Lunit's Global Regulatory Experience and Insights
- Conquer Cancer through AI -

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Lunit

Company Overview

Lunit

Core Competence

#1 Technology
#2 Medical Expertise

Best-in-Class A.I.
Global leader in AI technology

- Top-tier proprietary AI technology
- 30+ papers presented in top AI conferences
- Large-scale medical data for R&D (N = +4 million cases)

Top Ranked in AI Competitions
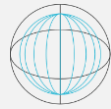
2015
Main Task (CLS-LOC)
IMAGENET

1	Microsoft	Microsoft
5	Lunit	Lunit
7	Google	Google

2016
MICCAI Grand Challenge
Tumor Proliferation Assessment

1	Lunit	Lunit
2	IBM	IBM
3	Microsoft	Microsoft

2017
Camelyon
CAMELYON17

1	Lunit	Lunit
2	Harvard Univ.	HARVARD UNIVERSITY
3	Eindhoven Univ. of Tech	TU/e EINDHOVEN UNIVERSITY OF TECHNOLOGY

Global Recognition
International spotlight

- The **only Korean company** spotlighted by World Economic Forum, CB Insights

WORLD ECONOMIC FORUM
2020 / 2022 / 2023
TECHNOLOGY PIONEER
GLOBAL INNOVATOR
ASSOCIATE PARTNER

AI 100 Lunit CB INSIGHTS
2017
CB Insights
AI 100

Digital Health 150 Lunit CB INSIGHTS
2019 / 2020 / 2021
CB Insights
DIGITAL HEALTH 150

Forbes Newsweek
BBC FIERCE Biotech MIT Technology Review

Renowned Scholars as Advisors
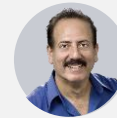
Eliot Siegel
Radiologist
Radiology IT KOL
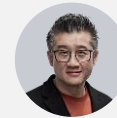
Tony Mok
Oncologist
Board member of AstraZeneca

Linda Moy
Breast Radiologist
KOL / RSNA Vice-chair

YoungKwang Chae
Oncologist
KOL in immunotherapy

Yung-jue Bang
Oncologist
KOL in Korea

+200 Publications in Major Peer-reviewed Journals

Journal of Clinical Oncology THE LANCET Digital Health JAMA Oncology JAMA Network Open ASCO American Society of Clinical Oncology

EJC European Radiology SCIENTIFIC REPORTS ESMO AACR

Radiology RSNA Clinical Infectious Diseases sitc Society for Immunotherapy of Cancer USCAP

+100 Research Partnerships

MASSACHUSETTS GENERAL HOSPITAL Stanford MEDICINE Northwestern Medicine COLUMBIA

Karolinska Institutet NHS UCSF University of California San Francisco UNIVERSITY OF OXFORD BROWN UNIVERSITY OF CAMBRIDGE

Core Competence #3 Global Business

Lunit to Acquire Volpara

- Finalizing the acquisition by the 2Q of 2024
- Volpara's AI mammography solutions, operational in over 2,000 U.S. medical sites
- Over 100 million high-quality images

Lunit x **Volpara** HEALTH

Global Sales Channel through Strong Business Partnerships

60% Global market share of device partners

FUJIFILM GE Healthcare PHILIPS IBM

HOLOGIC The Science of Sure SECTRA AGFA HealthCare

80% US Oncologists using Guardant Health products

GUARDANT

Global Big Pharma

Currently discussing research/collaboration agreement with multiple big pharmas

Number of paying sites worldwide [1]

