Clinical Development Partner Linical

*Please note that this translation is to be used solely as reference.
In case of any discrepancy between this translation and the Japanese original, the latter shall prevail.

2nd Quarter of FY 2026 Financial Results Briefing

December 5, 2025

Kazuhiro Hatano, Representative Director and President & CEO
Linical Co., Ltd.

TSE Standard 2183

Agenda

1. Company Overview
2. Financial Results for the Six Months Ended September 30, 2025
3. Management Strategy

Company Overview

Company overview	
Company name	Linical Co., Ltd.
Address	1-6-1 Miyahara, Yodogawa-ku, Osaka City
Establishment	June 7, 2005
Representative	Kazuhiro Hatano, Representative Director
Capital	214 million yen
Business description	CRO business accepting contract drug development work
Number of employees	669 (as of March 31, 2025)

Establishment history

2005 Yamanouchi Pharmaceutical Co., Ltd., and Fujisawa Pharmaceutical Co., Ltd., merged (Astellas Pharma Inc.)
→ Founding of the company **centered on members formerly in charge of new drug development at Fujisawa Pharmaceutical**.

Management philosophy

Linical provides quality as a **professional** and pursues the happiness of stakeholders: pharmaceutical companies, medical institutions, patients, shareholders and employees.

International certification

Linical has acquired **ISO/IEC 27001 certification**, an international standard for **information security management systems** (ISMS), at all group bases.

NSF-ISR

Practice our business philosophy and help patients

Management Philosophy

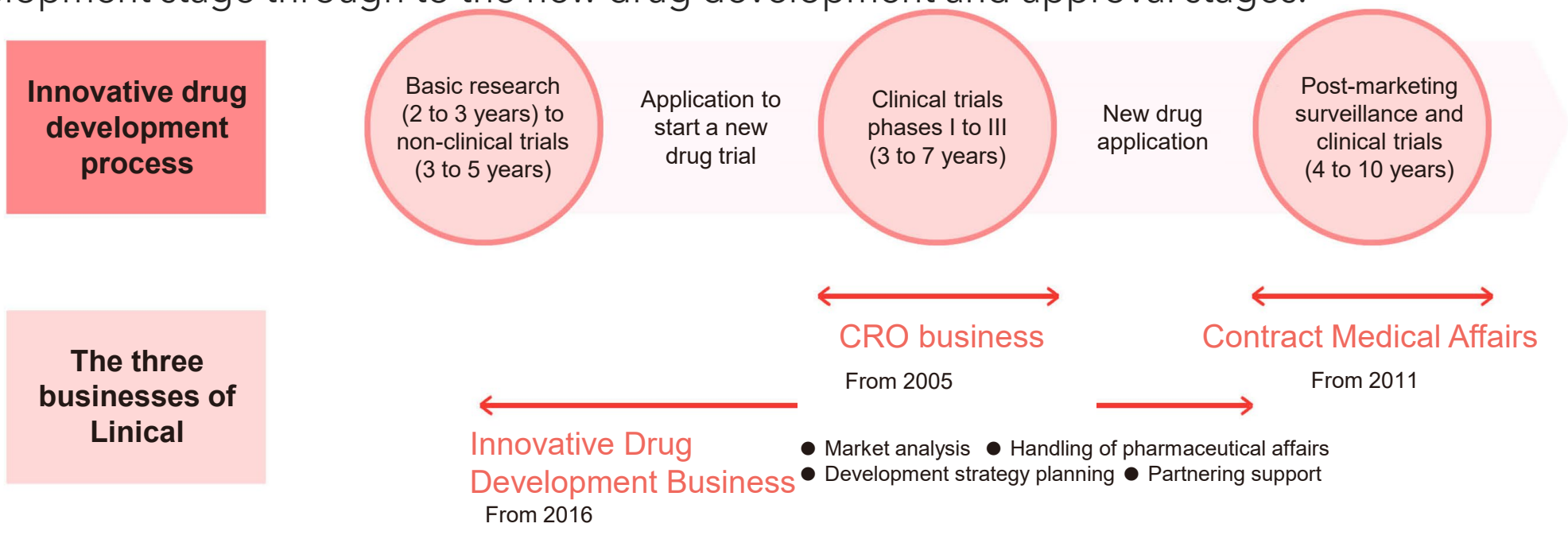
To promote the greater wellbeing of all our stakeholders – patients, business partners, shareholders, and employees – we strive constantly to offer **professional**, high-quality services to support all aspects of new drug development.

Blue: Integrity and Honesty
Red: Unending enthusiasm
Yellow: Continuing spirit of inquiry

Our corporate logo expresses **our passion to pursue happiness of patients** through our business activities.

The Three Businesses of Linical

- We specialize in clinical development and cover the entire process from the innovative drug development stage through to the new drug development and approval stages.



