

US-JAPAN

HBD EAST Think Tank Meeting 2023

December 14, 2023

Points to Consider in the Application of AI for Medical Devices

Director, Division of Medical AI Research and Development,
National Cancer Center Research Institute

Ryuji Hamamoto

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



国立研究開発法人
国立がん研究センター
National Cancer Center Japan

Project Leader: Ryuji Hamamoto



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)

Precision Medicine **CANCER**

Support system for
personalized medicine

New cancer diagnostic
system

Promoting the movement from
R&D to industrialization

Reduction of the medical insurance

New drug design system

Application for healthcare industry

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



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

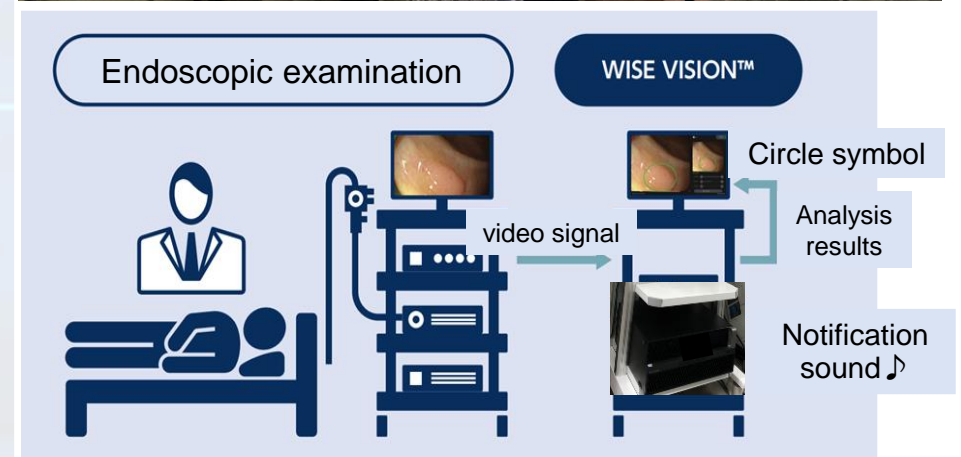
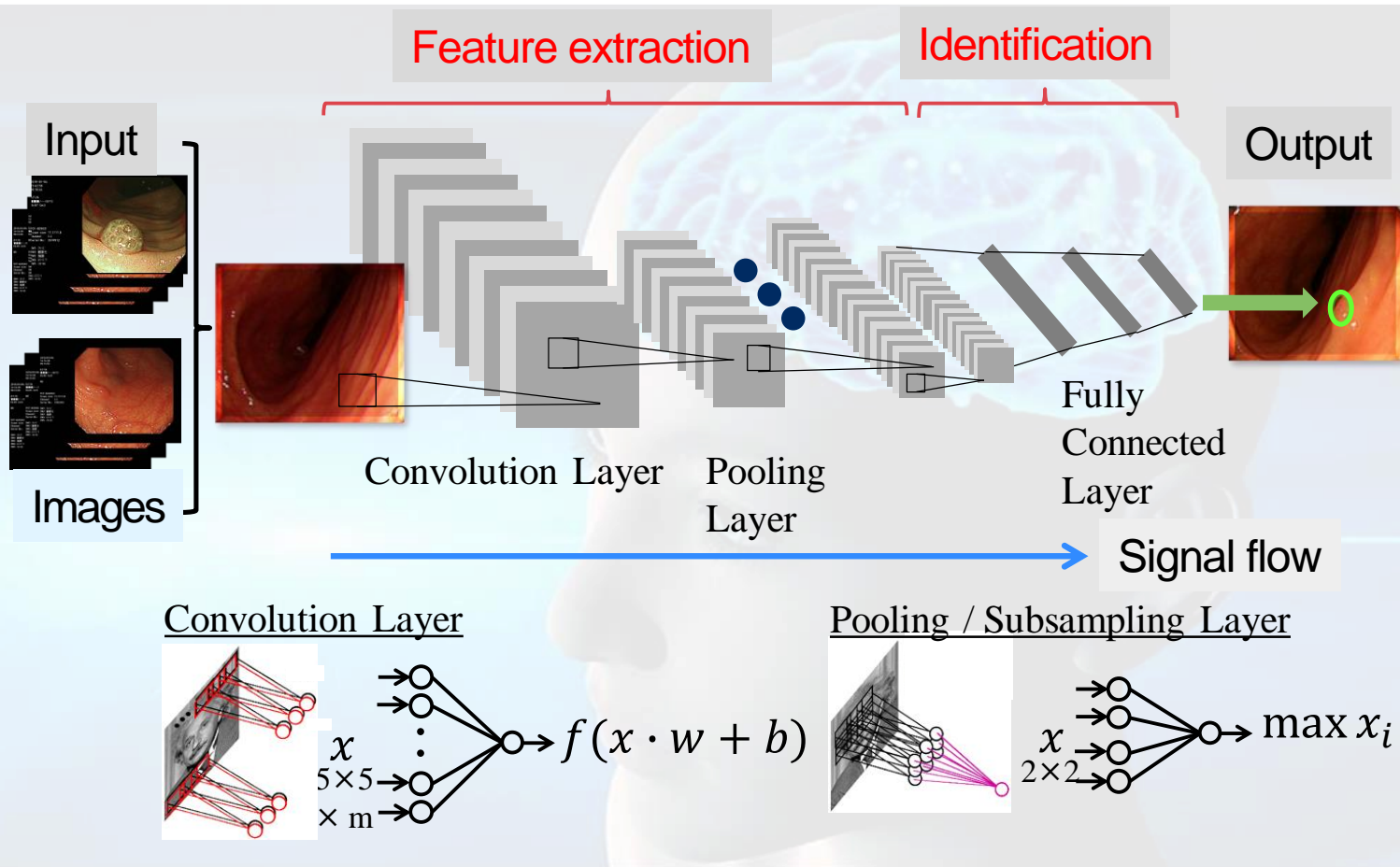
Hitachi, Ltd.

