

Recent innovation and development of CADe/CADx medical devices in Japan

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FUJIFILM Corporation
The Japan Federation of Medical Devices Associations

**NEVER
STOP**

FUJIFILM
Value from Innovation

The medical device using AI in Japan

Approval statement of medical device utilizing AI in FY2024

AIを活用した医療機器（プログラム）の承認状況（R5.9末現在）

No.	承認日（一変承認日）	販売名
1	H30.12.6	内視鏡画像診断支援ソフトウェア EndoBRAIN
2	R1.9.17	医用画像解析ソフトウェアEIRL aneurysm
3	R1.12.25	類似画像症例検索ソフトウェアFS-CM687型
4	R2.4.27	内視鏡画像診断支援ソフトウェア EndoBRAIN-UC
5	R2.5.8	肺結節検出プログラム FS-AI688型
6	R2.6.3 (R2.8.11)	COVID-19肺炎画像解析AIプログラム InferRead CT Pneumonia ※一変時に販売名を変更
7	R2.6.19	AI-Radコンパニオン
8	R2.6.29 (R3.3.29)	内視鏡画像診断支援プログラム EndoBRAIN-EYE
9	R2.6.29	COVID-19肺炎画像解析プログラム Ali-M3
10	R2.7.15	内視鏡画像診断支援ソフトウェア EndoBRAIN-Plus

AIを活用した医療機器（プログラム）の承認状況（R5.9末現在）

No.	承認日（一変承認日）	販売名
11	R2.8.20	医用画像解析ソフトウェアEIRL X-Ray Lung nodule
12	R2.9.2 (R4.9.20)	内視鏡検査支援プログラムEW10-EC02
13	R2.11.24	乳がん診断支援プログラムRN-デカルト
14	R2.11.30	WISE VISION 内視鏡画像解析A
15	R3.5.26	COVID-19肺炎画像解析プログラム FS-AI693型
16	R3.7.7	胸部X線画像病変検出 (CAD) プログラム LU-AI689型
17	R3.9.1	肋骨骨折検出プログラム FS-AI691型
18	R3.10.11	画像診断支援ソフトウェア KDSS-CXR-AI-101
19	R3.12.9	胸部X線肺炎検出エンジン Doctor Net JLK-CRP
20	R3.12.24	HOPE LifeMark-CAD 肺炎画像解析支援プログラム for COVID-19

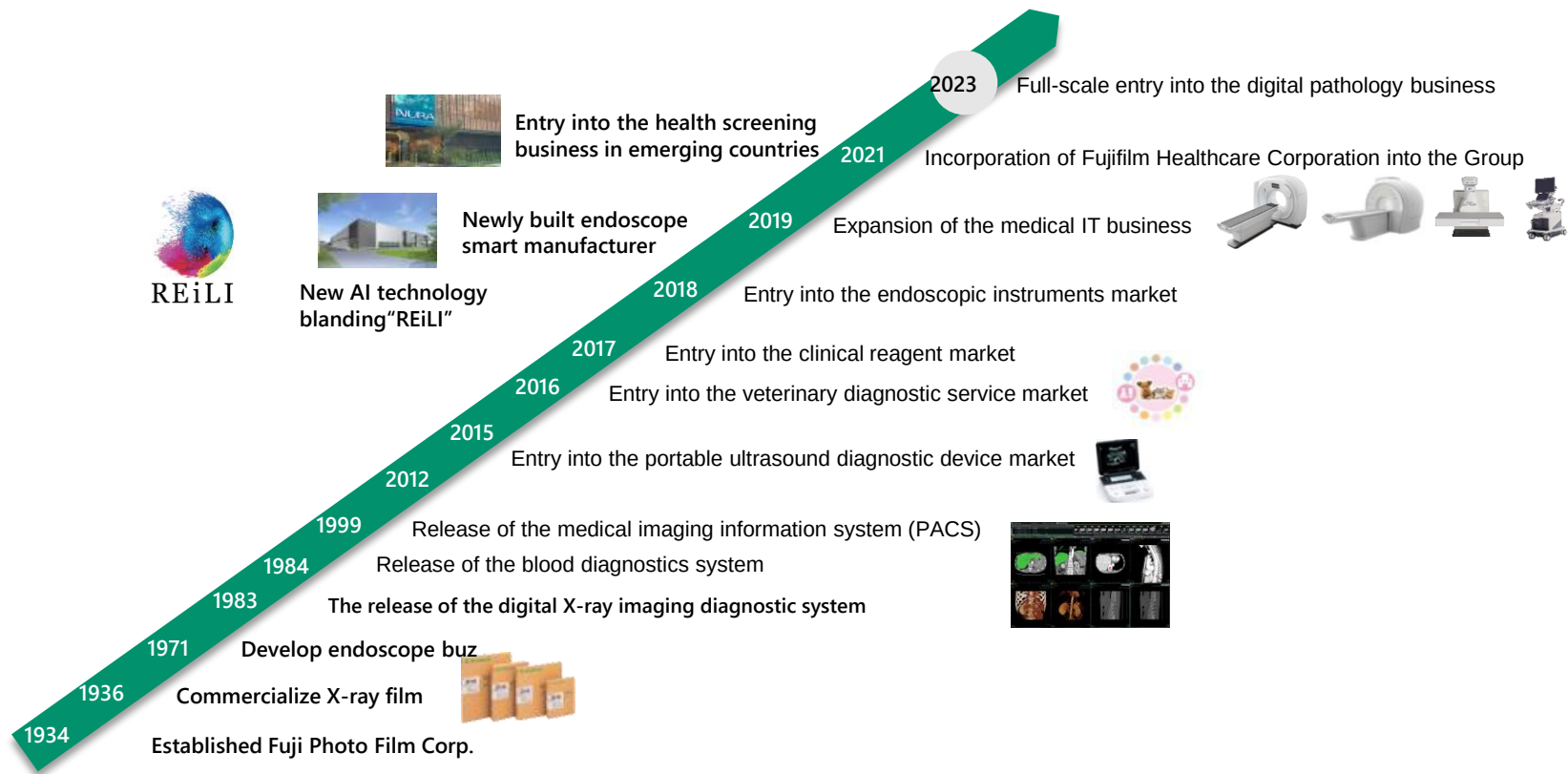
AIを活用した医療機器（プログラム）の承認状況（R5.9末現在）

No.	承認日（一変承認日）	販売名	製造販売承認を受けた者	品目の概要など
21	R4.4.26	nodoca(ノドカ)	アイリス株式会社	咽頭画像と診療情報から、インフルエンザウイルス感染症に特徴的な所見や症状を検出することで、当該感染症を診断支援
22	R4.6.2	COVID-19肺炎解析ソフトウェア SCO-PA01	キヤノンメディカルシステムズ株式会社	X線CT画像からCOVID-19肺炎に見られる画像所見の可能性を2段階の確信度で表示支援
23	R4.9.20	内視鏡検査支援プログラム EW10-EG01	富士フイルム株式会社	内視鏡画像から食道・胃腫瘍性病変の検出支援
24	R4.11.14	医用画像解析ソフトウェア EIRL Colon Polyp	エルビクセル株式会社	内視鏡画像から大腸ポリープ候補の検出支援
25	R4.12.16	医用画像解析ソフトウェア EIRL Chest XR	エルビクセル株式会社	胸部X線画像から肺結節、無気肺等の異常所見陰影候補の検出支援
26	R5.1.17	内視鏡画像診断支援ソフトウェア EndoBRAIN-X	サイバネットシステム株式会社	大腸内視鏡画像から大腸病変の腫瘍/非腫瘍を判別支援
27	R5.5.23	Appleの不規則な心拍の通知プログラム	パシフィックブリッジメディカル株式会社	脈拍数データを解析し、心房細動を示唆する不規則な心拍を検出し、ユーザーに通知する家庭用のプログラム

