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 2024 Financial Results Briefing

Friday, December 1, 2023

Linical Co., Ltd.
Kazuhiro Hatano, President and CEO

TSE Standard 2183

Agenda

1. Company Overview
2. Financial Results for the Six Months Ended September 30, 2023
3. Management Strategy

Corporate Profile

Company name	Linical Co.,Ltd. (TSE Standard 2183)
Head Office	1 -6 -1 Miyahara, Yodogawa-ku, Osaka
Establishment	June 7, 2005
Representative	Kazuhiro Hatano, President and CEO
Capital Stock	214 million yen
Business Description	Clinical Research & Development (CRO) business and Contract Medical Affairs Business
Number of Employees	799 (382 in Japan and 417 overseas) * As of March 31, 2023

- History of establishment

April 1, 2005: Yamanouchi Pharmaceutical Co., Ltd., and Fujisawa Pharmaceutical Co., Ltd., merged to form Astellas Pharma Inc.

June 7, 2005: Linical Co., Ltd. was established centered on members with experience in drug development at Fujisawa Pharmaceutical Co., Ltd., aimed at the ideal contract drug development (CRO) business originating in Osaka.

Management Philosophy

Management Philosophy

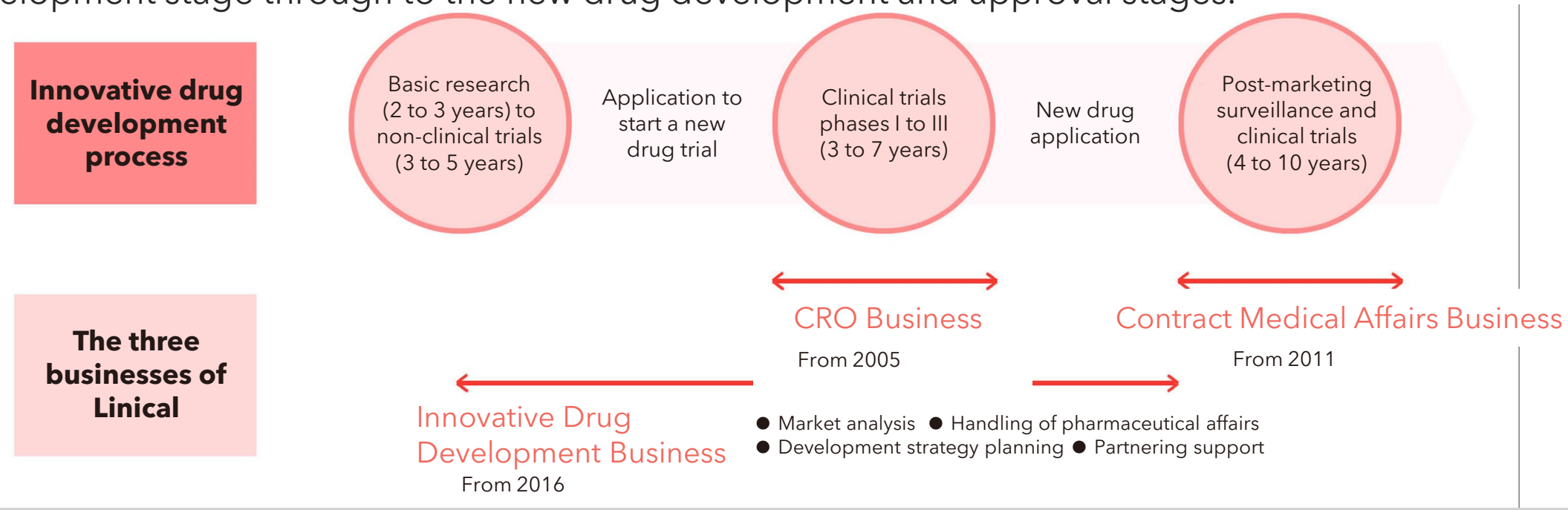
To promote the greater wellbeing of all our stakeholders — patients, business partners, shareholders, and employees — we strive constantly to offer professional, high-quality services to support all aspects of new drug development.

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

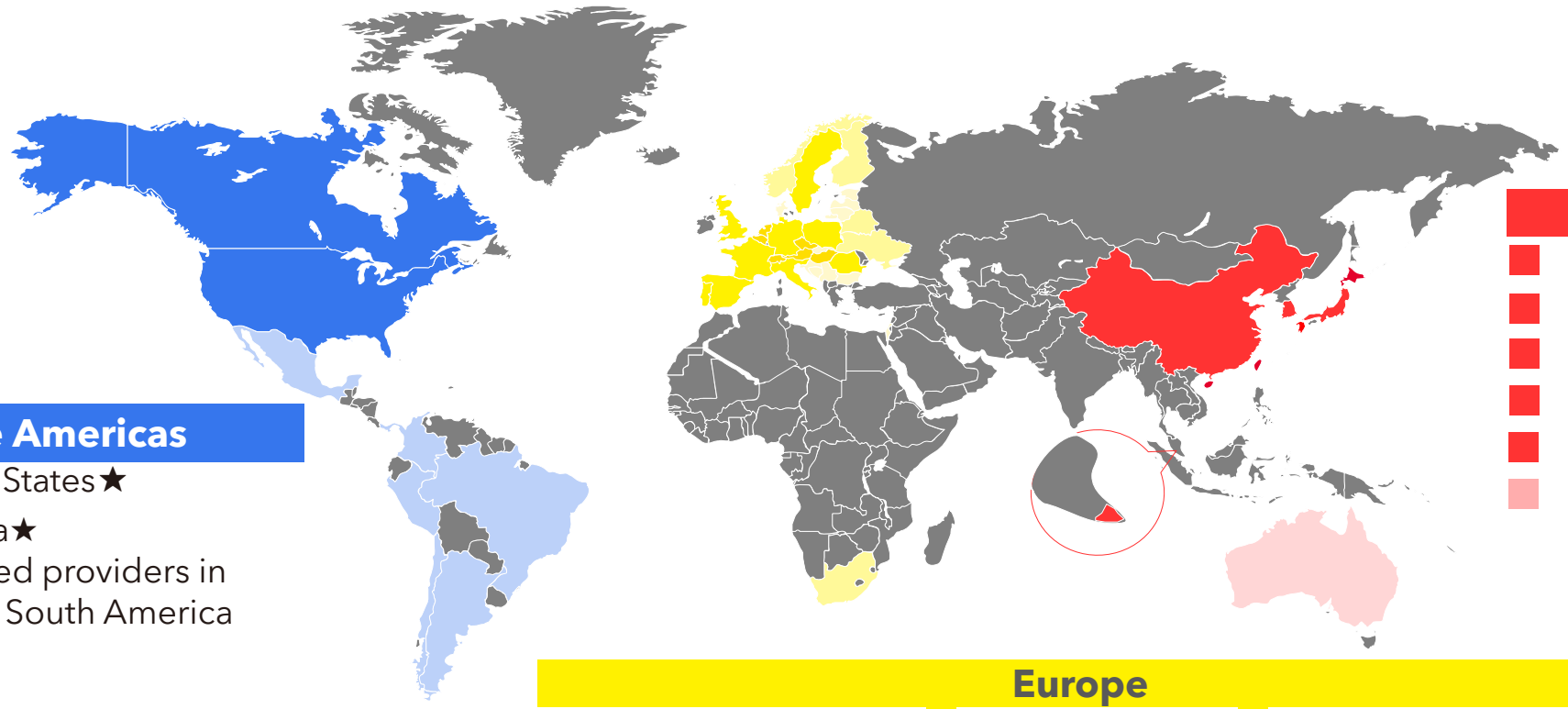
- We specialize in clinical development and cover the entire process from the innovative drug development stage through to the new drug development and approval stages.



- We have developed three businesses centered on CRO Business.
- Contract Medical Affairs Business: We support post-marketing clinical research and marketing activities
- 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.

