Fujitsu Limited Press Conference
August 26, 2024

Fujitsu Uvance Healthy Living

Fujitsu Uvance Healthy Living
Business Strategies and Partnerships related to Clinical trials

Disclaimer: This document is a reference translation.

Fujitsu uvance Healthy Living

Agenda 10:30-11:30

- Presentations by speakers with guest appearances
- Q&A session
- Photo session

Speakers:

■ Fujitsu Limited

- EVP, Global Solutions (Social Solutions & Technology Services)
  Naoko Otsuka
- Head of Healthy Living, Social Solution Business Unit
  Tatsuki Araki
- Head of Clinical Trial Solution Department, Life Science Division, Social Solution Business Unit
  Michio Hamamatsu

Guests:

■ Paradigm Health, Inc.

- CEO
  Kent Thoelke

■ National Cancer Center Hospital East

- Deputy Director
  Koichi Goto

Fujitsu uvance

EVP, Global Solutions (Social Solutions & Technology Services)

Naoko Otsuka


Fujitsu
uvance
Healthy Living
Sustainability Transformation for Creating a Sustainable World
Planet
Solving global environmental issues
People
Developing a Digital society
Prosperity
Improving people's Well-being


Healthy Living
Launching a new business to solve “Drug Loss”

Current situation of “Drug Loss”

Some Drugs and treatments approved in Europe and the United States are not approved in Japan.

341 diseases

There is no treatment for rare diseases.
as of 2024

143 items

Not approved in Japan
(approved in Europe and the United States)
as of 2023

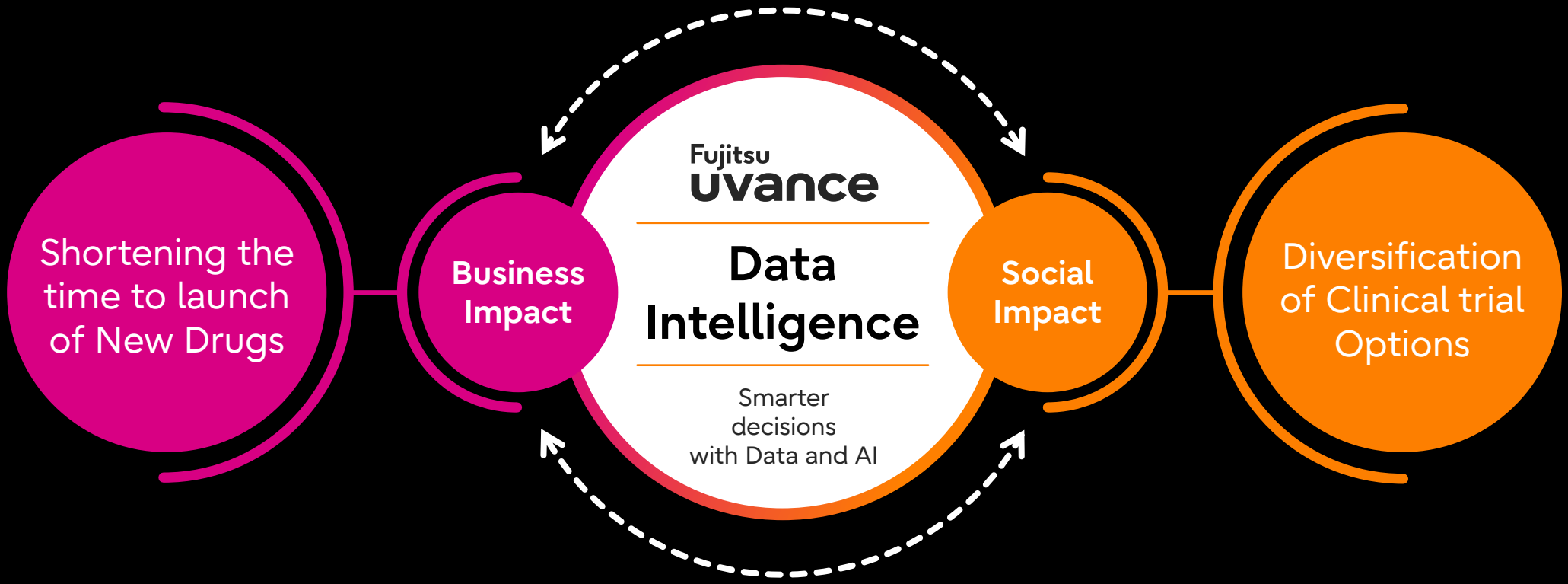
86 items

Domestic development not yet initiated
as of 2023

*left source : From the Ministry of Health, Labour and Welfare website: Health & Medical > Health > Designated Intractable Diseases > List of Designated Intractable Diseases

*middle From the Ministry of Health, Labour and Welfare website https://www.mhlw.go.jp/content/11121000/001206963.pdf

*right From the Ministry of Health, Labour and Welfare website https://www.mhlw.go.jp/content/11121000/001206963.pdf


Shortening the time to launch of New Drugs
Business Impact
Fujitsu uvance
Data Intelligence
Smarter decisions with Data and AI
Social Impact
Diversification of Clinical trial Options

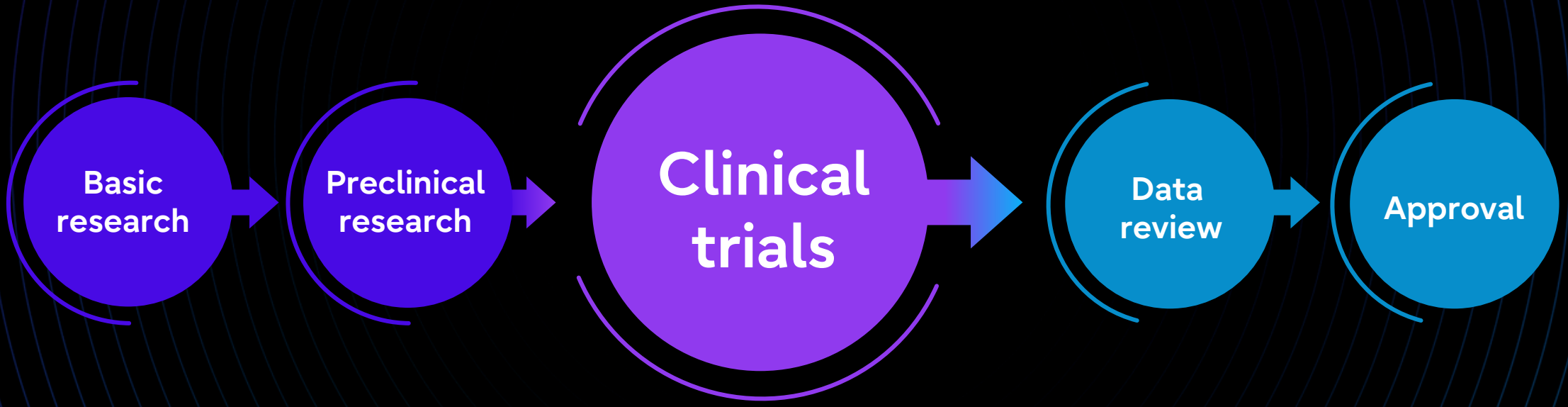
Fujitsu Uvance

Head
Healthy Living
Social Solution Business Unit

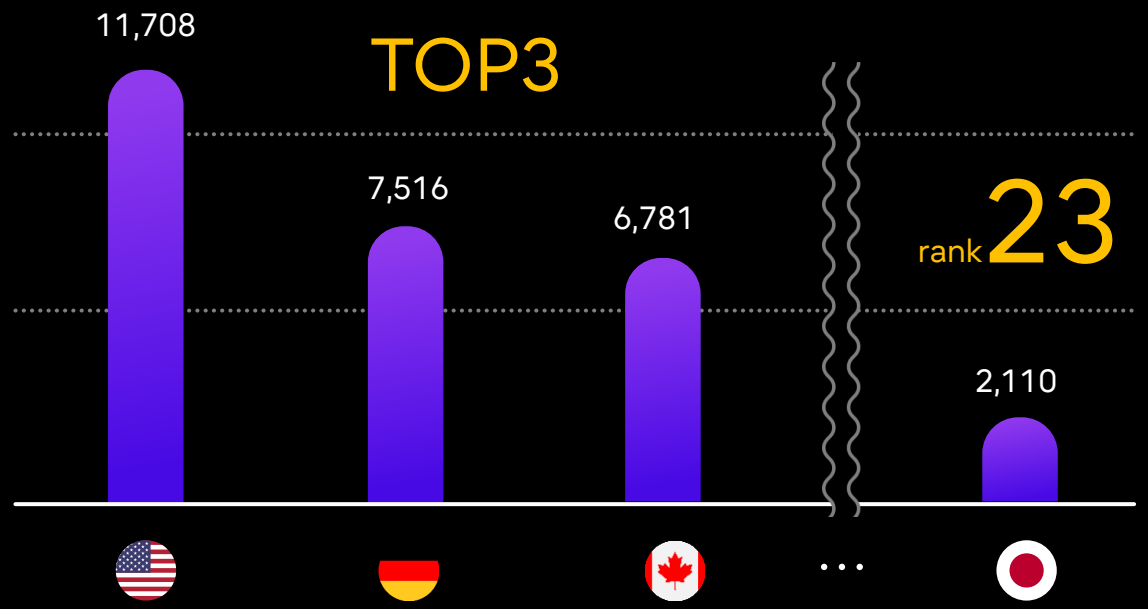
Tatsuki Araki

Analysis of the causes of “Drug Loss” in Japan

Drug development process



The Current Status of the number of Global Clinical Trials



*Source Office of Pharmaceutical Industry Research https://www.jpma.or.jp/opir/news/066/05.html