+3,000

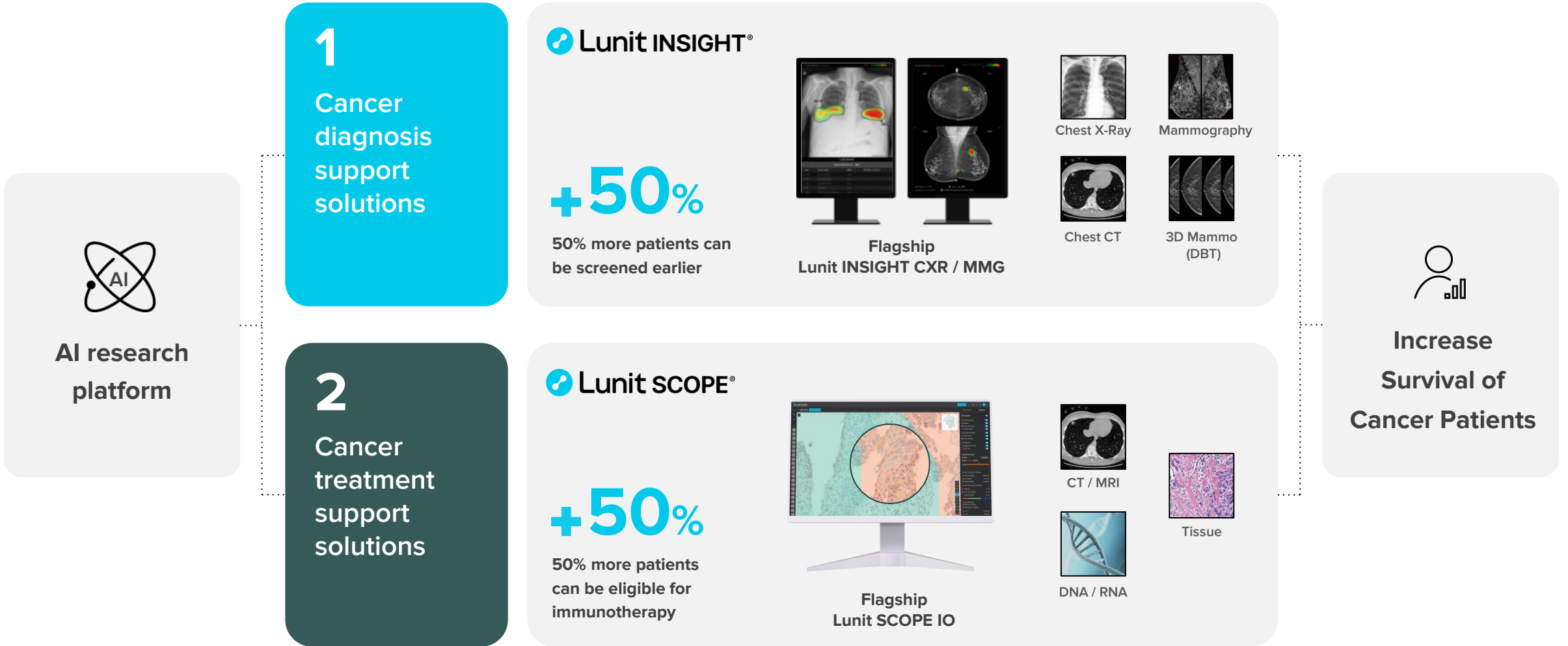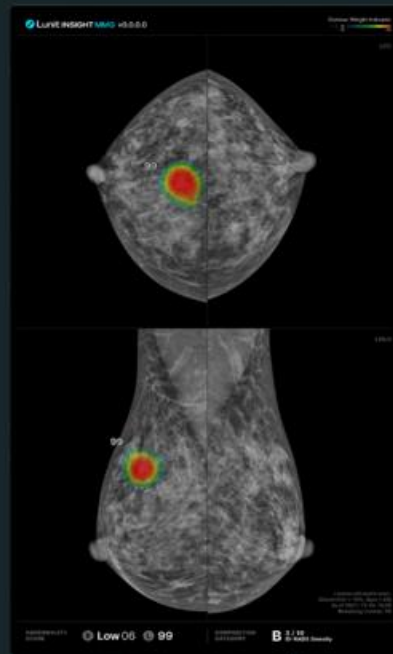|	
Global Customers	**84%**
Retention Rate	**+95%**
Lunit Users among Top 10 Hospitals in Korea [2]	**7**
Chest X-Ray exams in Korea[3] **Analyzed by Lunit INSIGHT CXR** 2021	**10%**
Lunit INSIGHT MMG Users among 45 Large Hospitals in Korea	**42%**