Our global network

Clinical Development Partner
Linical



The Americas

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

Asia

- Japan★
- China★
- South Korea★
- Taiwan★
- Singapore★
- Preferred providers in Australia

Europe

- Germany ★
- United Kingdom★
- Netherlands★
- Czech Republic★
- Spain★
- Sweden★
- France★
- Italy★
- Hungary★
- Poland★
- Romania★
- Slovakia
- Portugal
- Austria
- Belgium
- Switzerland
- Preferred providers in Scandinavia, Eastern Europe & South Africa

★ Office/employee locations
Current 18 countries and regions

Steady Growth in Overseas M&A

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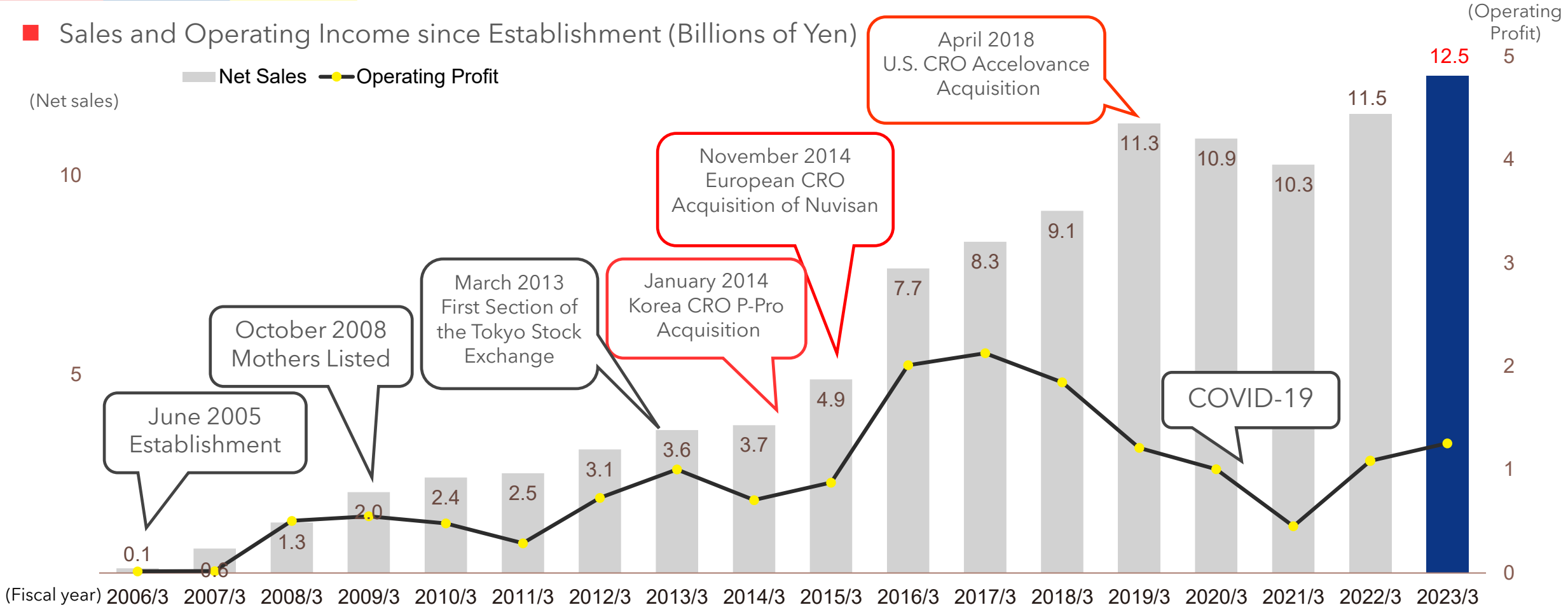
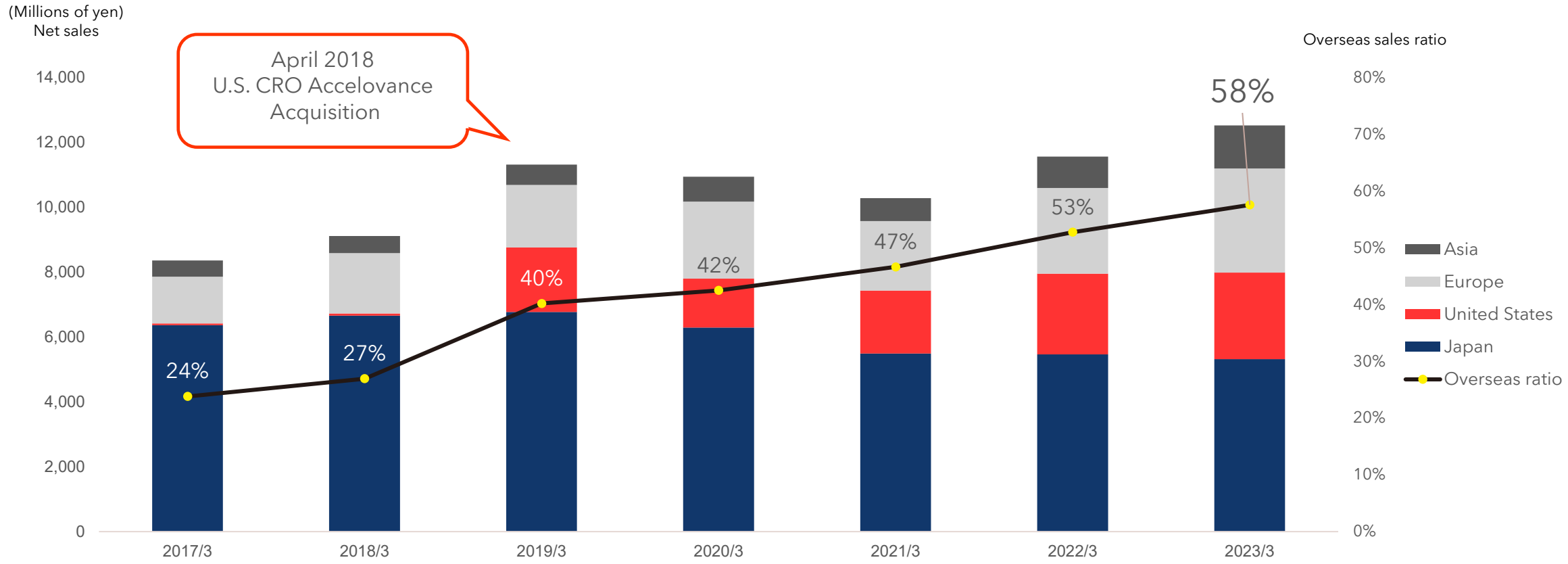
■ Sales and Operating Income since Establishment (Billions of Yen)



We achieved our highest ever sales for the second consecutive year. Operating profit also recovered, bringing the operating margin to a level in excess of 10%.

The Overseas Sales Ratio Reached About 60%

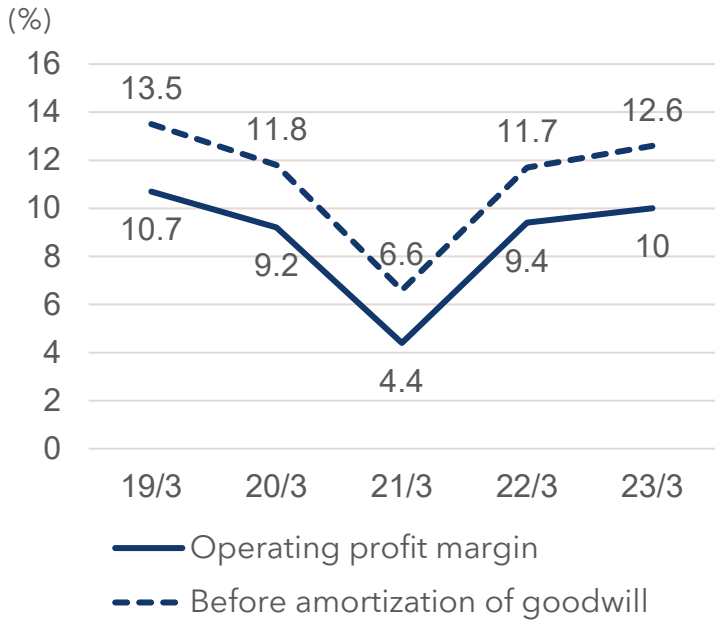


The overseas sales ratio has increased gradually and reached 58% in FY 2023.
As a global CRO, we are entrusted with multi-regional clinical trials, with each region working in cooperation.