Clinical Trial Process

Planning

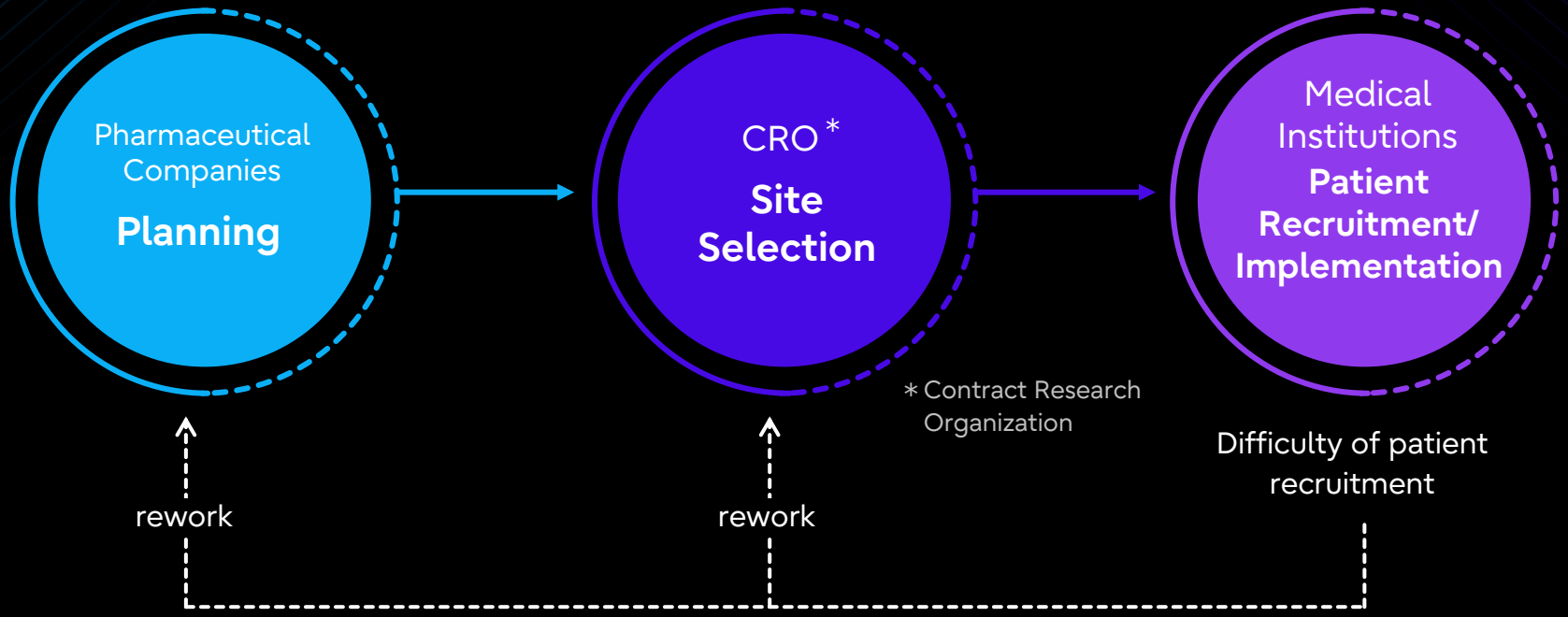
Pharmaceutical Companies

Implementation

Medical Institutions

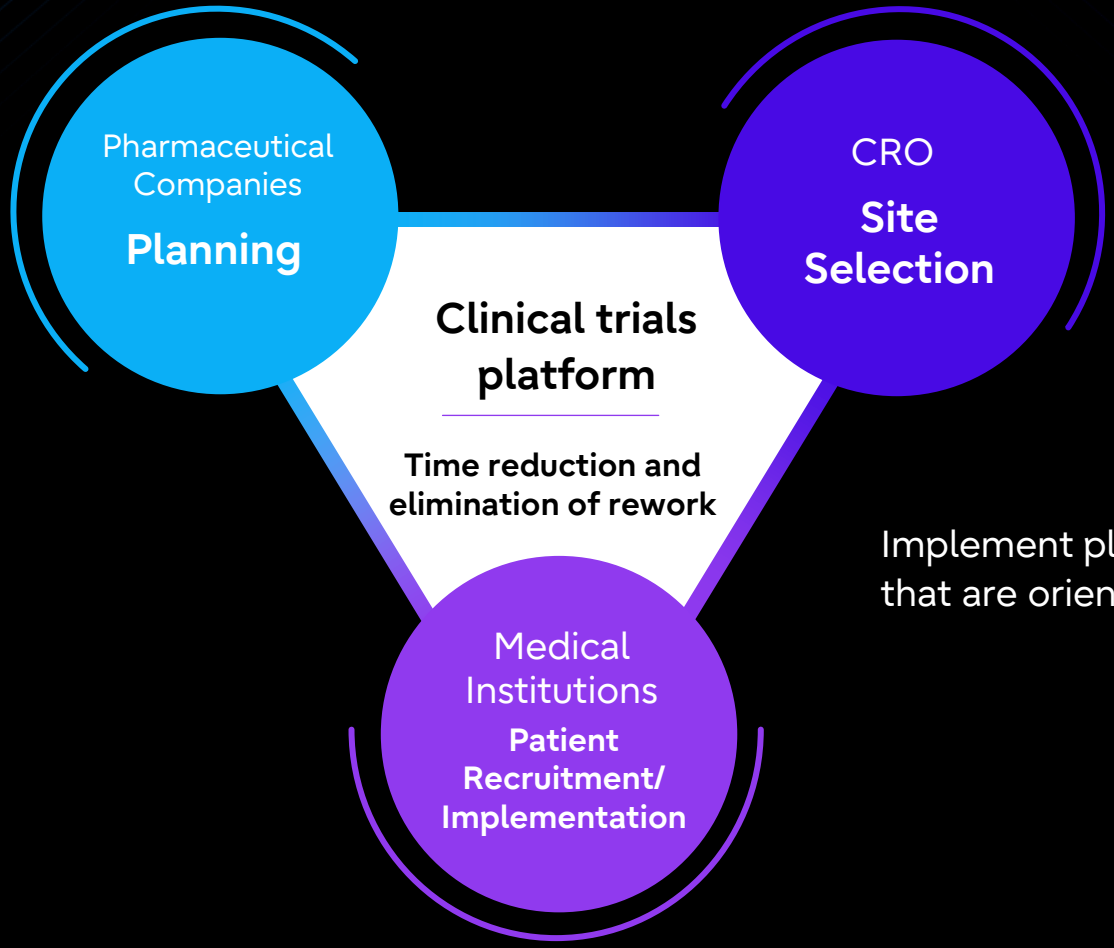
Paradigm Shift in the Clinical Trial Process

Monolog model to Dialog model



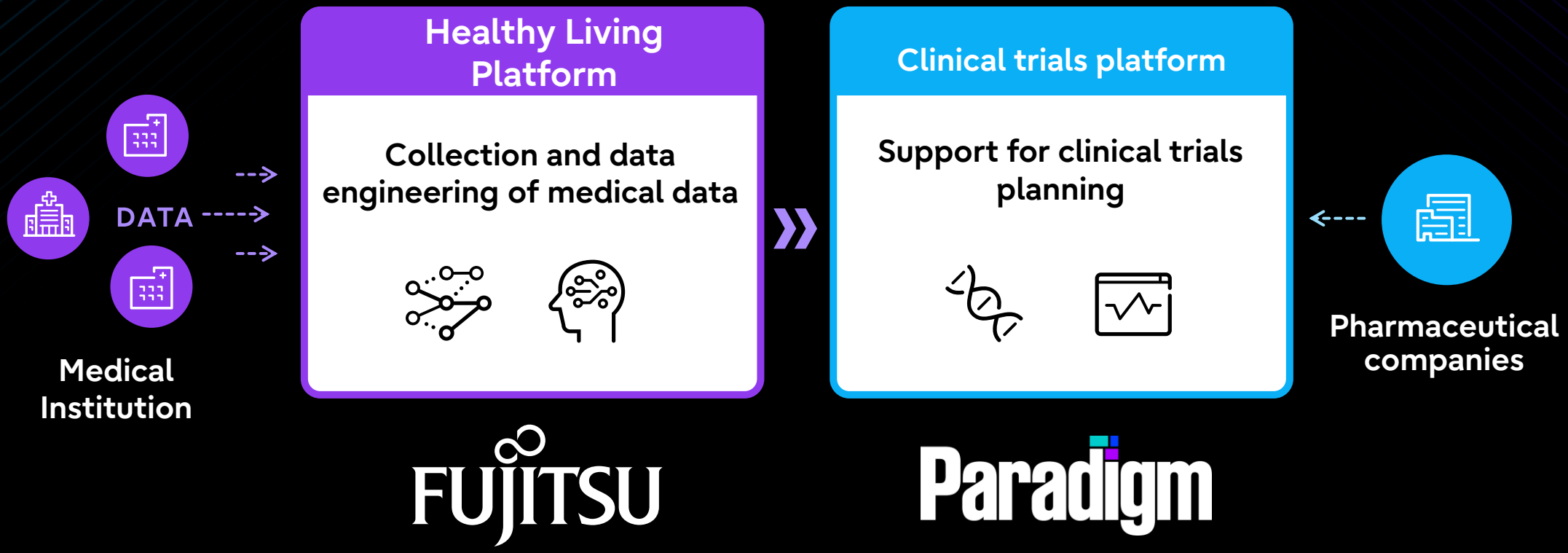
Paradigm Shift in the Clinical Trial Process

Monolog model to Dialog model



Implement planning for clinical trials that are oriented towards medical data

Platform integration connecting medical institutions and pharmaceutical companies



Accelerating the Digitalization of Clinical trials through strategic partnership with Paradigm

CEO
Paradigm Health, Inc.

Kent Thoelke

Paradigm

Japan Launch

www.paradigm.inc

Trial access limits stem from excessive burden of trial participation for healthcare providers and patients

Ineffective Current State

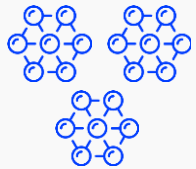
<15% of **sites** enroll patients within specified time periods[1]

8 **months** to start a study, on average[2]

<5% of **patients** participate in clinical research[3]

54% of **PIs** are "one-and-done"[4]

Trending in the Wrong Direction



Growing **trial volumes** → compounds in Ph I, II, and III studies have increased by 70% in the last decade[5]

Rising **trial complexity**

- Greater burden on sites and patients
- More difficult recruitment
- Ballooning data capture needs, increasing overhead and risk of error

Unprecedented **provider resource constraints** coming out of COVID

- Staff shortages, turnover, and burnout
- Narrow or negative margins
- Stretched IT resources

1. Brøgger-Mikkelsen M, Ali Z, Thomsen SF. *J Med Internet Res*. 2020.
2. Tufts Center for Drug Development Report.
3. Amy Corneli, et al. *Contemporary Clinical Trials Communications*. Volume 6, 2017.
4. Grant D. Huang, et al. *Contemporary Clinical Trials*. Volume 66, 2018.
5. Jeffries CRO Industry Model Growth Rates

Demonstrated Impact in the United States

- **175% increase in cancer patients enrolled on trials**

- Increased per-trial enrollment rate
- Reduced staff burden

- **45% increase in cancer patients enrolled on trials**

Paradigm

Pivotal moment for clinical trials in Japan

The Central Social Insurance Medical Council and Ministry of Health, Labour and Welfare improved the regulatory environment and increased the financial incentives for global pharmaceutical companies to conduct clinical trials in Japan

Pricing Reform

Increased pricing for innovative drugs to encourage global development

Accelerated Approval

Easing of the historical delays often associated with drug approval in country

Waived Requirements

Global phase III trials no longer require a domestic phase I trial prior to Japanese enrollment

