富士通 記者説明会
2024年8月26日

Fujitsu Uvance
Healthy Living

「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

Fujitsu Uvance
Healthy Living

式次第 10:30-11:30

本日の流れ

・登壇者によるゲストを交えたプレゼンテーション
・質疑応答
・フォトセッション

登壇者

■富士通株式会社

執行役員 EVP グローバルソリューション（ソーシャルソリューション＆テクノロジーサービス）
大塚 尚子（おおつか なおこ）

ソーシャルソリューション事業本部 Healthy Living Head
荒木 達樹（あらき たつき）

ソーシャルソリューション事業本部 Healthy Living Life Science事業部 Clinical Trial Solution 部長
浜松 紀夫（はままつ みちお）

■ゲスト

Paradigm Health, Inc. CEO
Kent Thoelke（ケント・トールケ）

国立研究開発法人国立がん研究センター東病院 副院長
後藤 功一（ごとう こういち）

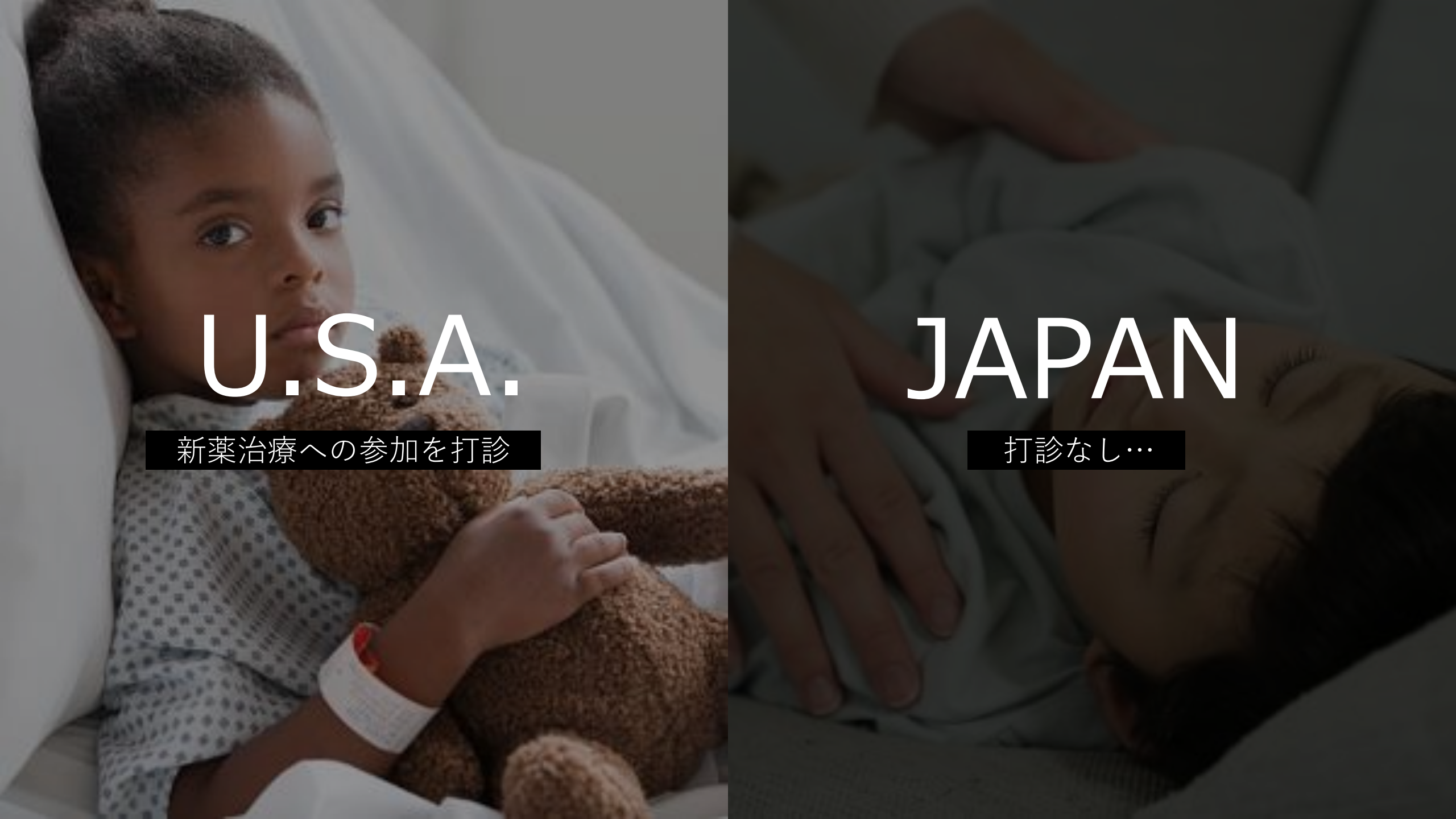
Fujitsu Uvance

執行役員 EVP
グローバルソリューション
（ソーシャルソリューション＆テクノロジーサービス）

おお つか なお こ
大塚 尚子


Fujitsu
uvance
Healthy Living
持続可能な世界に向けたサステナビリティ・トランスフォーメーション
Planet
地球環境問題
の解決
People
人々のウェルビーイング
の向上
Prosperity
地デジタル社会
の発展


Healthy Living
ドラッグ・ロス解消に向けた事業の立ち上げ



U.S.A.

新薬治療への参加を打診

JAPAN

打診なし…

ドラッグ・ロスの現状

欧米で認可されている薬や治療法が、日本では承認されていない

341病名

希少疾患の
治療法がない

2024年時点

143品目

日本で未承認
（欧米では承認済）

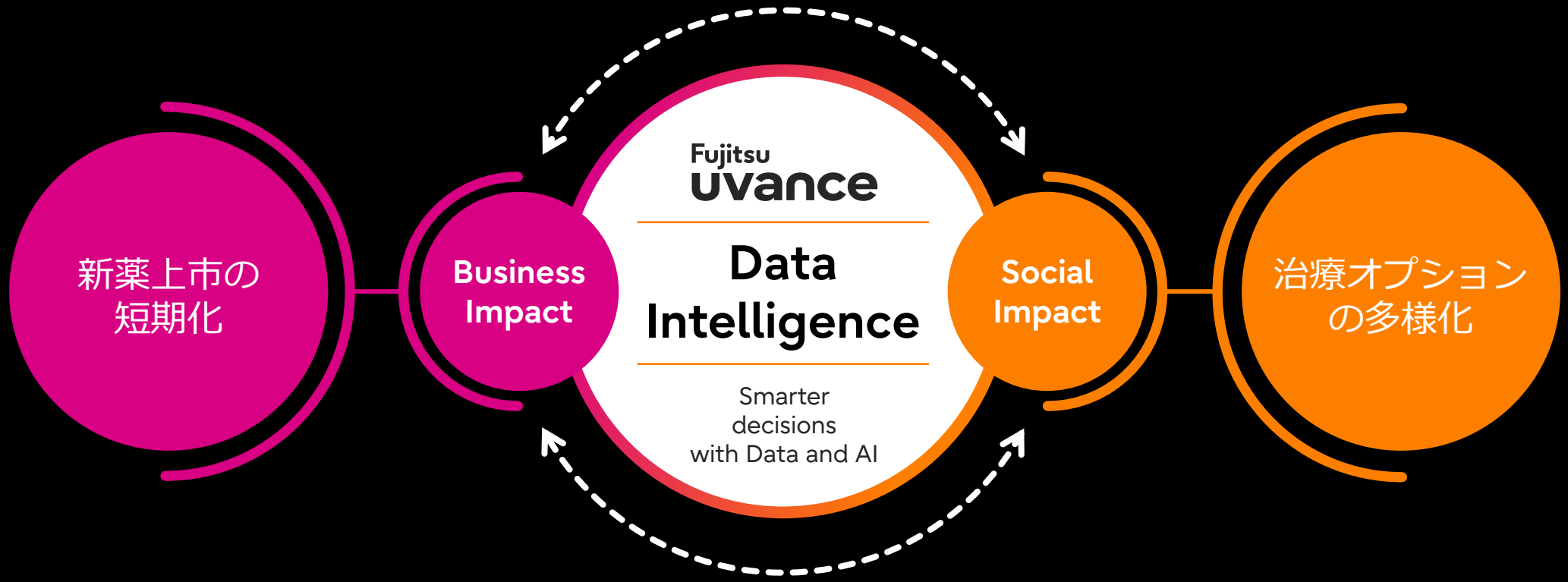
2023年時点

86品目

国内開発
未着手

2023年時点

＊左 出典：厚生労働省　HP　健康・医療＞健康＞指定難病　指定難病病名一覧より
＊中 厚生労働省ホームページ　https://www.mhlw.go.jp/content/11121000/001206963.pdf
＊右 厚生労働省ホームページ　https://www.mhlw.go.jp/content/11121000/001206963.pdf


新薬上市の
短期化
Business
Impact
Fujitsu
uvance
Data
Intelligence
Smarter
decisions
with Data and AI
Social
Impact
治療オプション
の多様化

