Future-Focused Real-World Data Utilization Strategies: Resilience and Innovation from Chugai

20th February 2026

CHUGAI PHARMACEUTICAL CO., LTD.

Clinical Development Division

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Wataru Ohtsuka

Agenda

1. Speaker Introduction
2. Company Overview
3. Why Chugai is committed to RWD utilization
4. Utilization of Real-World Data Specific to Japanese Populations
5. Case studies of RWD utilization at Chugai
6. Data science activities at Chugai
7. Future prospects

1. Speaker Introduction

Name: Nauta Yamanaka

Current Role: Driving initiatives for Real-World Data utilization at Chugai Pharmaceutical

Career Highlights:

- Statistical Analysis at a CRO during the early CDISC era
- Coordinator for an NPO supporting healthcare in Japan and Asian countries
- Business development and academic support at a Real-World Data vendor
- Promoting data utilization across diverse domains at Chugai Pharmaceutical

Interests: Advancing healthcare through data for today and tomorrow.

Previously lived in Delhi.

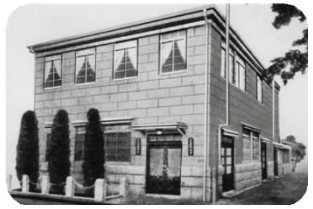
2. Company Overview

Company Outline

Company name:	Chugai Pharmaceutical Co., Ltd.
Representative:	Osamu Okuda
Foundation:	March 10, 1925
Establishment:	March 8, 1943 (Started strategic alliance with Roche since 2002)
Stated capital:	¥73,202 million
Financial year-end:	December 31
Revenue:	¥1,170.6 billion (FY2024.12)
Core operating profit:	\556.1 billion (FY2024.12)
Number of employees:	7,778 (Consolidated, as of December 31, 2024)
Principal lines of business:	Research, development, manufacturing, sale, importation, and exportation of the pharmaceuticals
Head office:	Tokyo
Majority shareholder:	Roche Holding Ltd. (61.11%)
Stock listing:	Prime Market of the Tokyo Stock Exchange (Securities code: 4519)

History of Chugai

- A mission of “creating drugs that benefit the world” since 1925 in keeping with founder Juzo Ueno’s spirit
- Bold innovation in pursuit of drugs that only Chugai can create



1925

Founded as Chugai Shinyaku Shokai

1970s

Focus on developing new drugs in-house

1980s

Venturing into bio-based drug discovery

1990s

Pursuit of antibody drug discovery

2000s

Strategic alliance with Roche

Acceleration of drug discovery technology development

2010s

The new challenge of mid-size molecule drug discovery

2025

Celebrating our centenary

Towards the next 100 years. Passing on the baton of our aspirations, to create a future beyond imagination.

100th ANNIVERSARY

2002— Strategic Alliance with Roche

- 2002: Chugai and Roche Enter into Strategic Alliance
- Though a member of the Roche Group, Chugai maintains autonomous and independent management, employing a unique business model focused on innovation that values individuality and diversity.

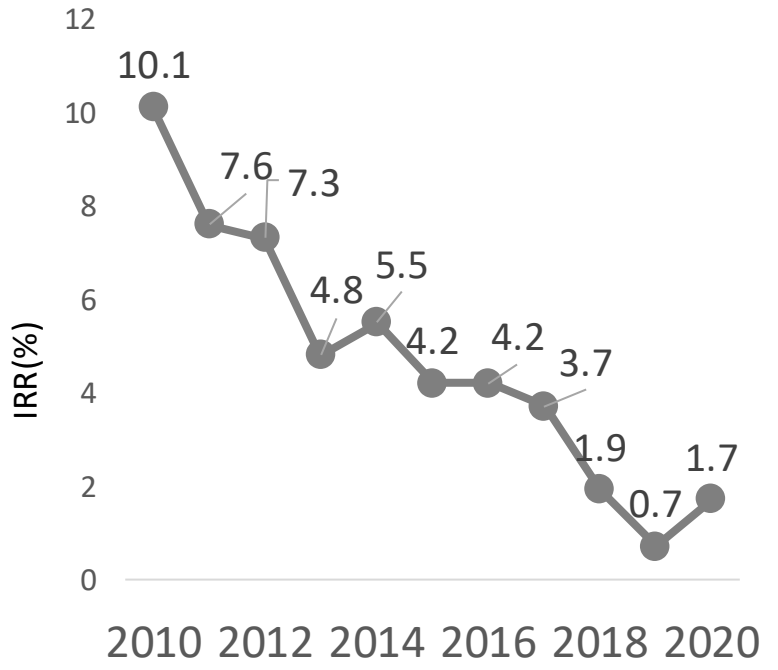
Foundation: 1925—

- Witnessing the shortage of medicines following the Great Kanto Earthquake two years earlier, Juzo Ueno founds Chugai Shinyaku Shokai with the desire to create drugs that benefit the world
- Ueno names the company “Chugai” with the meaning “domestic and overseas,” reflecting his aspiration to eventually market Japanese drugs overseas