Globalization

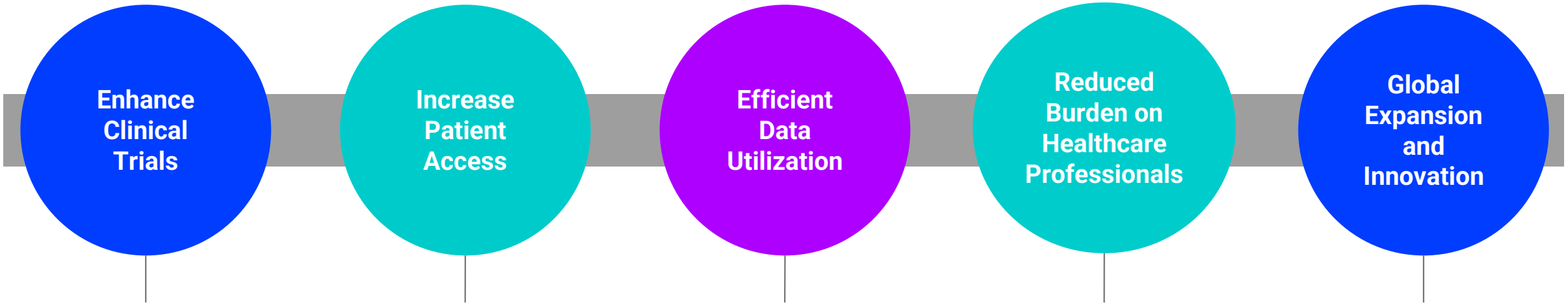
>50% of clinical trials in Japan are a part of a global research program, and the trend is expected to rise

Digitizing Data

Fujitsu is pioneering digitization of structured and unstructured patient data

Paradigm

Fujitsu + Paradigm Will Power Japan Clinical Trial Ecosystem



A new approach to Japan's clinical trial environment by leveraging Paradigm's advanced clinical trial platform to maximize efficiency by utilizing the latest advancements in digital technology, large language models, and analytics.

Every patient has access to the best possible care, including clinical trials as a care option. And earlier access to global trials gives Japanese patients the same access to innovative drugs and treatment options as those patients outside of Japan.

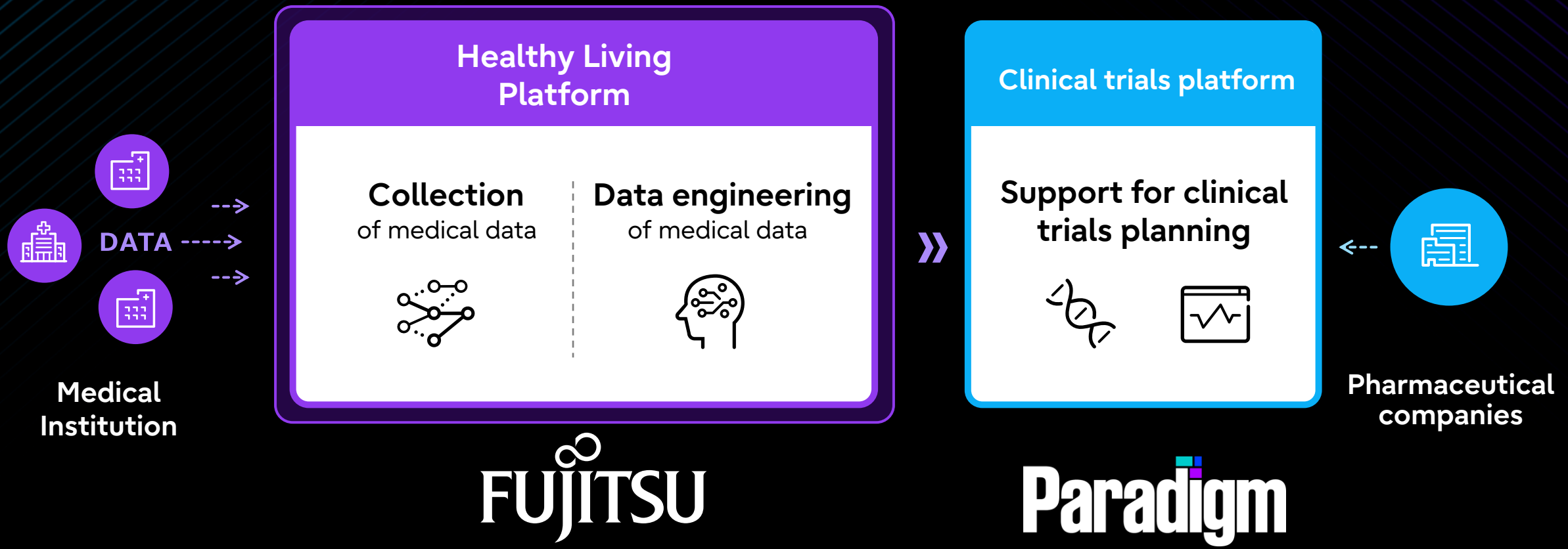
Fujitsu will collect and process data from medical institutions and Paradigm will process through its platform. This data-driven model significantly increases patient clinical trial recruitment and decreases the time to market for new drugs.

Reduced labor requirements to conduct trials by maximizing the process efficiency of matching patients to clinical trials and collecting their data. Japanese physicians and medical institutions can participate in more clinical trials without increasing their internal labor and costs.

Beyond deploying Paradigm's platform, we are developing new solutions that enhance the health and well-being of patients in Japan. This creates one of the most efficient clinical trial models in the world, ensuring Japan's inclusion in all global clinical trials.

Paradigm

Please visit www.paradigm.inc to learn more


DATA
Medical Institution
Healthy Living Platform
Collection
of medical data
Data engineering
of medical data
FUJITSU
Clinical trials platform
Support for clinical trials planning
Paradigm
Pharmaceutical companies

Aiming to Reduce the burden on Medical Institutions and further improve the Clinical trial environment

国立がん研究センター
東病院

×

FUJITSU

Deputy Director
National Cancer Center Hospital East

Koichi Goto

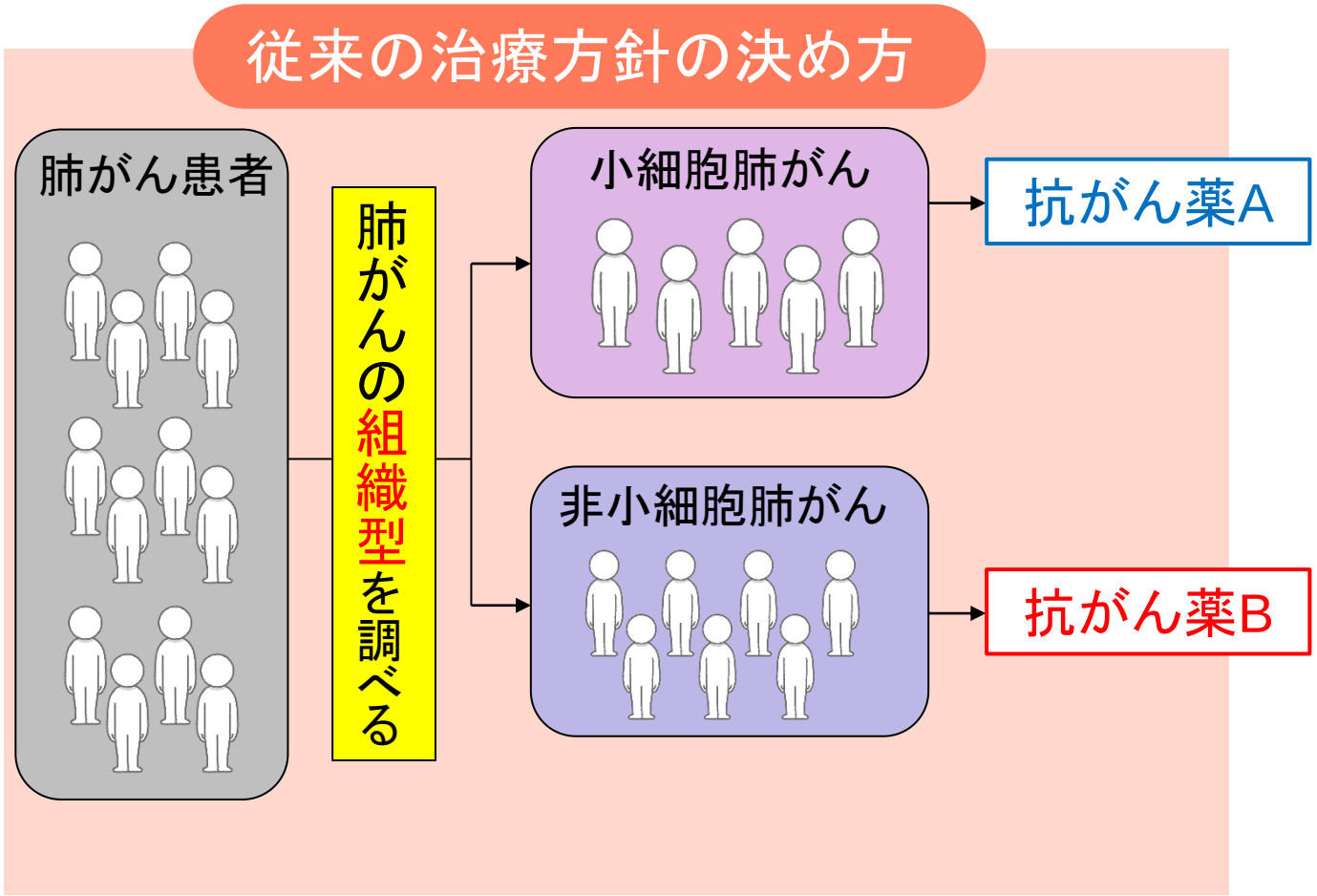
2024/8/26
Fujitsu Uvanceにおける
治験領域の新たなビジネス戦略と
パートナーシップについて