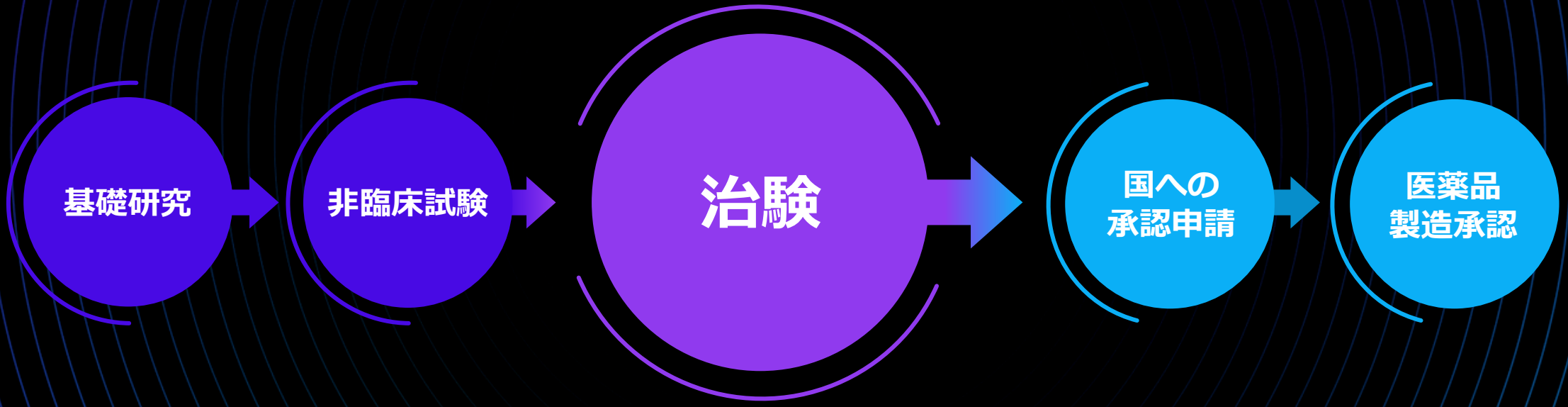
Fujitsu
Uvance

ソーシャルソリューション事業本部
Healthy Living
Head

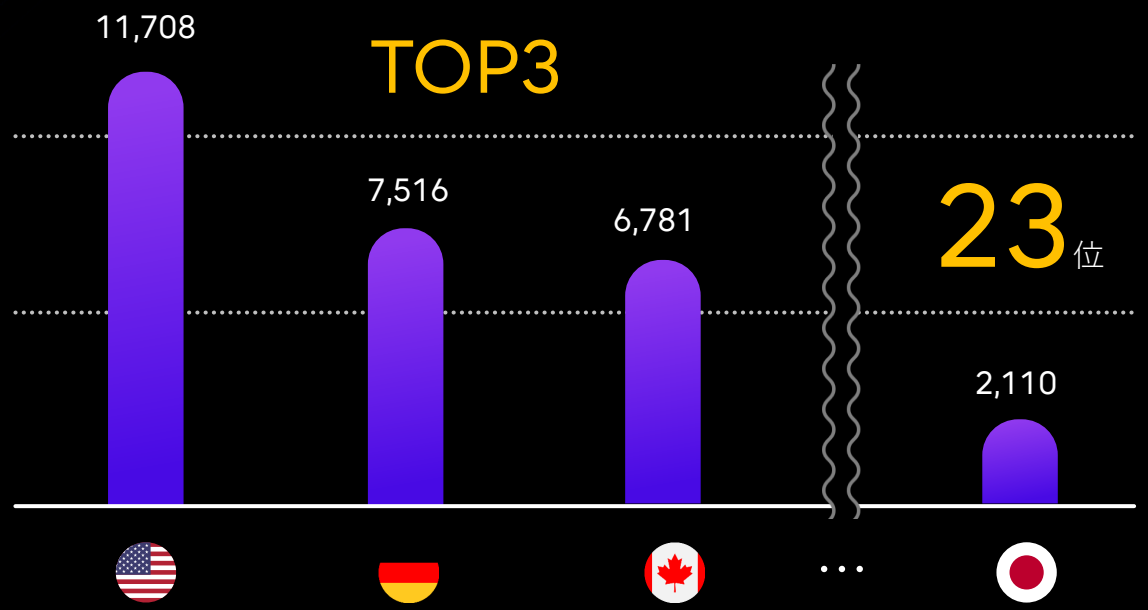
あら　き　　たつ　き
荒木 達樹

なぜ日本でドラッグ・ロスが起こるのか

新薬開発プロセス



国際共同治験数の現状



＊出典：医薬産業政策研究所「近年における国際共同治験の動向調査」より（国別 ClinicalTrials.gov 登録累積試験数〔2000年～2021年〕）

治験プロセス

治験の計画

製薬企業

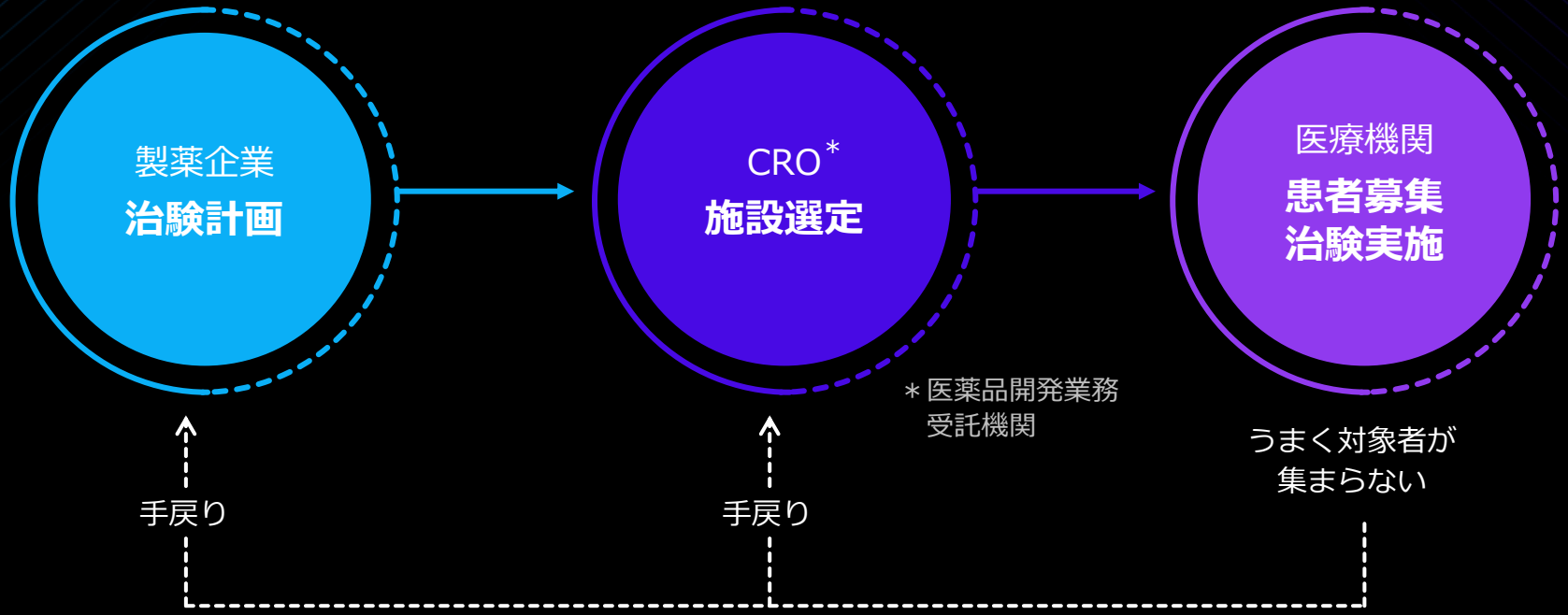
»