※承認申請時にAIを活用した旨が記述された医療機器プログラムの一部を例示として列挙したものであり、AIを活用した医療機器（プログラム）を網羅するものではない。

Medical device program / software developed by FUJIFILM

History of medical system development in FUJIFILM



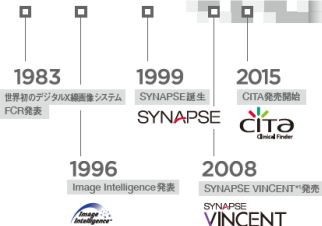
History of AI Technology Development in FUJIFILM

Development history of Medical IT systems and AI technologies healthcare field in FUJIFILM

REiLIブランド誕生
2018



REiLI



2019

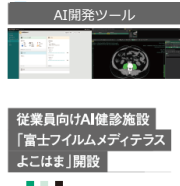
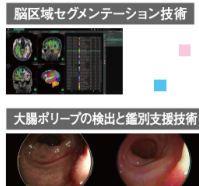
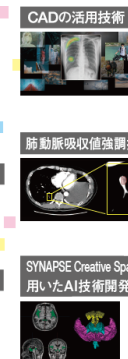
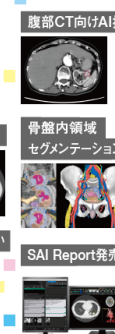
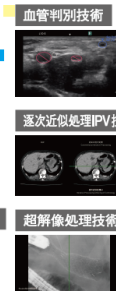
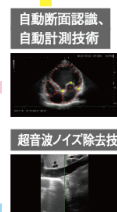
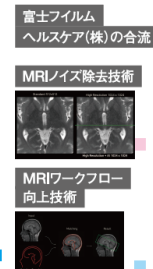
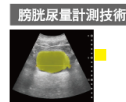
2020

2021

2022

2023

2024



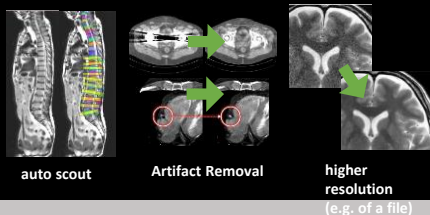
¹⁾ ボリュームアナライザー SYNAPSE VINCENT
販売名:富士医療診断ワークステーション FN-7941型 総販番号:22000BZX00238000
²⁾ SYNAPSE SAI Viewer用 画像表示プログラム
販売名:画像診断ワークステーション用プログラムFS-V686型 総販番号:231ABZXX00028000
³⁾ 当時 富士エロックス(株)

Workflow Integration

STEP
0

Image Quality
(Image Quality Improvement)

Supports improved visibility and low exposure

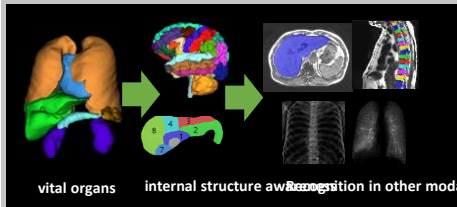


Improvement of technicians' imaging workflow and development of AI-based de-noising and image quality enhancement technologies

STEP
1

organ segmentation
(Segmentation)

Assists in understanding anatomical structures

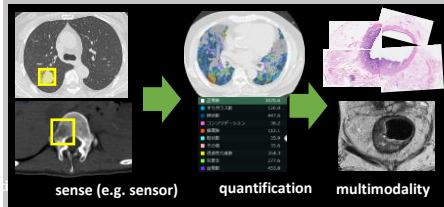


Development of technologies for organ extraction and further detailed structure recognition

STEP
2

Computer-Aided Diagnosis
(Computer-Aided Diagnosis)

Assists in the detection and measurement of lesions



Developing more advanced AI technologies for detecting abnormal findings, quantifying disease states, and using multimodal information

STEP
3

Reporting
(Reporting)

Assists with reporting



Seamless integration with viewers, Able to utilize technology from Steps 0 to 2.

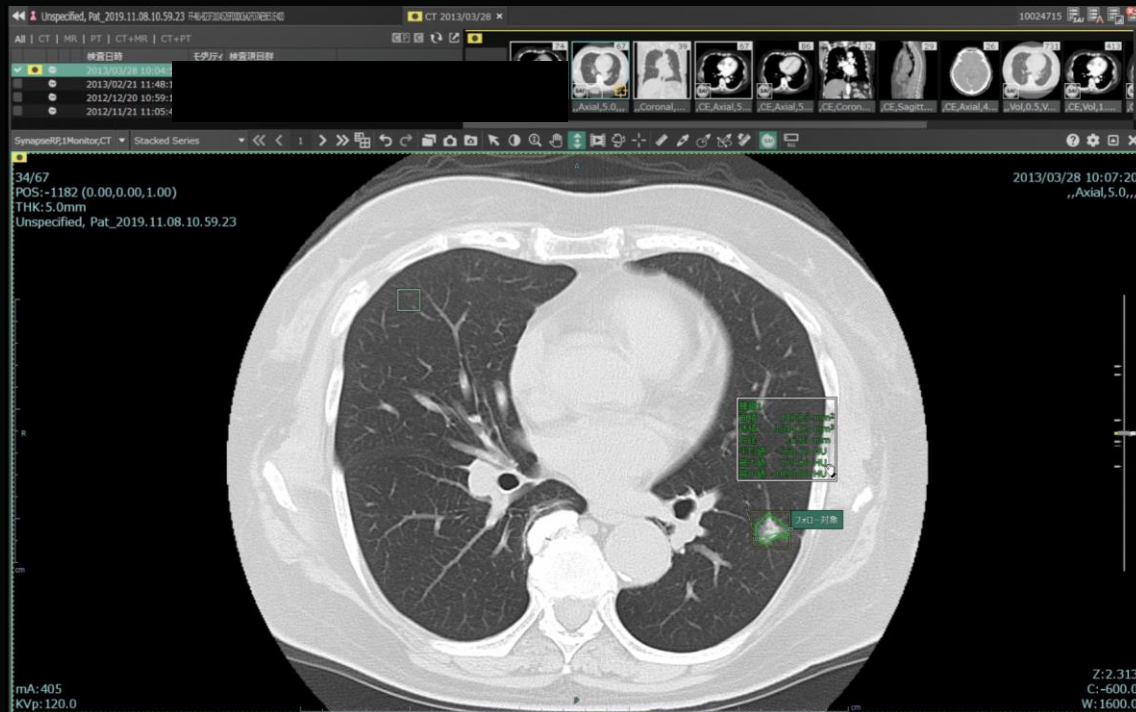
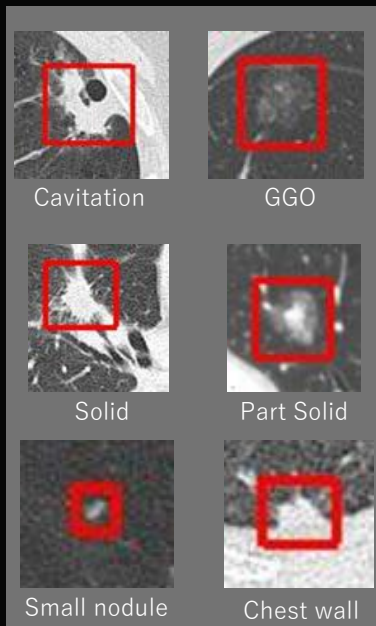
Reading workflows are studied and incorporated into the software