1. CRO Business: Implementing on client's behalf and supporting operations related to clinical trials conducted in the drug development stage

2. Contract Medical Affairs business: We support post-marketing clinical research and marketing activities

3. Innovative Drug Development Business: We provide consulting services that give total support for a wide range of pharmaceutical development activities including market analysis, the formulation of pharmaceutical affairs and development strategies, the selection of marketing partners, and the conclusion of contracts.

Global CRO originating from Japan

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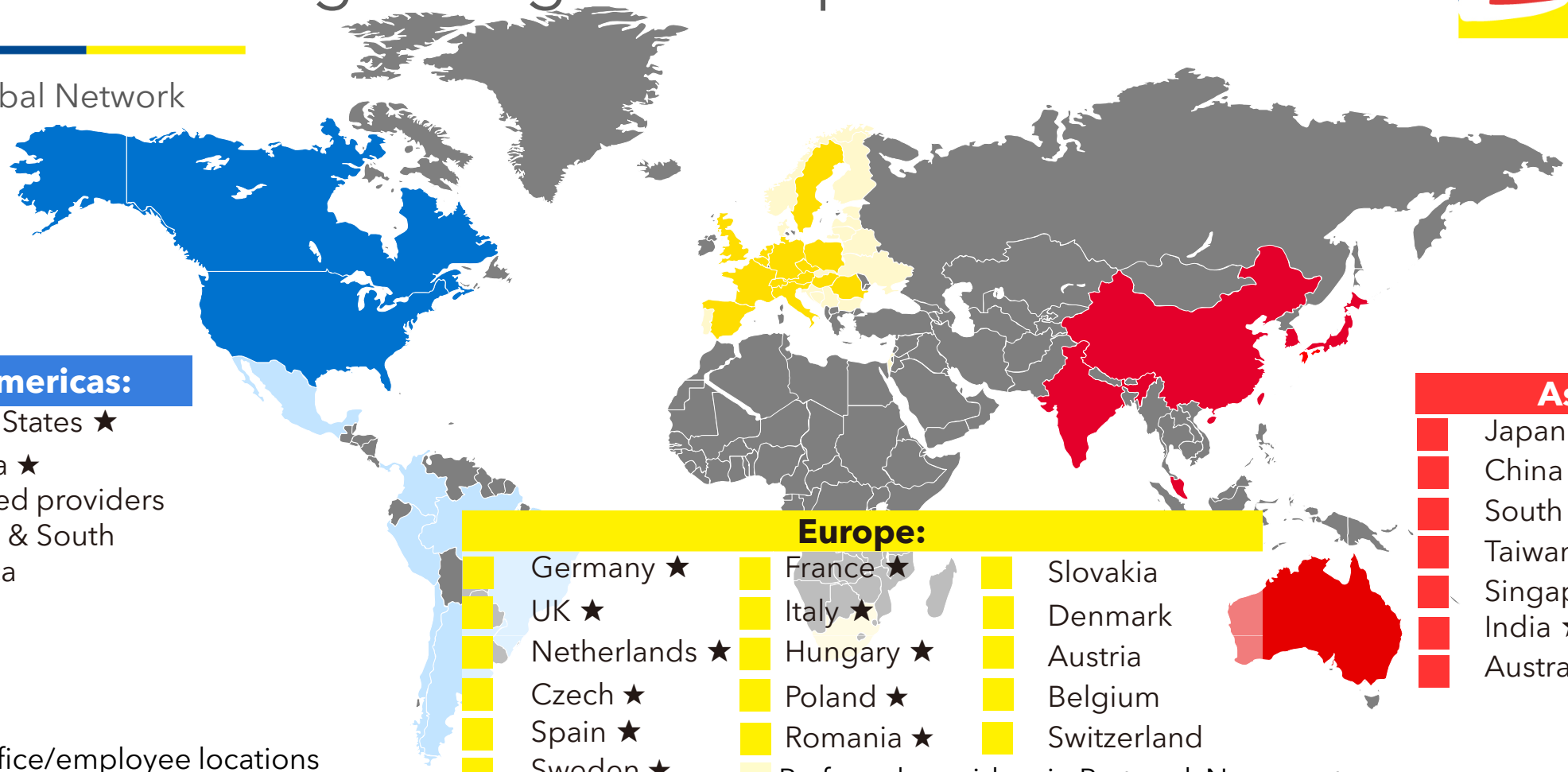
- Our Global Network



The Americas:
- United States ★
- Canada ★
- Preferred providers in Latin & South America

Europe:
- Germany ★
- UK ★
- Netherlands ★
- Czech ★
- Spain ★
- Sweden ★
- France ★
- Italy ★
- Hungary ★
- Poland ★
- Romania ★
- Slovakia
- Denmark
- Austria
- Belgium
- Switzerland
- Preferred providers in Portugal, Norway etc.