治験の実施

医療機関

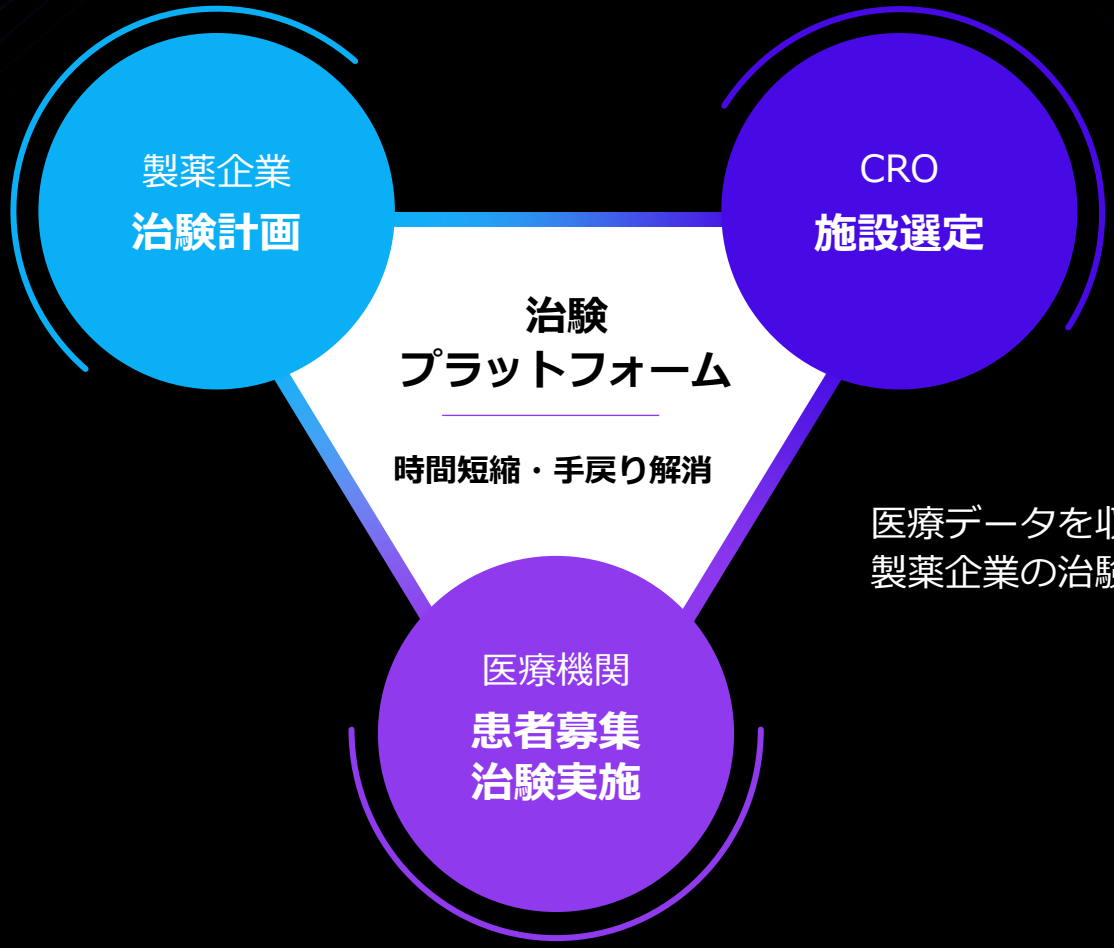
治験プロセスのパラダイムシフト

モノローグ型からダイアローグ型へ



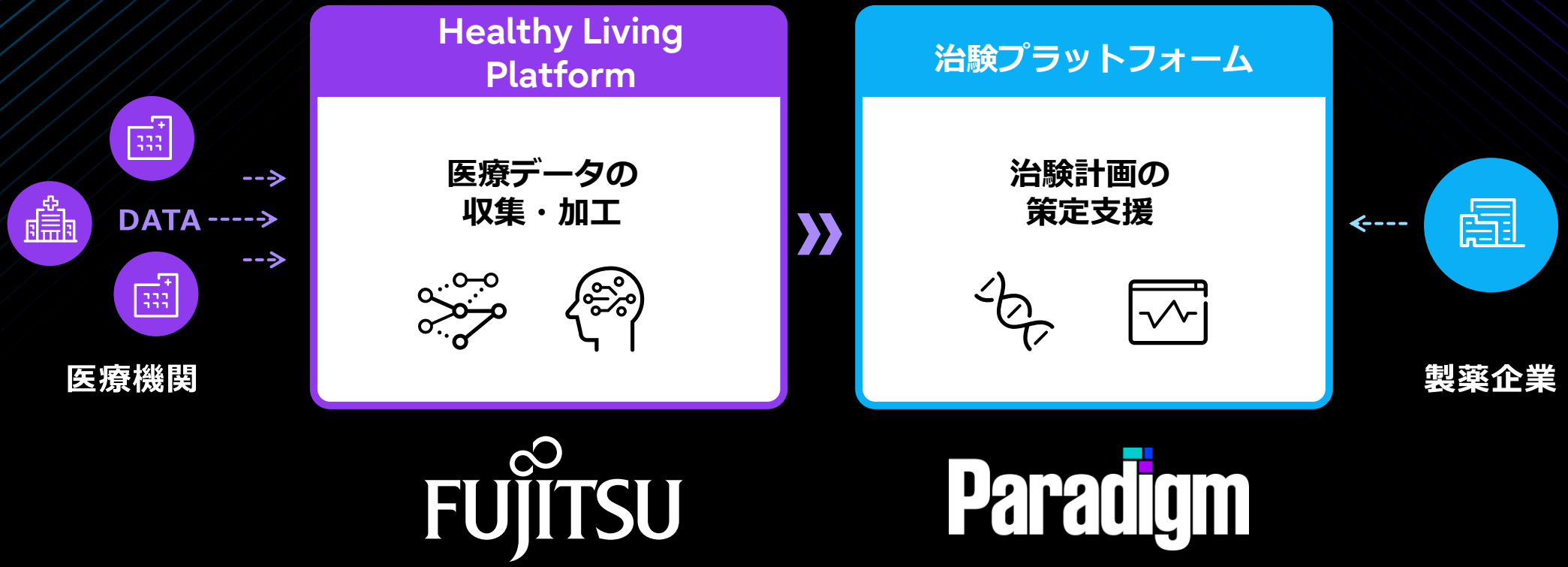
治験プロセスのパラダイムシフト

モノローグ型からダイアローグ型へ



医療データを収集し、
製薬企業の治験計画に活かす

医療機関と製薬企業を繋ぐプラットフォーム



Paradigmとのパートナーシップにより
治験領域のデジタル化を加速

×

CEO
Paradigm Health, Inc.

ケント　トールケ
Kent Thoelke

Paradigm

Japan Launch

www.paradigm.inc

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

Ineffective Current State

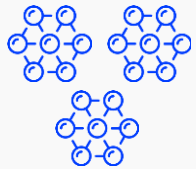
<15% of **sites** enroll patients within specified time periods[1]

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

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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**

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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

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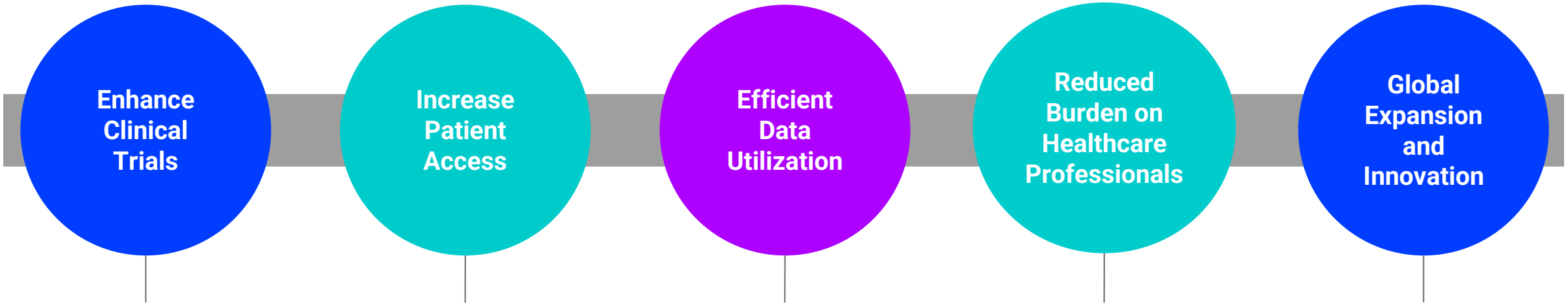
Paradigm

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.

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Paradigm

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医療機関

DATA

Healthy Living Platform

医療データの
収集

医療データの
加工

FUJITSU

治験プラットフォーム

治験計画の
策定支援

Paradigm

製薬企業

医療機関の負荷を減らし
治験環境のさらなる向上を目指す

国立がん研究センター
東病院

×

FUJITSU

国立がん研究センター東病院
副院長・呼吸器内科長

後藤（ごとう） 功一（こういち）

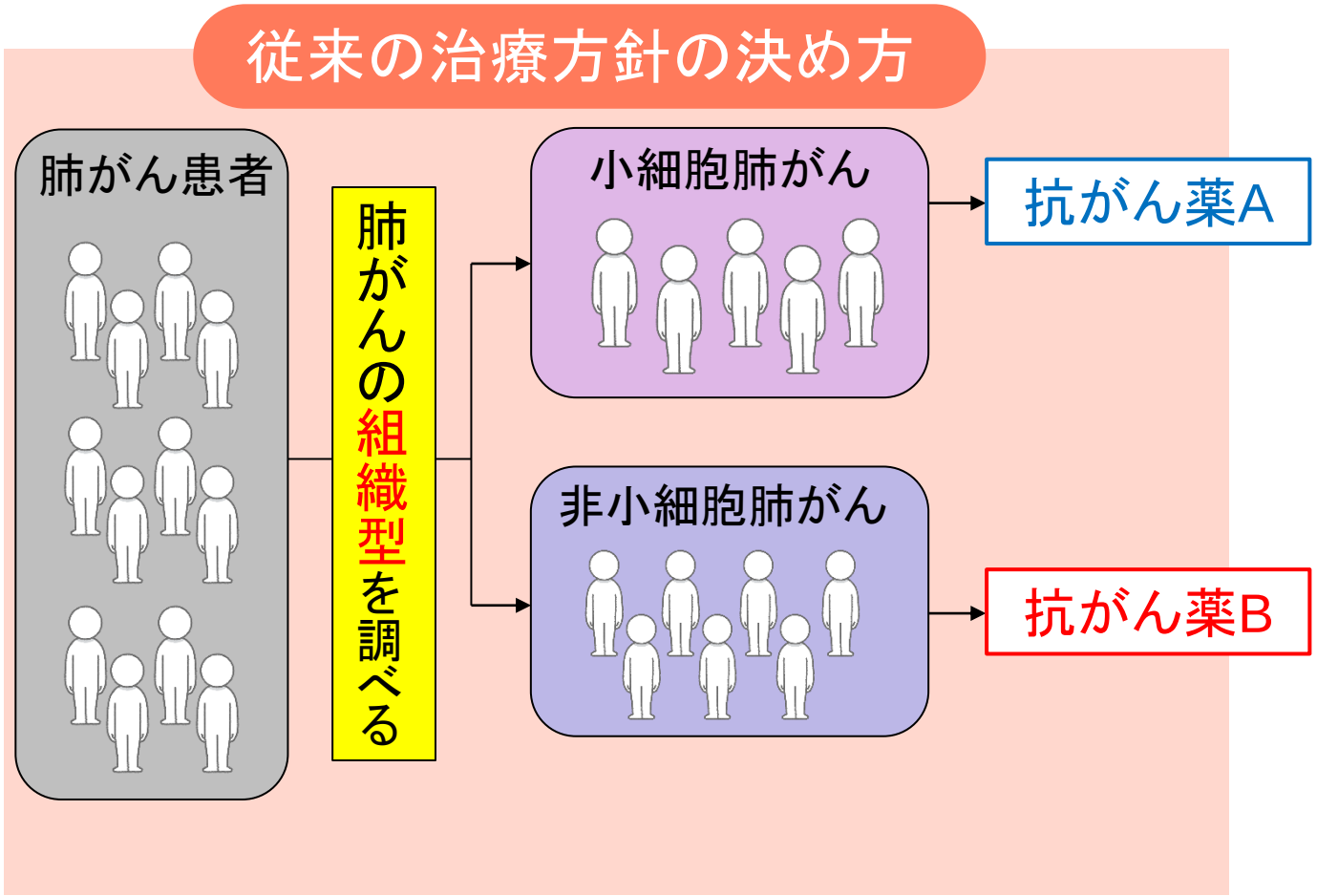
2024/8/26
Fujitsu Uvanceにおける
治験領域の新たなビジネス戦略と
パートナーシップについて