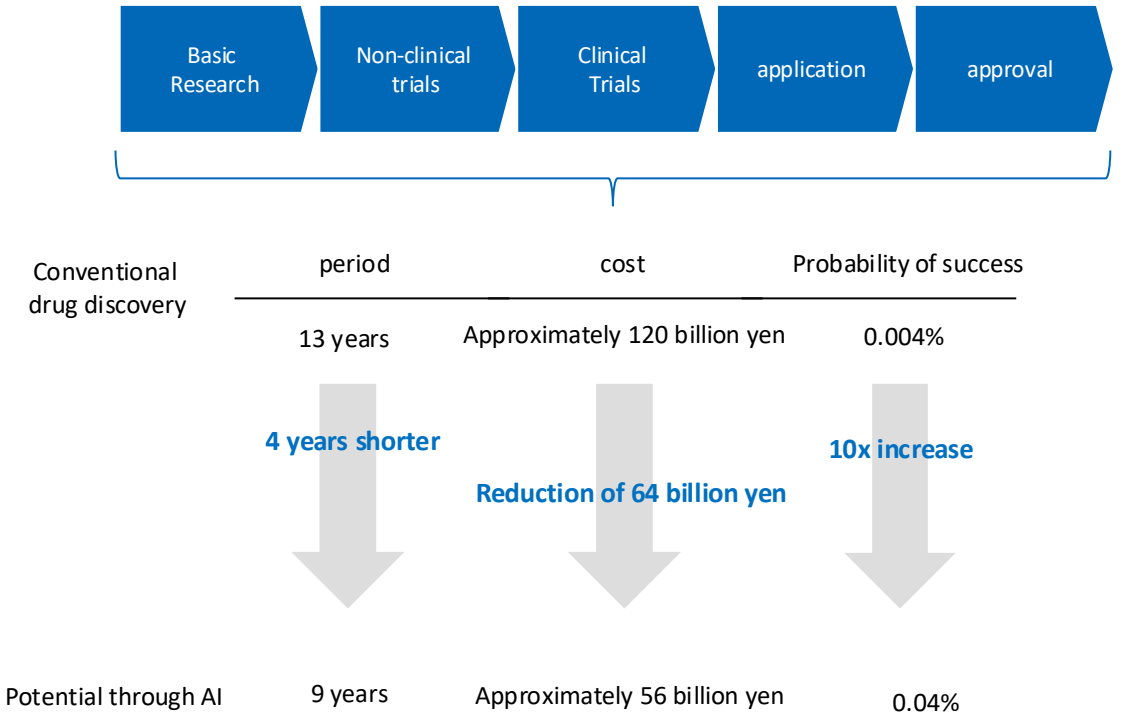
3. Why Chugai is Committed to RWD Utilization

Need for Digital Solutions in Pharma R&D

Mega Pharma's R&D Productivity (IRR)*1



The potential of AI in drug discovery*2



*1: Deloitte "Measuring the return from pharmaceutical innovation 2020" (covering 12 major global companies)

**2: Prepared by processing and creating "The 3rd Roundtable Meeting on the Promotion of AI Utilization in the Health and Medical Field (March 29) Submitted by Okuno Members" (Ministry of Health, Labour and Welfare)

About Chugai Pharmaceutical

One of Japan's top prescription pharmaceutical manufacturers

- Revenues **¥1,170.6 billion**
- Operating profit **¥556.1 billion**
- Operating margin **47.5%**

Unique Business Model

- Strategic alliance with Roche since 2002 helps us deliver Chugai's innovative products to patients worldwide
- Countries approving Chugai products

More than 110

Unique Technology and Science

- World-class antibody engineering technologies
- Strong drug discovery capabilities backed by research infrastructure in various modalities including antibodies and small and mid-size molecules
- Breakthrough Therapy[1] designations **9 times**

Leading the Industry through Digital Transformation

- Awarded METI's DX Platinum certification 2023-2025

1 A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms

DX – “CHUGAI DIGITAL VISION 2030”

Value Creation

Productivity innovation

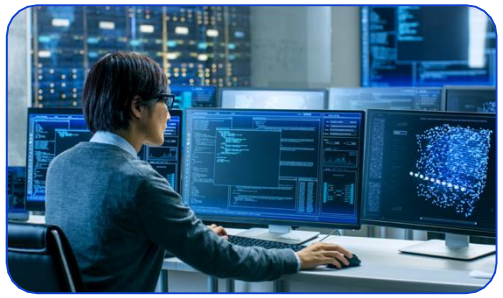
Climate Reform

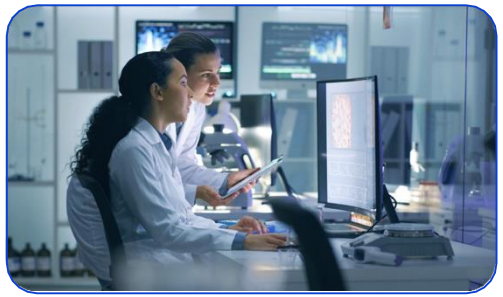
CHUGAI DIGITAL VISION 2030

Utilizing digital
Increasing the sophistication of the early phase of research and development
Utilizing digital technologies such as AI to improve the probability of success in drug development, and significantly reduce the time and cost of drug discovery