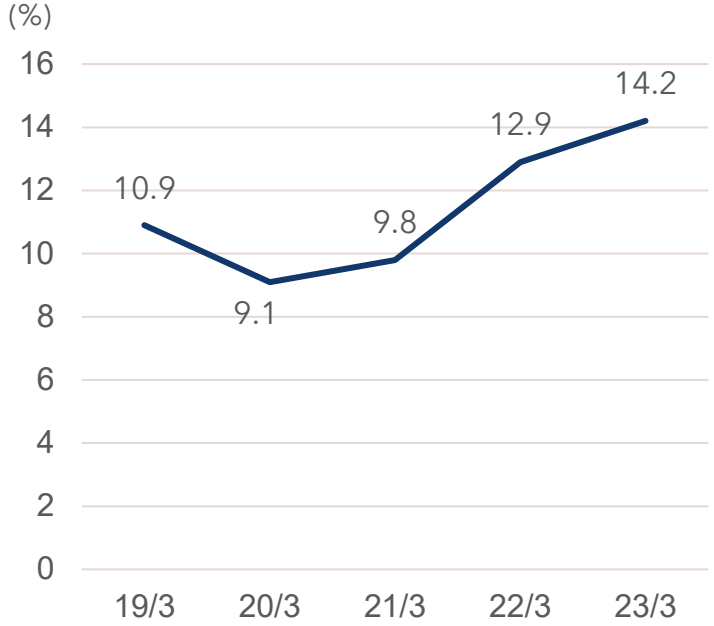
Key Financial Indicators (Past 5 Years)

Clinical Development Partner Linical

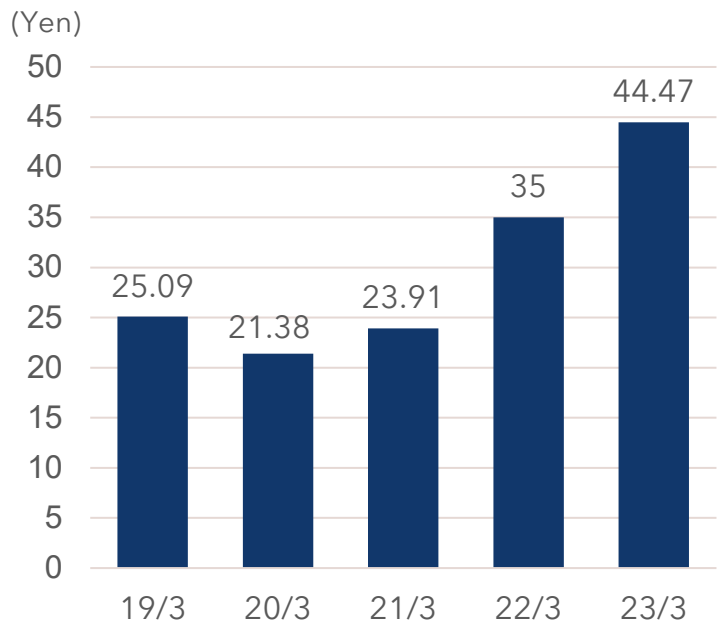
Operating profit margin



ROE



EPS



Medium to long-term goal of in excess of 20%
(Before amortization of goodwill)

All indicators have recovered to pre-COVID-19 levels and are on an improvement trend.
We will aim for continuous improvement.

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Consolidated Financial Results

Units: millions of yen, %	Results for the First Half, FY ended March 2023		Results for the First Half, FY ending March 2024		
	Amount	Net Sales	Amount	Net Sales	Year-on-Year
Net Sales	5,920	100.0%	6,064	100.0%	+2.4
Cost of Sales	4,080	68.9%	4,079	67.3%	▲0.0
SG&A Expenses	1,467	24.8%	1,563	25.8%	+6.6
Operating Profit	373	6.3%	421	6.9%	+12.8
Ordinary Profit	614	10.4%	483	8.0%	▲21.3
Net Profit	468	7.9%	178	3.0%	▲61.8

■ Net sales: Increased
Sales increased due to a significant increase in sales in the United States and yen depreciation.

■ Operating profit: Increased
Profits increased in the United States and Japan, and also increased overall.

■ Ordinary profit: Decreased
Foreign currency exchange gains generated with foreign currency deposits, etc. were below the amount last term.

■ Quarterly net income: Decreased
Insurance income was received last term, and business restructuring expenses were incurred this term in association with the integration of management systems at subsidiaries in Europe and the United States.

Financial Results by Region

Clinical Development Partner Linical

Unit: Millions of yen	Results for the First Half, FY ended March 2023			Results for the First Half, FY ending March 2024					
	Net Sales **	Operating Profit	Ordinary Profit	Net Sales	Rate of Change %	Operating Profit	Rate of Change %	Ordinary Profit	Rate of Change %
Japan	2,912	341	537	2,682	△ 7.9	370	8.6	478	△11.0
United States	1,407	42	25	1,998	42.0	304	613.2	308	1,102.5
Europe	1,862	120	157	1,578	△ 15.3	△118	-	△147	-
Korea	408	36	67	442	8.3	14	△ 60.2	11	△ 83.2
Taiwan	63	△ 15	△ 15	50	△ 20.1	△16	-	△16	-
China	201	21	14	165	△ 17.9	1	△ 95.3	△5	-
Consolidation Adjustments*	△ 933	△172	△ 171	△ 853	-	△134	-	△146	-
Total	5,920	373	614	6,064	2.4	421	12.8	483	△ 21.3

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

Full-Year Forecast

Clinical Development Partner Linical

Unit: Millions of yen	FY ended March 2023 Results		FY ending March 2024 forecasts		
	Amount	Sales Ratio	Amount	Sales Ratio	Rate of Change
Net Sales	12,516	100%	13,300	100%	106.3%
Operating Profit	1,256	10.0%	1,400	10.5%	111.4%
Ordinary Profit	1,283	10.3%	1,400	10.5%	109.1%
Net Profit	1,004	8.0%	1,008	7.6%	100.4%
	Amount (yen)	Payout ratio (%)	Amount (yen)	Payout ratio (%)	
Dividend per share	14	31.5	15	33.6	

The full-term forecast is unchanged.

Balance of Goodwill and Remaining Amortization Period (As of March 2023)