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

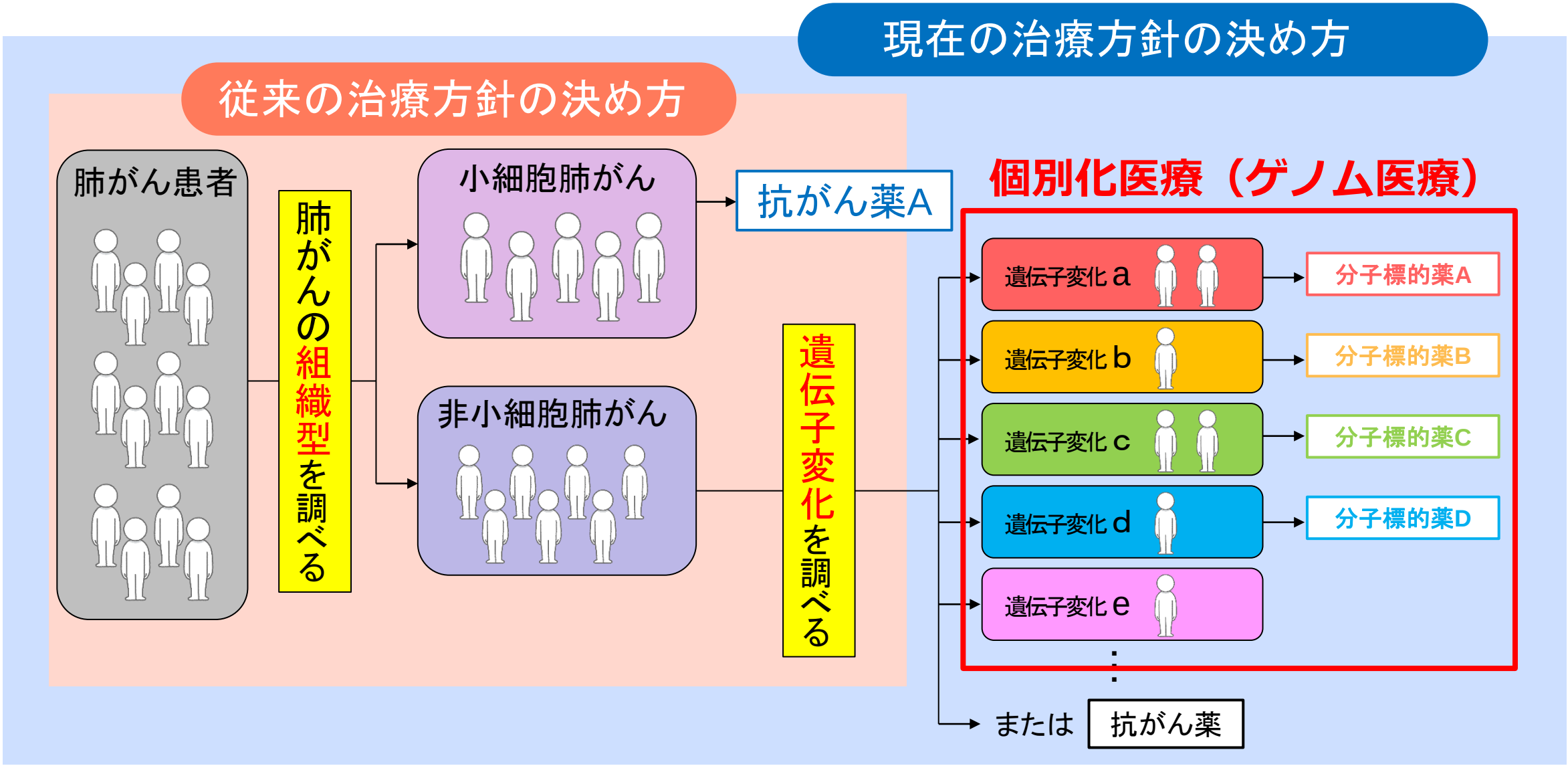
～遺伝子スクリーニング基盤(LC-SCRUM-Asia)の確立で飛躍的に進歩した肺がんの個別化医療～