富士通/Paradigm/PREMIAとの共同研究による LC-SCRUM-CD (Clinical Development)の立ち上げについて

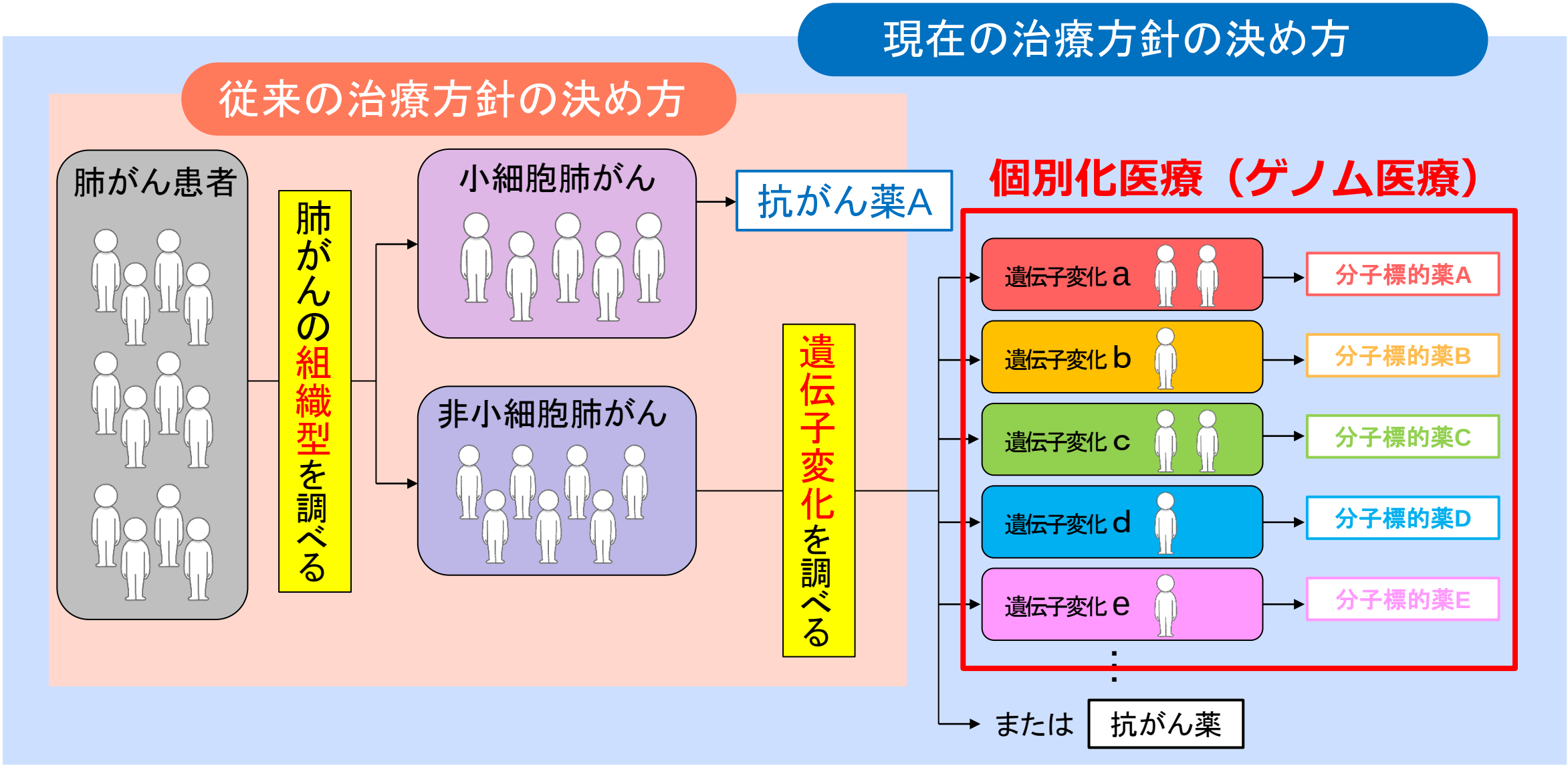
～遺伝子スクリーニング基盤(LC-SCRUM-Asia)の確立で飛躍的に進歩した肺がんの個別化医療～

国立がん研究センター東病院　副院長・呼吸器内科長
後藤　功一

進歩した肺がんの治療選択



進歩した肺がんの治療選択

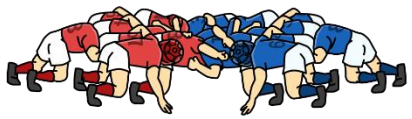


LC-SCRUM-Asiaの活動目的

- **有効な治療薬を患者さんへ届けること**
  - 希少がんの遺伝子スクリーニング
  - 遺伝子解析の結果に基づいた治療開発
  - コンパニオン診断薬の開発のサポート

- **マルチ診断薬を患者さんへ届けること**
  - マルチ診断薬の性能評価
  - マルチ診断薬の承認申請

LC-SCRUM-Asia概要図



Pharmaceutical Companies

Global Pharmaceutical Companies
Diagnostic companies
Venture companies

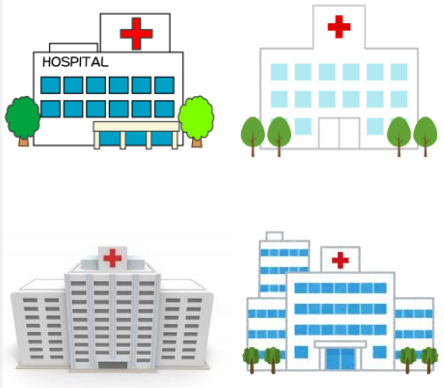
Contract

SCRUM-Japan Participation fee

Data Sharing

Business fee
- Pt enrollment
- Pt identification
- Therapy & Dx development

Institutions in Japan



Contract

LC-SCRUM-Asia

Contract

Datacenter fee

Enrollment

Data Sharing

Enrollment

Data Sharing

PREMIA
PRECISION MEDICINE ASIA

- LC-SCRUM data center
- Database construction
- Clinical Trials
- Companion diagnostics

Contract

Test Fee

Analysis Data

Contract

Contract

Clinical data

Sample Submission

Analysis Report

Genomic Data

LSI Medience
Genomic analysis

Company of Temporal LDM

ACCERISE·SITE
Clinical data collecting

Contract

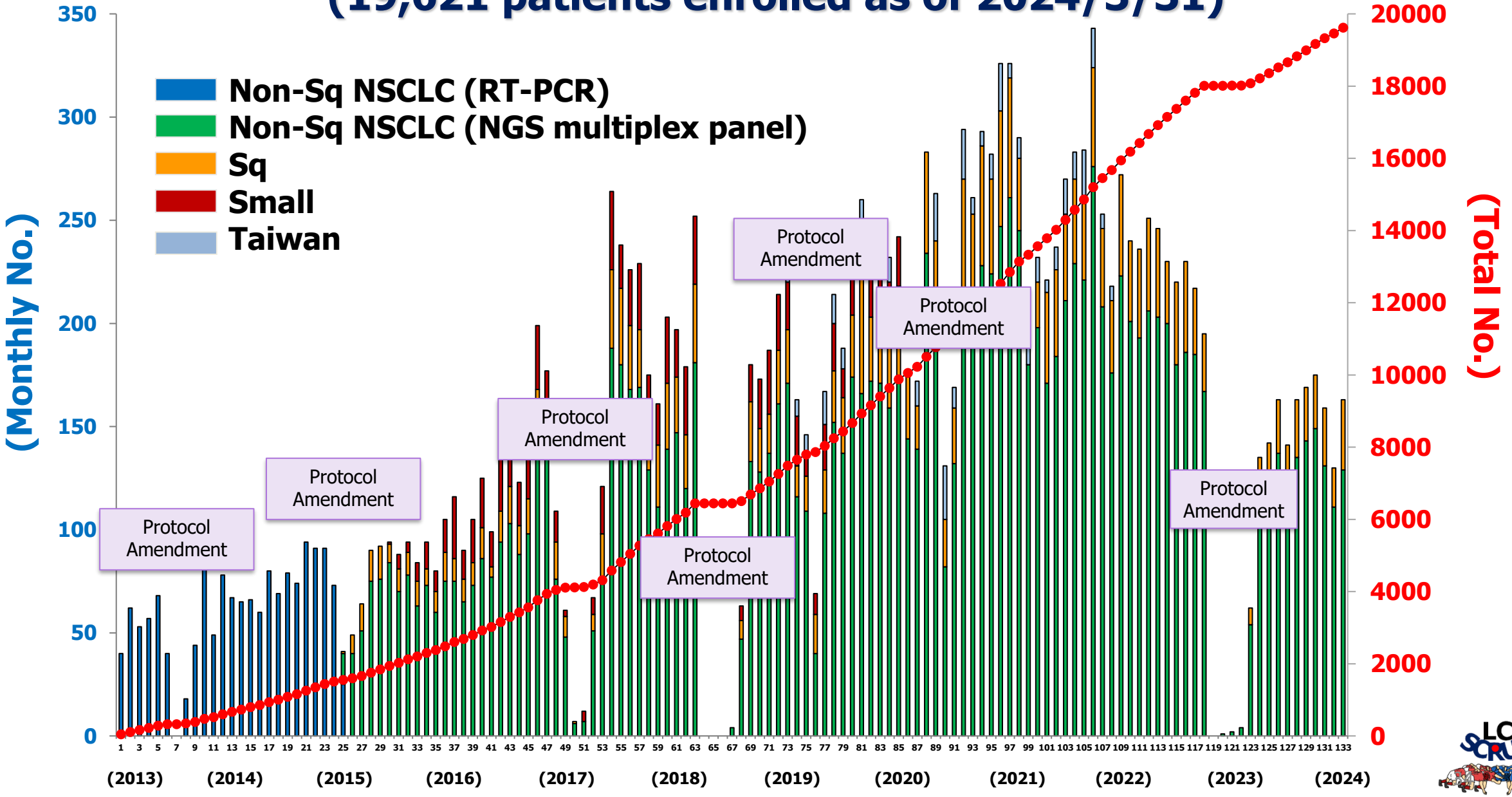
Clinical data

SCRUM-Japan supported by

- Amgen Inc.
- Astellas Pharma Inc.
- AstraZeneca K.K.
- Nippon Boehringer Ingelheim Co., Ltd.
- Bristol-Myers Squibb K.K.
- CHUGAI PHARMACEUTICAL Co., Ltd.
- DAIICHI SANKYO COMPANY, LIMITED
- Eisai Co., Ltd.
- Eli Lilly Japan K.K.
- Janssen Pharmaceutical K.K.
- Kyowa Kirin Co., Ltd.
- Merck KGaA
- MSD K.K.
- MEDICAL ＆ BIOLOGICAL LABORATORIES CO., LTD.
- Novartis Pharma K.K.
- ONO PHARMACEUTICAL CO., LTD.
- Pfizer Japan Inc.
- Sumitomo Pharma Co., Ltd.
- TAIHO PHARMACEUTICAL CO., LTD.
- Takeda Pharmaceutical Company Limited.
- Bayer
- Merus
- abbvie