Next-generation AI reading support platform

SYNAPSE



1. Lung nodule detection



Finding sentence creation

Lung Nodule Characterization Analysis



Solid

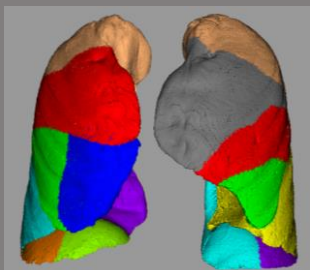
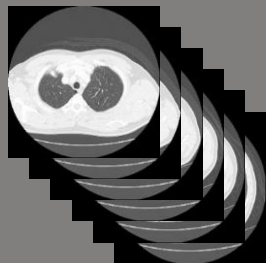
Cavitation -

Irregular +

Bronchial Tubular
Sign -

Lobulated +

Lung segments recognition



Left lower lobe

S6/S10

Finding candidate creation

性状分析結果

境界	-
形状	不整
辺縁性状	-
鋸歯状	-
スピキュラ	-
分葉	+
直線	-
吸収値	充実型
気管支透亮像	-
空洞	-
石灰化	-
脂肪	-
胸膜陥入	-
胸膜接触	-

所見文

● 候補1

左下葉S6/S10に2.85 cmの不整形な充実型結節を認めます。分葉状で、内部に空洞や気管支透亮像は認めません。

● 候補2

左下葉S6/S10に2.85 cmの不整形な充実型結節を認めます。分葉状です。

● 候補3

左下葉S6/S10に2.85 cmの結節を認めます。

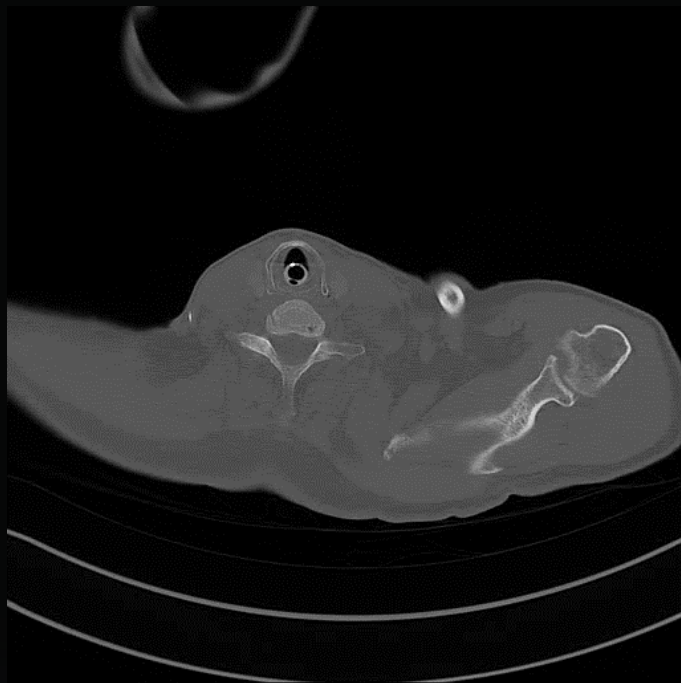
保存+レポート転記

保存

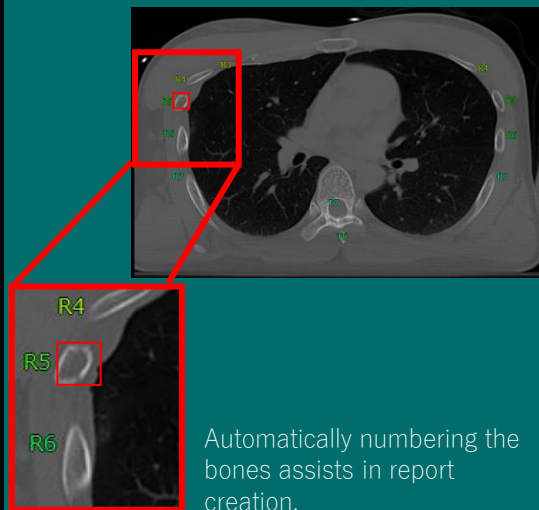
キャンセル

2. Bone Fracture Detection Program

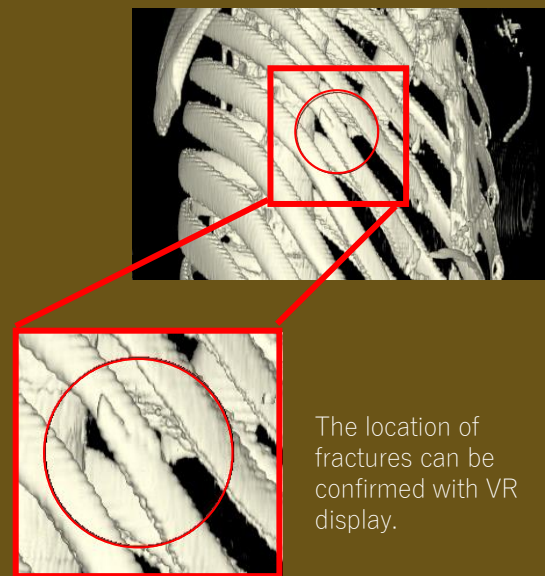
By automatically detecting rib fractures from CT images, it supports the prevention of missed rib fractures



