

*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.



First Half of FY 2023 Financial Results Briefing

Friday, November 25, 2022

Linical Co.,Ltd.

TSE Prime 2183

Contents



- | | |
|---|------------|
| 1. Company Overview | P. 2 - 4 |
| 2. Financial Results for the Six Months
Ended September 30, 2022 | P. 5 - 13 |
| 3. Growth Strategy | P. 14 - 39 |

1. Company Overview

Global CRO from Japan

■ Locations of Overseas Bases

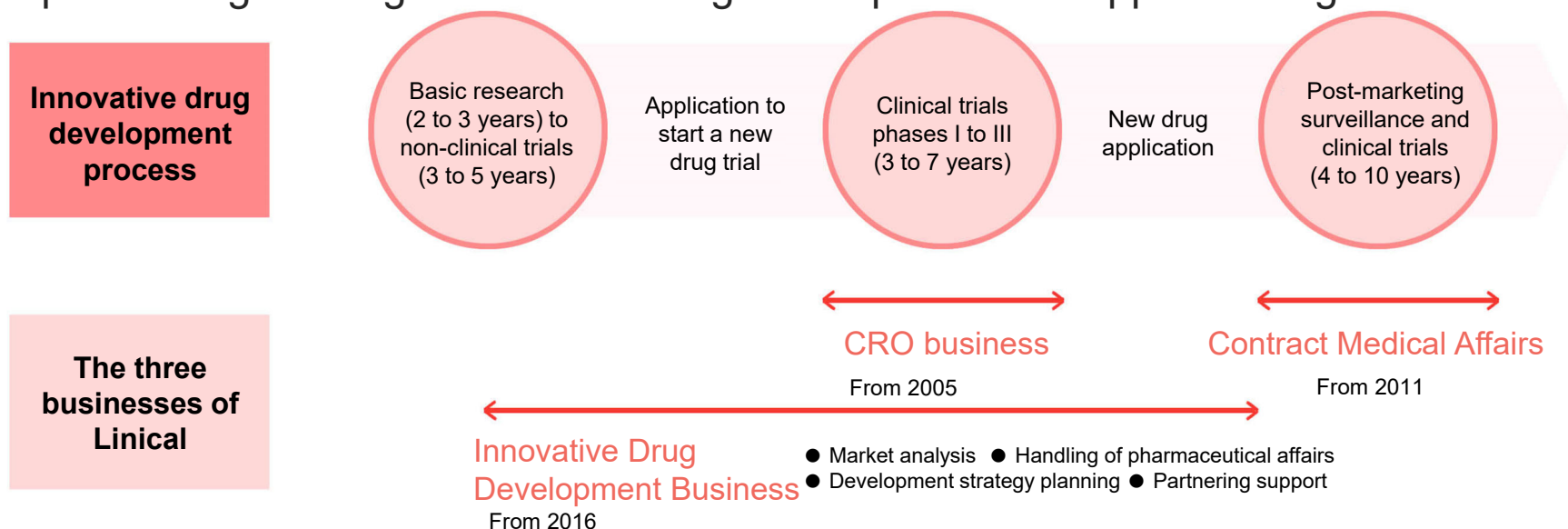


October 2022
Establishment of an
Italian subsidiary

Linical aims to be a **global CRO originating in Japan** and undertakes to new drug development as a drug development professional
We have advanced overseas positively since the founding of the company and currently operate in 18 countries and regions

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.

2 . Financial Results for the Six Months Ended September 30, 2022

Financial Results Highlights for the Six Months Ended September 30, 2022



■ Sales

Year-on-year change

5,920 million yen **+7.2%**

- In addition to increased sales in Europe, sales increased in overseas business due to the weak yen.

■ Operating profit

Year-on-year change

373 million yen **-26.4%**

- Although we recorded an operating loss in the first quarter, business recovered in both the United States and Europe in the second quarter, and we achieved increased profit year-on-year in Europe.

■ Hard backlog

As of November 14, 2022

Compared to the end of the previous period

23,601 million yen **+4.8%**

- Demand for clinical trials among pharmaceutical companies overseas, mainly in Europe and the United States, is vigorous.
- Demand is also tending to increase in Japan.