Dramatic productivity gains across the entire value chain
Utilizing digital technologies such as AI and robotics to significantly improve the efficiency of business processes

Building a company-wide foundation to support innovation creation
Promote the establishment of a global-level IT infrastructure and the development of digital human resources





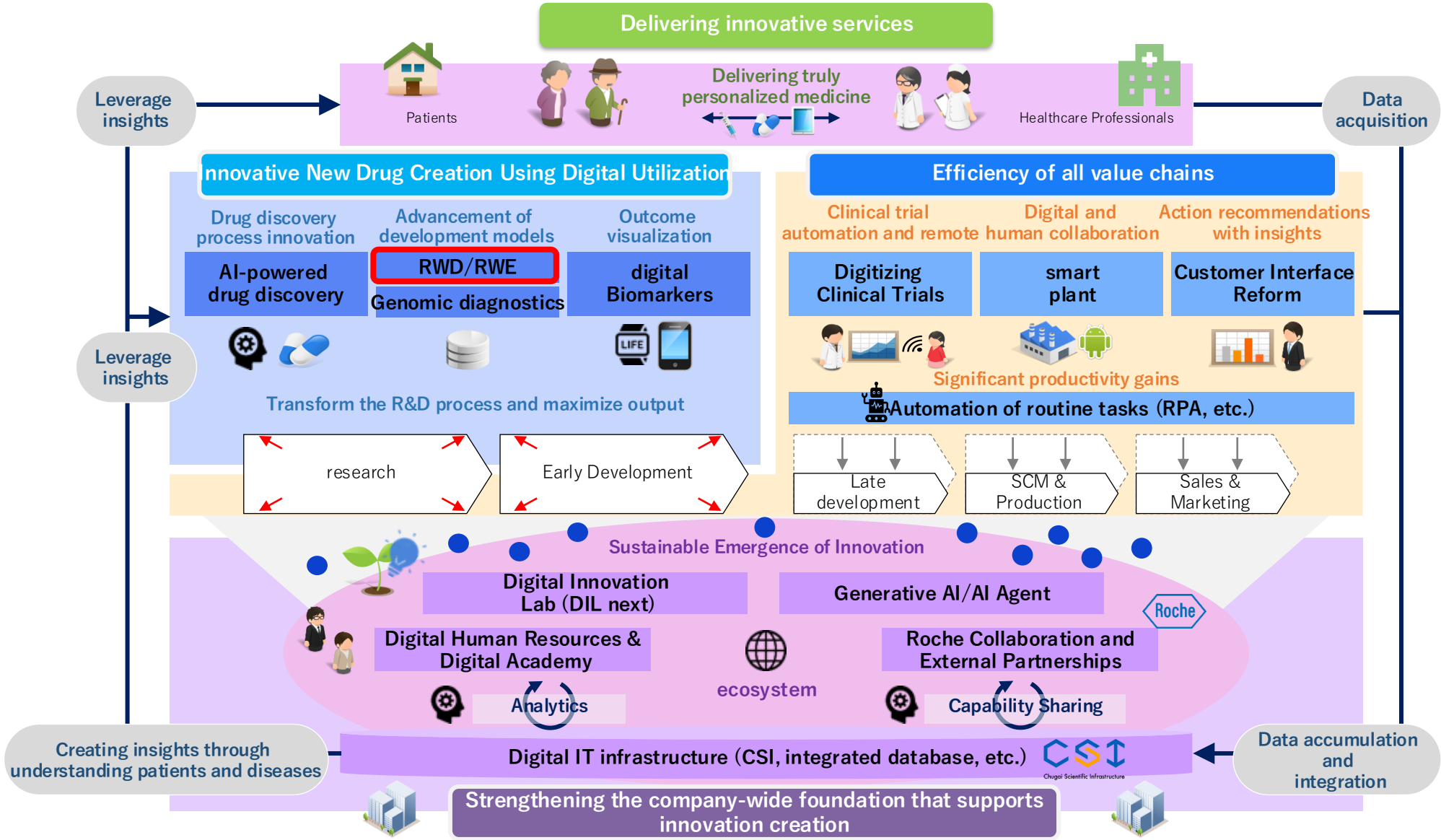
DXプラチナ企業 2023-2025 Digital Transformation

In "DX Stocks"

Selected as a "DX Platinum Company 2023-2025"

Chugai Pharmaceutical is the only one selected as a DX stock in the pharmaceutical industry for the fifth consecutive year

CHUGAI DIGITAL VISION 2030



Examples of RWD Utilization in Drug Development

Usage Scenarios	✓ Understanding the actual status of treatment / diagnosis, natural history, and number of patients ✓ Consideration of indications and medical needs	✓ Control group selection ✓ Setting Selection Exclusion Criteria ✓ Setting Effectiveness Thresholds ✓ Setting up external control or hybrid control	✓ Selection of facilities with competitive advantages	✓ Registry Promotion ✓ Confirmation of the impact of newly derived hypotheses from competitor results ✓ Registry-based (randomized) clinical trial	✓ Interpretation of results ✓ Confirmation of newly obtained hypotheses	✓ External control ✓ Explanation of validity threshold validity ✓ Generating evidence to support UMN and efficacy (e.g., comparison within RWD) ✓ Explanation of the validity of the extension of the scope of approval ✓ Explanation of the actual situation of use in public notice applications	✓ Proof of value in HTA ✓ Post-marketing database survey ✓ Generalizing evidence from clinical trials (generating evidence for a wider audience)