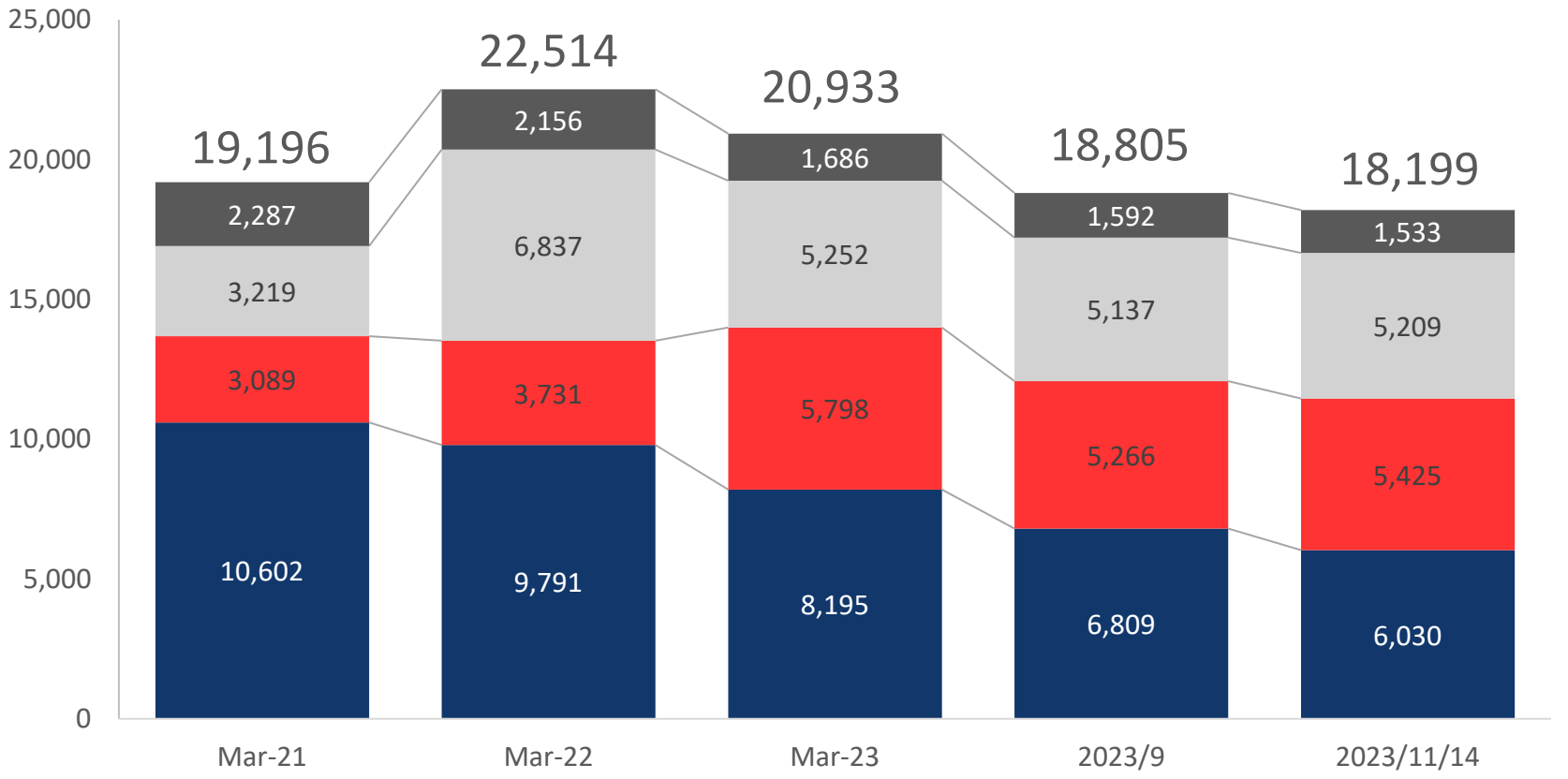
Clinical Development Partner Linical

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	1,326	10 to 11	129	10.8 68.7	4 7.75	2.7 8.9
USA *1	2,058	11	187	40	4	10
TOTAL	3,384	—	316	119.5*	—	21.6

*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 2023.

Hard Backlog by Region

(Millions of yen)



* 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.

The hard backlog decreased from the end of last term due to the discontinuation of large-scale trials in Europe, the United States and Japan.
The details in each region are described on the next page.

Market Environment by Region

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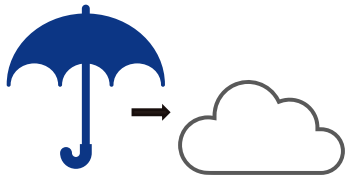
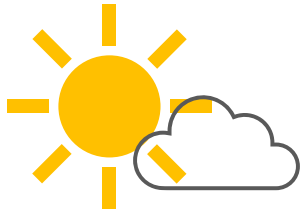
Japan

- May 8: COVID-19 reclassified as a Class 5 infectious disease -> Normalization of clinical trial environment
- Progress is steady. We are digesting the hard backlog steadily and recording sales. The impact of COVID-19 pandemic is expected to remain on an annual basis.
- Non-COVID-19-related drug development was flat. The number of companies entering different industries, etc. is increasing so we will promote new development.



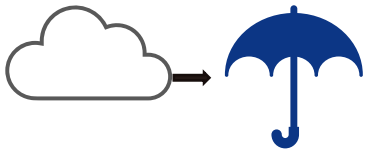
United States

- New drug development in the United States market is vigorous and there are many inquiries for new projects, including large ones.
- Uncertainty in business sentiment is impacting the funding of US biotech companies.
- We will aim for the early establishment of a system able to cover large-scale trials throughout all of the United States.



Europe

- The deterioration of business sentiment in Europe makes it difficult for biotech ventures to raise funds.
- We will aim to acquire European trials by further advancing cooperation with US business and demonstrating synergies in sales.



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Global Pharmaceutical Market Size in 2026 (Forecast)

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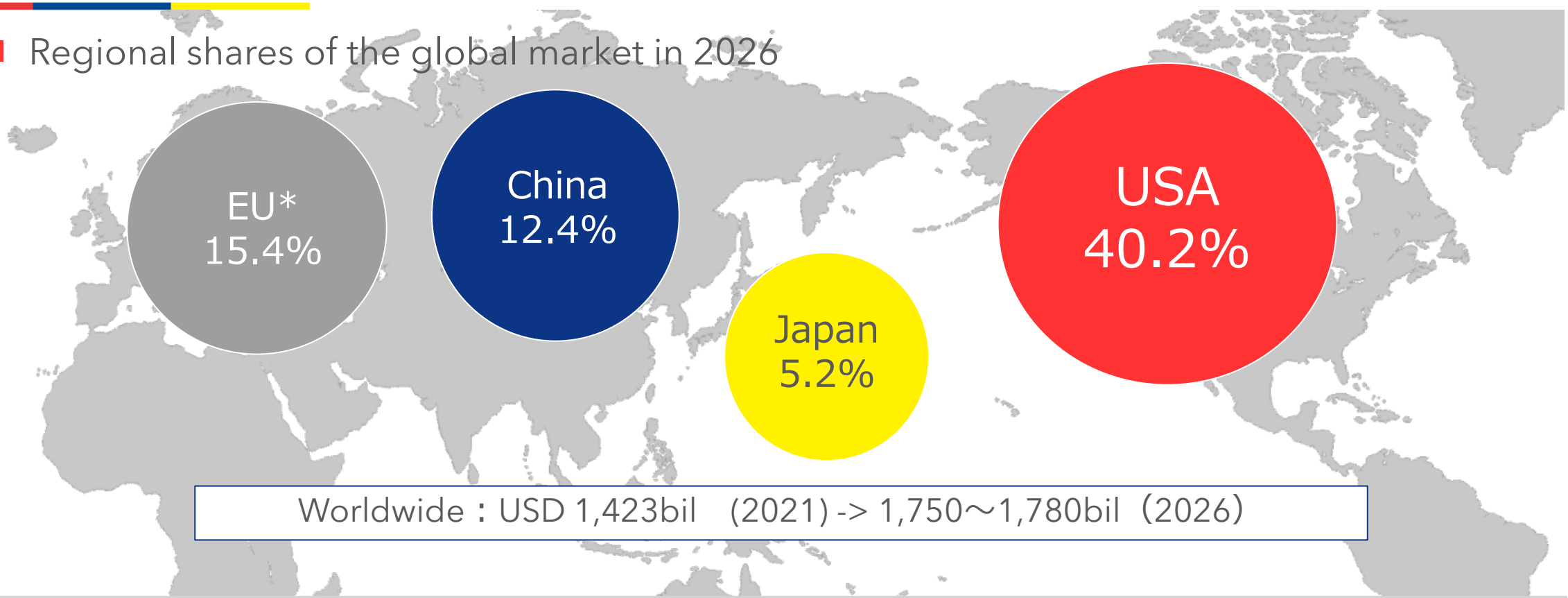
- Regional shares of the global market in 2026



Worldwide：USD 1,423bil　(2021) -> 1,750～1,780bil（2026）

To 2026, the global pharmaceutical market is expected to grow at an annual average of 3 to 6%. Japan is the only developed country with a forecast for negative growth.
Business expansion globally, including the United States, the largest market, is essential.

*EU : Germany, France, Italy, UK and Spain

Source: IQVIA The Global Use of Medicines 2022 OUTLOOK TO 2026

Expansion of Our Business (Mid-long terms)

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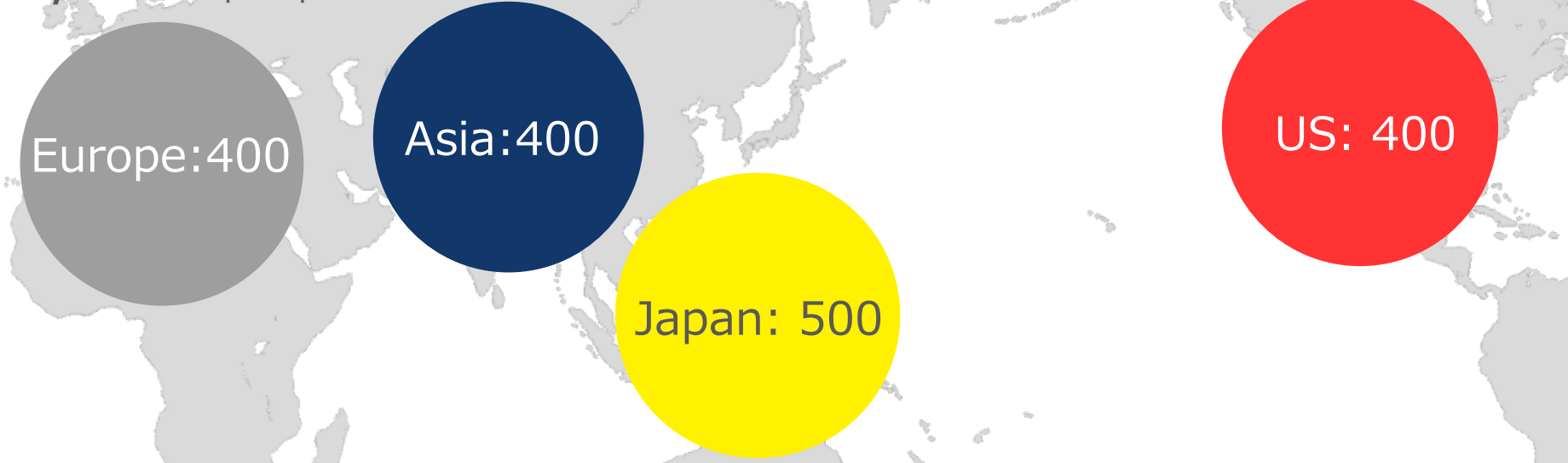
Number of employees

