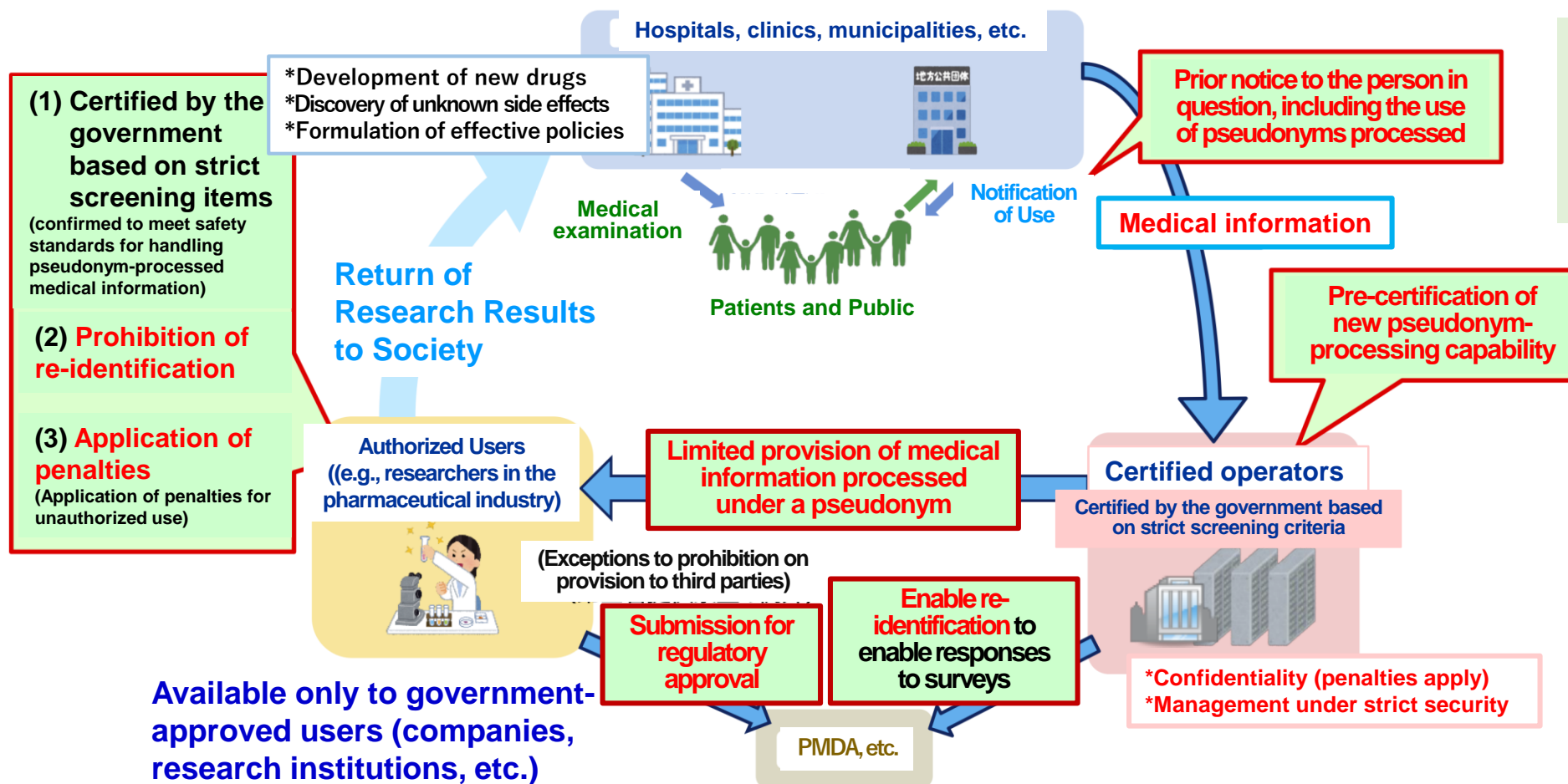
Outcome 2: Preparation of case studies for the utilization of digital data for AI research and development.

# Revised Next Generation Medical Infrastructure Act

## A mechanism for the utilization of pseudonymized processed medical information is established

\*From the viewpoint of research needs and social benefits of medical information, create and provide new "pseudonym-processed medical information".

\*In this case, from the viewpoint of personal information protection, the provision of pseudonym-processed information is limited to government-approved users.



Revised Next Generation Medical Infrastructure Law passed by the Plenary Session of the House of Councillors on May 17, 2023.

Source: Cabinet Office, Review of the Next Generation Medical Infrastructure Act  
([https://www.kantei.go.jp/jp/singi/kenkouiryou/data\\_rikatsuyou/dai8/siryou1.pdf](https://www.kantei.go.jp/jp/singi/kenkouiryou/data_rikatsuyou/dai8/siryou1.pdf)) Accessed May 24, 2023

# Acknowledgements



**\*Division of Medical AI Research and Development**  
**National Cancer Center Research Institute**  
**\*Cancer Translational Research Team**  
**RIKEN Center for Advanced Intelligence Project**  
**\*Department of NCC Cancer Science**  
**Tokyo Medical and Dental University**  
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