Asia:
- Japan ★
- China ★
- South Korea ★
- Taiwan ★
- Singapore ★
- India ★
- Australia ★

★ Office/employee locations

Currently has employees in about 20 countries/regions. Providing services in about 30 countries including affiliated partners

Performance Trends

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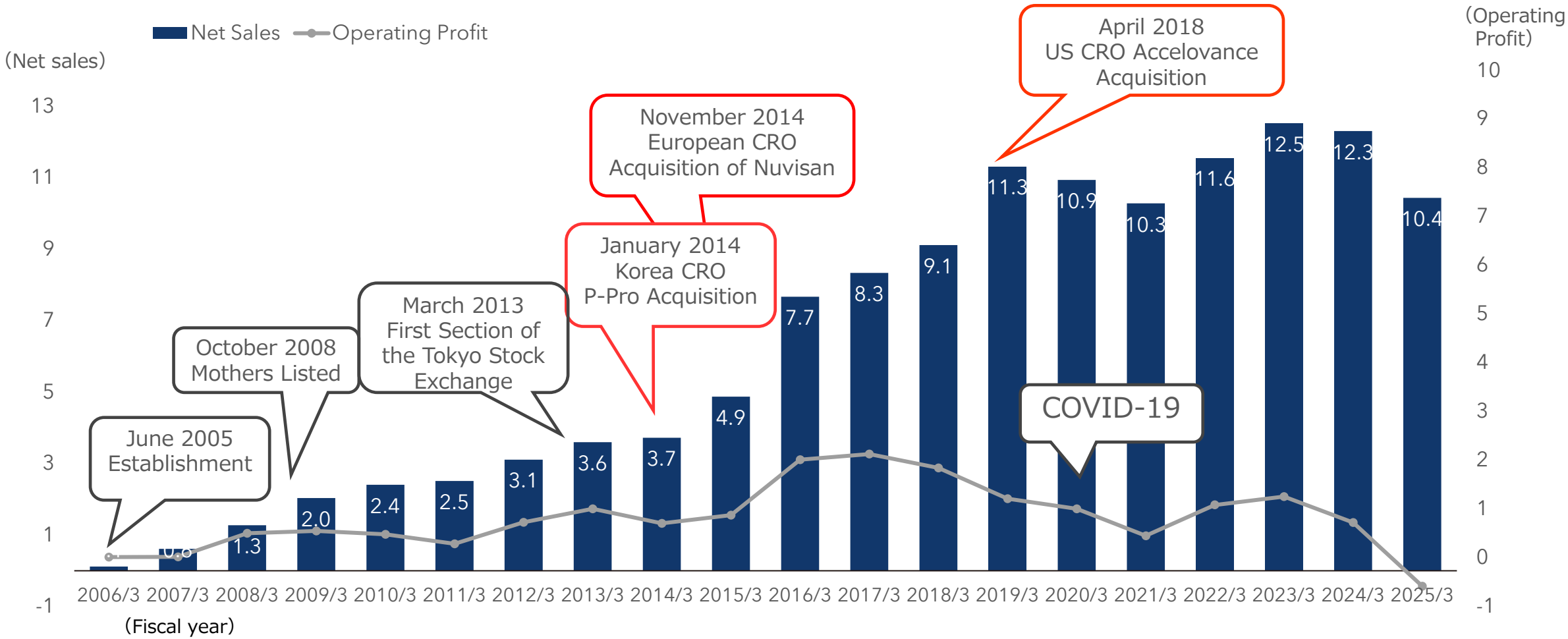
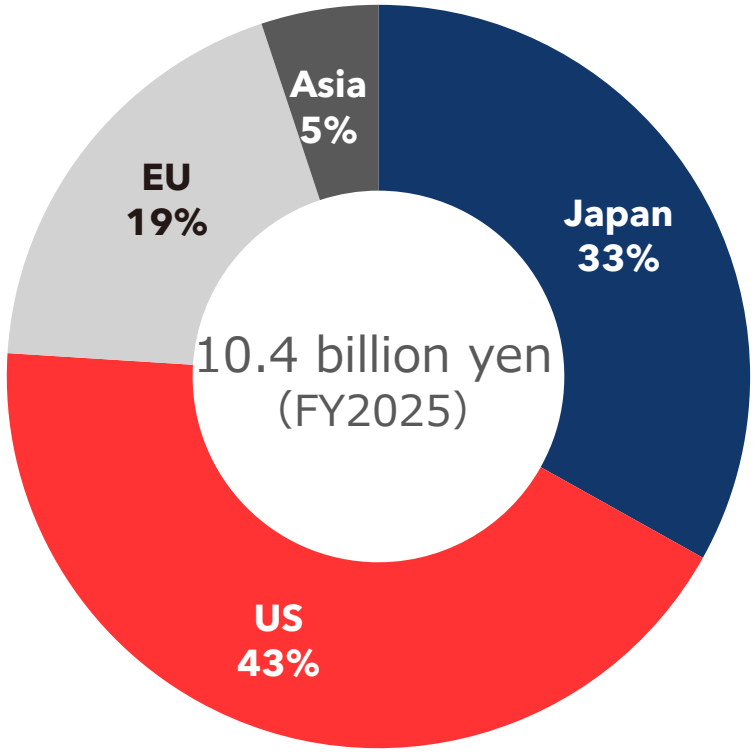
■ Sales and Operating Income since Establishment (Billions of Yen)