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

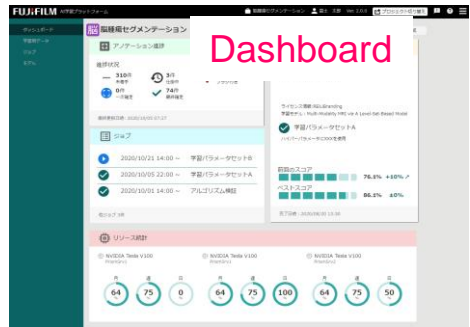
Annotation

Setting up learning models

Training

Application of AI

Project Management



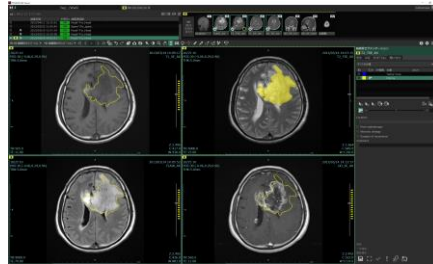
Annotation worklist



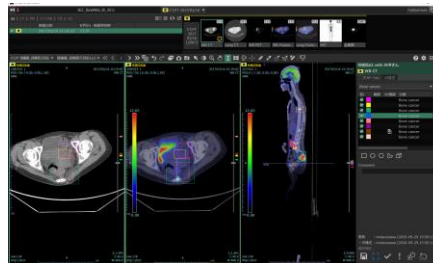
Training status management



Annotation

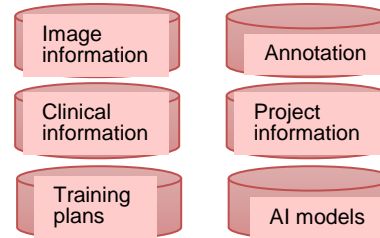


The image editing technology developed in SYNAPSE SAI viewer^{*1} and SYNAPSE VINCENT^{*2} can be used.



Advanced annotation using multiple series is also possible.

Training management



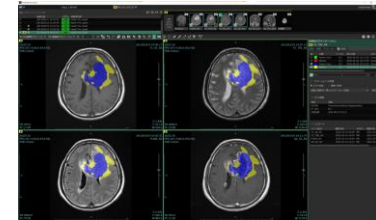
Centralized management of information required for AI development.