1) Japan Pharmaceutical Manufacturers Association How far existing domestic real-world data can be used for drug development (April 2019)
2) Japan Pharmaceutical Manufacturers Association Toward Promoting the Utilization of RWD in Pharmaceutical Companies – Current Status, Issues, Issues, and Future Prospects (April 2020)

4. Utilization of Real-World Data Specific to the Japanese Population

Health Insurance structure in Japan

Universal Health Insurance

Universal health coverage :

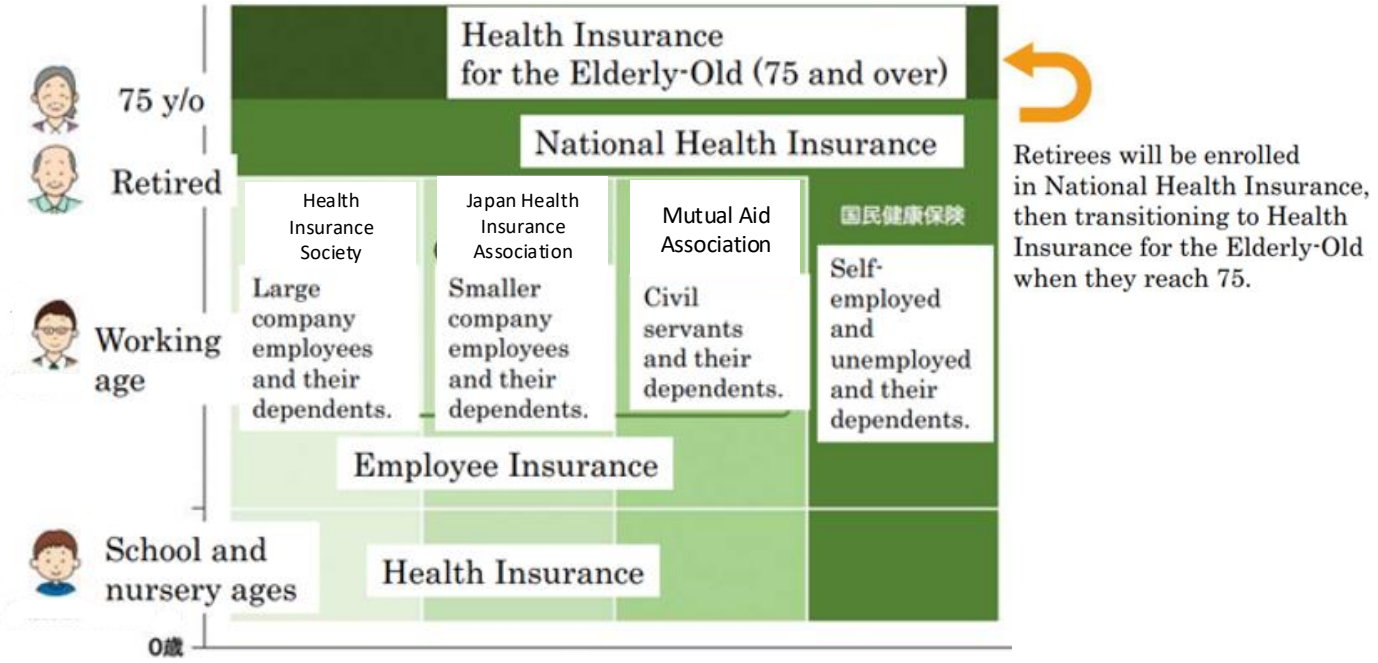
- People can receive medical care at any insurance-registered clinic or hospital by presenting a Health Insurance Card (to be integrated into the Individual Number Card from Dec 2025).

Reimbursement system :

- Patients generally pay 30% of the cost, while 70% is covered by insurance.
- For children under school age and ages 70–74, the share is 20%, and for those 75+, 10%, with adjustments based on income or local subsidies.

Free choice of provider :

- People can choose their medical provider.



Japan Medical Association
https://www.med.or.jp/people/info/kaifo/system/ (last access : 2025/12/17)