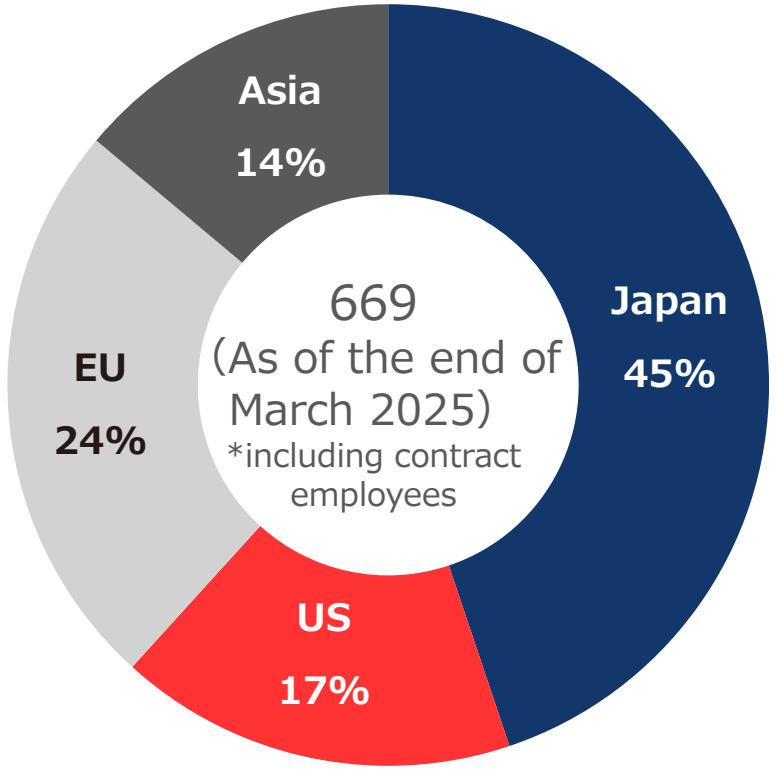
Growth centered on overseas business through M&As in South Korea, Europe, and the United States

Sales and Employee Ratios by Region

- Net Sales : Overseas ratio 67%



- Number of employees: Overseas ratio 55%



Overseas ratio is more than 50% in terms of both sales and number of employees

Case 1. Existing customer: Regenerative medicine (derived from iPS cells)

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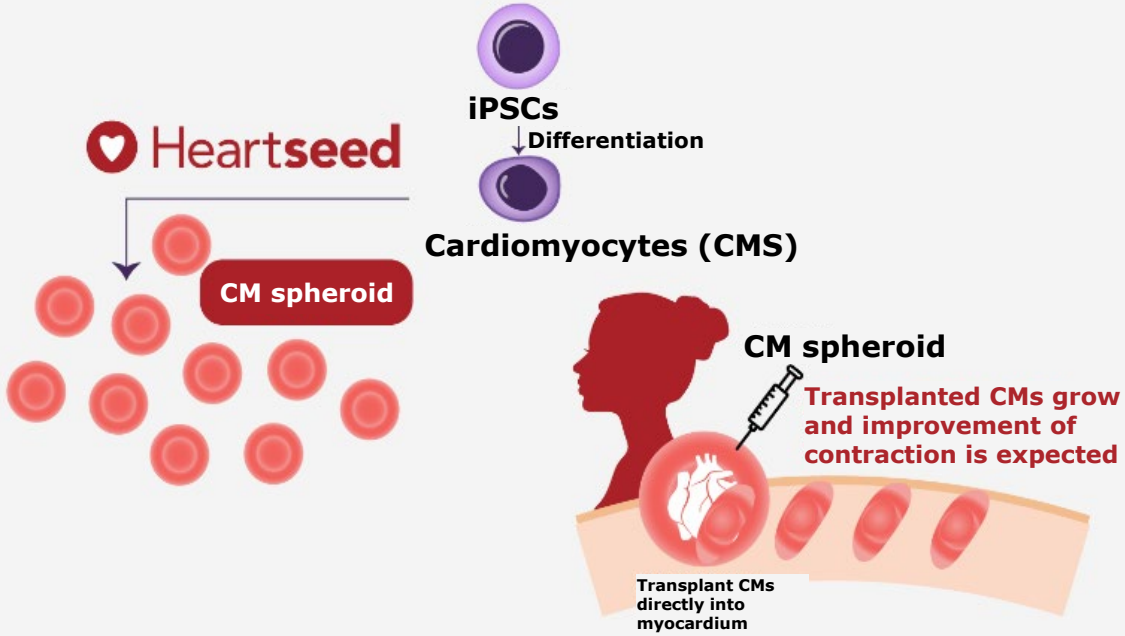
Linical is providing comprehensive support for Heartseed's domestic Phase I/II clinical trials as a CRO.