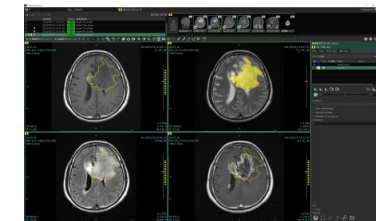
- *Progress management of correct data
- *PC schedule management for AI training
- *Automatic execution of learning
- *Learning model management

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

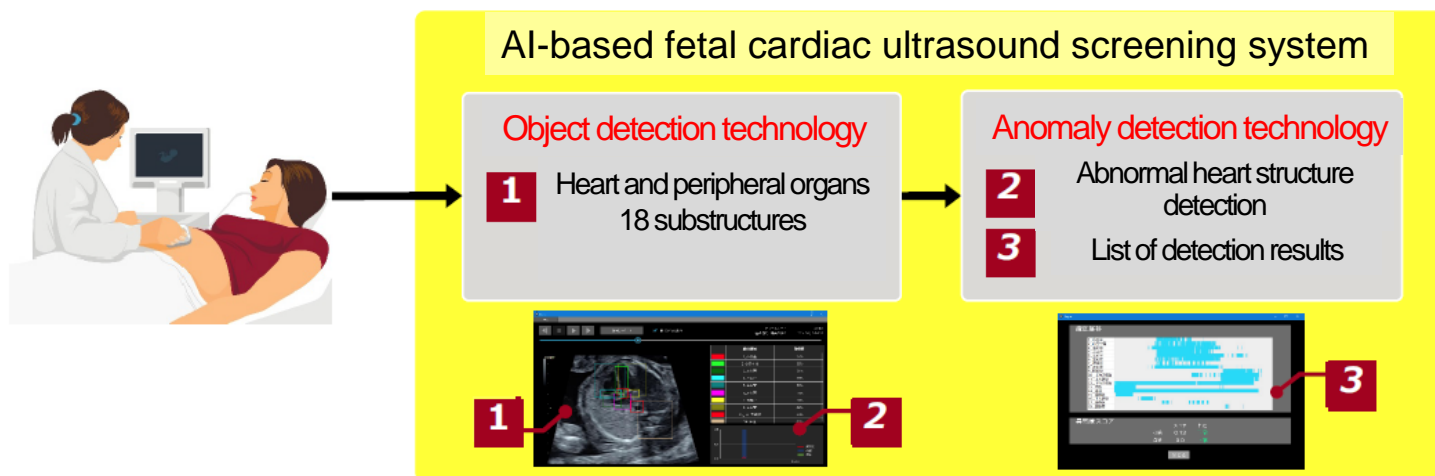
*2 Trade name: Fuji Diagnostic Imaging Workstation FN-7941
 Certification Number: 22000BZX00238000

Purpose of this research

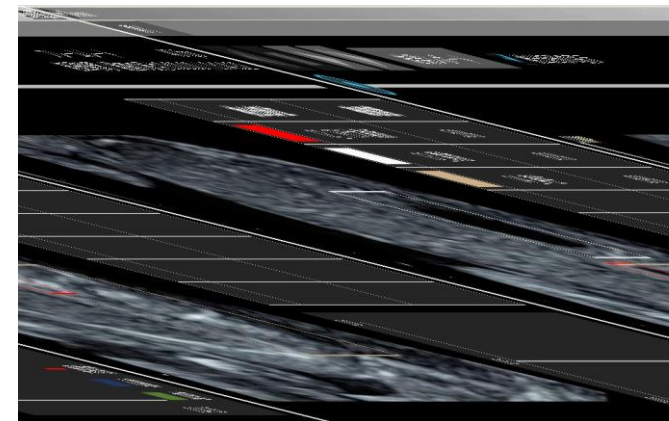
We develop fundamental technologies for a fetal cardiac ultrasound screening system.

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

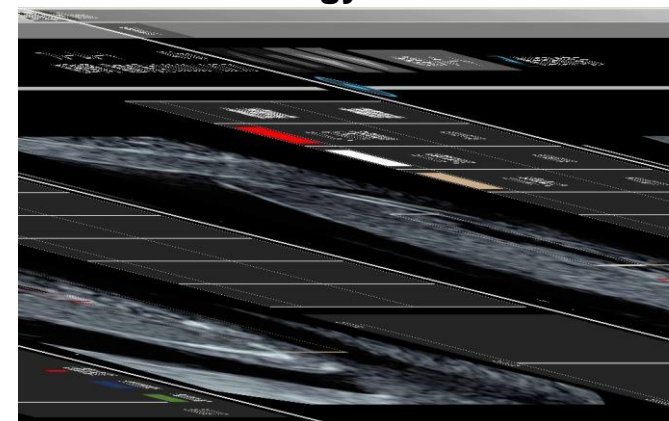
*Development of a method for displaying detection results that improves the efficiency of diagnosis.