Bone numbering



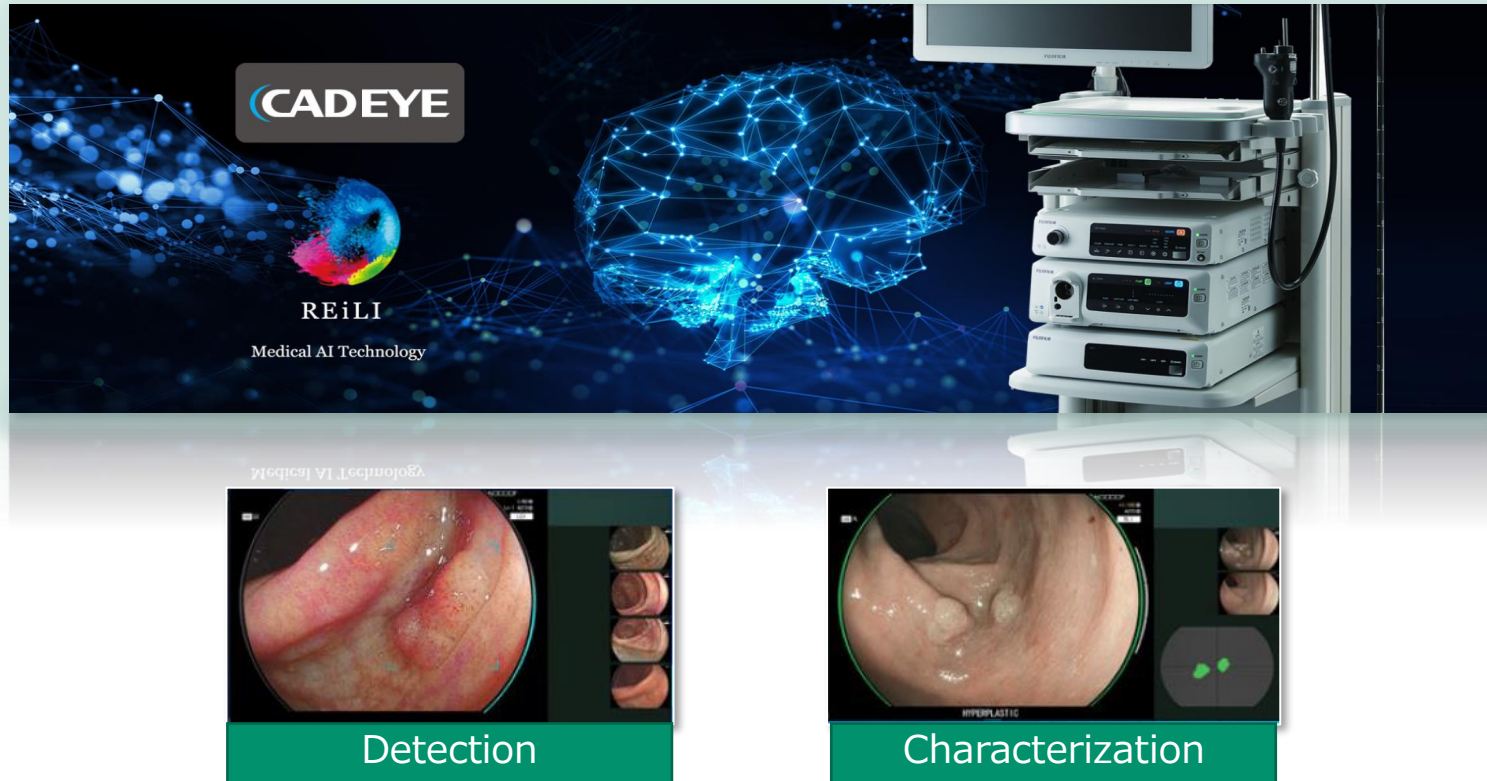
VR display



Integration of Viewer and 3D workstation

3. Endoscope diagnosis system for Lower Gastrointestinal Tract

Released domestically in November 2020. Currently being sold in over 60 countries worldwide.



3. Endoscope diagnosis system for Lower Gastrointestinal Tract

Detection Assistance Mode

白色光 LCI

Notification sound

Notify with sound upon detection

Detection Box

Outline suspected lesion areas with a square

Visual Assist Circle

Illuminate the nearest boundary line when a lesion is detected at the margin

画面はイメージです

The screenshot displays the endoscopic view of the lower gastrointestinal tract. A red overlay, labeled 'Detection Box', highlights a suspected lesion area. A blue line, labeled 'Visual Assist Circle', illuminates the nearest boundary line when a lesion is detected at the margin. The interface includes a 'Notification sound' icon and a 'Detection Assistance Mode' label. Technical data is shown on the right, including 'HT NR', 'SE', and a '3.8' measurement. The bottom right corner indicates '画面はイメージです' (Image is simulated).

3. Endoscope diagnosis system for Lower Gastrointestinal Tract

Characterization assistance
mode

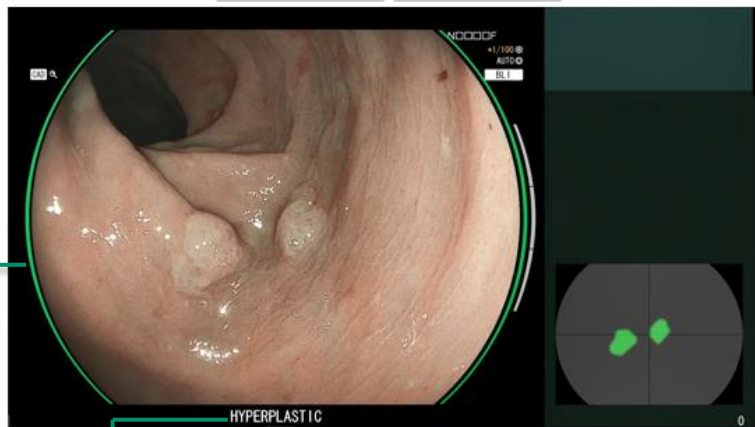


Colon polyp

HYPERPLASTIC

過形成ポリープ

SSL



画像はイメージです

Estimation result

HYPERPLASTIC
or NEOPLASTIC

Visual Assist Circle

Illuminates in green or yellow
based on the estimated results

NEOPLASTIC

良性腫瘍(腺腫)

悪性腫瘍(がん)