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

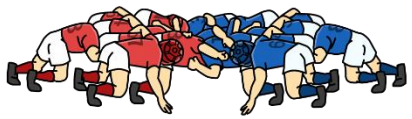


LC-SCRUM-Asiaの活動目的

- **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

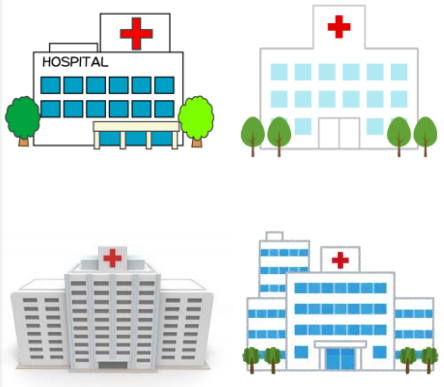
Contract

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

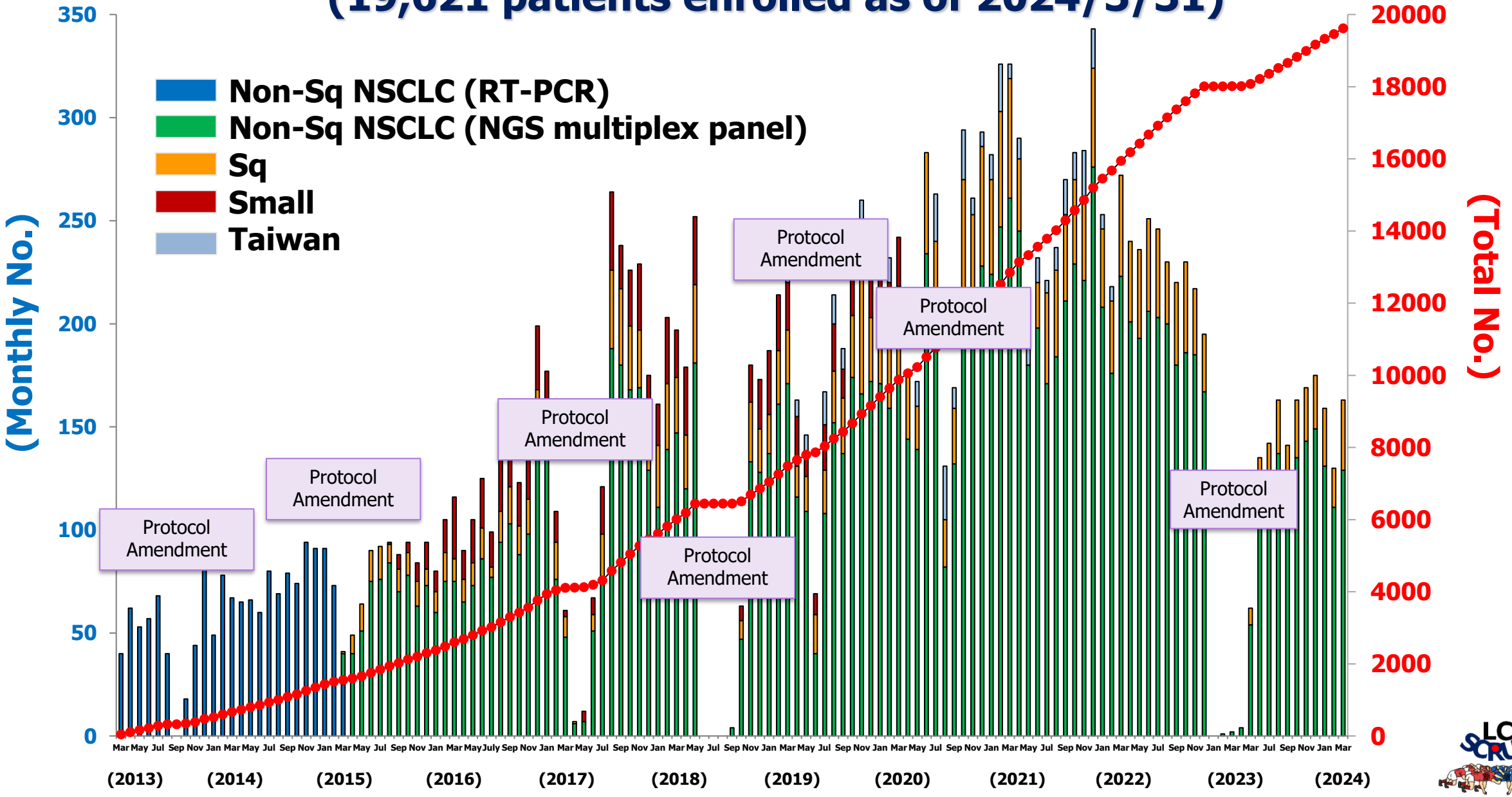
Clinical data

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

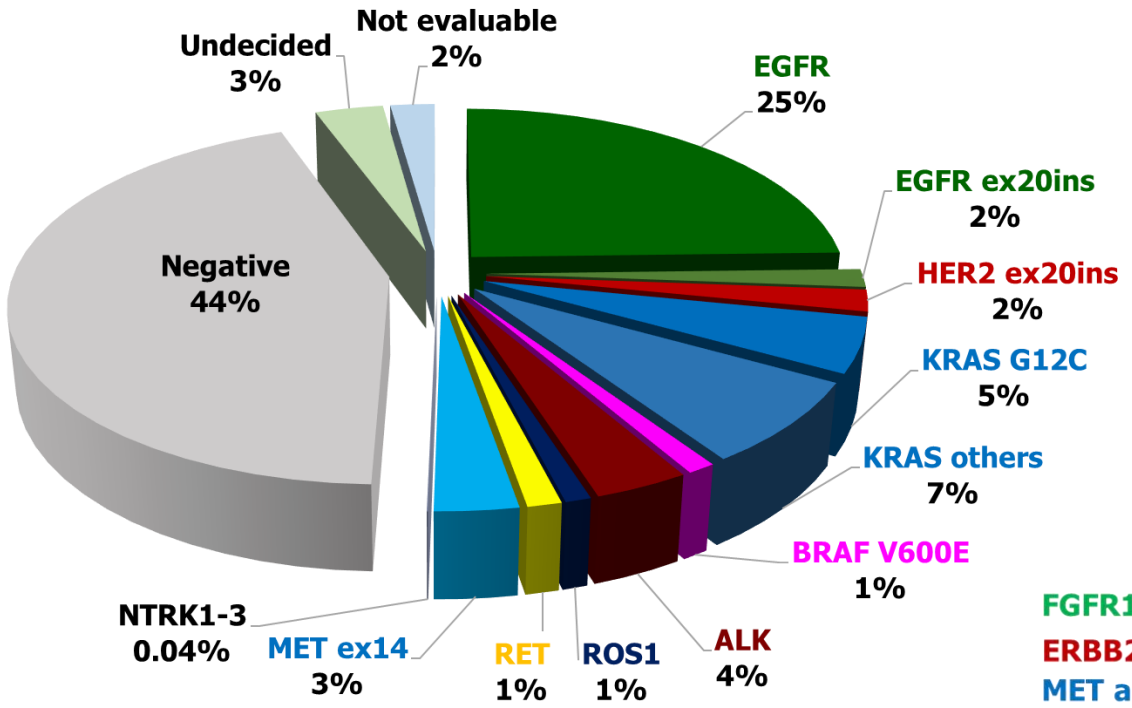
Patient Enrollment in LC-SCRUM-Asia

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

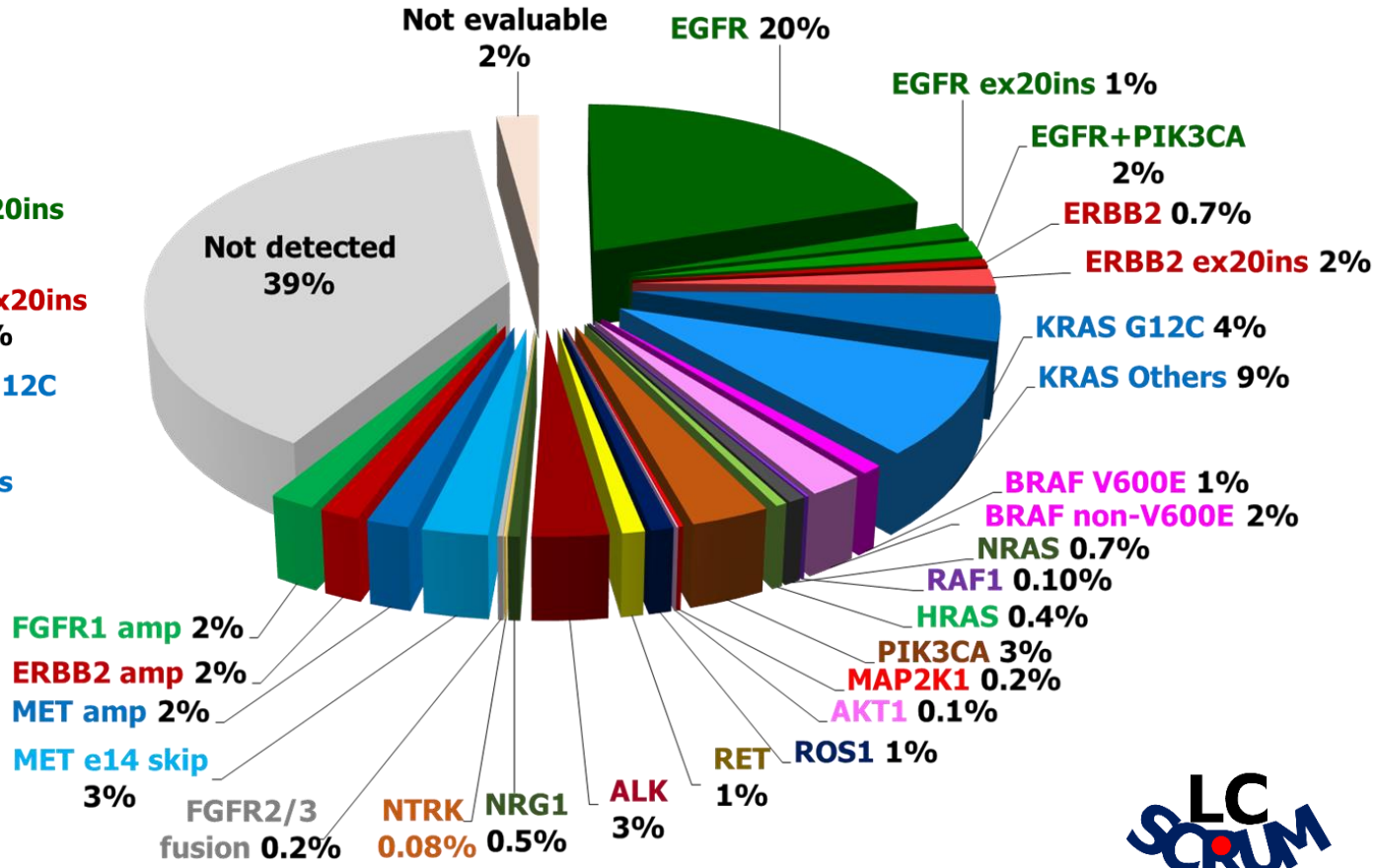


Oncogene Driver Identified in LC-SCRUM-Asia

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

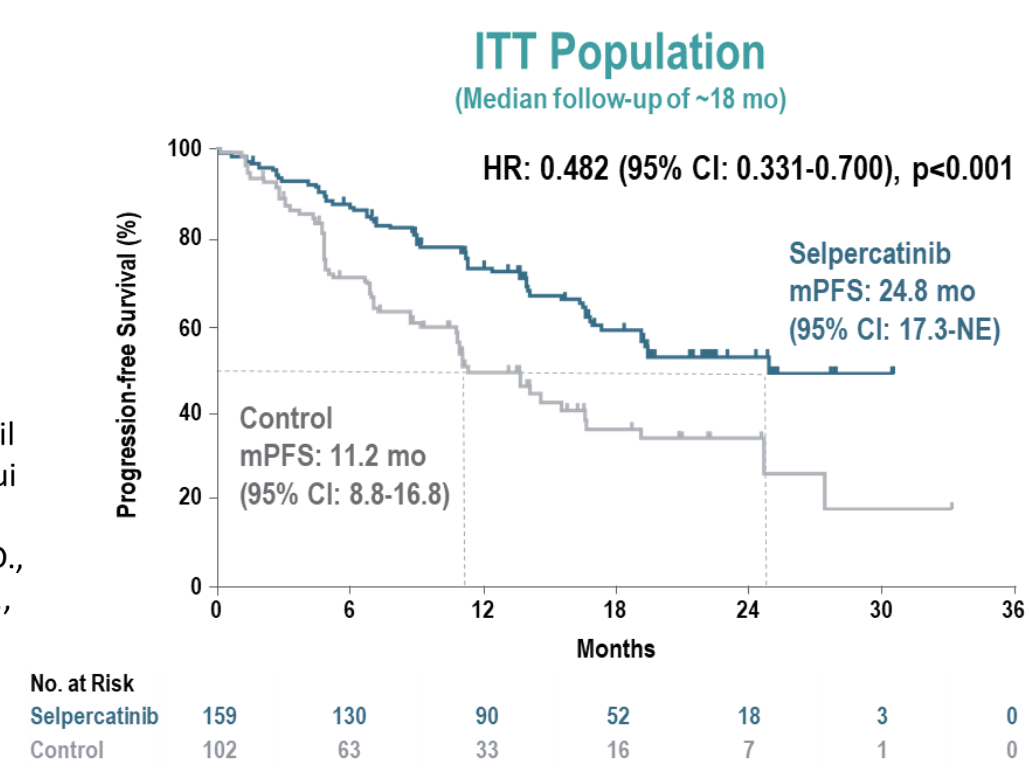
(2013/Feb-2024/Mar: NSCLC 16,656 pts)

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

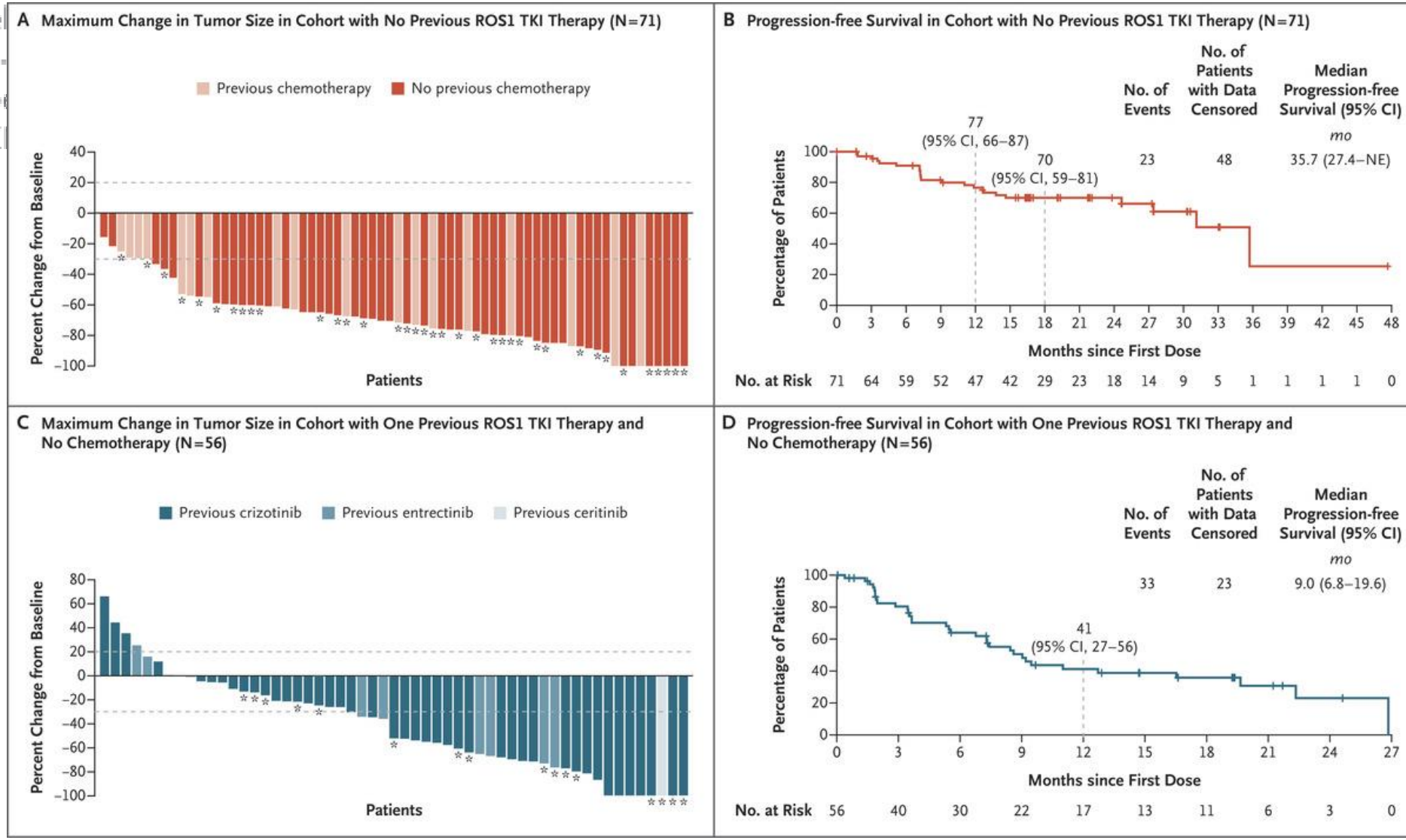
Selpercatinib
(Upon BICR confirmed PD)