Global

More than 1,500 people

As of the end of March 2023

799 people



Number of countries where we do business

60 countries

As of the end of October 2022

About 20 countries

- 2nd targets
  - [1] 500 people in Japan, 400 people in Asia, 400 people in Europe, 400 people in the United States
    => Building of a framework with more than 1,500 people
  - [2] Maintenance of profitability and improvement of profit margins while investing in growth (including M&A) in each region
  - [3] Expansion into about 60 countries worldwide

Initiatives for the Strengthening of Profitability

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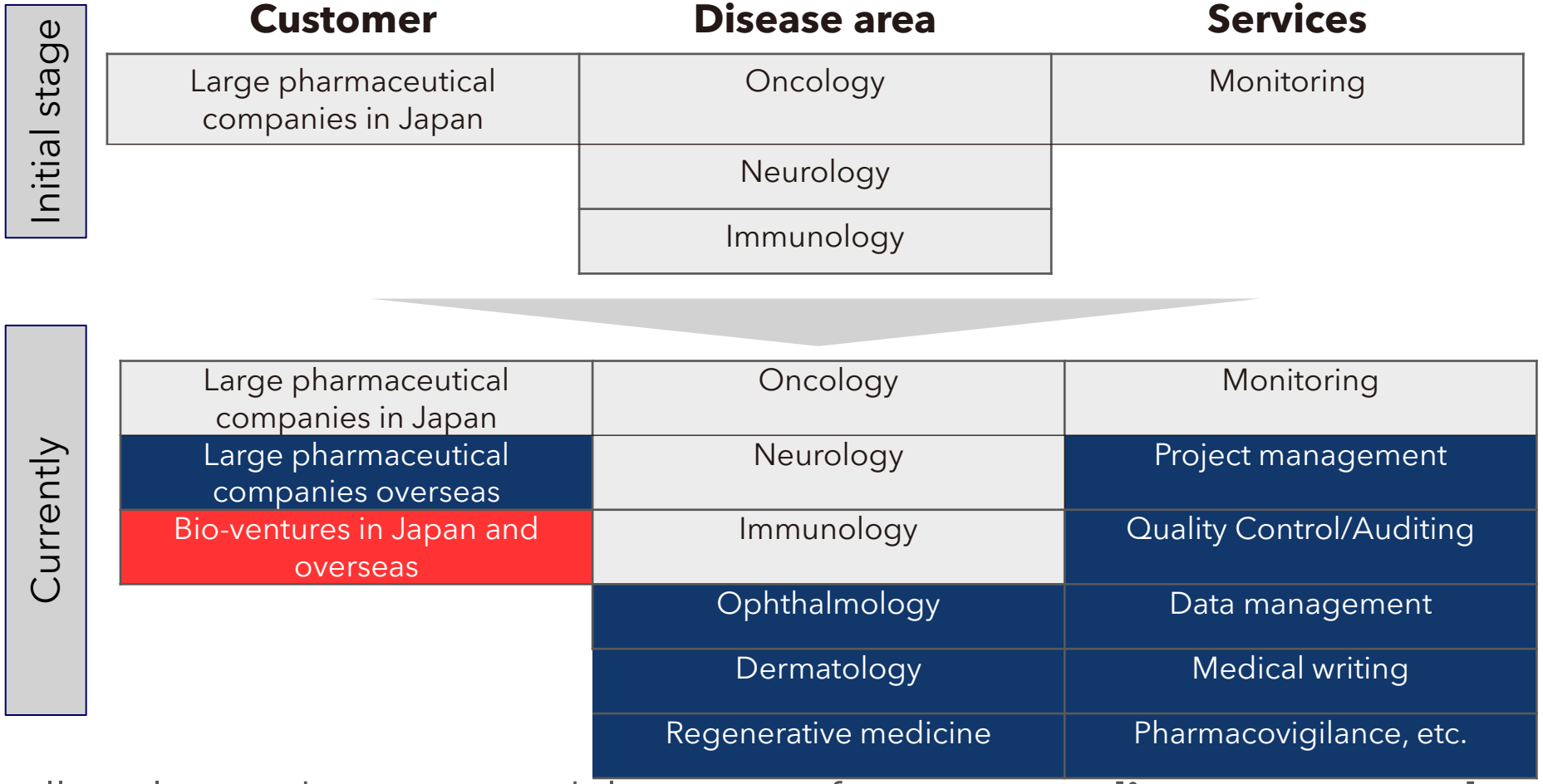
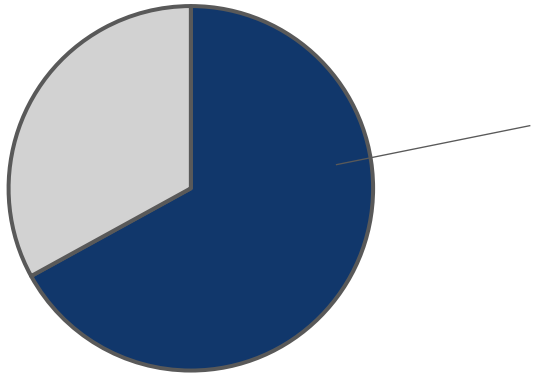


We will evolve our business model in terms of **customers, disease areas and services** based on changes in the market environment and customer needs.

Approaches to Biopharma Companies

- New active ingredient applications and sales by emerging biopharma companies *



67%

Emerging biopharma companies originated 67% of all new drugs in 2022.
The main actors in drug development are biopharma companies.

* EBP companies: Companies with annual sales of USD 500 million or less and R&D expenditures of USD 200 million or less
Source: IQVIA Institute

- Linical's customer base

At the time of founding

Large pharmaceutical companies in Japan

Currently

Large pharmaceutical companies in Japan
Large pharmaceutical companies overseas
Bio-ventures in Japan and overseas

We will take over original customer bases in association with the acquisition of overseas CROs.
This includes some that have grown significantly from ventures (US).

Strategies for Biopharma Companies

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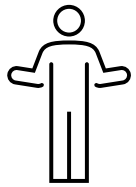
- Needs of emerging biopharma companies for CROs

They seek help from CROs with extensive experience and know-how, but want CROs to respond flexibly to meet their size and needs.

We will differentiate from major global CROs by combining **global one-stop CRO services** with **detailed solution proposals** tailored to their needs.



We would like to enter the Japanese pharmaceutical market and distribute and sell our products, but ...

- Knowledge of the Japanese market and pharmaceutical affairs is insufficient
- Lack of sufficient development and marketing capabilities
- Or, who need a strategic partner or licensee

Packaged service starting from **Innovative Drug Development Business**

Innovative Drug Development Business (IDDB) as an Entry Point to the Japanese Market

Characteristics of Linical's Innovative Drug Development Business (IDDB)

[1] Three services that can respond flexibly to the various needs of customers

Market Analysis/Research

Development & Regulatory Strategy
PMDA Consultation
Medical Writing

Strategic Partnering / Licensing

[2] A very experienced group of professionals

Support by a group of professionals with many years of experience in a wide range of pharmaceutical development at large pharmaceutical companies and in academia
The company expanded personnel from internal and external sources in FY 2023 in association with business expansion.

We will use IDDB as an entry point to acquire contracts for clinical trials.