1) Excludes demo and research use; only commercial sales
2) Newsweek. World's Best Hospitals – South Korea. 2020;
3) Source: KOSTAT.go.kr Appx. 40M Chest X-ray exams performed annually in Korea

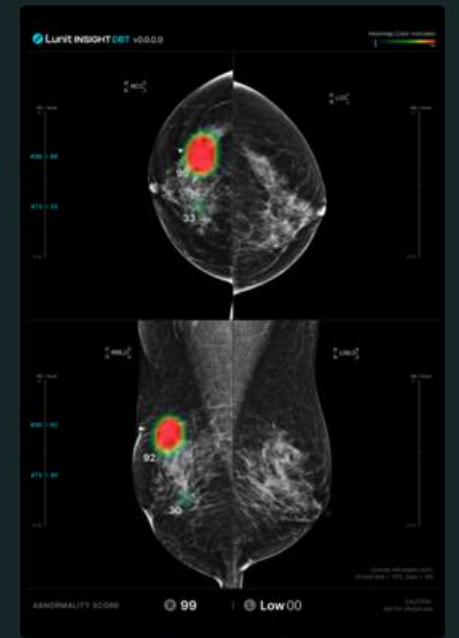# Conquer Cancer through AI | Increase cancer survival through AI-powered cancer diagnosis and treatment

AI research platform

1 Cancer diagnosis support solutions

Lunit INSIGHT®

+50%

50% more patients can be screened earlier

Flagship Lunit INSIGHT CXR / MMG

Chest X-Ray

Mammography

Chest CT

3D Mammo (DBT)

2 Cancer treatment support solutions

Lunit SCOPE®

+50%

50% more patients can be eligible for immunotherapy

Flagship Lunit SCOPE IO

CT / MRI

Tissue

DNA / RNA

Increase Survival of Cancer Patients

AI Solutions Registration status

Product registration status

Lunit INSIGHT have obtained licenses from more than 40 countries around the world

It has been submitted to more countries and is under review

* Lunit INSIGHT CXR 35 + countries / Lunit INSIGHT MMG 40 + countries)

Lunit INSIGHT CXR

Lunit INSIGHT MMG

■ approved
■ submitted
■ preparation

Proven to Be Best-in-Class in a variety of clinical settings

Research

150+ Publications in Major Peer-reviewed Medical Journals

Journal of Clinical Oncology® EJC THE LANCET Digital Health SCIENTIFIC REPORTS

Radiology JAMA Network | Open™

Clinical Infectious Diseases European Radiology RSNA JAMA Oncology

100+ Research Partnerships

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☑ **Robust research** with strong clinical evidence in peer-reviewed journals

Research

- A total of 172 clinical evidences are available. (Post 159)
- After the product approval, studies are increasing. Many post-marketing commitment were conducted to test performance and workflow in various clinical environments

Lunit INSIGHT CXR : Pre 5 → **Post 83**

Lunit INSIGHT MMG : Pre 4 → **Post 74**

Lunit INSIGHT DBT :Pre 4 → **Post 2**

[Clinical evidences status (2024.2)]

Lunit INSIGHT	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
CXR	3	2	6	6	19	14	19	18	(1)	88
MMG	1	1	2	4	13	12	29	14	(2)	78
DBT	-	-	1	1	1	-	1	2	(0)	6

Real World Evidence | Building solid evidence through prospective studies

Study Directions

Why should we do post-marketing commitment?

Study designed

Retrospective ←→ Prospective
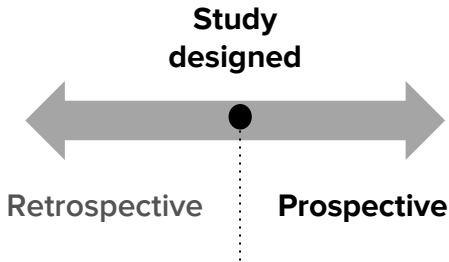
Outcome is measured after the baseline state of the subjects is determined and controlled intervention applied.