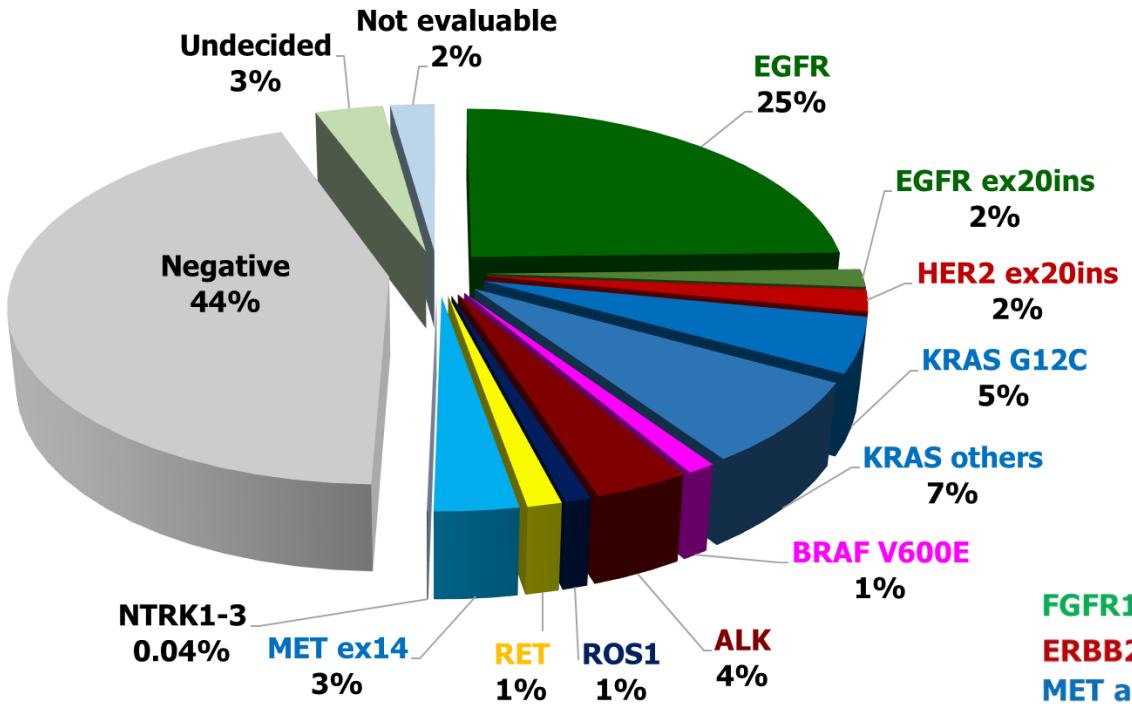
Patient Enrollment in LC-SCRUM-Asia

(19,621 patients enrolled as of 2024/3/31)

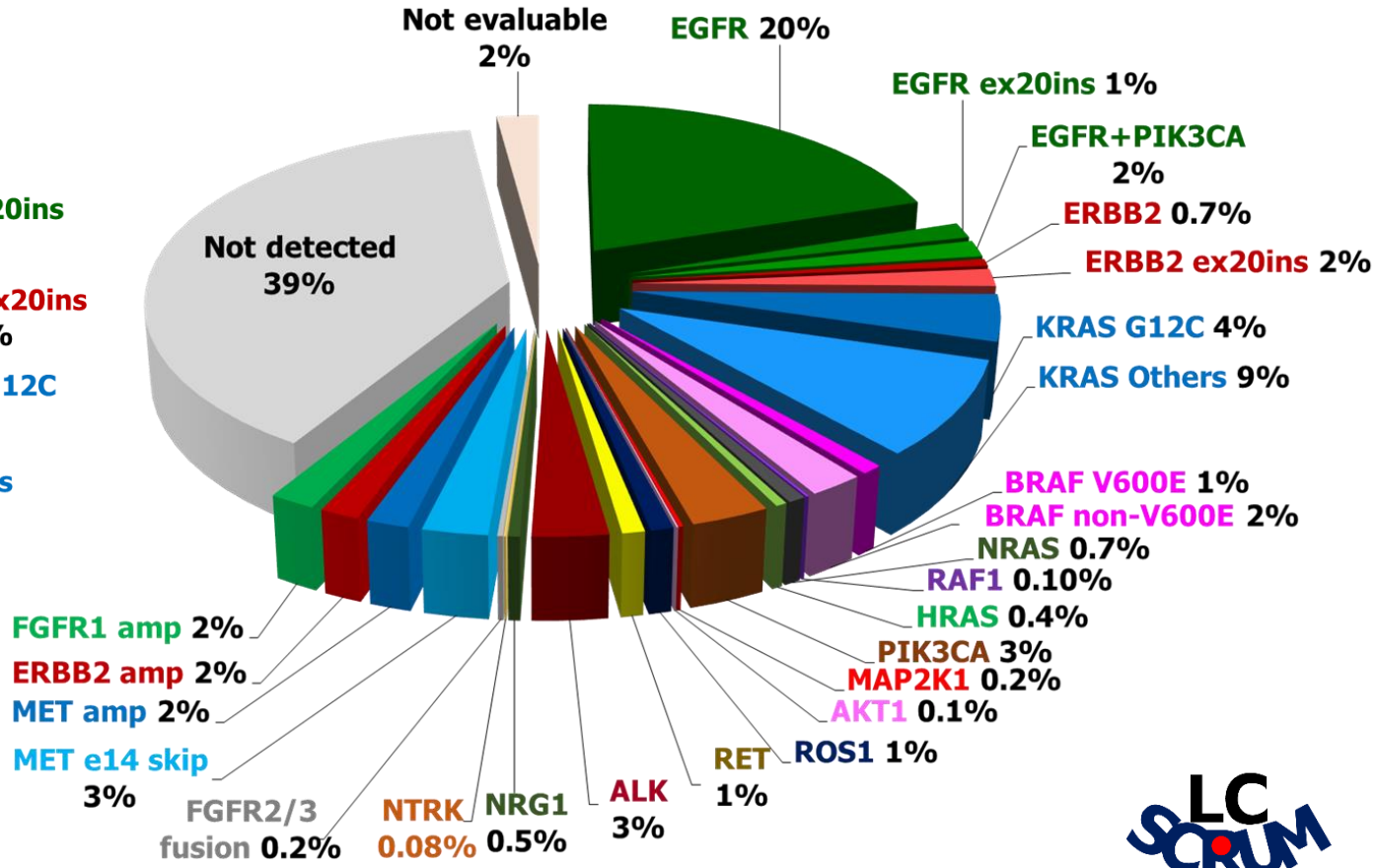


Oncogene Driver Identified in LC-SCRUM-Asia

Amoy Pan Lung Cancer PCR Panel
(Sep. 2019−Dec. 2022, Non-sq NSCLCs, N=7,356)



Oncomine Precision Assay: NGS
(Oct. 2020−Apr. 2024, NSCLCs, N=8,069)



Non-Small Cell Lung Cancer with Rare Driver Oncogenes Identified in Genomic Screening of LC-SCRUM-Asia

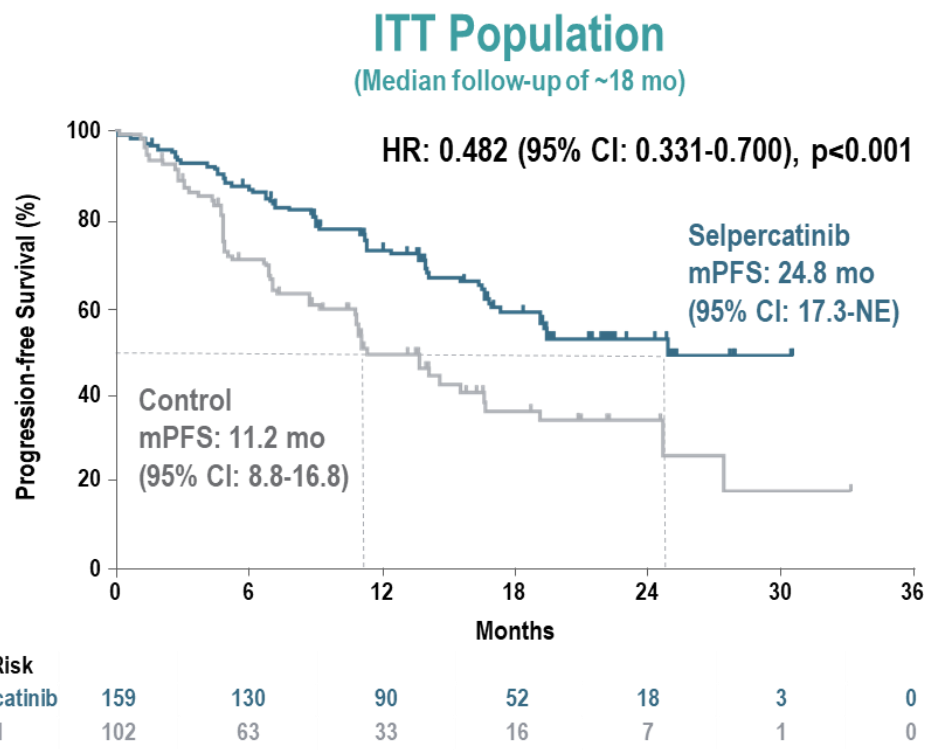
(2013/Feb-2024/Mar: NSCLC 16,656 pts)

Rare Driver Oncogenes	No. of Pt	Screening starting
ALK fusion	528	Feb/2013
RET fusion	276	Feb/2013
ROS1 fusion	293	Feb/2013
NTRK fusion	7	Jun/2019
NRG1 fusion	51	Apr/2015
MET Ex14 skipping	331	May/2017
BRAF V600E mutation	168	Mar/2015
HER2 Ex20 insertion	320	Mar/2015
EGFR Ex20 insertion	142	Jun/2019
KRAS G12C mutation	944	Mar/2015

The NEW ENGLAND JOURNAL of MEDICINE

First-Line Selpercatinib or Chemotherapy and Pembrolizumab in RET Fusion-Positive NSCLC

Caicun Zhou, M.D., Ph.D., Benjamin Solomon, M.B., B.S., Ph.D., Herbert H. Loong, M.B., B.S., Keunchil Park, M.D., Ph.D., Maurice Pérol, M.D., Edurne Arriola, M.D., Ph.D., Silvia Novello, M.D., Ph.D., Baohui Han, M.D., Ph.D., Jianying Zhou, Andrea Ardizzoni, M.D., Milena P. Mak, M.D., Ph.D., Fernando C. Santini, M.D., Yasir Y. Elamin, M.D., Alexander Drilon, M.D., Jürgen Wolf, M.D., Nalin Payakachat, Ph.D., Minji K. Uh, Ph.D., Deborah Rajakumar, B.D.S., M.Sc., Hongmei Han, M.S., M.Ap.St., Tarun Puri, M.D., Viktoriya Soldatenkova, Aimee B. Lin, Ph.D., Boris K. Lin, M.D., Ph.D., and Koichi Goto, M.D., Ph.D.