Experience of IDDB since Its Establishment in Oct 2016

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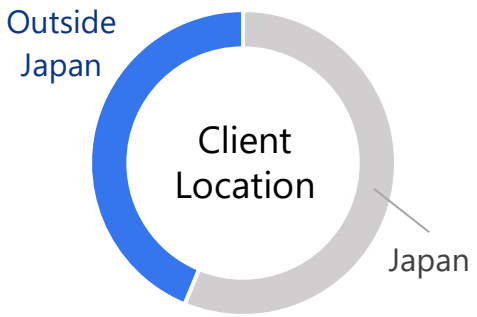
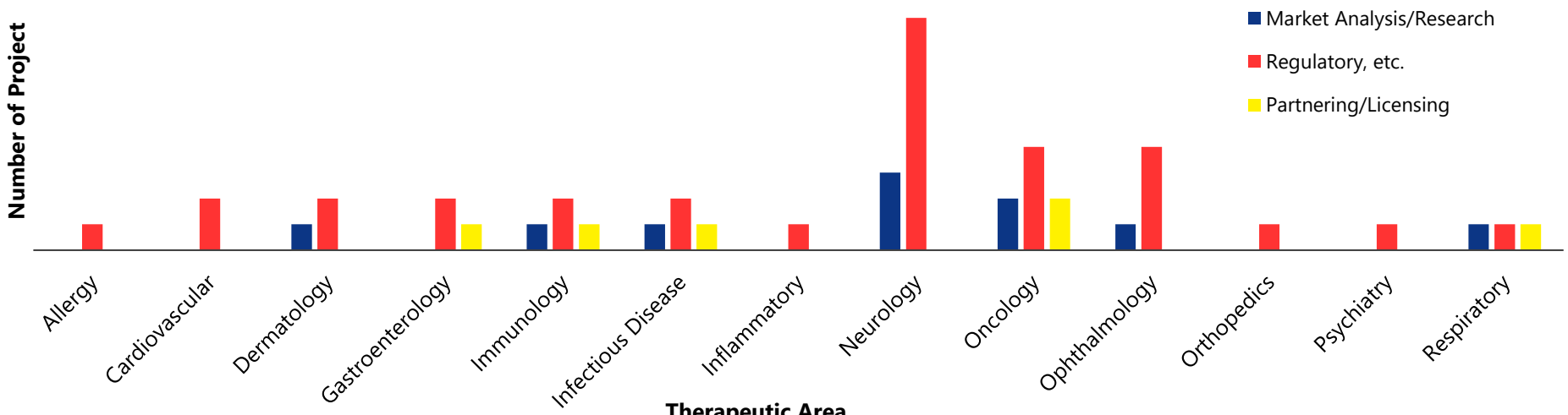
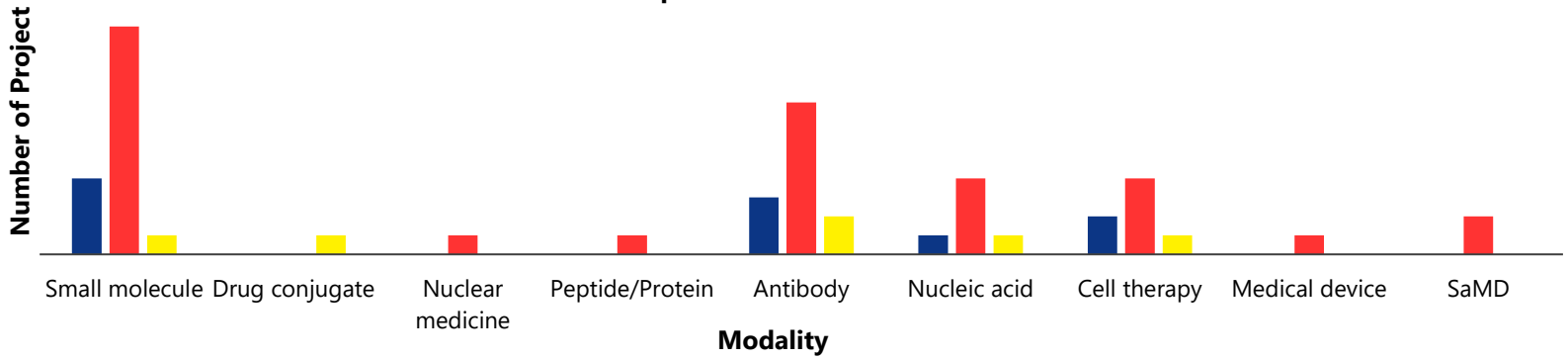
44%

of our clients are companies outside Japan





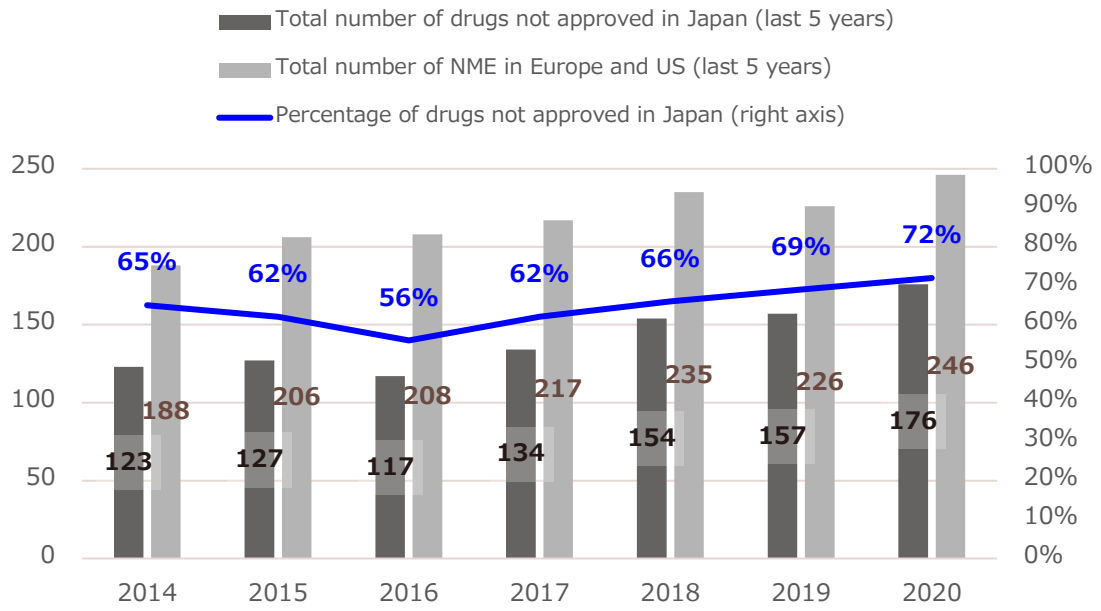


Wide-range therapeutic areas and modalities

Social Issues in Japan

From Drug Lag to Drug Loss

Increase in "drugs not approved in Japan" that are sold in other countries, but not in Japan



72%

of the number of NMEs approved in the United States and Europe over the last five years were “drugs not approved in Japan”. (as of the end of 2020)

Note: Targeting drugs containing new molecular entities (NMEs) approved in Japan, the United States and Europe from 2010 to 2020, we surveyed the numbers of drugs not approved in Japan and NMEs in Europe and the United States over the past five years at each survey point (end of December each year) and calculated the totals for five years. In cases of NMEs approved in both Europe and the United States, they are counted only once in the year they are first approved.
Source: Prepared based on graphs of the Office of Pharmaceutical Industry Research

There are also concerns about “drug loss,” whereby new drugs from overseas do not enter Japan.

Reference: Office of Pharmaceutical Industry Research, "Drug Lag: Drugs not yet approved in Japan and their characteristics" Office of Pharmaceutical Industry Research News No. 63 (July 2021)

Various Background Issues Have Been Pointed Out

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The declining attractiveness of Japan as a pharmaceutical market

Among major economies, only Japan is expected to see negative growth. Drug price issues in the context of a universal healthcare system (e.g., evaluation of innovation, etc.)

A complex drug price system with many revisions and exceptions

Revisions are made every year, and rules on exceptions are increasing and becoming more complicated. Overseas biotech start-ups do not have people around to teach them such complicated rules, and they do not have food for thought to consider investment in Japan.

The special pharmaceutical affairs and clinical trial environment

Initial data from Japanese patients and approval applications in Japanese are required, so it takes longer to obtain approval than in Europe and the United States. Procedures with medical institutions, clinical trial costs, etc.