Consolidated Financial Results

Units: millions of yen, %	FY ending March 2023				
	1Q	2Q	Cumulative total	Sales Ratio	Rate of Changes
Net Sales	2,868	3,051	5,920	-	107.2%
Cost of Sales	2,138	1,941	4,080	68.9%	106.1%
SG&A Expenses	756	710	1,467	24.8%	125.5%
Operating Profit	-26	400	373	6.3%	73.6%
Ordinary Profit	89	524	614	10.4%	123.9%
Net Profit	76	391	468	7.9%	185.6%

- Net sales: Increased
 - Contribution of European business
 - Increased sales in overseas business due to the weak yen
- Operating profit: Decreased
 - We recorded an operating loss in the first quarter. Operating rates declined temporarily due to delays in the commencement of large-scale international clinical trials in Europe and the United States under the impact of the Russo-Ukrainian War, etc.
 - Profit recovered in both the United States and Europe in the second quarter. We achieved increased profit year-on-year in Europe.

Financial Results by Region

Unit: millions of yen	Results for the First Half, FY ending March 2023					
	Net sales **	Year-on- year %	Operating Profit	Year-on- year %	Ordinary Profit	Year-on- year %
Japan	2,912	95.2%	341	125.8%	537	183.4%
United States	1,407	117.8%	42	21.6%	25	13.8%
Europe	1,862	127.8%	120	138.0%	157	219.8%
Korea	408	120.9%	36	57.5%	67	84.2%
Taiwan	63	109.0%	-15	-	-15	-
China	201	106.4%	21	60.2%	14	53.8%
Consolidation Adjustments *	-933	-	-172	-	-171	-
Total	5,920	107.2%	373	73.6%	614	123.9%

* Amortization of goodwill is included in consolidated adjustments. ** Net sales are the figures before deducting internal transactions.

- Japan: Sales decreased and profit increased.
 - Sales decreased due to changes in the timing of commencement of clinical trials due to the sponsor's reasons, etc.
 - Profit increased year-on-year due to strict control of personnel expenses by adjusting the number of employees hired.
- United States: Sales increased and profit decreased.
 - Delays in the commencement of large-scale projects recovered in the second quarter. Sales also increased due to the weak yen.
 - Profit decreased due to a temporary decrease in the personnel utilization rate and an increase in personnel expenses in association with the abovementioned delays.
 - The utilization rate improved in the second quarter.
- Europe: Both sales and profit increased.
 - We digested the strong orders of the previous fiscal year and made great progress in the second quarter even in the abovementioned delayed clinical trials.

Situation by Segment



■ CRO business * Including Innovative Drug Development Business

Year-on-year change			Year-on-year change				
Net Sales	5,468	million yen	+6.4%	Operating Profit	1,014	million yen	-14.8%

■ Contract Medical Affairs

Year-on-year change			Year-on-year change				
Net Sales	451	million yen	+17.7%	Operating Profit	164	million yen	+30.1%

Sales and profit in the contract medical affairs business increased significantly compared to the same period of the previous fiscal year.

[1] Multiple orders received in the previous fiscal year started operation in earnest.

[2] Contract changes occurred in association with additional workloads, extension of registration period, etc., on multiple projects.

Balance of Goodwill and Remaining Amortization Period (As of March 2022)



Units: Millions of yen	Amount	Remaining Amortization Period	Annual Amortization * 4
KOREA	Termination of depreciation in FY 2019		
EUROPE ※1※2	1,349	11 – 12	120
USA ※1※3	2,056	12	171

*1 Goodwill generated by the acquisition of Linical Accelovance America, Inc. (hereinafter LAA) has been apportioned pro rata to its European subsidiary EURORE.

*2 Aside from goodwill, intangible assets recognized by purchase price allocation had a balance of 84 million yen at the end of the fiscal year ended March 2022.