Reliability ↑	Data quality ↑
Bias ↓	Recall errors ↓

Lunit INSIGHT CXR

Flagship prospective CXR study

10,476 Patients with chest X-Ray
RCT study on 'lung nodule detection rate' at Seoul National University Hospital (Korea)

Outcome	Detection rate of actionable lung nodules	Detection rate of malignant lung nodules
A Group (n=5238) Radiologist + AI	31 (0.59%)	8 (0.15%)
B Group (n=5238) Radiologist only	13 (0.25%)	0 (0.0%)

Radiology

Large-scale Prospective RCT*

Lunit INSIGHT MMG

*Randomized Controlled Trial

: Research method in which subjects are randomly divided into control and experimental groups for comparison

Flagship prospective MMG study

55,579 women screened for breast cancer
Study on 'Double Reading' by Karolinska Institutet (Sweden)

Outcome	Detection rate of cancer per 1,000 women	Recall rate per 1,000 women
1 Radiologist + Lunit INSIGHT MMG	4.3	28
2 Radiologists	4.1	29.3
Lunit INSIGHT MMG	4.1	15.5

THE LANCET
Digital Health

Large-scale Prospective Study

Real World Evidence

Fast triage
of normal cases

According to the abnormality scores generated by AI, radiologists can successfully triage up to 60% of the entire cases without human interpretation, which can reduce their workload by more than half in mammogram interpretation.

<Triage 60% of the entire cases w/o human interpretation>
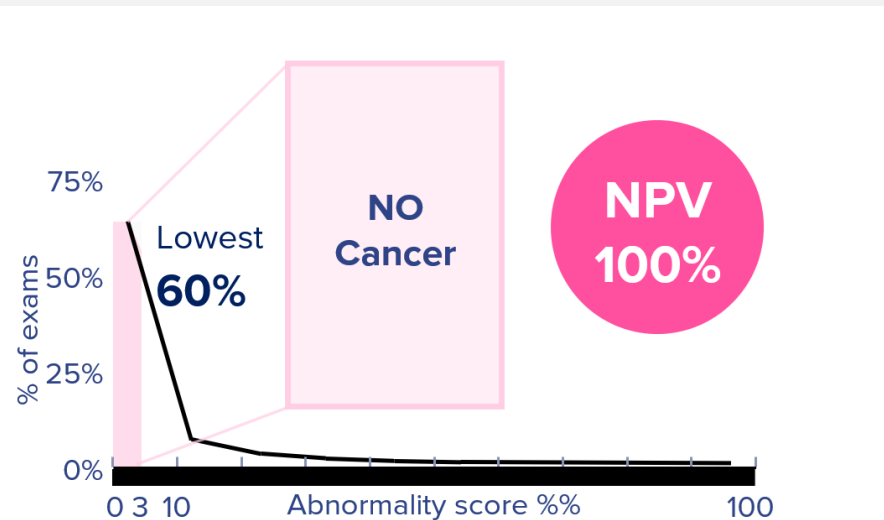
Dembrower, et al. Lancet Digital Health. 2020 September

THE LANCET
Digital Health

Karolinska
Institutet

Sweden

Excellent **Prospective study Results** & The integration into **Sweden's national cancer screening program**

THE LANCET
Digital Health

1 The **1st prospective study** to conduct a large-scale clinical trial of 55,579 patient mammograms using AI

Prospective study Result	Cancer Detection Rate (CDR)	Recall Rate (RR)
R1 R2 Two radiologists	4.1	29.3
R1 One radiologist + AI	4.3	28.0
AI alone	4.1	15.5

2 The integration of Lunit AI will enable **Capio S:t Göran Hospital** to analyze approximately 78,000 patients' mammography images each year, significantly contributing to **Sweden's national cancer screening program.**

Insights:
Regulation of post-marketing commitment

Lunit

Limitations of AI Medical Devices's Pivotal Study

AI = Software = Data

- The greatest benefits of AI software resides in its ability to learn from real-world use and experience, and its capability to improve its performance for patients.

- There are many limitations to pre-marketing clinical trials, and many insights are being gained in post-marketing commitment.