Key Eligibility Criteria

- Stage IIIB-IIIC[1], IV non-squamous NSCLC
- No prior systemic therapy for metastatic disease
- *RET* fusion identified via NGS or PCR
- ECOG PS 0-1
- Symptomatic CNS metastases excluded

Stratification factors:

- Geography (East Asian vs. non-East Asian)
- Brain metastases (present vs. absent/unknown)[2]
- Investigator's choice of treatment with pembrolizumab

R 2:1[3]

Selpercatinib (160 mg BID)
N= 159

Carboplatin (AUC 5) or **Cisplatin** (75 mg/m^2)
+ **Pemetrexed** (500 mg/m^2)
+/- **Pembrolizumab** (200 mg)
N=102

Optional Crossover

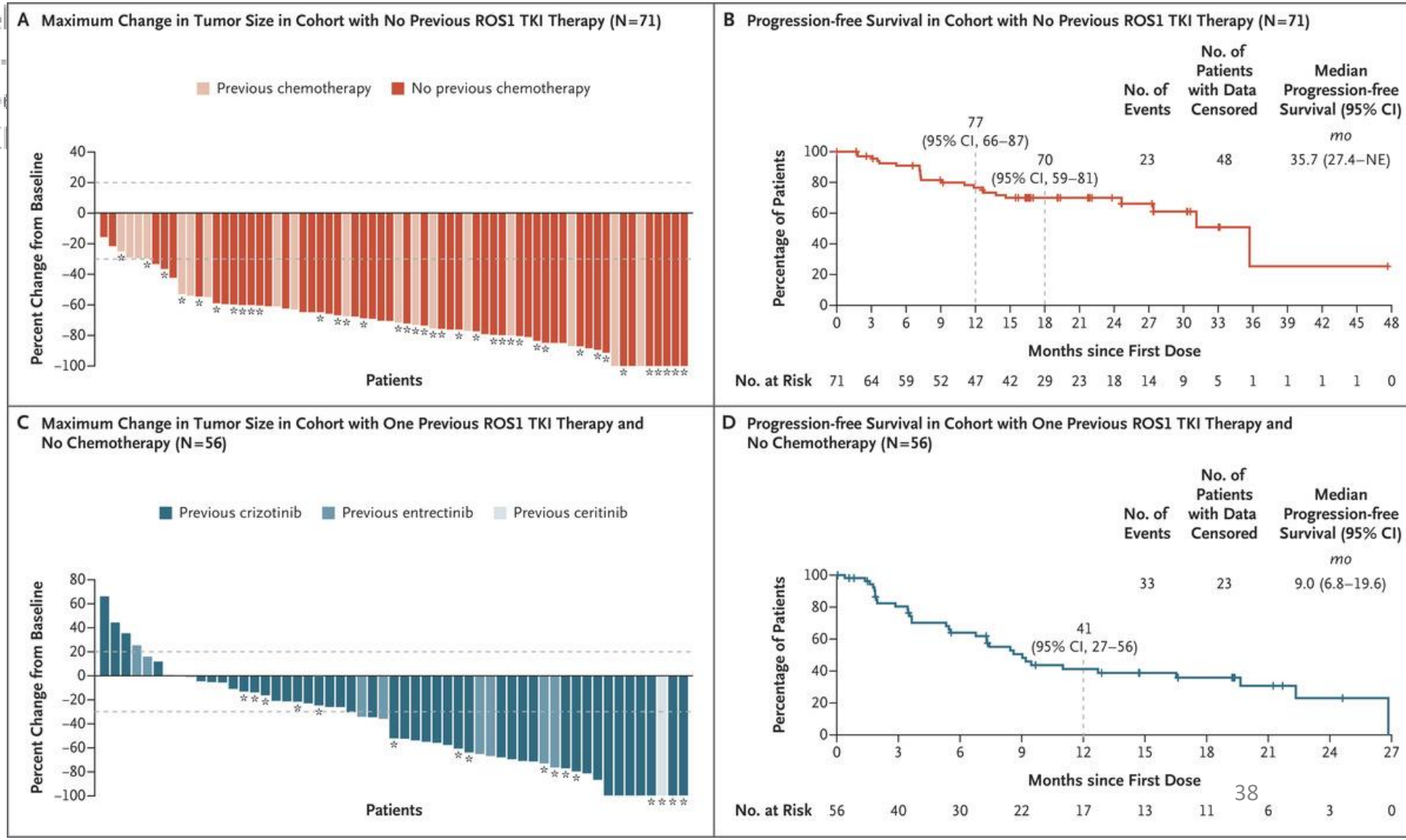
Selpercatinib
(Upon BICR confirmed PD)

(N Engl J Med. 2023;389:1839-1850)

Repotrectinib in *ROS1* Fusion–Positive Non–Small-Cell Lung Cancer

A. Drilon, D.R. Camidge, J.J. Lin, S.-W. Kim, B.J. Solomon, R. Dziadziuszko, B. Besse, K. Goto, A.J. de Langen, J. Wolf, K.H. Lee, S. Popat, C. Springfeld, M. Nagasaka, E. Felip, N. Yang, V. Vel… W. Yao, M.S. Beg, X. Hu, D. Moro-… M. Mehta, D. Trone, A. Grabe… for the TRIDE…

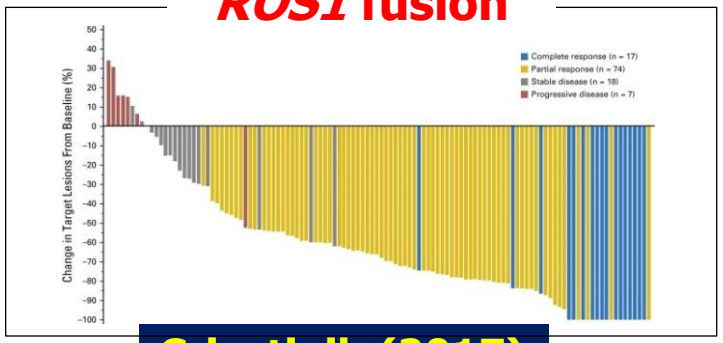
The NEW ENGLAND JOURNAL of MEDICINE



(N Engl J Med 2024;390:118-131)

PMDA Approval of Targeted Therapies for NSCLC

ROS1 fusion

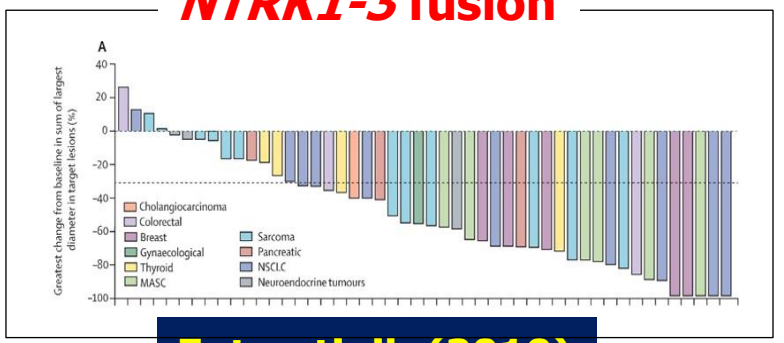


Crizotinib (2017)

BRAF V600E

Dabrafenib+Trametinib (2018)

NTRK1-3 fusion

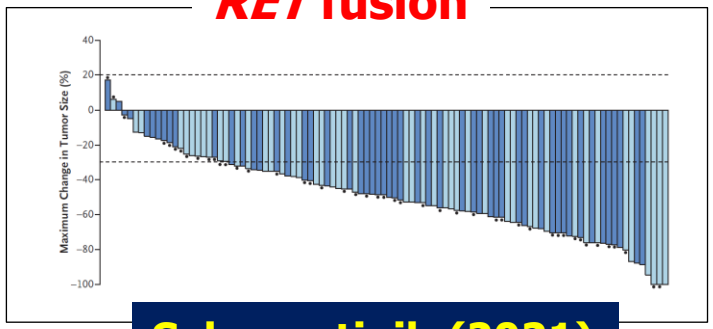


Entrectinib (2019)

MET ex14 skipping

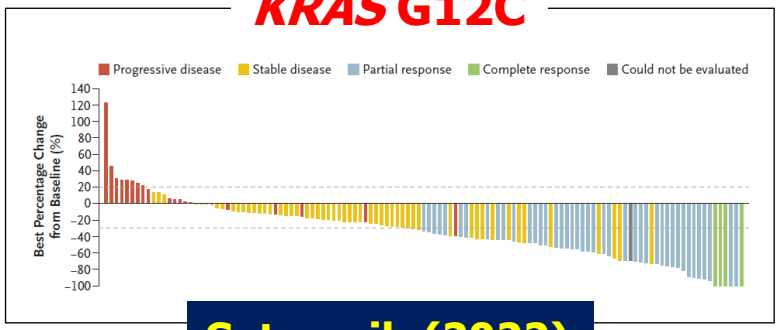
Tepotinib (2020) **Capmatinib (2020)**

RET fusion



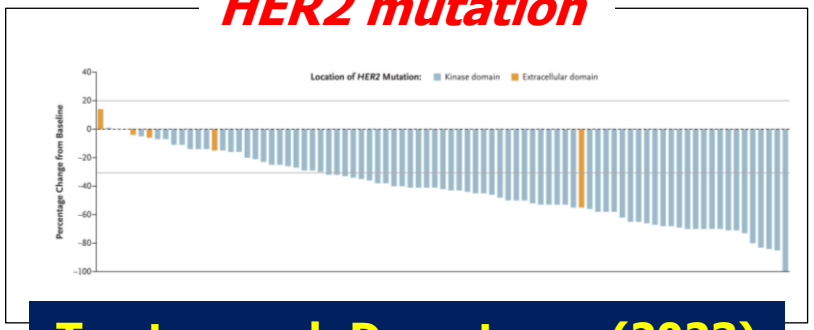
Selpercatinib (2021)

KRAS G12C



Sotorasib (2022)