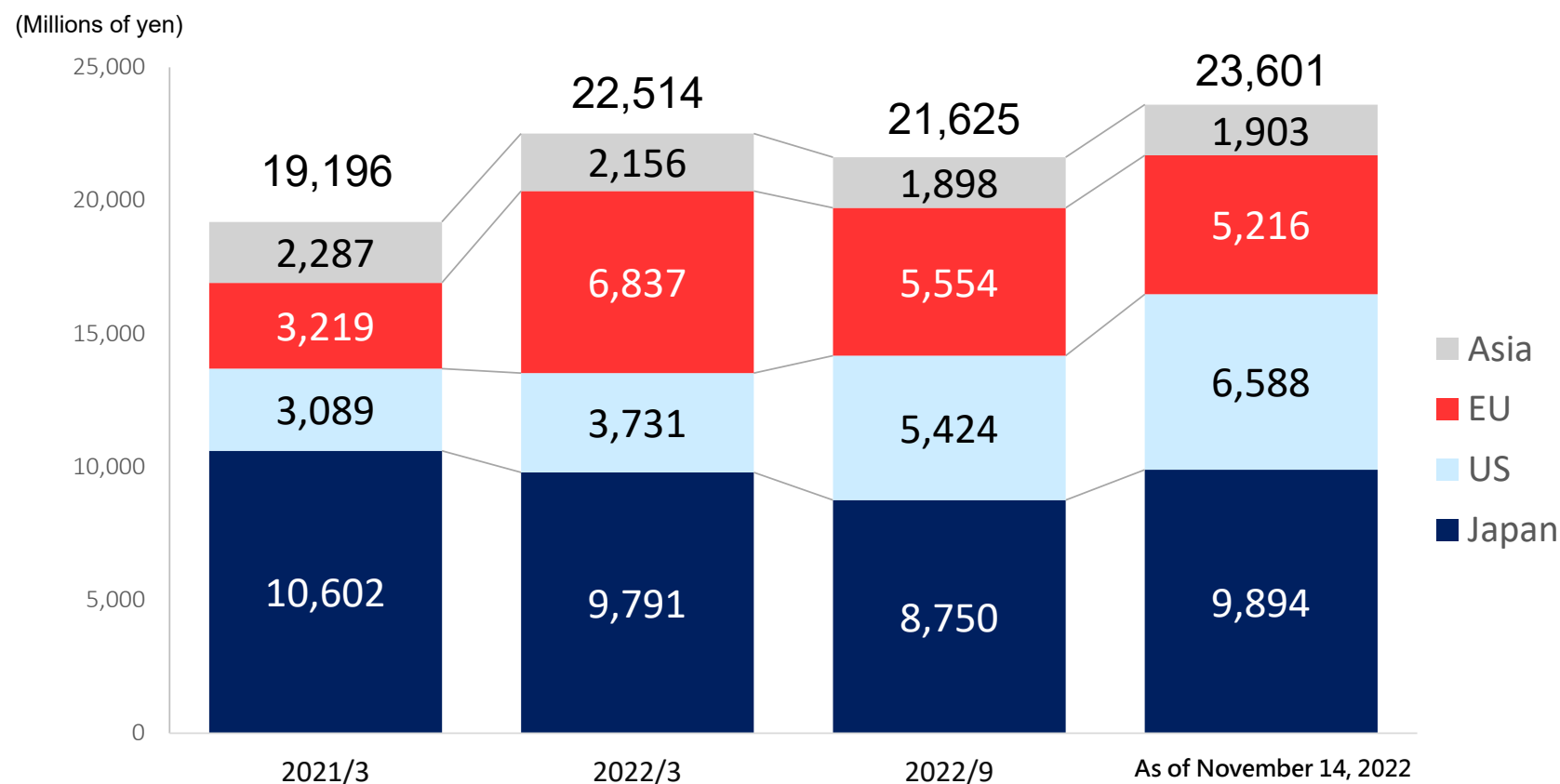
Their remaining periods for amortization range from five to nine years.

*3 Aside from goodwill, intangible assets recognized by purchase price allocation had a balance of 46 million yen at the end of the fiscal year ended March 2022.

Their remaining period for amortization is five years.