Foreign emerging biopharma companies need to verify the cost-effectiveness of adding Japan to the countries where they implement development taking the factors above into consideration so the hurdle to doing so is high.

Specific Examples of the Japanese Pharmaceutical and Clinical Trial Environment

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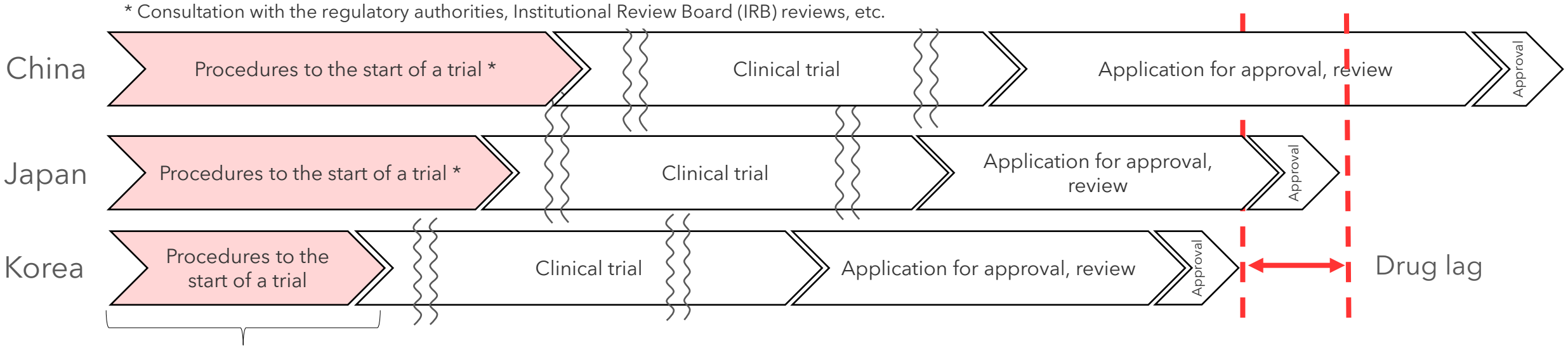
Preparation of applications for approval in Japanese

ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)
National pharmaceutical regulatory authorities and representatives of the pharmaceutical industry collaborate to develop guidelines on pharmaceutical regulations. Japan is a founding member.

Common technical documentation (CTD)
Form for the international standardization of documentation for drug approval applications (ICH-M4)
In Japan, even if the original text is in English, **some parts must be written in Japanese** (similarly, Chinese in China).

+3 months

Procedures to the start of a trial: Differences in timelines to approval in Asia



Korea takes about 2/3 of the time of Japan.

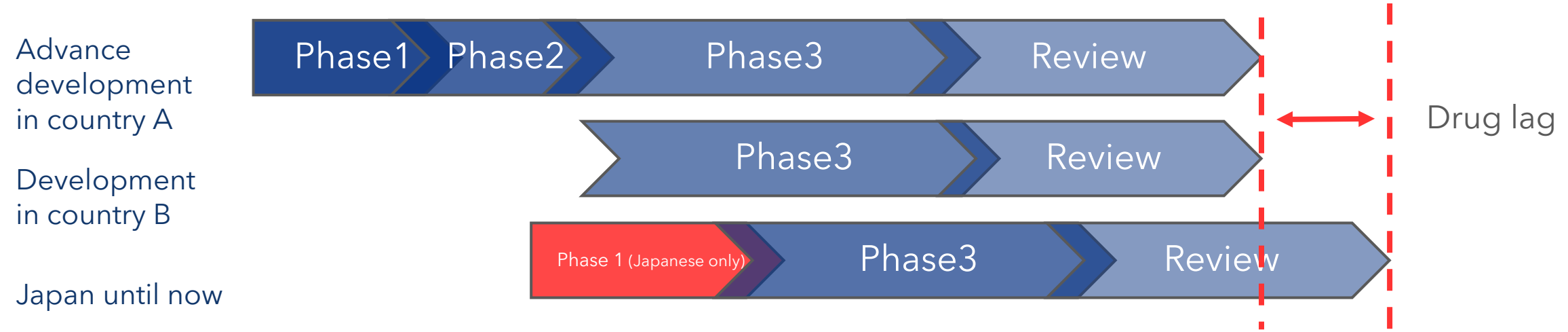
Source: Internal survey

Moves to Eliminate Drug Lag and Loss

- No need for an additional phase 1 clinical trial with Japanese patients when implementing an international joint clinical trial

On September 13, 2023, the Ministry of Health, Labour and Welfare presented the idea that, “in principle, it is not necessary to implement an additional phase 1 clinical trial with Japanese patients before an international joint clinical trial.”
(3rd Meeting of the Committee on Pharmaceutical Regulations for the Strengthening of Drug Discovery and Securing of Stable Supply, etc.)

< Example of Japan participating in an international joint clinical trial from phase 3 (image) >



Because it takes a certain amount of time and money to implement additional phase 1 clinical trials with Japanese patients, there was a danger that the development of phase 3 clinical trials might be delayed (drug lag) or that Japan would not participate in development (drug loss).
This may lower the hurdle for Japan's participation in international joint clinical trials.

Growing Interest in the Japanese Market among Overseas Customers

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- New Contracts for Entry to the Japanese Market by European Biotechnology Companies

Disease area	Details of contract services	Period
Cancer	Consulting (drug discovery support)	November 2023 ~
Cancer	Phase1/2	November 2023 ~

- Market interest among Taiwanese customers (hearing in October 2023)

Pharmaceutical companies in Taiwan	**Japan**	EU	United States	Asia-Pacific	Other
A				✓	
B	✓ (including IDDB)			✓	
C	✓		✓	✓	
D	✓ (including IDDB)				
E	✓ (including IDDB)		✓	✓	
F (medical devices)	✓		✓	✓	
G	✓ (including IDDB)		✓		✓
H	✓		✓	✓	
I (foreign capital)				✓	✓
J (foreign capital)				✓	

Results for Contract Acceptance in Japan (By Phase and by Disease Area)