Available Data Sources in Japan

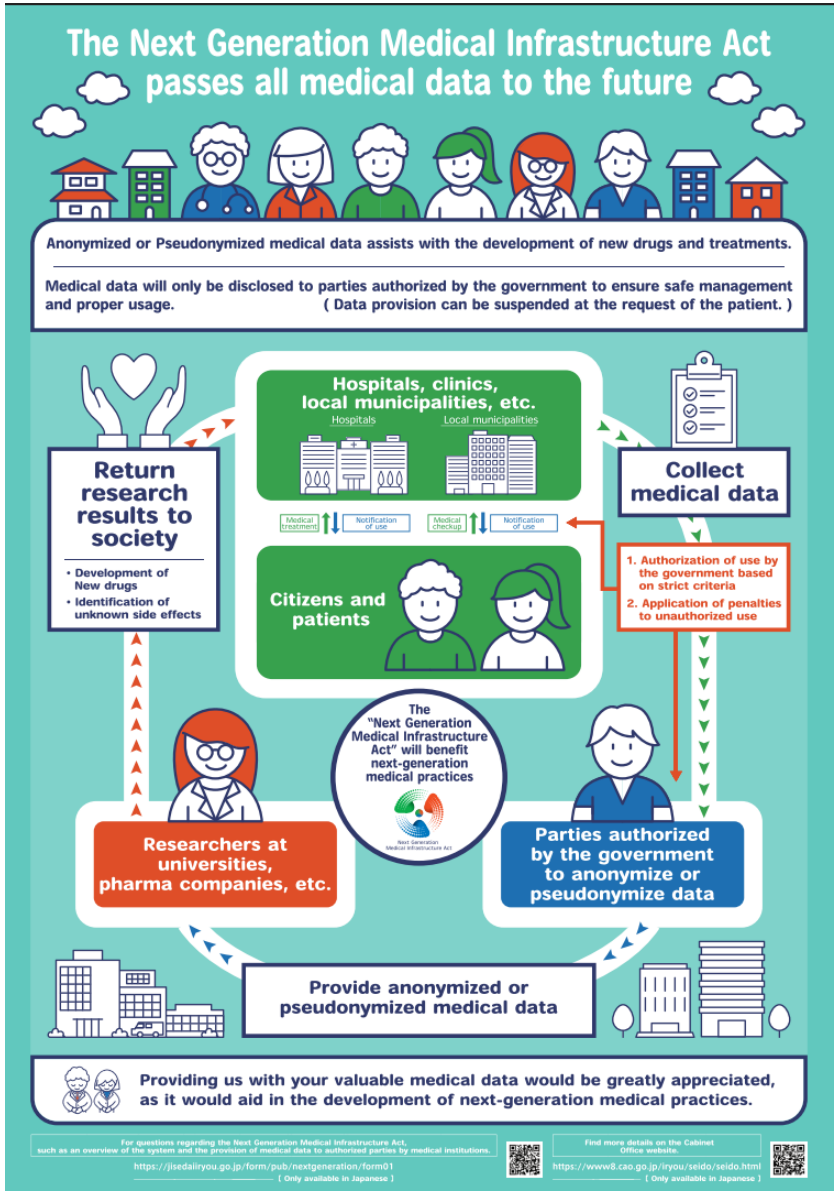
- claims data, health checkup records, electronic medical records, and patient registries
  - each with its own strengths and limitations
- Key challenges: data standardization, privacy protection, and ethical considerations

RWD (conceptual diagram)

https://www.chugai-pharm.co.jp/english/innovation/digital/real_world_data.html
(last access : 2025/12/17)

Next Generation Medical Infrastructure Act (2024, revised)

- Pseudonymized medical data
  - Enables use of pseudonymized diseases and test values, including rare cases, for research and regulatory applications.
- Linkage with public databases
  - Allows integration of medical data with national databases (NDB, nursing care DB) for analysis and research.



Cabinet Office
https://www8.cao.go.jp/iryou/institutions/pdf/jisedai_poster_e.pdf
(last access : 2025/12/17)

Beyond Structured Data

- Limitations of Structured Data
  - Cannot capture key clinical details such as:
    - Treatment effects / Side effects, adverse events / Clinical rationale for decisions / Reasons for treatment changes / Patient outcomes / mortality information
- Potential of Unstructured Data
  - Clinical notes, radiology reports, and pathology reports contain rich clinical details
  - Natural language processing (NLP) may unlock these insights

Our Approach: Explore whether essential clinical details can be extracted from unstructured text

5. Case Studies of RWD Utilization at Chugai

Extraction of Clinical Outcome Information from Unstructured Data

Detection of Brain Metastases from Head MRI Reports in Patients with Advanced and Recurrent Breast Cancer

Nauta Yamanaka*1 , Taku Nishizawa*1 , Yoshiaki Motomura*1 ,
Tomoko Kanayama*2, Toshiyuki Sakurai *3,
Shigemi Matsumoto*4, Manabu Muto*5

*1 Chugai Pharmaceutical Co., Ltd.,
*2 Prime Research Institute for Medical RWD, Inc.(PRiME-R),
*3 NTT,Inc.
*4 Department of Real World Data R&D, Graduate School of Medicine, Kyoto University,
*5 Department of Medical Oncology, Graduate School of Medicine, Kyoto University

Presented at the 45th Annual Conference of the Japan Federation of Medical Informatic (November 2025).