画像はイメージです

Status bar

Displays the
analysis status

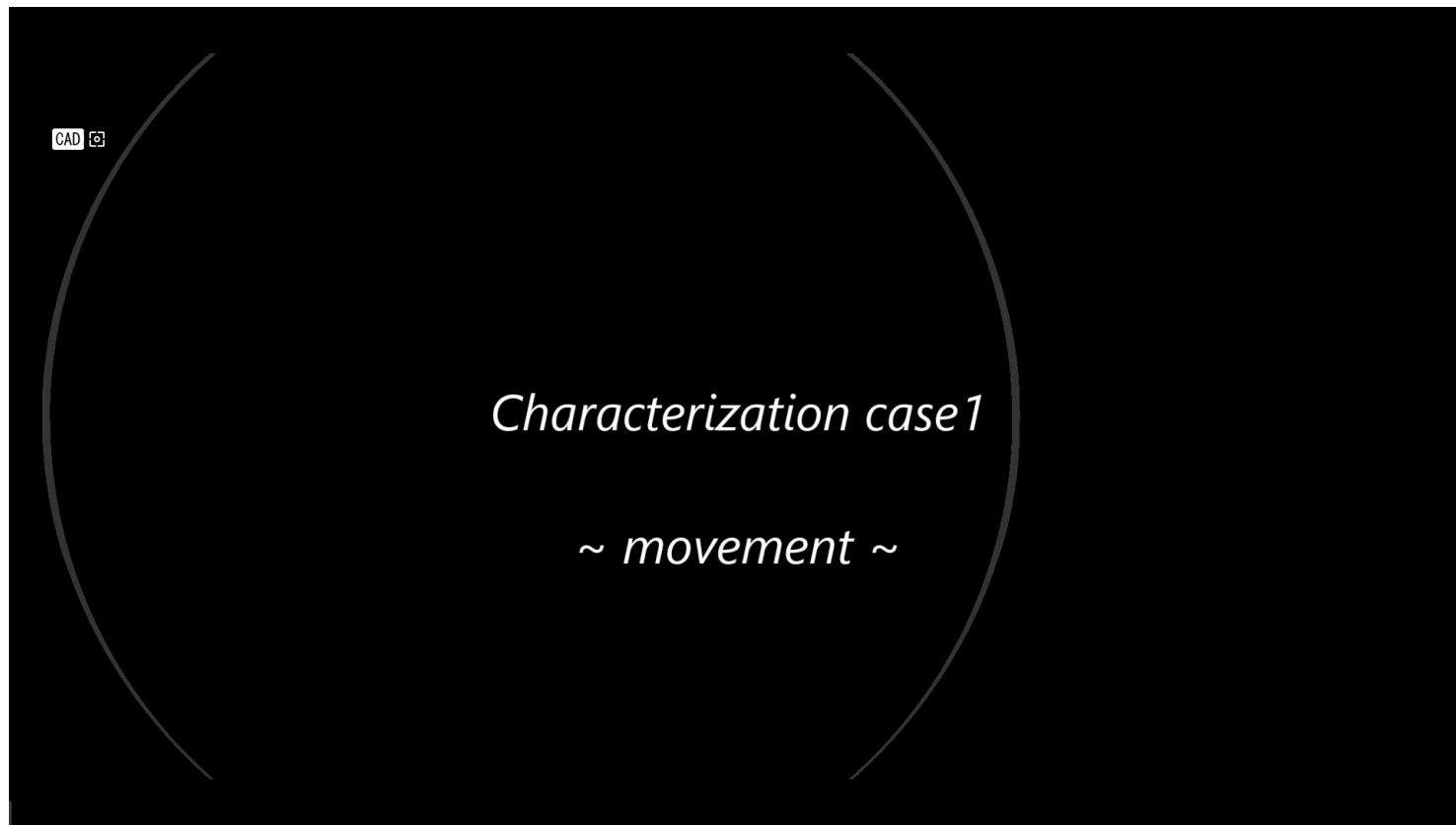
Position map

Shows the location of the area being
analyzed by the software for
tumorous/non-tumorous assessment

3. Endoscope diagnosis system for Lower Gastrointestinal Tract

Detection Case 1 LCI

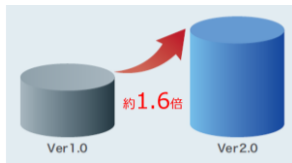
3. Endoscope diagnosis system for Lower Gastrointestinal Tract



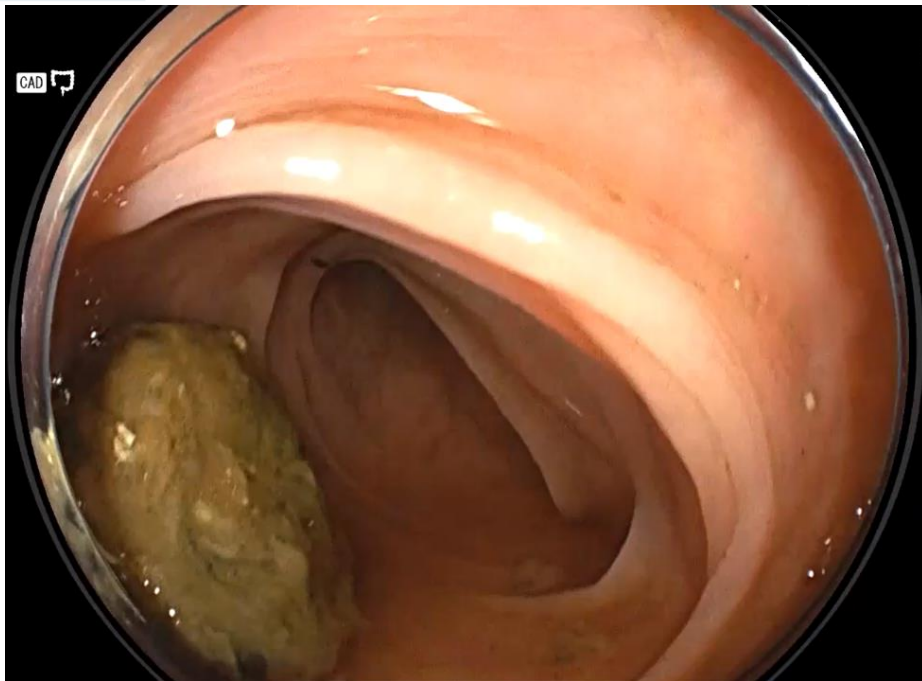
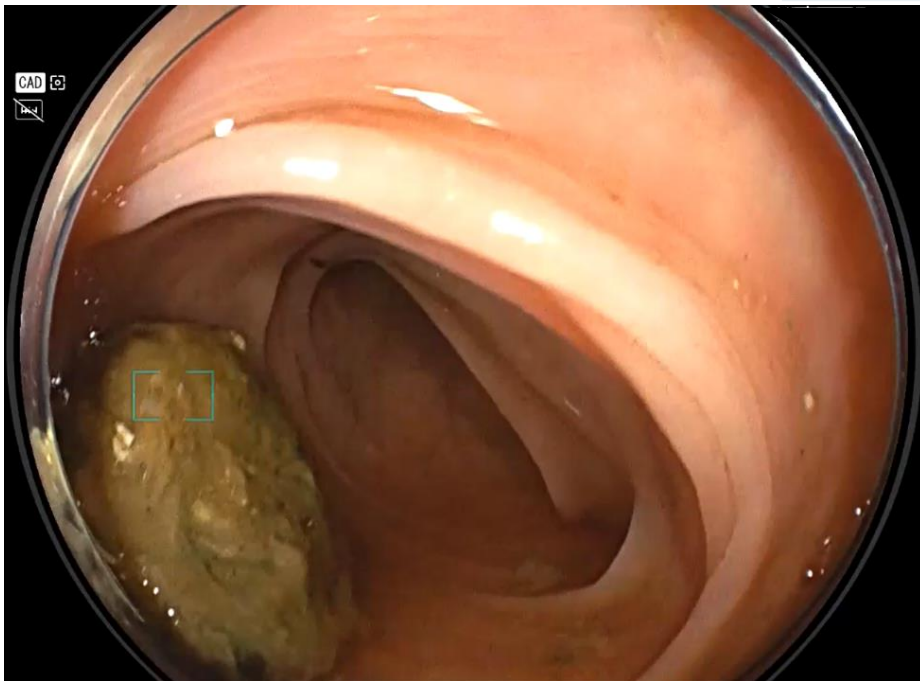
3. Endoscope diagnosis system for Lower Gastrointestinal Tract

Currently, FUJIFILM are selling Ver2.0, which has approximately 1.6 times more training data.