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

Personal Information Protection Law

Protection of human subjects and proper promotion of research

Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects

Quality, safety and efficacy

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

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.

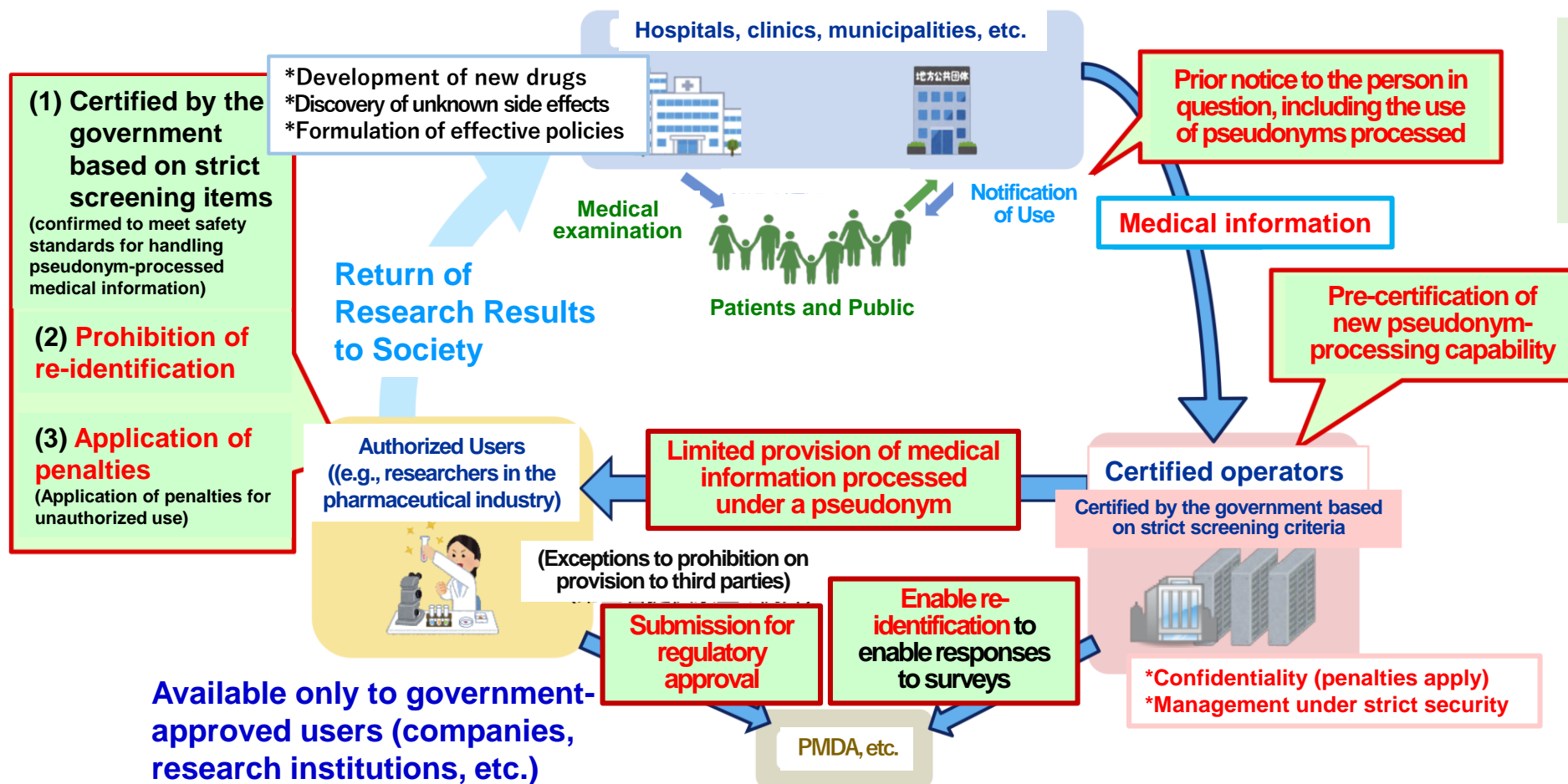
Outcome 2: Preparation of case studies for the utilization of digital data for AI research and development.

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) Accessed May 24, 2023

Acknowledgements



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