- Development regulatory affairs (including PMDA consultation and protocol preparation)
- Monitoring
- Data management and statistical analysis
- Safety management
- Auditing
- Vendor management (clinical trial product transportation, external testing, laboratory imaging)



Cited with permission from the website of Heartseed Inc.

Heartseed Biotechnology venture founded by Keiichi Fukuda, Professor Emeritus of Keio University
They established "cardiac regenerative medicine," a therapy that transplants microtissues (cardiomyocytes) derived from allogeneic iPS cells into the heart, and are developing HS-001 to contribute to treatment for patients with severe heart failure

Case 2. Potential customer: Gene delivery drugs

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Design and manufacture HSV-based vectors* using a viral vector system as the gene delivery platform.

*: Vectors are DNA or RNA molecules that are used to transport foreign genetic material into another cell.

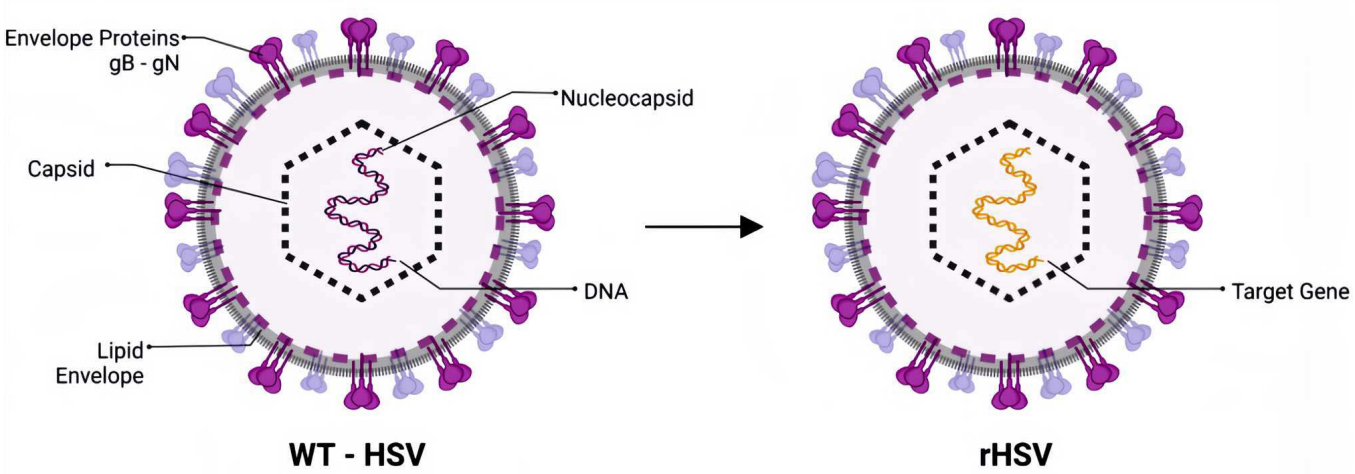

Figure source : https://www.cd-bioparticles.net/hsv-vectors

< HSV vector features >

- HSV vectors have been applied widely as vectors for gene therapy and are promising as a carrier for gene therapy for various diseases.
- They have high infectivity against a variety of cell types, both mitotic and nondividing cells.
- Because their viral genome is extremely large (~150 kb), a large number of therapeutic genes can be carried on a single vector.
- Applications include gene delivery to the nervous system, tumor-lysing agents, and the development of vaccines against cancer, HSV, and other infectious diseases.

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Consolidated Financial Results

Units: Millions of yen, %	Results for the Six Months Ended September 30, 2024		Results for the Six Months Ended September 30, 2025		
	Amount	Sales Ratio	Amount	Sales Ratio	Year-on-Year
Net Sales	5,426	100.0	4,859	100.0	△10.4
Cost of Sales	4,111	75.8	3,787	77.9	△7.9
SG&A Expenses	1,507	27.8	1,583	32.6	5.0
Operating Profit	△192	△3.6	△511	△10.5	–
Ordinary Profit	△239	△4.4	△543	△11.2	–
Net Profit	△280	△5.2	△927	△19.1	–

■Net sales:
Although sales in Japan, Europe, Taiwan and China increased, consolidated net sales fell year-on-year, as sales in the United States and Korea decreased.

■Operating Profit:
Business in Taiwan and China was in the black, but because business in Japan, the United States, Europe, and South Korea posted operating losses, we made an operating loss on a consolidated basis.

■Net Profit:
Income taxes-deferred increased due to the reversal of deferred tax assets.