Limitations of pre-marketing clinical study

6 category	Limitations
Population	Too Few
research design	Too Simple
Age, gender, etc	Too Median-aged
Range	Too Narrow
Period	Too Brief
Result	Too Indirect

Brian L. Strom MD et al. 2019, Pharmacoepidemiology

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Opportuities in the Use of RWE & post-marketing commitment

Differences between Pre-market & Post-market

- Pre-market clinical trials have limitations such as restricted environments, small sample sizes.
- But RWE reflects real-world usage environments.

Items	Pre-market	Post-market
Protocol flexibility	Low	High
Data quantity	Limited	Rich
Data collection	Hard	Easy
Data treatment	Hard	Easy
Readers/Investigators	Hired	Voluntary
Time control	Hard	Easy
Cost	High	Low
Utilization of the result	Low	High

Real world Data, Evidences (RWD, RWE)

- Case histories, report
- Retro database studies
- Performance data that exist within the device such as self-diagnostics and error codes
- Large-scale prospective RCT results

RWD can provide new insights into medical device benefits, workflows, and interactions with patients and healthcare institutions.

- Watching how the product works in the real world.
- Obtaining its true value among various countries and workflows.
- Building the use experience with AI in the market.
- Giving positive business impact by having good user experience.

Ideas to upgrade managing AI MD based on clinical data

Flexibility on the threshold set is needed in the field.

- Open the possibility of using different threshold adjustment under manufacturer's responsibility.
- Manufacturer must monitor its result and ensure the performance whatever threshold is selected by the user.

US Recommendations based on Previous Abnormality Scores

10   30   100

Screening
Low prevalence rates
10%

Clinics
High prevalence rates
70%
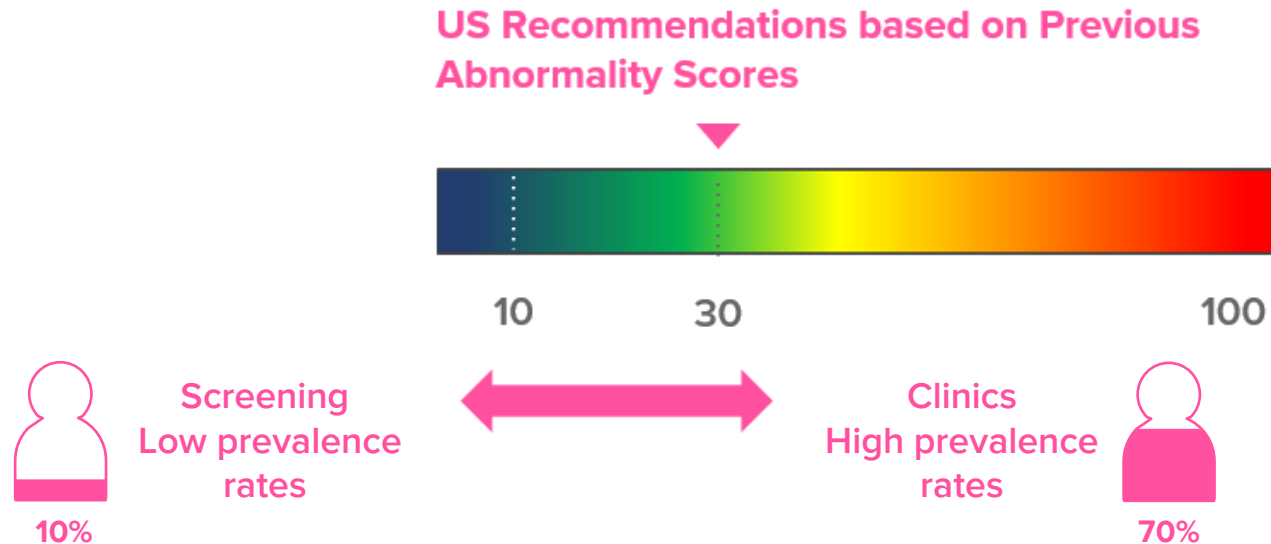
When healthcare institutions prioritize sensitivity, they may lower the threshold, whereas they can raise the threshold when they prefer higher specificity.