Extraction of Clinical Outcome Information from Unstructured Data

Background

- **Brain metastasis is a clinically significant complication in cancer patients**
  - Negatively affects QoL and survival outcomes
  - Understanding its epidemiology is essential for treatment strategies
- **International reports exist for breast cancer patients**
  - Comprehensive clinical data in Japan remain limited
- **Clinical details are often recorded in unstructured formats**
  - Example: narrative radiology reports
  - Creates major challenges for automated data extraction and analysis

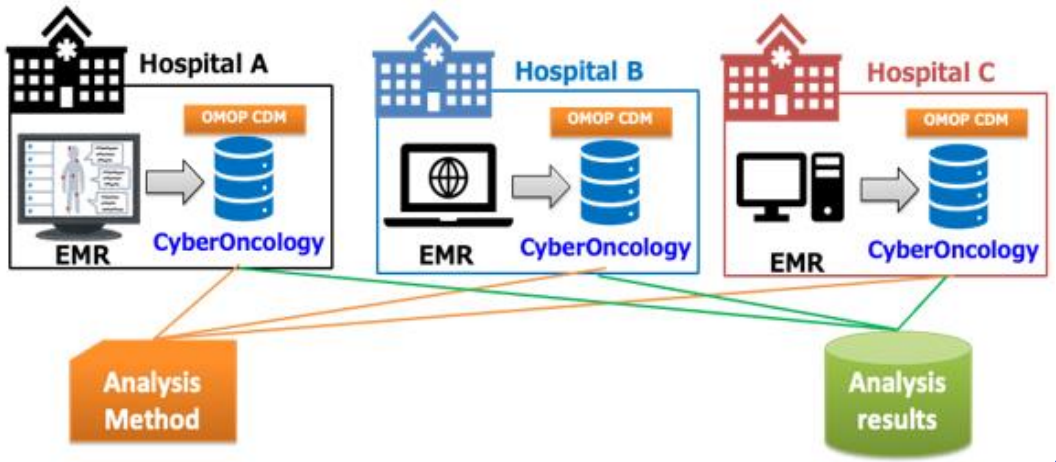
Extraction of Clinical Outcome Information from Unstructured Data

Objective

- Evaluate the feasibility of developing an automated detection system
- Extract brain metastasis information from unstructured MRI reports
- Across multiple institutions within the J-CONNECT consortium framework

J-CONNECT：

- Industry-academia collaboration initiatives to promote comprehensive collection and utilization of RWD in cancer care
- Medical institutions, companies with various technologies and solutions, and pharmaceutical companies participate.
- “CyberOncology”, a structured input support tool for EMRs, allows for standardized data collection across institutions
- Established in 2023
- In the future, conversion to OMOP/CDM format is also being considered.
- Goal: Build robust RWD to ultimately generate Real World Evidence (RWE)