Ver.1.0



Ver.2.0



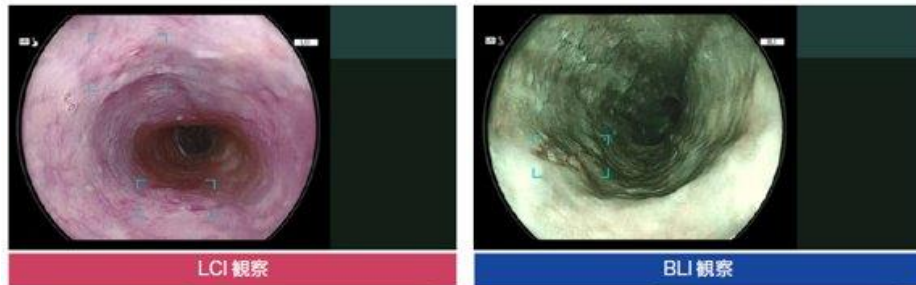
4. Endoscope diagnosis system for Upper Gastrointestinal Tract

Detection support

Suspicion region of esophageal squamous cell carcinoma



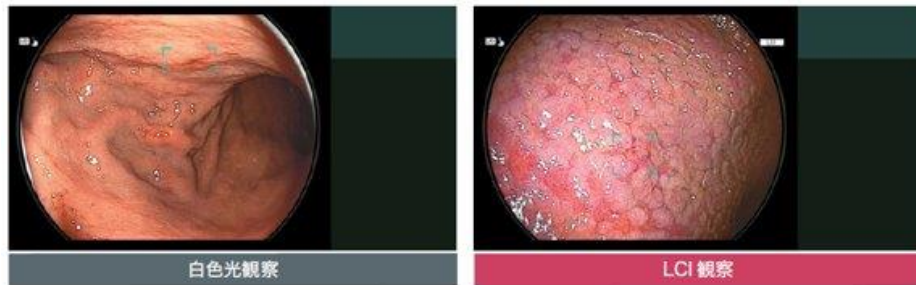
食道扁平上皮癌である可能性のある領域を検出し、その結果を内視鏡画像に重ねてリアルタイムにモニターに表示します。