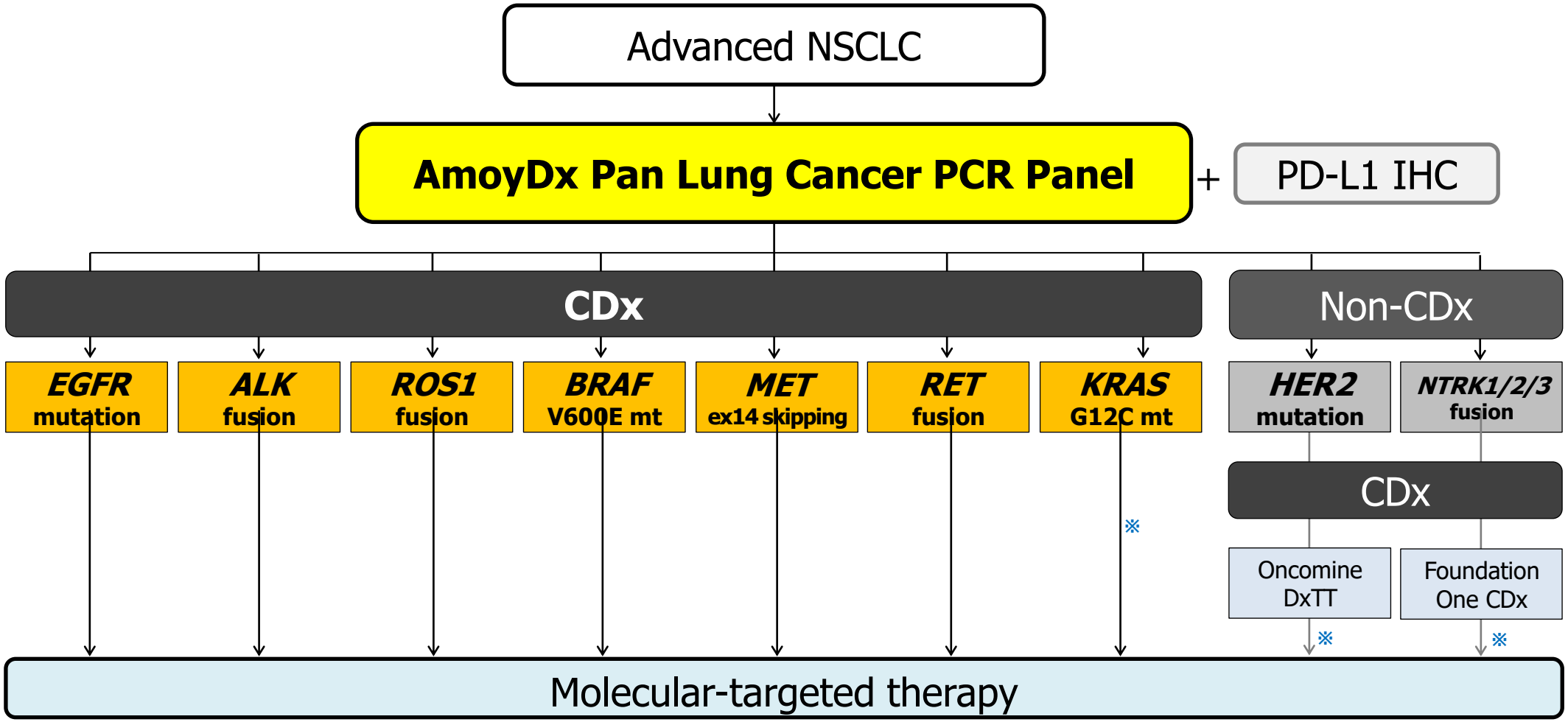
HER2 mutation



Trastuzumab Deruxtecan (2023)

Wu YL, et al. JCO 2018. Planchard D, et al. Lancet Oncol 2016. Doebele RC, et al. Lancet Oncol 2020, Paik PK, et al. NEJM 2020. Wolf J, et al. NEJM 2020. Drilon A, et al. NEJM 2020. Skoulidis F, et al. NEJM 2021, Li BT. et al. NEJM 2021

進行非小細胞肺がんにおけるマルチ診断薬を用いた治療方針の決定



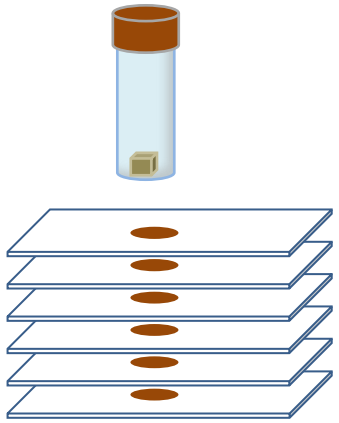
※ : for ≧2nd –line therapy

日本肺癌学会バイオマーカー委員会. 肺癌患者におけるPCRを用いたマルチ遺伝子検査の手引き. 2023年5月10日 第1.0版. 一部改変

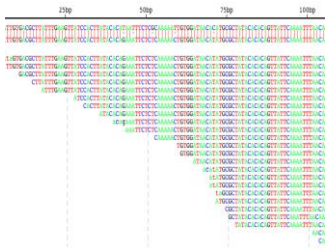
LC-SCRUM-Asiaにおける遺伝子変化のスクリーニング

遺伝子解析

Sample

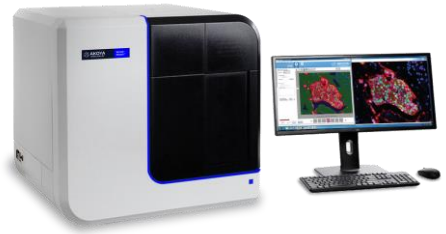


OPA (NGS)



5 days

Multiplex IHC



14-21 days

Reporting

OPA

EGFR	+/-
ALK	+/-
ROS1	+/-
RET	+/-
KRAS	+/-
BRAF	+/-
MET	+/-
HER2	+/-

Multiplex IHC

MET	+/-
HER3	+/-
TROP2	+/-
CEACAM5	+/-
ITGB6	+/-
MTAP	+/-
DAPI	+/-
	+/-

遺伝子変化に
対応した臨床試験の
紹介と登録の推進
（手作業）

Biomarker-matched clinical trial

- ✓ Targeted Tx
- ✓ ICI
- ✓ ADC

Correlation analysis between
genomic alterations and protein expression

LC SCRUM

LC-SCRUM-CD (Clinical Development)

遺伝子情報

臨床試験

Sample submission

Clinical Labo

PREMIA PRECISION MEDICINE ASIA

Genomic data

Clinical Trial DB

Paradigm

Reporting

Reporting

Clinical trial information

Email address registry

Decision making

Genomic information

Clin. trial information

Study site

Patient

Genomic information

Clin. trial information

LC SCRUM

Study management

Selection of candidate patient

Supported by Fujitsu/Paradigm/PREMIA

Clinical trial information

Patient Enrollment

EDC

Clinical data

臨床情報

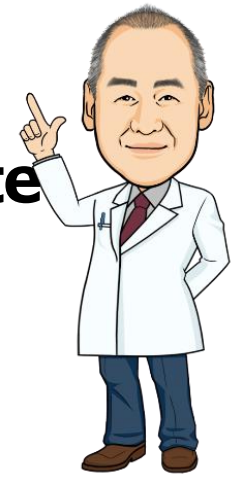
Clinical data

FUJITSU

Paradigm, a healthcare technology company focused on improving access to clinical research for patients

Conclusions

- Approximately 20,000 lung cancer patients were already enrolled into LC-SCRUM-Asia for 11 years.
- Various genomic alterations were screened in LC-SCRUM-Asia.
- Through the genome screening, LC-SCRUM-Asia has contributed to the development of lung cancer precision medicine.
- LC-SCRUM-CD, which is a novel collaborative project between Fujitsu, Paradigm, Premia and NCC is initiated from 2024 to promote precision medicine for cancer patients.



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- We would also like to acknowledge all the patients, their families, physicians, staff members who participated in LC-SCRUM-Asia.

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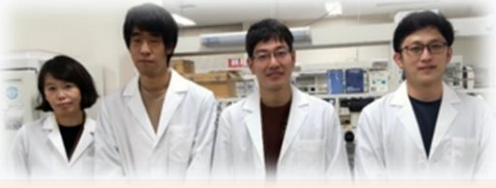

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Patient-centric Clinical Trials

Automatic creation of **clinical trial-related document**
by LLM which is specialized for the Clinical trials

Fujitsu Uvance

Head of Clinical Trial Solution Department
Life Science Division
Social Solution Business Unit

Michio Hamamatsu

Address various issues related to the utilization of clinical trial data and the efficiency of labor-intensive tasks using data and AI