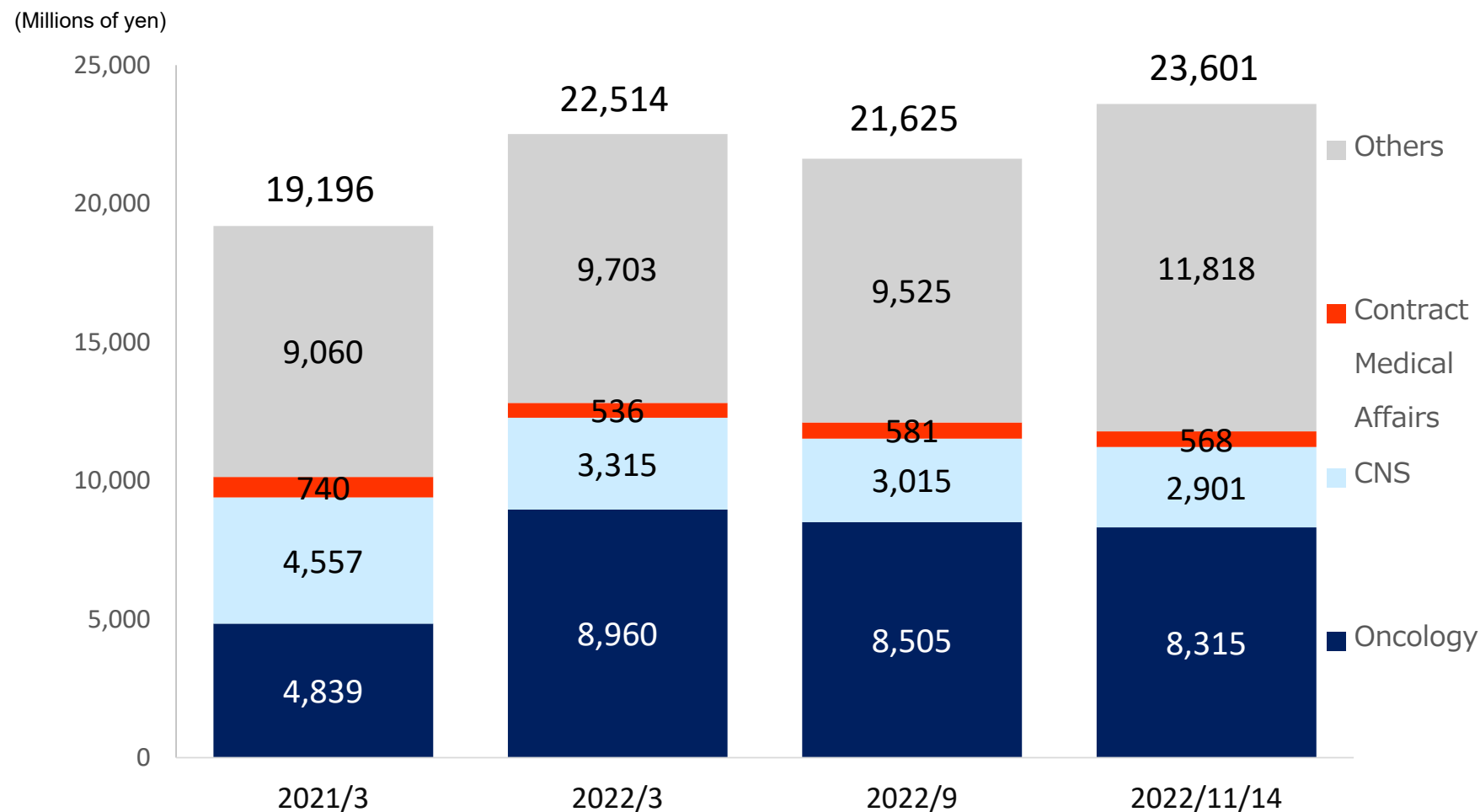
*4 Figures have been converted at the exchange rate as of the end of the fiscal year ended March 2022.

Hard Backlog by Region



The hard backlog remains at a high level of more than 20,000 million yen.

Hard Backlog by Therapeutic Focus



Forecasts for the Current Fiscal Year (No Change)