Ideas to upgrade managing AI MD based on clinical data

Reconsider the software's nature - frequent updates.

- Post-market clinical trial is a good tool to find out the improvement points of the product.
- The newest version of the product delivery on-time is essential to all.
- Ease the software MD change requirements will be helpful.
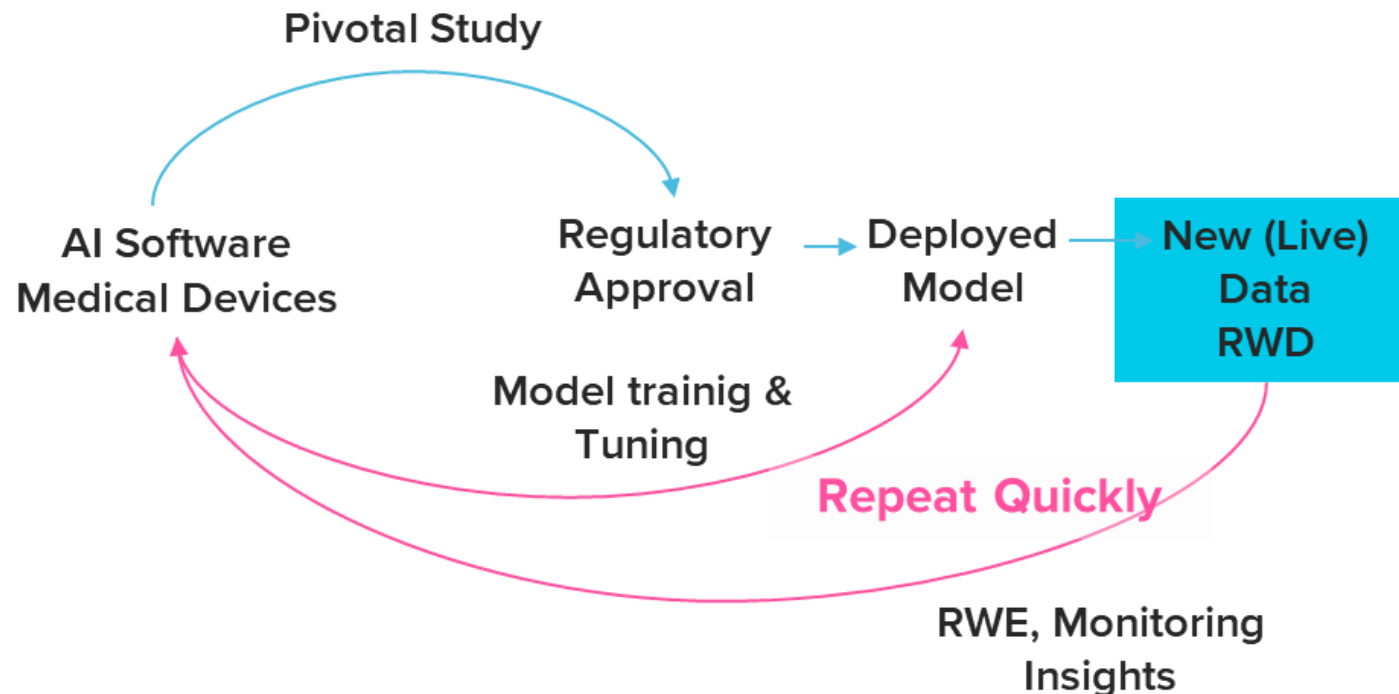
Ideas to upgrade managing AI MD based on clinical data

Data, more data.

- Efficient methods are needed to facilitate the use and acceptance of clinical data
- Obtaining suitable medical image for both clinical trials and deep learning is hard for everyone. Government-level image source operation will be helpful.
- Lack of information gives pain to everyone.

Open, government-owned archiving center for AI MD clinical data and evidence.

- Support for sourcing large quantities and high-quality data is necessary.
- Centralization of medical standard data for openness required
- Set-up of digital healthcare RWE clinical environments

THANK YOU

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