Delay in the digitalization of clinical trial-related document creation tasks

Documentation period required before the start of clinical trials

6months

Time required to create 100 items of documents

20,000hours

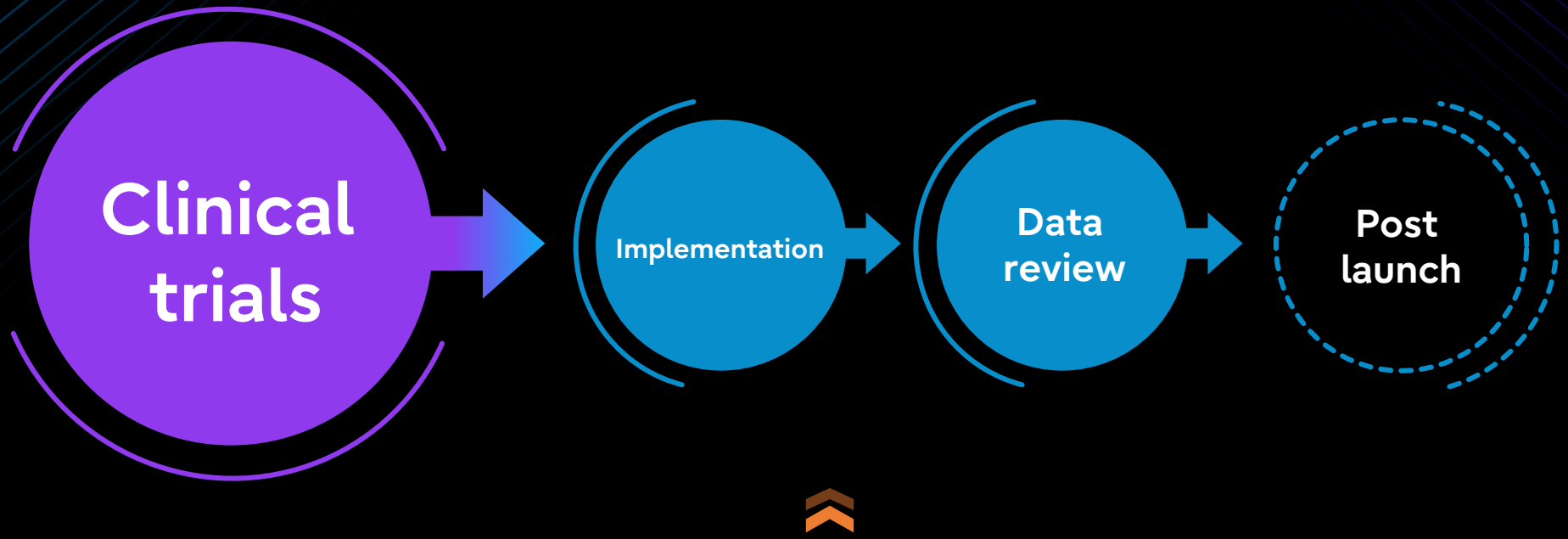
Lead time for the data analysis

3month

The key to solving issues is the step of creating the clinical trial protocol

*According to our research in 2024

Transform drug development process end-to-end

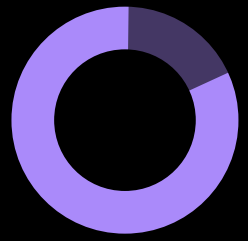


Patient-centric Clinical Trials

Patient-centric Clinical Trials

Introduction effects

Document creation automation



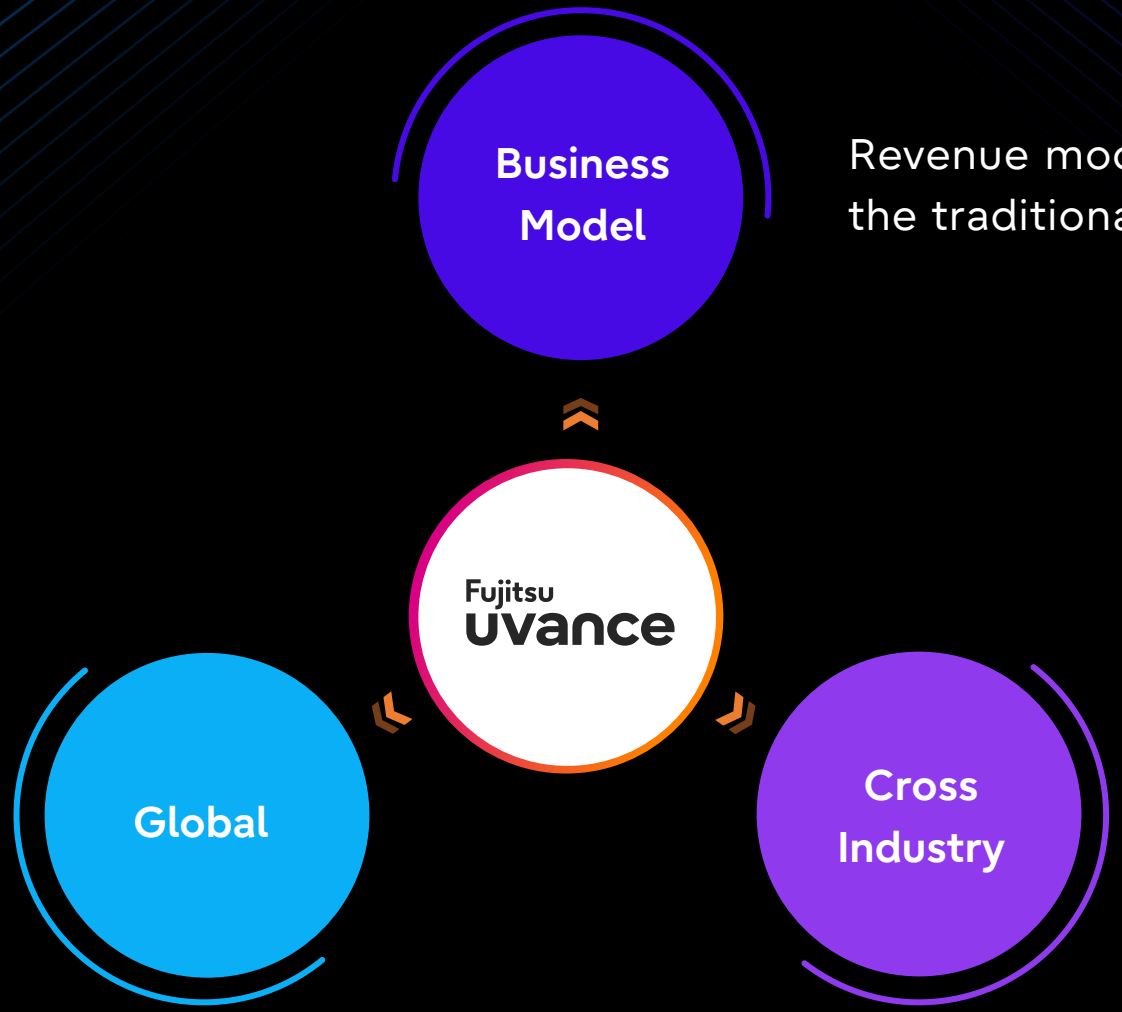
80%

proven

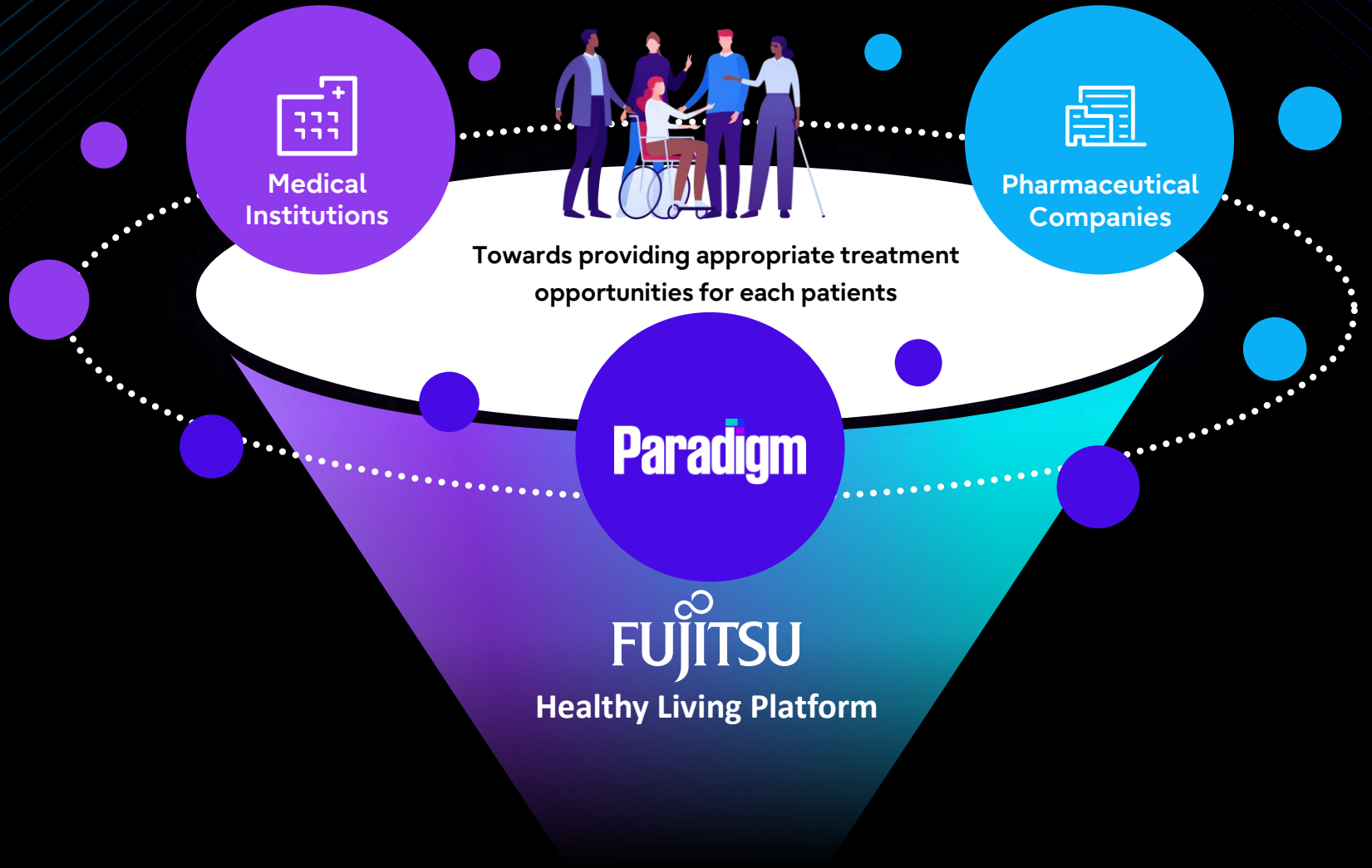
Documentation period

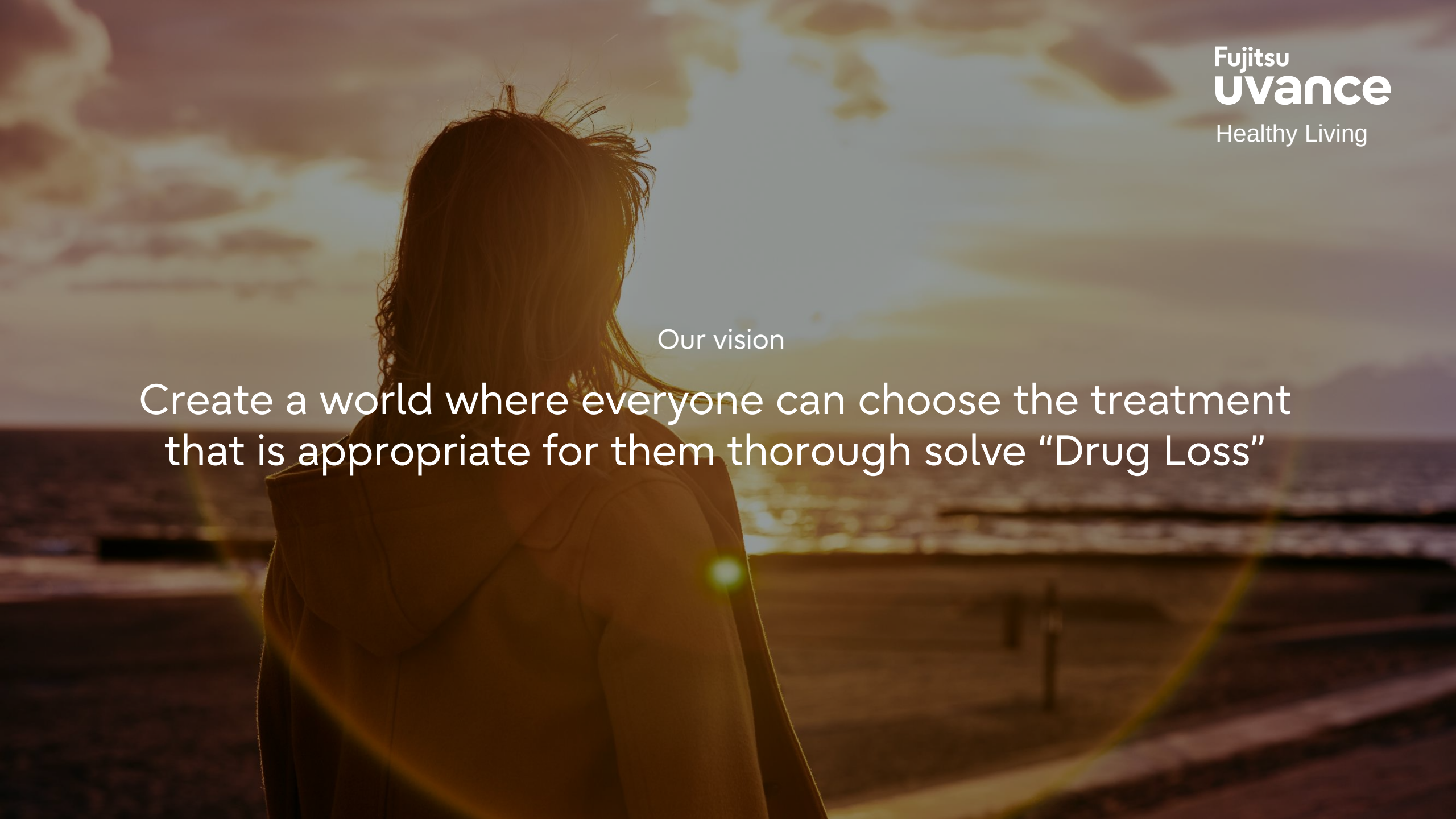
50% ↓

estimation


Business Model
Revenue model different from the traditional business model
Fujitsu uvance
Global
Global business through co-creation with other companies
Cross Industry
Cross-industry business connecting different sectors

Creation of an ecosystem that enables the utilization of medical data





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Healthy Living

Our vision

Create a world where everyone can choose the treatment that is appropriate for them thorough solve “Drug Loss”