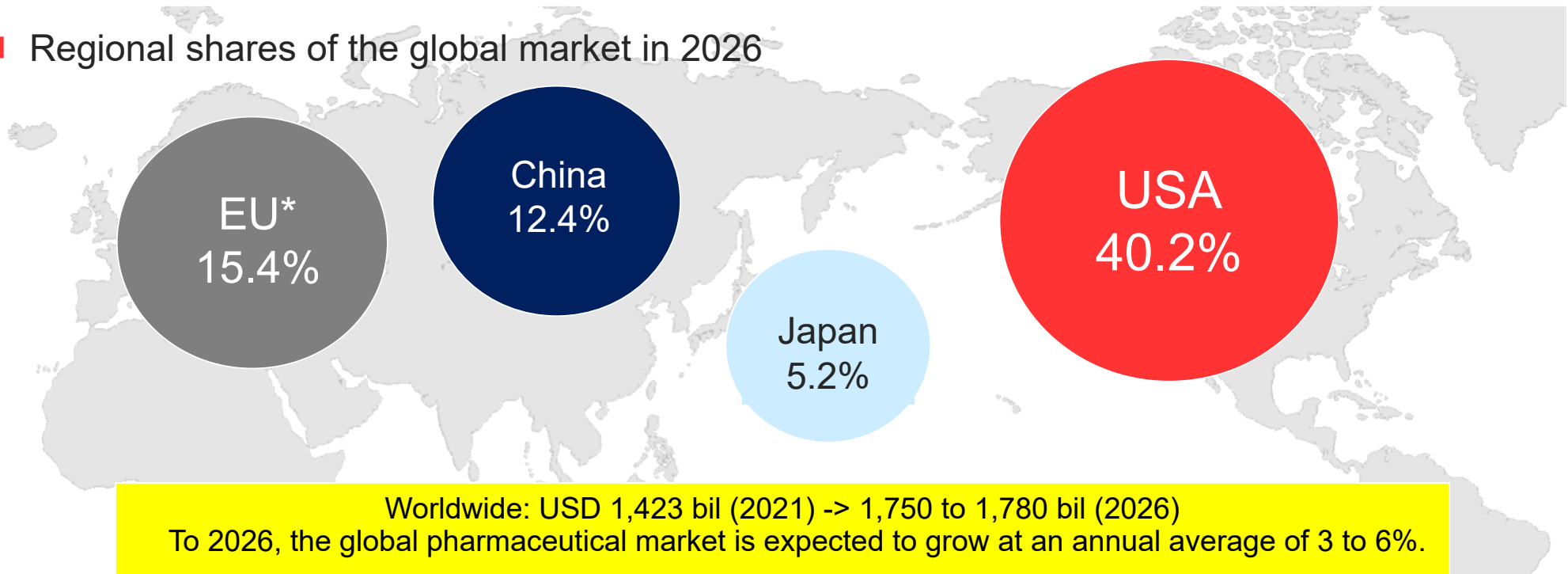
Unit: millions of yen	FY Ended March 2022 Results		FY Ending March 2023 Forecasts		
	Amount	Sales Ratio	Amount	Sales Ratio	Rate of Change
Net Sales	11,555	-	12,440	-	7.7%
Operating Profit	1,085	9.4%	1,224	9.8%	12.7%
Ordinary Profit	1,183	10.2%	1,204	9.7%	1.7%
Net Profit	790	6.8%	871	7.0%	10.2%
	Amount (yen)	Payout ratio	Amount (yen)	Payout ratio	
Dividend per share	14	40.0	14	36.3	

- Acceleration of recorded sales due to the thorough implementation of the progress management of orders, early conclusion of contracts and start of work on informally agreed projects, and increase in sales due to the acquisition of new projects currently under negotiation
- We are controlling labor costs and expenses strictly in accordance with orders.

3. Growth Strategy

Global Pharmaceutical Market Size in 2026 (Latest Forecast)