(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…

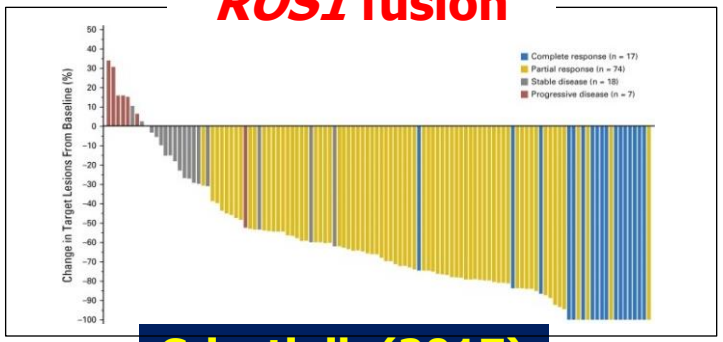
The NEW ENGLAND JOURNAL of MEDICINE



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

PMDA Approval of Targeted Therapies for NSCLC

ROS1 fusion

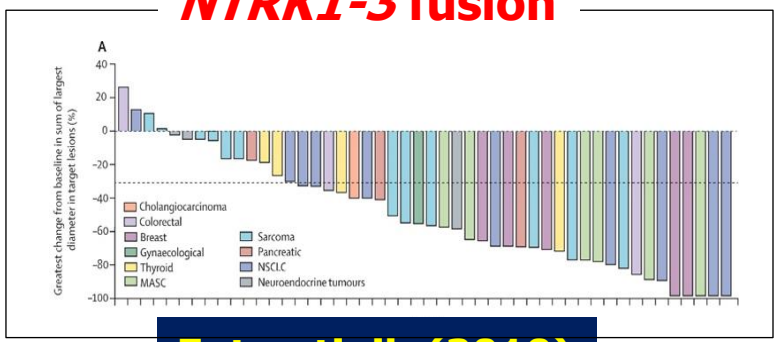


Crizotinib (2017)

BRAF V600E

Dabrafenib+Trametinib (2018)

NTRK1-3 fusion

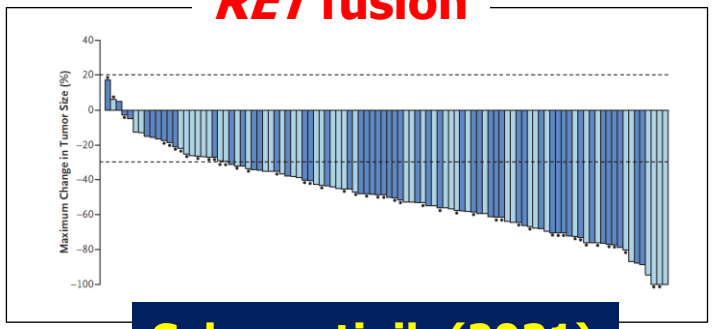


Entrectinib (2019)

MET ex14 skipping

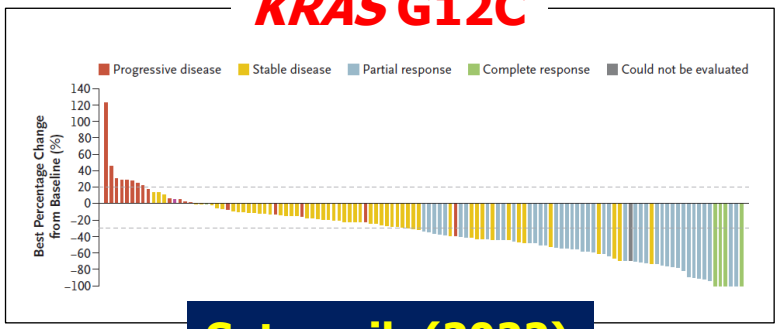
Tepotinib (2020) **Capmatinib (2020)**

RET fusion



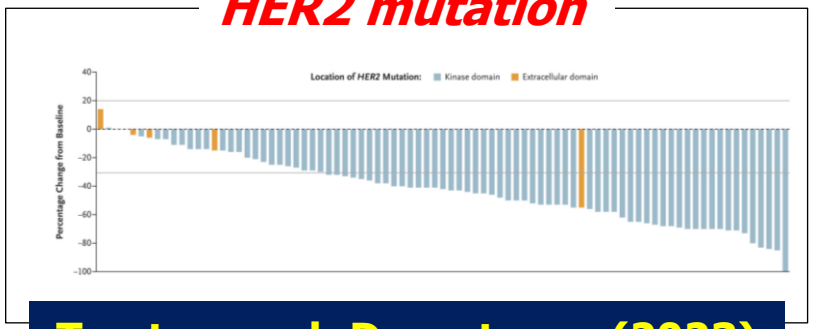
Selpercatinib (2021)

KRAS G12C



Sotorasib (2022)

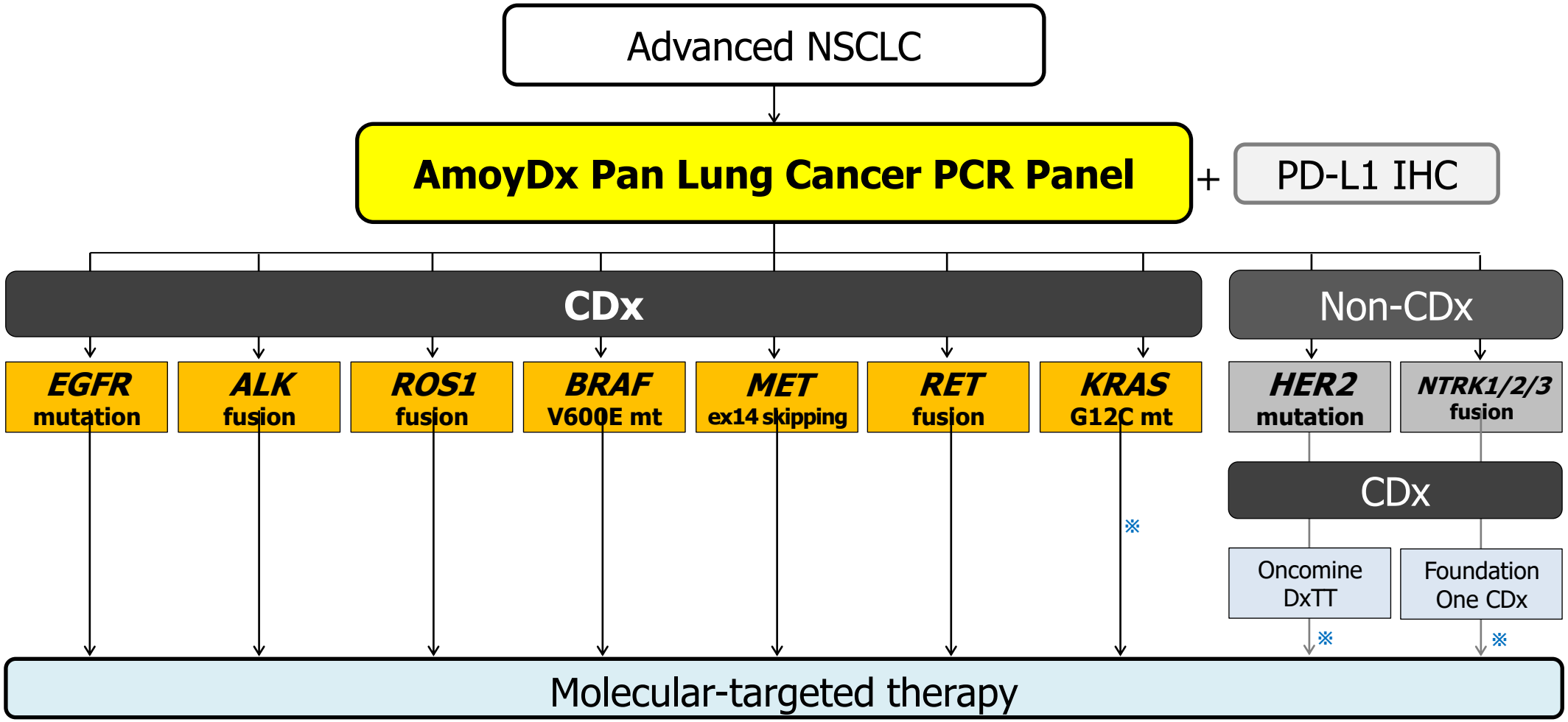
HER2 mutation



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



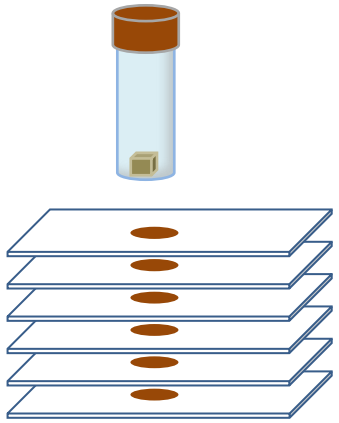
※ : for ≧2nd –line therapy

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

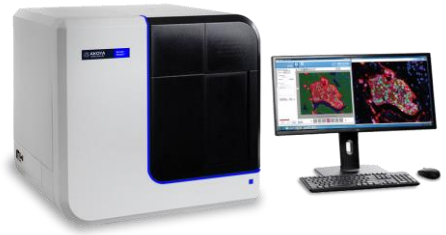
Sample



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-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

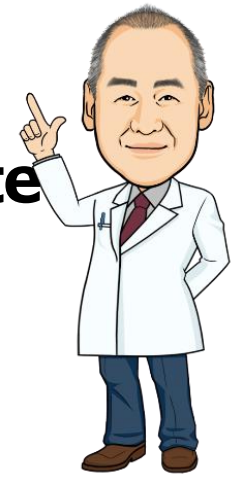
Clinical data

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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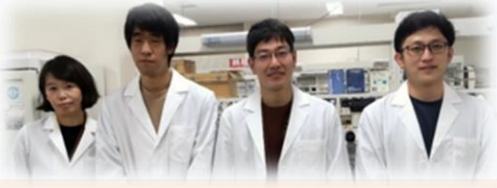

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SCRUM-Japan supported by
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- TAIHO PHARMACEUTICAL CO., LTD.