Suspicion region of gastric tumorous lesions



胃腫瘍性病変である可能性のある領域を検出し、その結果を内視鏡画像に重ねてリアルタイムにモニターに表示します。

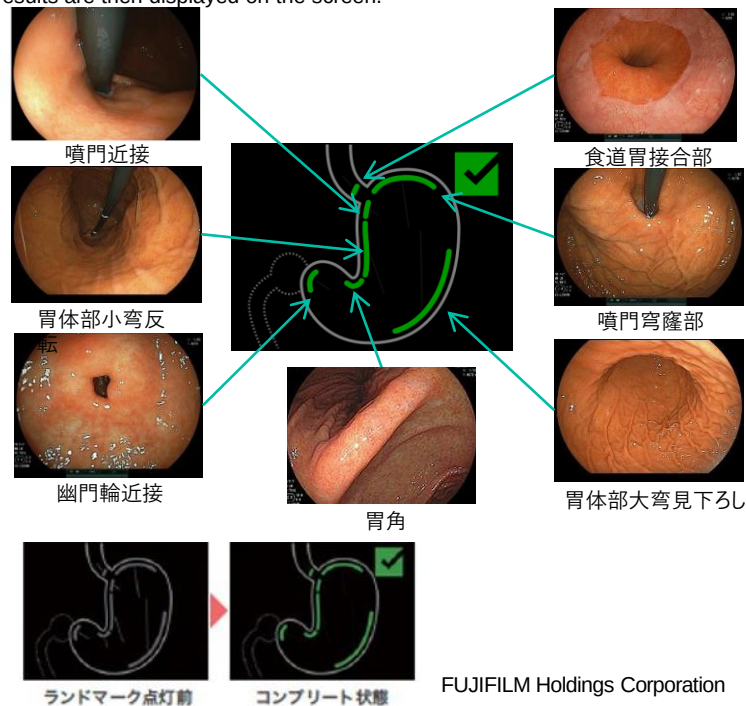


Observation support

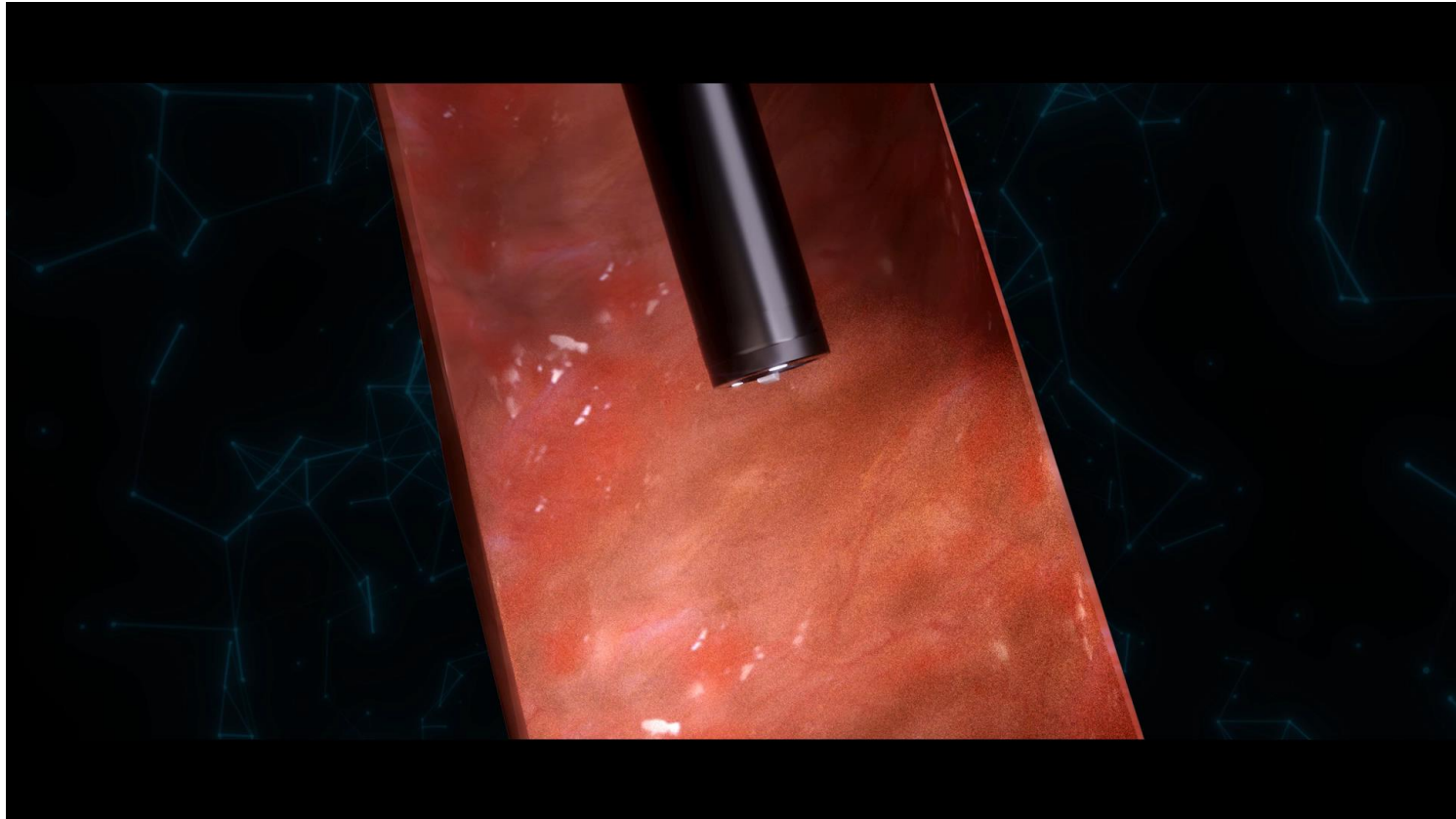
Landmark photo checker



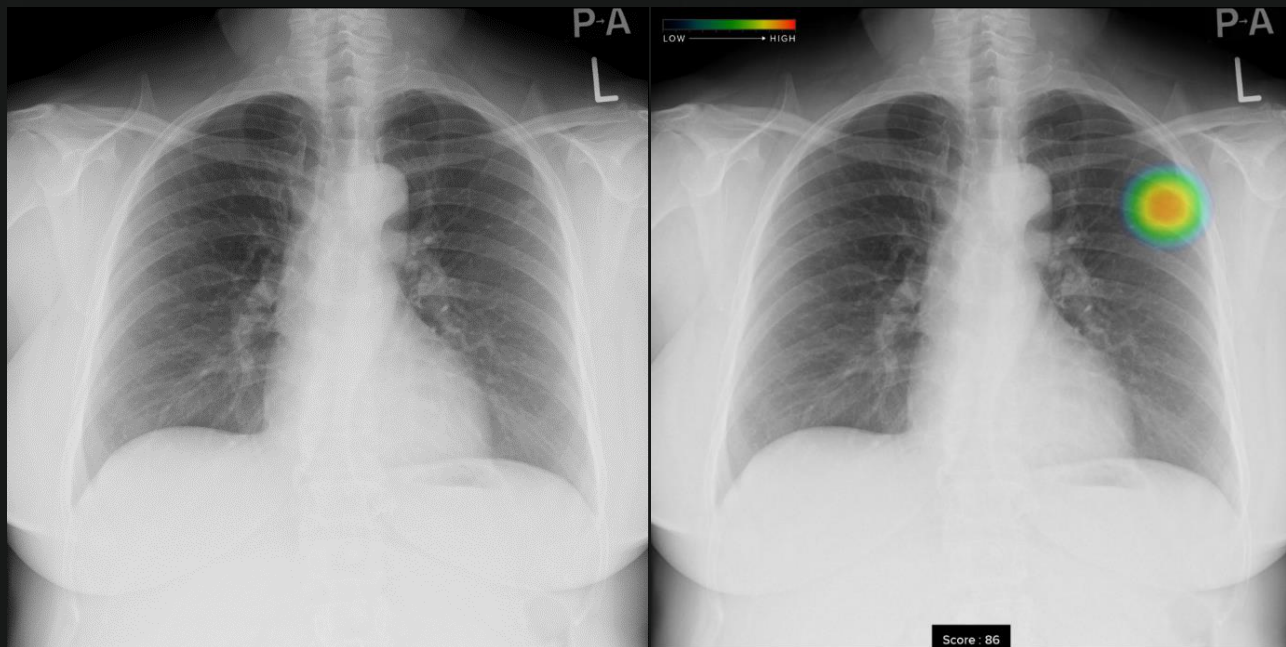
Automatically detects and determines if the appropriate "landmarks" requiring intentional scope manipulation are correctly captured in the still images. The results are then displayed on the screen.



4. Endoscope diagnosis system for Upper Gastrointestinal Tract



5. Abnormal detection software for chest X-ray



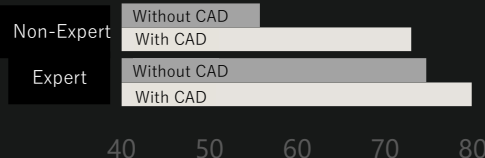
Displays presence possibility of abnormal findings as Heat Map and supports overlook

- Nodule and mass (Lung cancer)
- Consolidation (Pneumonia and Tuberculosis)
- Pneumothorax

This program can be worked on dedicated processing PC, receiving and sending DICOM.
※Customizing is required for display configuration

Reader study result

Sensitivity for target findings (%)



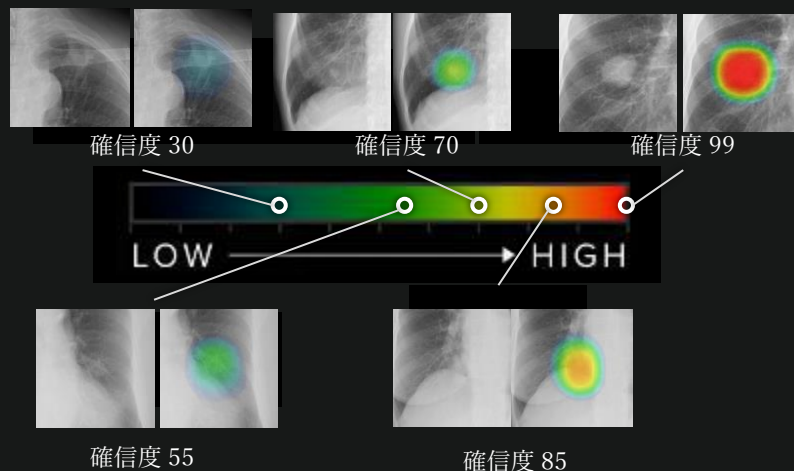
267画像（正常例:195例、異常例72例）に対して
専門医3名、非専門医7名に対して読影試験を実施。

販売名：胸部X線画像病変検出（CAD）プログラム LU-AI689型
承認番号：30300BZX00188000

5. Abnormal detection software for chest X-ray

Heat Map

The software analyzes the potential presence of abnormal regions using AI technology. The regions are highlighted with colors based on the confidence level of the analysis results.



- Red shows a higher confidence and blue shows a lower one.
- Maximum confidence value is shown as “Score” on result image.

Threshold for score	Sensitivity (%)	Positive prediction(%)	Specificity (%)	Negative prediction(%)
15	93.1	67.0	83.1	97.0
30	90.3	82.3	92.8	96.3
45	87.5	91.3	96.9	95.5
60	84.7	93.9	98.0	94.6
80	73.6	98.2	99.5	91.1

267画像（正常例:195例、異常例72例）に対する画像単位の単体性能評価

6. AI Development Solution

※Release β ver in FY22
Plans official entry in FY24

It is possible to execute the entire process of developing image diagnosis support AI technology without advanced engineering knowledge such as programming. We aim to democratize medical AI technology development and create an ecosystem of win-win collaboration between academia and industry for the implementation of AI in society.

【4 functionalities】

①Project management

The dashboard allows for a quick overview of annotation progress and the learning status of AI.



②Annotation tool

Efficient and intuitive browsing and annotation are possible without the need for manuals.



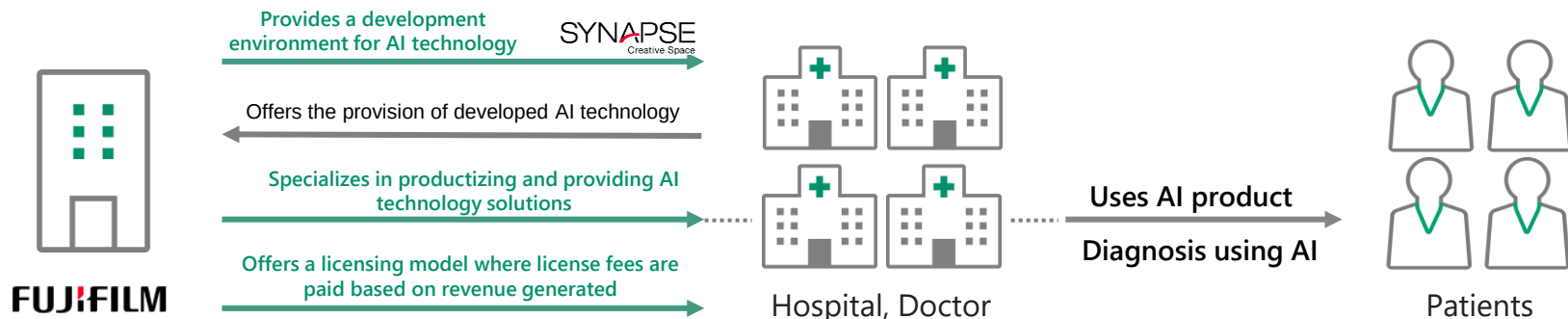
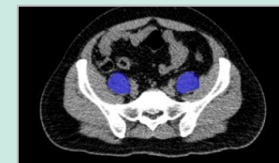
③Training platform

Machine learning tool to make it easy to handle AI model creation using the learning engine. We also centrally manage all the necessary information for AI development.