Financial Results by Region

Unit : Millions of yen	Results for the Six Months Ended September 30, 2024			Results for the Six Months Ended September 30, 2025					
	Net Sales **	Operating Profit	Ordinary Profit	Net Sales **	Rate of Change %	Operating Profit	Rate of Change %	Ordinary Profit	Rate of Change %
Japan	1,892	△215	△230	1,975	4.4	△114	–	△78	–
United States	2,513	410	431	1,923	△23.5	△76	–	△56	–
Europe	1,565	△54	△102	1,709	9.2	△142	–	△206	–
Korea	375	△73	△80	327	△12.8	△58	–	△83	–
Taiwan	42	△28	△25	98	130.9	14	–	11	–
China	115	△7	△4	143	24.7	50	–	47	–
Consolidation Adjustments*	△1,077	△223	△227	△1,318	–	△184	–	△178	–
Total	5,426	△192	△239	4,859	△10.4	△511	–	△543	–

* Amortization of goodwill is included in consolidation adjustments. ** Net sales have calculated before deducting internal transactions.

Overview of Results by Region

Japan: Increased revenue and contraction of operating loss

- Revenue increased and the operating loss contracted after being consigned multiple new projects by pharmaceutical companies from Japan and overseas and recording sales.
- We will aim for the improvement of results by implementing measures to increase the personnel utilization rate and controlling expenses strictly.

United States: Decreased revenue and switch to operating loss

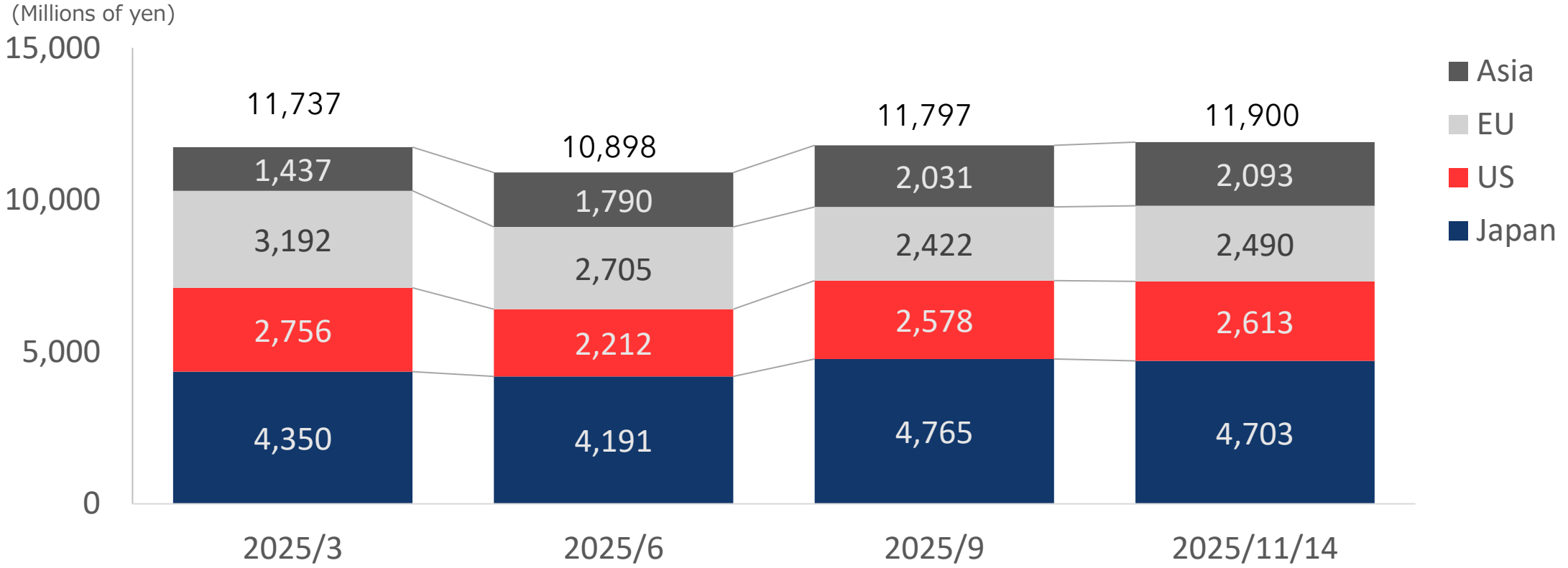
- Revenue decreased and an operating loss was incurred as we were unable to compensate for the decline in sales associated with the completion of a major project.
- Although orders for multiple large global clinical trials were accepted informally, the start of the trials was delayed due to a delay in the review of the trial plans by the United States Food and Drug Administration (FDA) so these projects did not contribute to sales.

Europe: Increased revenue and expansion of operating loss

- Revenue increased due to the extension of the duration of existing projects and contract changes to add man-hours.
- The operating loss increased as outsourcing and other expenses increased.

Hard Backlog by Region

* Hard backlog:
The balance of the amount for orders for contract business already concluded.
This is an indicator that shows the amount of sales to be generated over the next one to five years and serves as the basis for the group's future results forecasts.



- As of November 14, 2025, the order (hard) backlog increased by 1.4% to 11.9 billion yen compared to the end of March 2025.