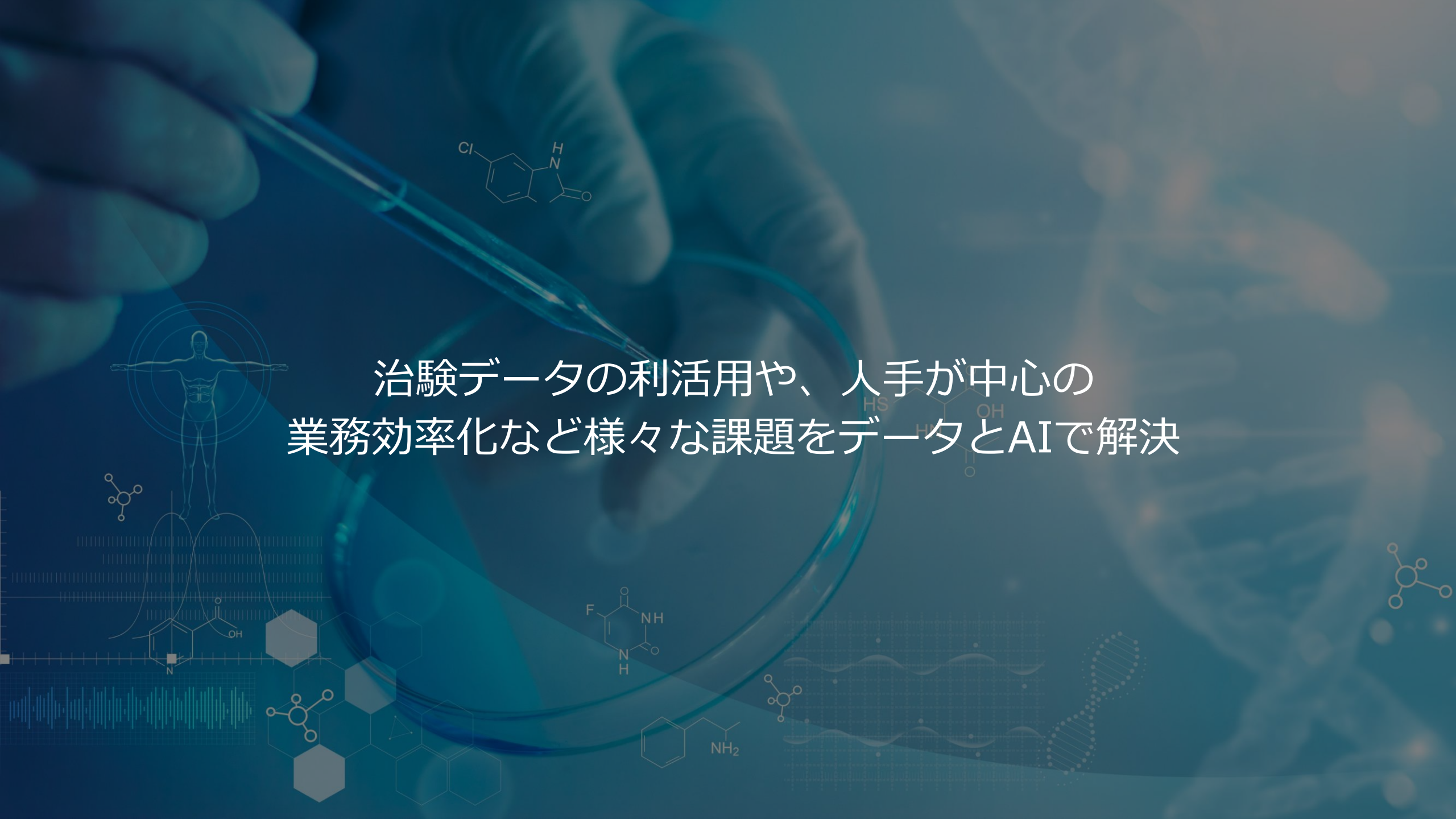
Patient-centric Clinical Trials

治験特化型のLLMを活用した治験関連文書の自動生成

Fujitsu Uvance

ソーシャルソリューション事業本部
Healthy Living　Life Science事業部
Clinical Trial Solution部長

はま　まつ　　みち　お
浜松 紀夫



治験データの利活用や、人手が中心の
業務効率化など様々な課題をデータとAIで解決

治験文書作成業務のデジタル化の遅れ

治験開始までに必要な
ドキュメント作成期間

6カ月

100種類の
ドキュメント制作

2万時間

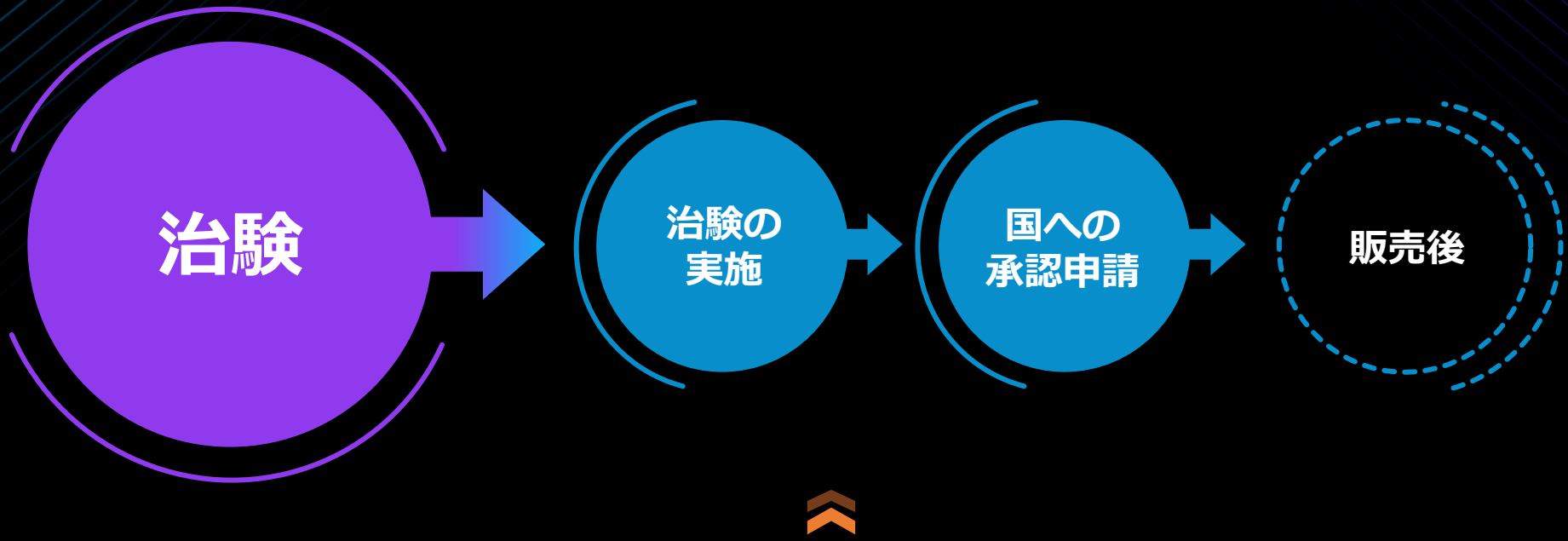
データ分析までの
リードタイム

3カ月

解決の「カギ」は、治験実施計画書を作成するステップ

＊2024年 当社調べ

医薬品開発をEnd to Endで変革

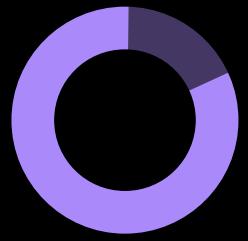