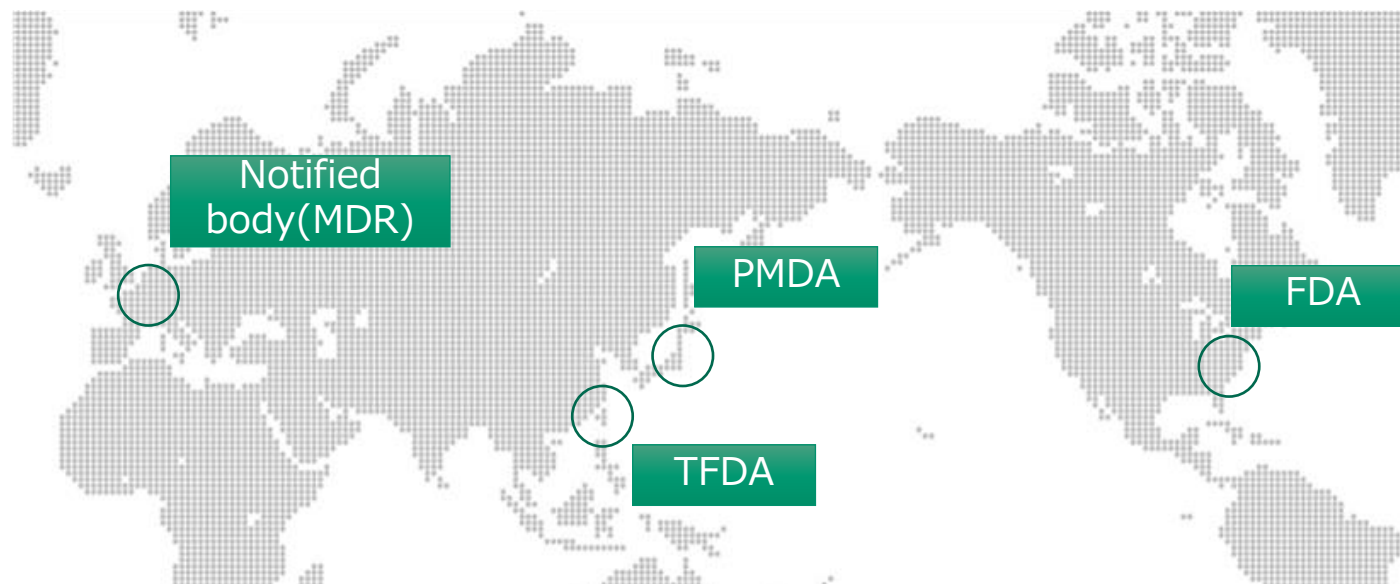


④AI Execution

The learning platform enables flexible processing and execution of AI generated by it.



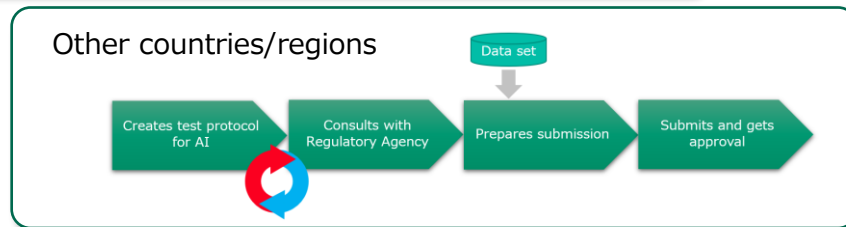
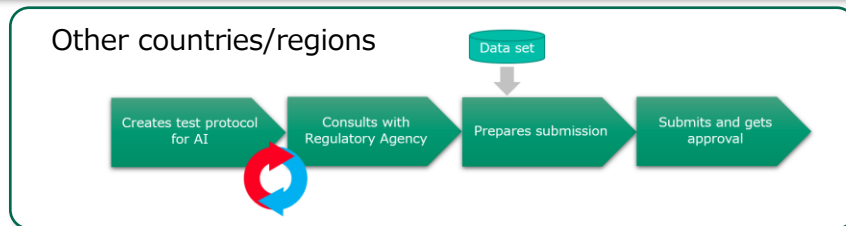
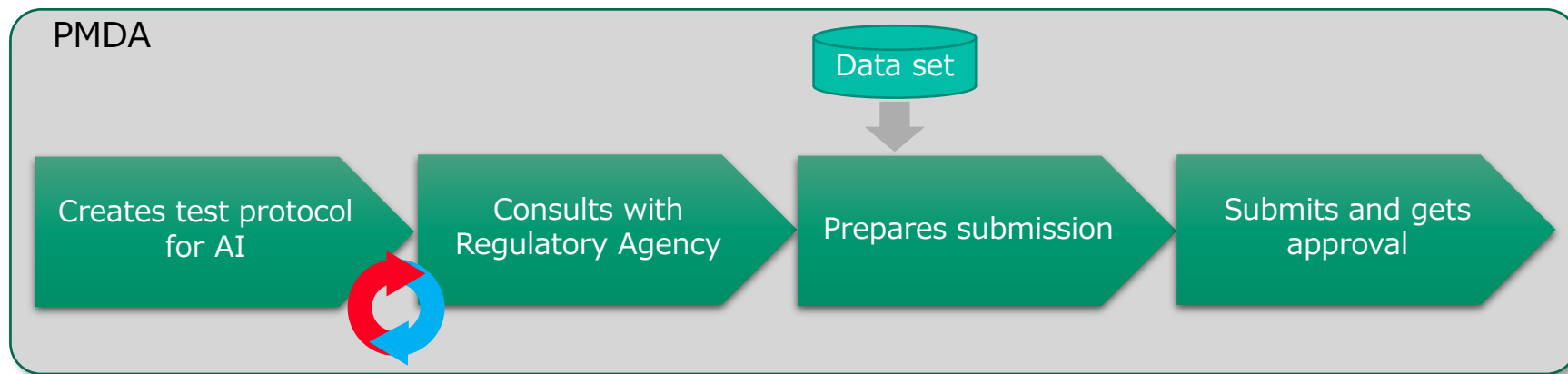
7. AI Medical Devices to Worldwide.



Big Challenge: Performance test of AI product for each regulation

- Test protocol,
 - Dataset for countries
 - Reviewer for countries
- Cyber security
- Etc.

7. AI Medical Devices to Worldwide.



Different data sets and different readers are required in test in some countries/regions...

Standardization of AI protocol can be useful to reduce time to submission and push the introduction of AI in clinical use globally.