Hard Backlog by Region

Japan:

- We received new orders from Japanese and overseas pharmaceutical companies, and the hard backlog increased compared with the end of March 2025.
- Japanese pharmaceutical companies contracted us to conduct studies in Australia and Asia, managed by our Japan base, and the establishment of the Australian base has shown its effect.

United States and Europe:

- Although we accepted orders informally for multiple large international joint clinical trials, including trials in the United States, Europe, and Australia, and have concluded contracts for some of them, the contracts for others have not been completed due to delays in trial start dates or the postponement of trial implementation, resulting in a decrease in the hard backlog from the end of the fiscal year ended March 2025.

Asia:

- In South Korea, the hard backlog increased from the end of the fiscal year ended March 2025 as a result of being commissioned to do multiple projects, including domestic projects in South Korea and data management and statistical analysis services via group companies.
- In Taiwan, the hard backlog increased due to the acquisition of global projects to be executed in Taiwan and the United States.

Full-Year Forecast

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Unit: Millions of yen	FY ended March 2025		FY ending March 2026 Previous Forecasts			FY ending March 2026 Latest Forecasts		
	Amount	Sales Ratio	Amount	Sales Ratio	Rate of Change	Amount	Sales Ratio	Rate of Change
Net Sales	10,437	100.0	11,200	100.0	7.3	9,350	100.0	△10.4
Operating Profit	△583	△5.6	300	2.7	—	△1,350	△14.4	—
Ordinary Profit	△498	△4.8	320	2.9	—	△1,400	△15.0	—
Net Profit	△539	△5.2	150	1.3	—	△1,700	△18.2	—

We revised full-year forecasts in light of conditions through the first half of the fiscal year

(Reference) Balance of Goodwill and Remaining Amortization Period (As of March 2025)

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Unit : Millions of yen	Goodwill			Related intangible assets other than goodwill *2		
	Balance at End of Term	Remaining Amortization Period(year)	Annual Amortization *3	Balance at End of Term	Remaining Amortization Period(year)	Annual Amortization *3
KOREA	Termination of depreciation in FY 2019			Termination of depreciation in FY 2019		
EUROPE *1	1,195	8-9	147	6 57	2 5.7	3 10
USA *1	1,949	9	220	22	2	11
TOTAL	3,144	—	368	85	—	24

*1 Goodwill generated by the acquisition of Linical Accelovance America, Inc., has been apportioned pro rata to its European subsidiary.
*2 Intangible assets other than goodwill recognized by purchase price allocation.
*3 Figures have been converted at the exchange rate as of the end of the fiscal year ended March 2025.

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Growth Strategy

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We will strengthen the provision of high-quality services and our financial base towards further overseas business expansion in future.

Governance

We will reform and strengthen our organizational structure to improve profitability while expanding services.

Sales

We will differentiate ourselves from major global CROs by strengthening our ability to provide finely detailed proposals to clients.

IT Investment

We will use digital technology to address needs for the greater efficiency of clinical trials and promote the streamlining of management.

Growth Strategy - Governance

We will reform and strengthen our organizational structure to improve profitability while expanding services.

Strengthening of communication between bases

We will share the state of progress and issues at each base promptly and strengthen systems that allow cooperation.

Securing and development of human resources

We will hire and develop excellent human resources so that we can provide highly specialized services, and strengthen initiatives for the retention of human resources.

Collaboration between services

In addition to monitoring services, we will strengthen collaboration between different services such as drug discovery support work and data management work, and provide prompt, flexible services.

Growth Strategy - Sales

We will differentiate ourselves from major global CROs by strengthening our ability to provide finely detailed proposals to clients.

Sales organization reform

We will advance the standardization of procedures and accumulate know-how so that we can carry out sales activities organized on a global basis.

Enhancement of sales strategies for each customer

While targeting with a focus on emerging biopharmaceutical companies in Europe and the United States, we will enhance our sales strategy to meet the different needs of each customer, including major pharmaceutical companies and Japanese pharmaceutical companies.

Development of global sales human resources

We will secure personnel who can take charge of sales activities in global collaboration.

Growth Strategy - IT Investment

We will use digital technology to address needs for the greater efficiency of clinical trials and promote the streamlining of management.

Use of AI in clinical trials

We will consider the introduction of a system and develop human resources familiar with both technology and clinical development towards the use of AI in clinical trial work.

Promotion of DX in each function

We will develop group-wide integrated digital tools and a system environment and improve productivity through DX.

Strengthening of cooperative relationships

Strengthening of the system-related partner network needed for Decentralized Clinical Trial (DCT) and the use of AI

Application of AI in Clinical Trials

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Promoting the introduction of tools for the use of AI in each phase of clinical trials

Trial design formulation

- The AI model extracts information from trial documents.
- It evaluates how each element of the protocol affects the results.

Case registration

- AI searches medical records to identify potential patients who meet the clinical trial criteria.
- This enables faster and more accurate trial subject enrollment.