Patient-centric Clinical Trials

Patient-centric Clinical Trials

導入効果

文書作成の
自動作成化



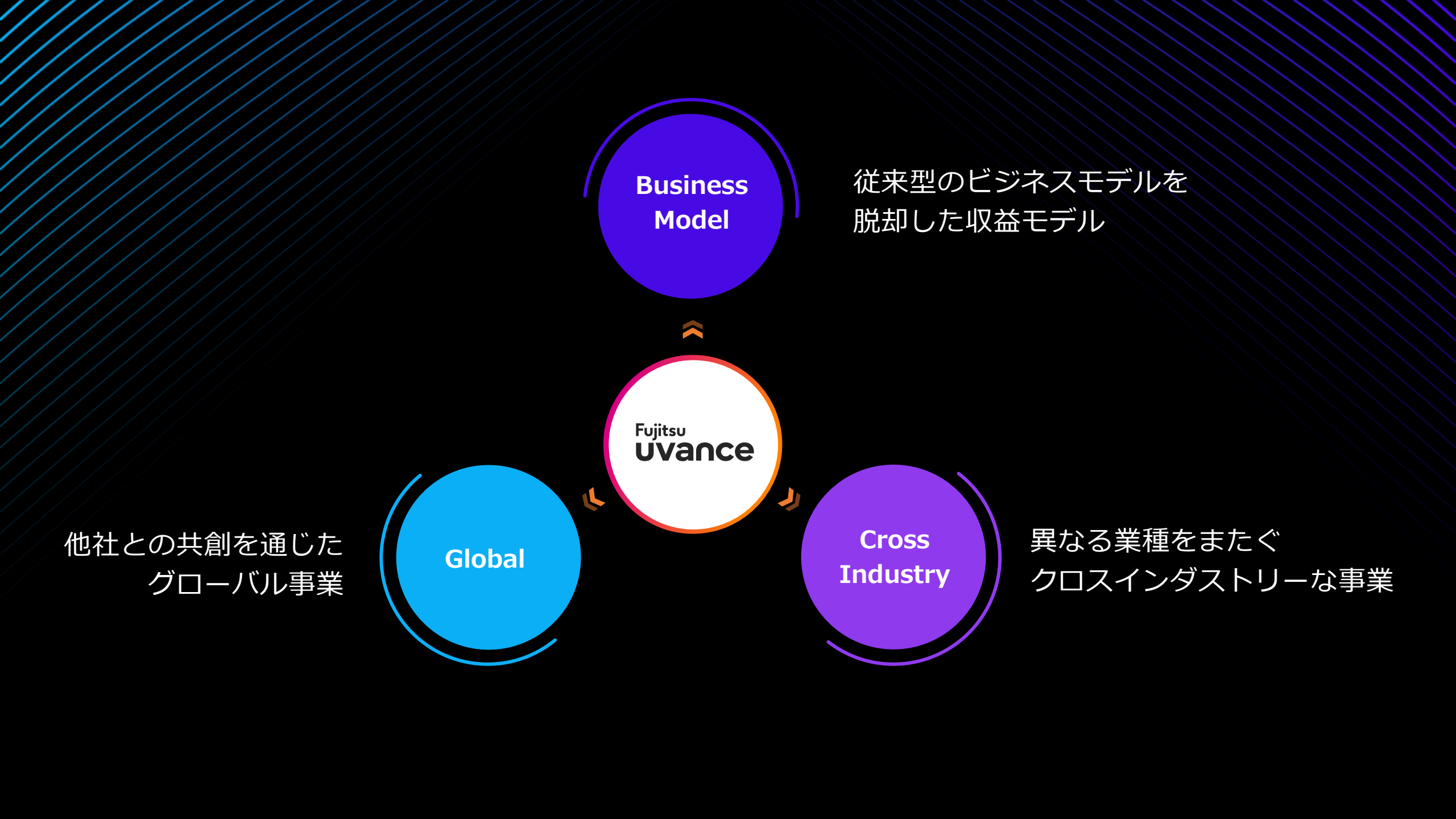
80%

（実証結果）

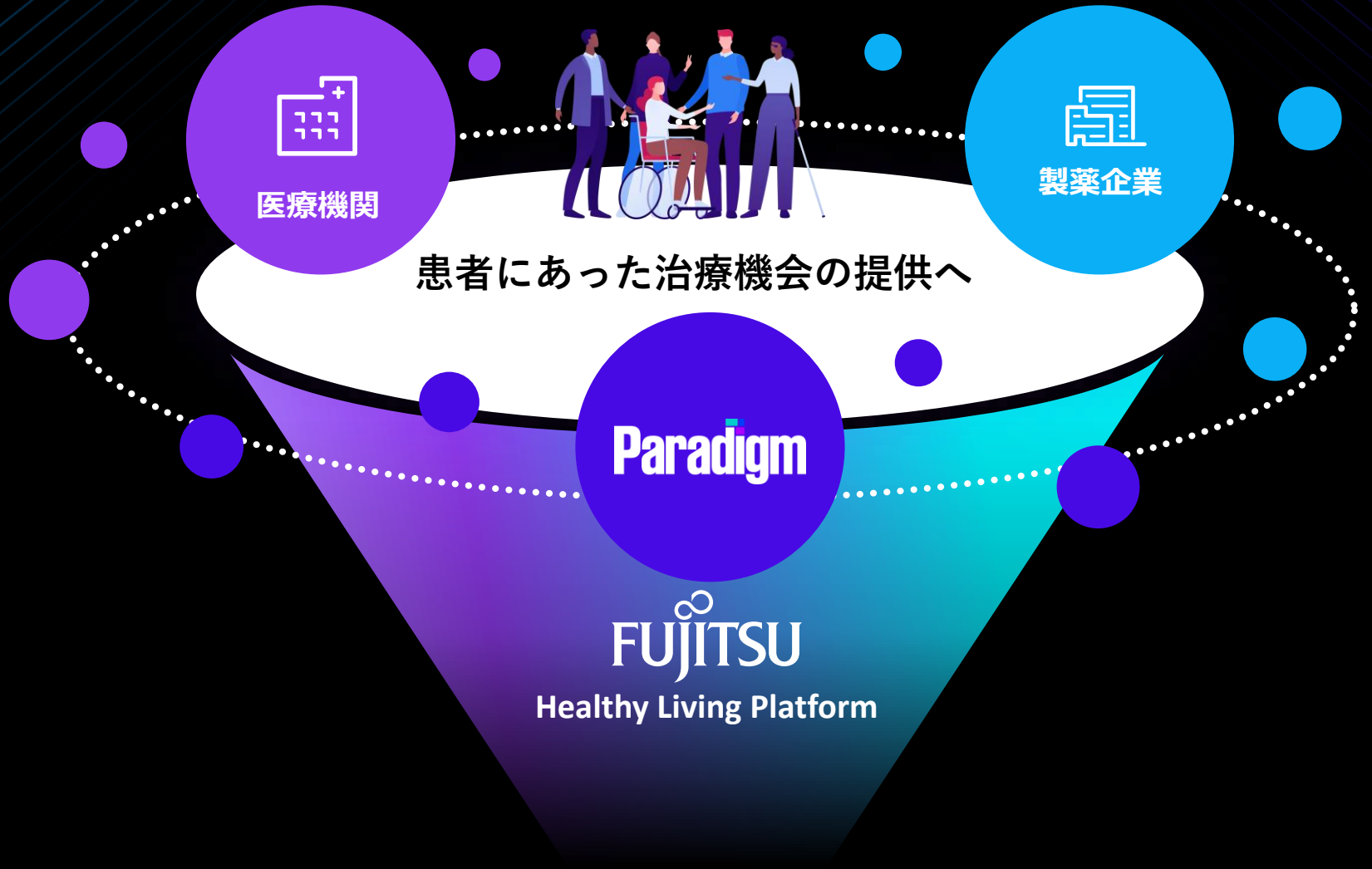
文書作成の
作業期間（全体）

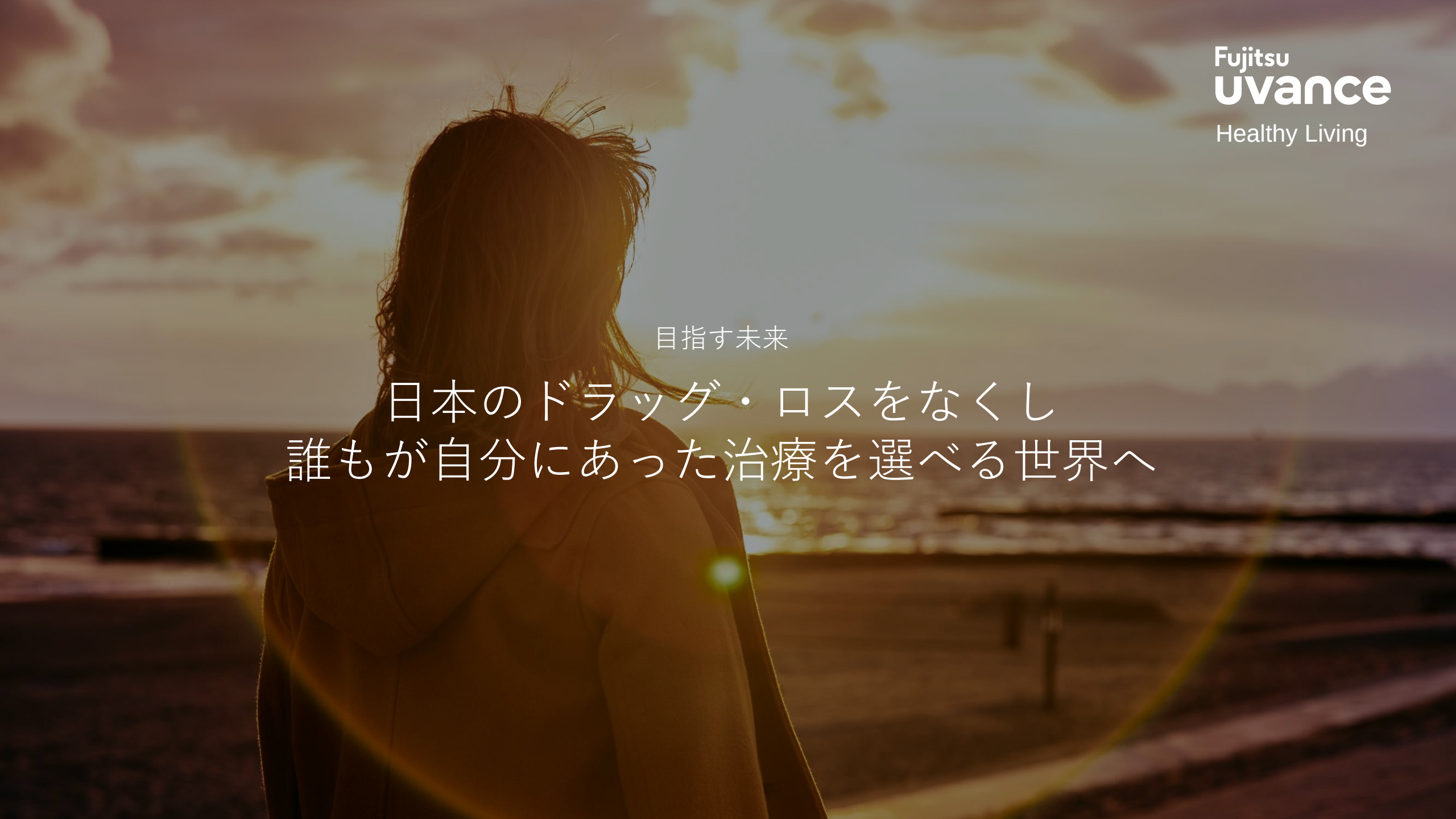
50%↓

（当社試算）


Business Model
従来型のビジネスモデルを
脱却した収益モデル
Fujitsu uvance
Global
他社との共創を通じた
グローバル事業
Cross Industry
異なる業種をまたぐ
クロスインダストリーな事業

医療データを介したエコシステムを創出





Fujitsu
Uvance
Healthy Living

目指す未来

日本のドラッグ・ロスをなくし
誰もが自分にあった治療を選べる世界へ