Extraction of Clinical Outcome Information from Unstructured Data

Method

Institutions: Three J-CONNECT participating institutions

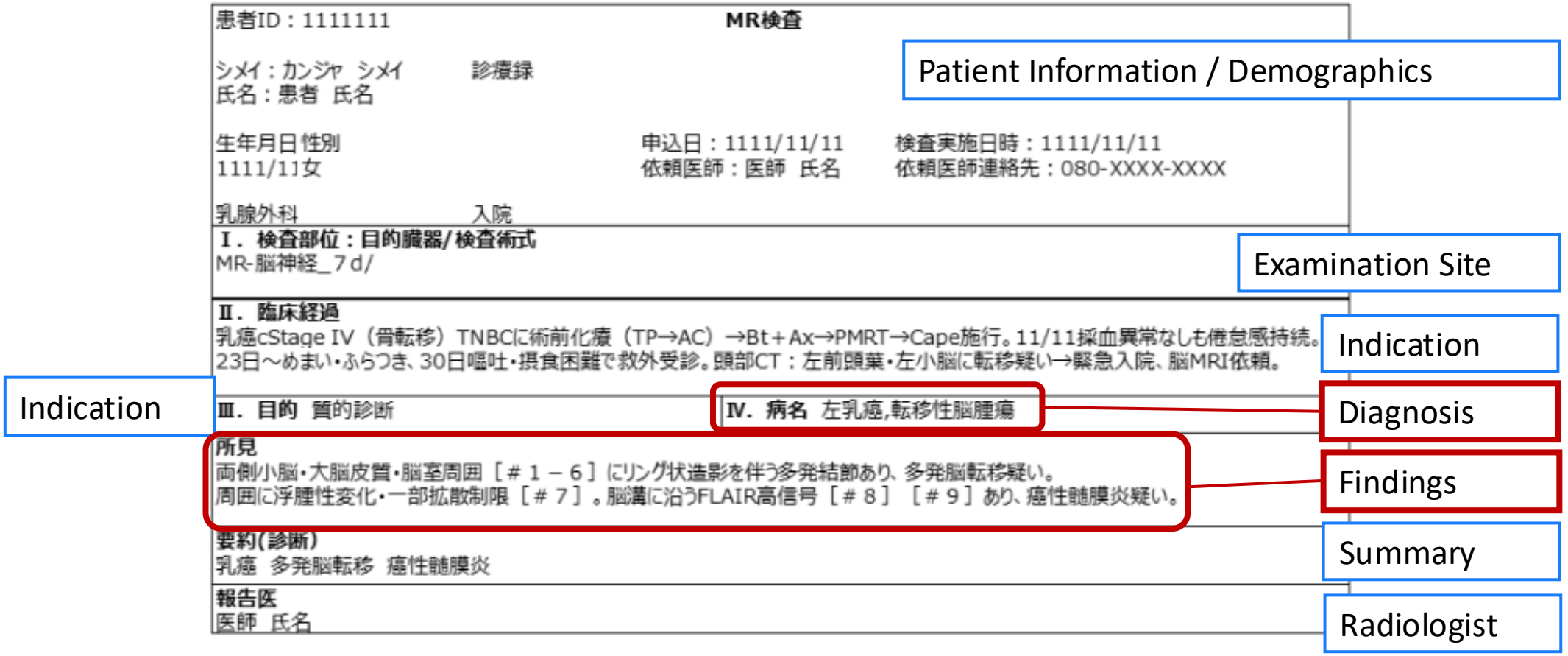
Study Period: 2018–2021

Patients: 258 cases of advanced/recurrent breast cancer registered in the CONNECT2 study (one of the J-CONNECT projects)

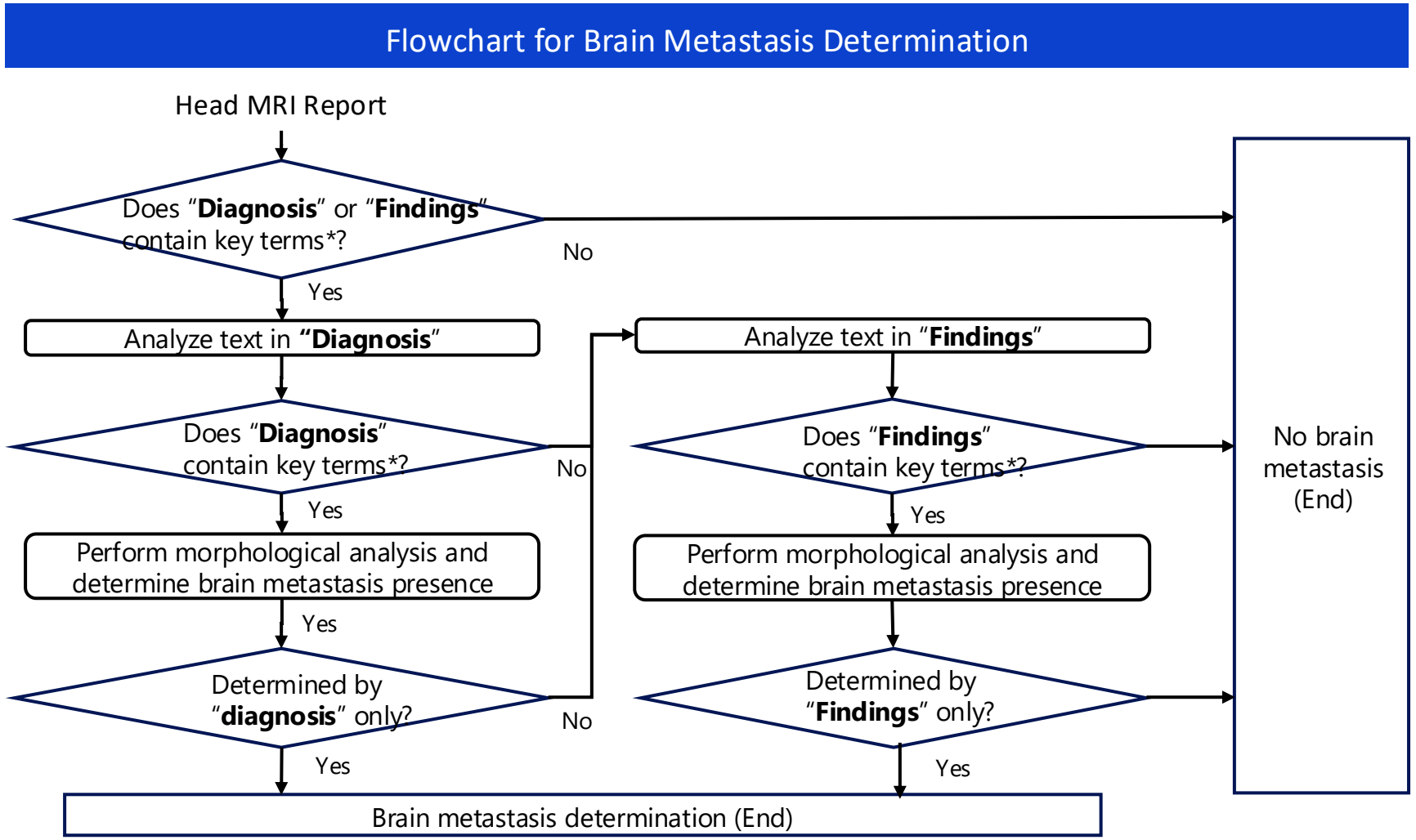
Program Development:
- Developed an automated detection system using **dependency parsing** and **morphological analysis**
- Applied rules for disease-term relationships based on dictionaries and institution-specific expressions
- Validated accuracy using F1-score and error rate