Data analysis

- AI analyzes huge amounts of trial data.
- It can mine patient records to find patterns and predict reactions individually.

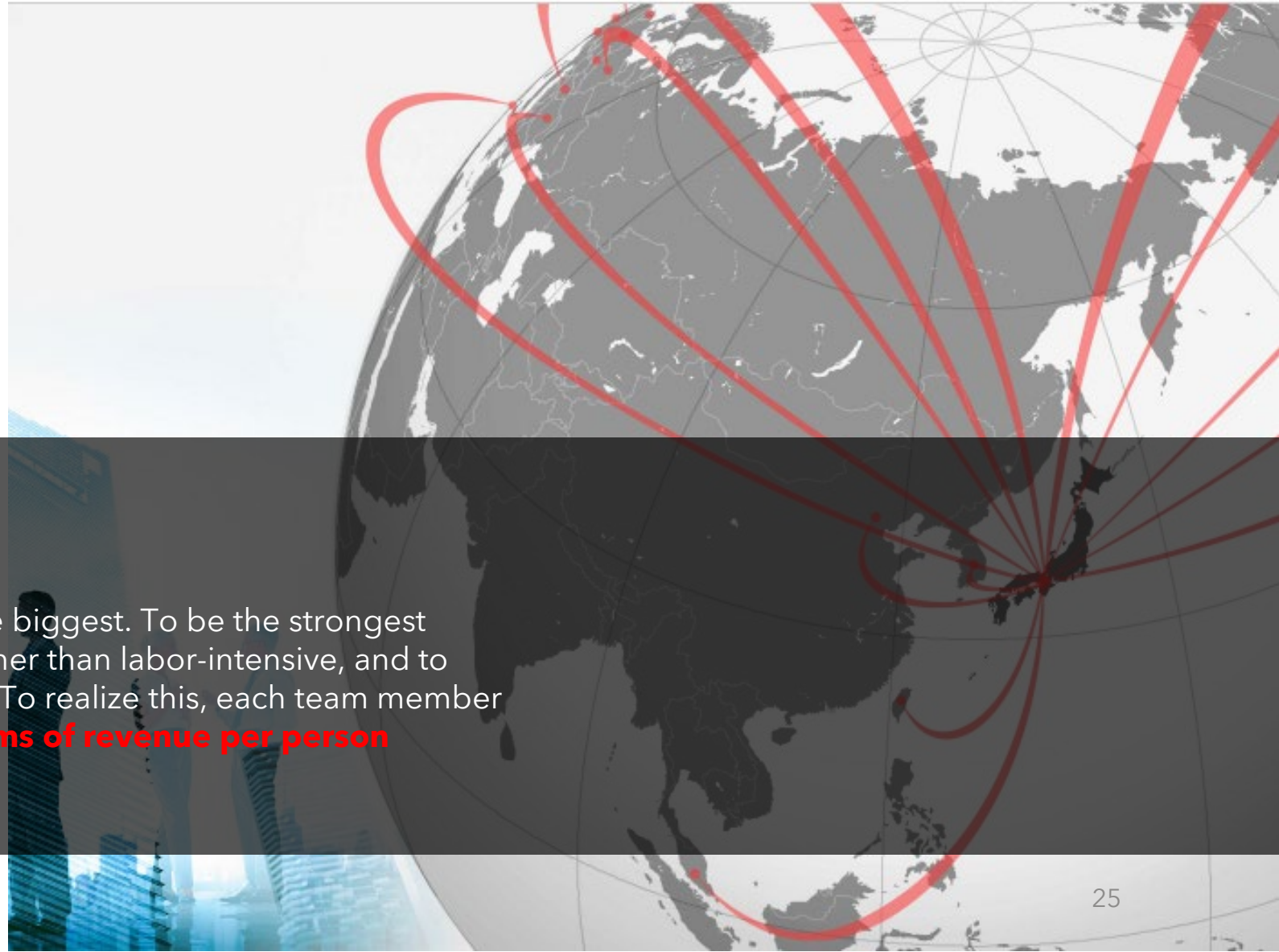
Risk monitoring

- AI monitors clinical trial data in real time.
- It issues alerts when safety concerns arise.

Regulatory

- AI checks for inconsistencies and errors between data to support regulatory compliance.

The way we want to be



To be the “Strongest” CRO

We are aiming to be the strongest CRO, not the biggest. To be the strongest CRO, we need to be **knowledge-intensive** rather than labor-intensive, and to achieve the highest profitability in the industry. To realize this, each team member will aim to **outperform the competition in terms of revenue per person**

Cautionary Notes

Those plans, forecasts, strategies, etc., stated in this document that are not historical facts are forecasts concerning future results. These are forecasts that have been determined by the company based on information currently available so please do not place undue reliance on them.

Please understand that the company will bear no responsibility whatsoever for any damage, etc., resulting from errors in the information stated in this document. In addition, this document is not aimed at soliciting investment.

Users are asked to make investment decisions at their own judgment.