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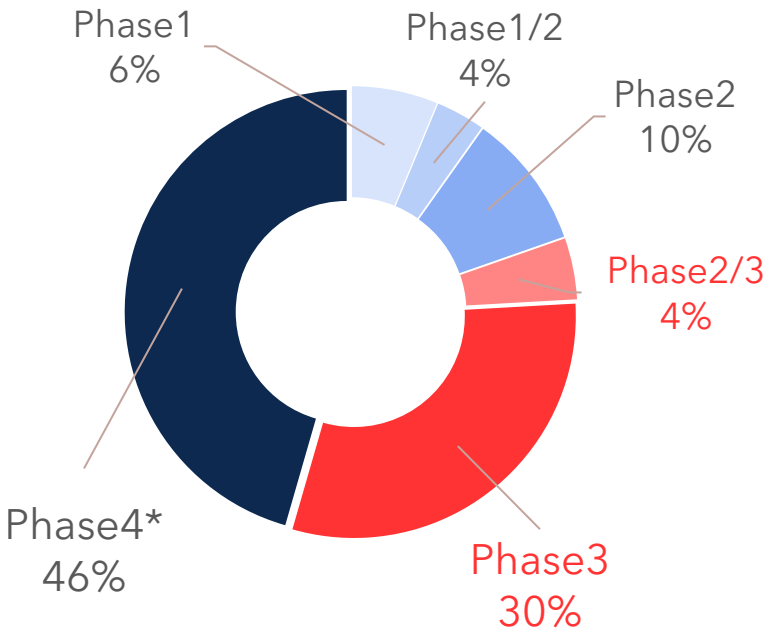
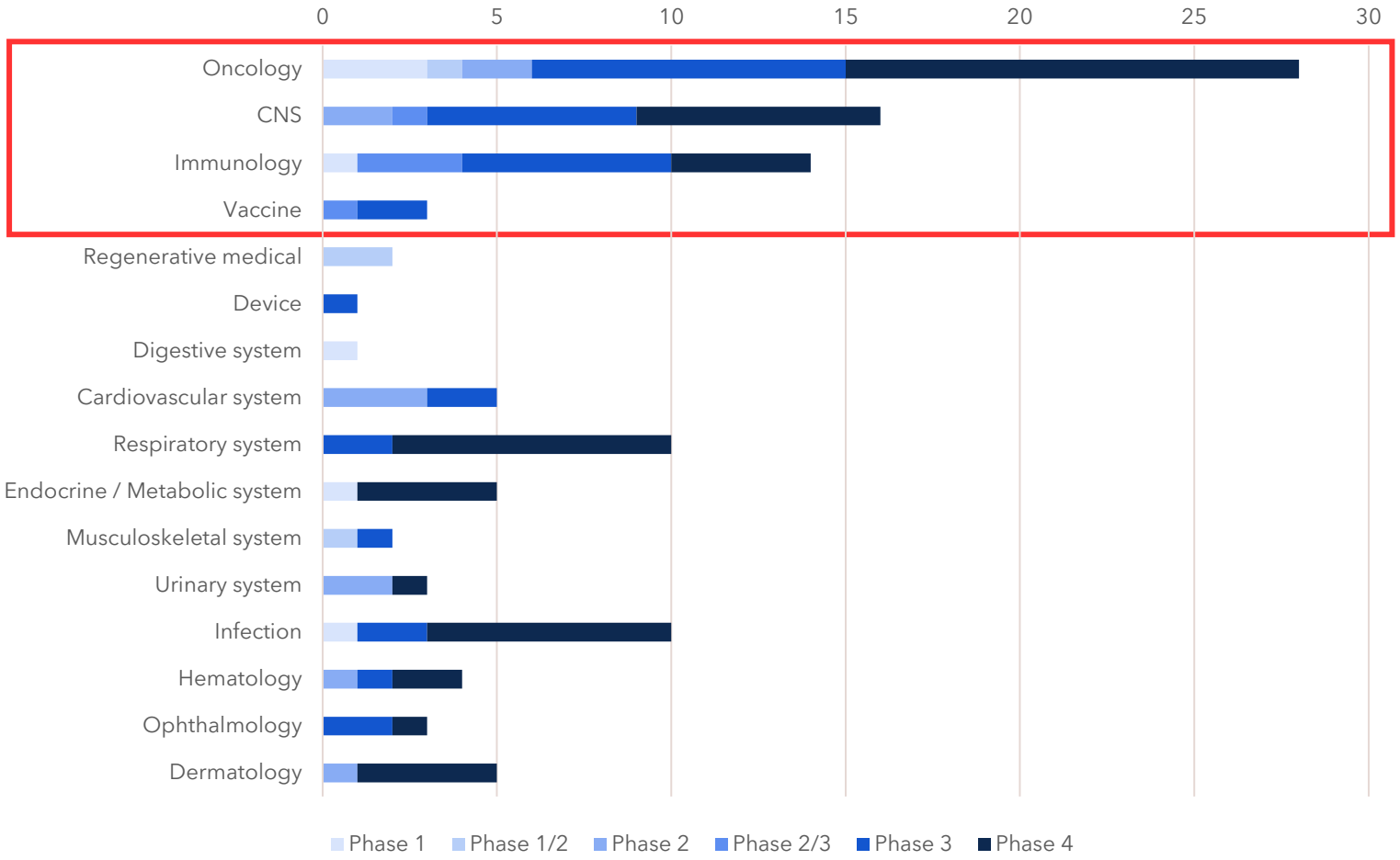
- Our clinical studies experiences past 5 years (from Apr 2018 to Mar 2023)





Since our founding, our strength has been in large-scale Phase 3 clinical trials in oncology, the central nervous system and immunology.

Strengthening of Profitability

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Further growth of overseas business

- Most important market - We will conduct M&A quickly to realize growth in the United States.
- We will strengthen management and sales capabilities in Europe and the United States.
- Expansion into the southern hemisphere

Expansion of the customer base

- We are acquiring repeat orders from major Japanese pharmaceutical companies and contracts from European and American pharmaceutical companies.
- We are focusing on European and American biotech start-ups with promising development pipelines. We will aim to differentiate ourselves from major global CROs and expand our customer base by making detailed proposals that match needs.

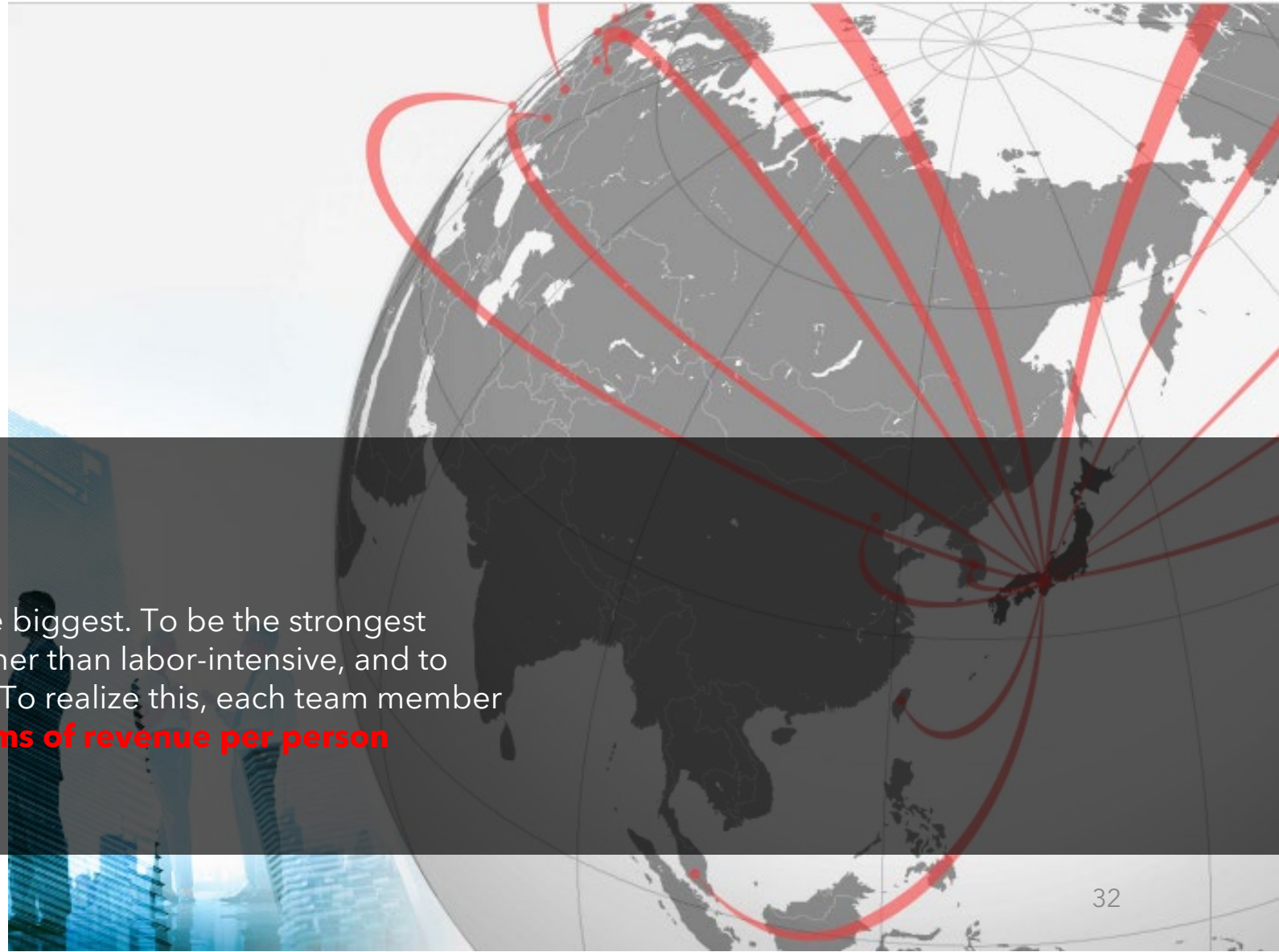
Expansion of disease areas

- We will strengthen collaboration with medical institutions, external experts and partners to conduct high-quality clinical trials in a short period of time in areas where needs for new drug discovery modalities are expanding (rare diseases, ophthalmology, dermatology, etc.) in addition to oncology, central nervous system, and autoimmune diseases.

Expansion of service areas

- For biotech companies that have limited experience and resources in global development compared to major pharmaceutical companies, we will provide high-quality, proposal-based services that meet customer needs quickly and flexibly on a global one-stop basis by strengthening the development of internal expert human resources and the use of external resources through collaboration.

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**