Extraction of Clinical Outcome Information from Unstructured Data

Example of a Head MRI Reports



Extraction of Clinical Outcome Information from Unstructured Data

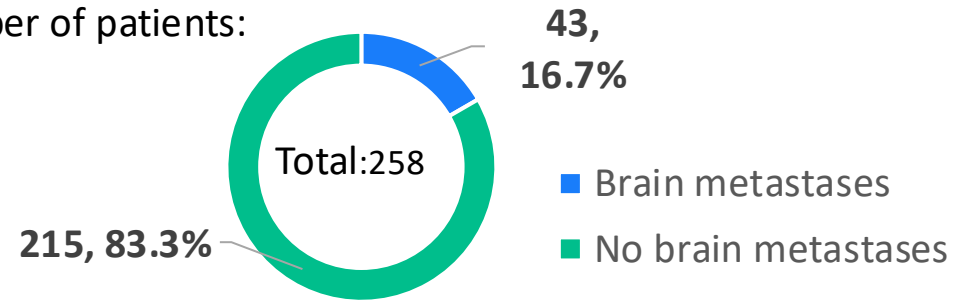


*:Key terms:
- metastasis
- Carcinomatous meningitis
- Leptomeningeal metastasis

Extraction of Clinical Outcome Information from Unstructured Data

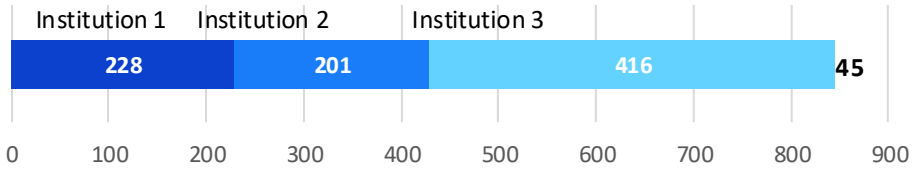
Result

Number of patients:



Reference Values:

- MRI Reports Reviewed



- Model Performance

Institution	Initial		Tuned	
	F1 score	Error	F1 score	Error
Institution 1	— (Perfect classification)		—	—
Institution 2	0.97	0.04	0.98	0.02
Institution 3	0.68	0.07	0.93	0.01

Conclusion and Discussion

- **Using unstructured brain MRI reports from advanced/recurrent breast cancer patients, we could determine brain metastasis prevalence via our detection system.**
- **The 16.7% result requires further validation, but this approach may scale to more institutions and patients and extend to other metastases or cancers like lung cancer.**

6. Data Science Activities at Chugai

Our Data Science Initiatives

- Consultation Framework
  - DS Ambassadors & Easy Access
    - Local contact points in each department
    - Dedicated form for quick consultation

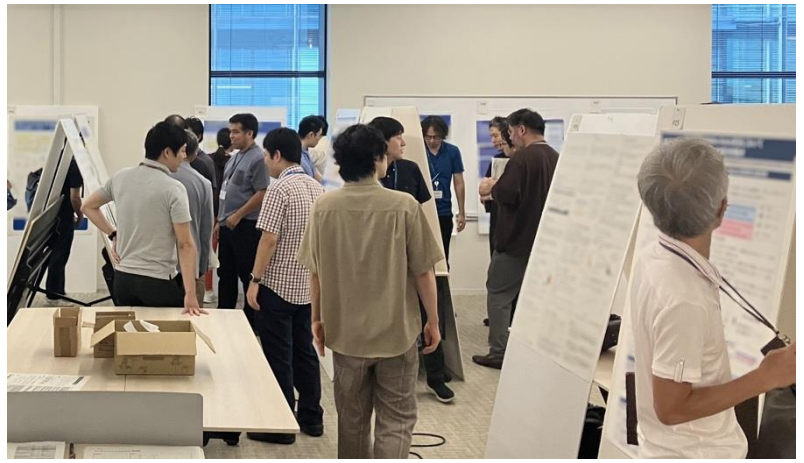
- Human Resource Development
  - CHUGAI DIGITAL ACADEMY (CDA)
    - Digital talent development program
    - Includes data science courses and practical training

- Awareness & Engagement
  - Data Science Day
    - Annual event to share case studies
    - Promotes innovation and collaboration

- RWD Utilization
  - RWD Portal & Representatives
    - Centralized portal and Teams channels
    - Department reps gather needs and share updates

Advancing RWD Utilization Through Data Science

- Building a comprehensive ecosystem for RWD utilization centered on data science
  - Infrastructure Development
    - Secure data platforms and analytical environments
    - Company-wide access to curated data
  - Investment in Talent & Technology
    - Data science talent development
    - Adoption and development of cutting-edge technologies
  - Internal Collaboration
    - Real-time knowledge sharing via RWD portal and dedicated channels
    - Cross-functional collaboration through company-wide events like "Data Science Day"



Data Science Day 2025

7. Future prospects

From RWD to RWE: Driving Evidence Creation

- Current State
  - Ongoing challenges, but progress through data infrastructure, regulatory evolution, and use case accumulation
- Acceleration Opportunities
  - Data access frameworks still evolving
  - Collaboration with industry and academia can accelerate progress
- Vision for the Future
  - RWD to play a recognized role in clinical trial design, regulatory submissions, and value demonstration

INNOVATION BEYOND IMAGINATION

CHUGAI PHARMACEUTICAL

A member of the Roche group