■ Regional shares of the global market in 2026



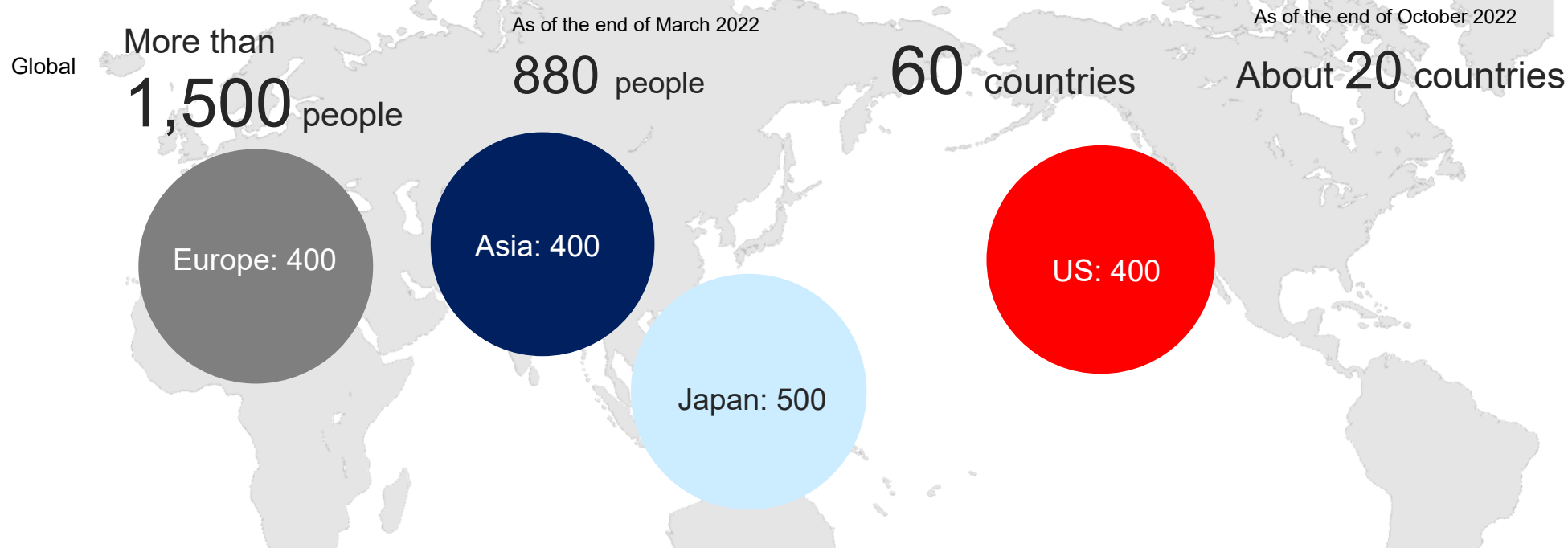
The global CRO market is also expected to grow in association with the expansion of the pharmaceutical market.
Japan is the only developed country with a forecast for negative growth.
Business expansion globally, including the United States, the largest market, is essential.

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

Expansion of Our Business (2nd targets)

■ Number of employees

■ Number of countries where we do business



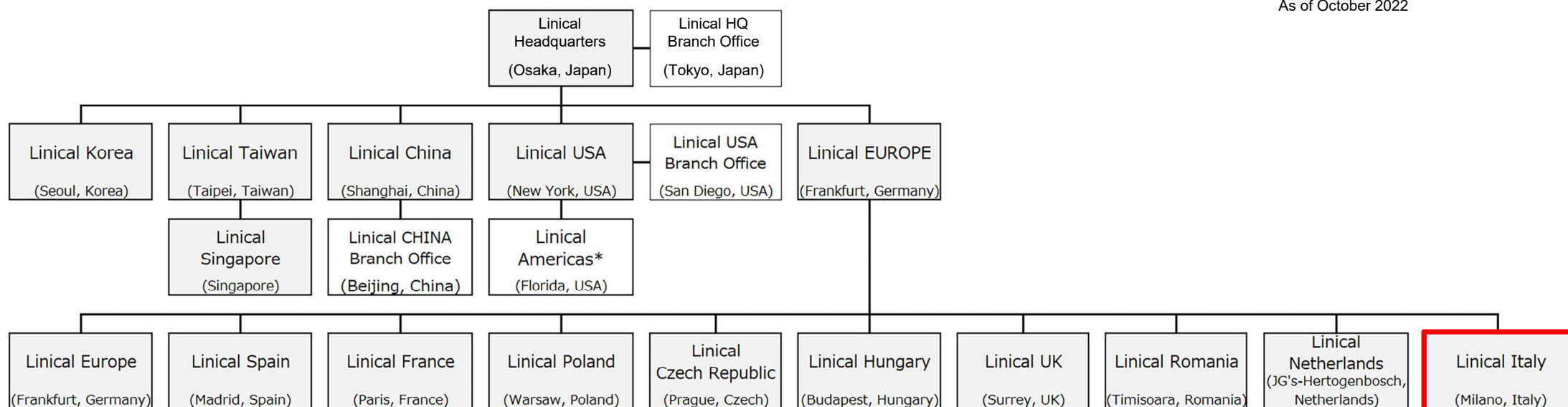
- 2nd targets
- [1] 500 people in Japan, 400 people in Asia, 400 people in Europe, 400 people in the United States
=> Building of a framework with more than 1,500 people
 - [2] Maintenance of profitability and improvement of profit margins while investing in growth
(including M&A) in each region
 - [3]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

Progress in Expansion of the System

• Establishment of a subsidiary in Italy (October)

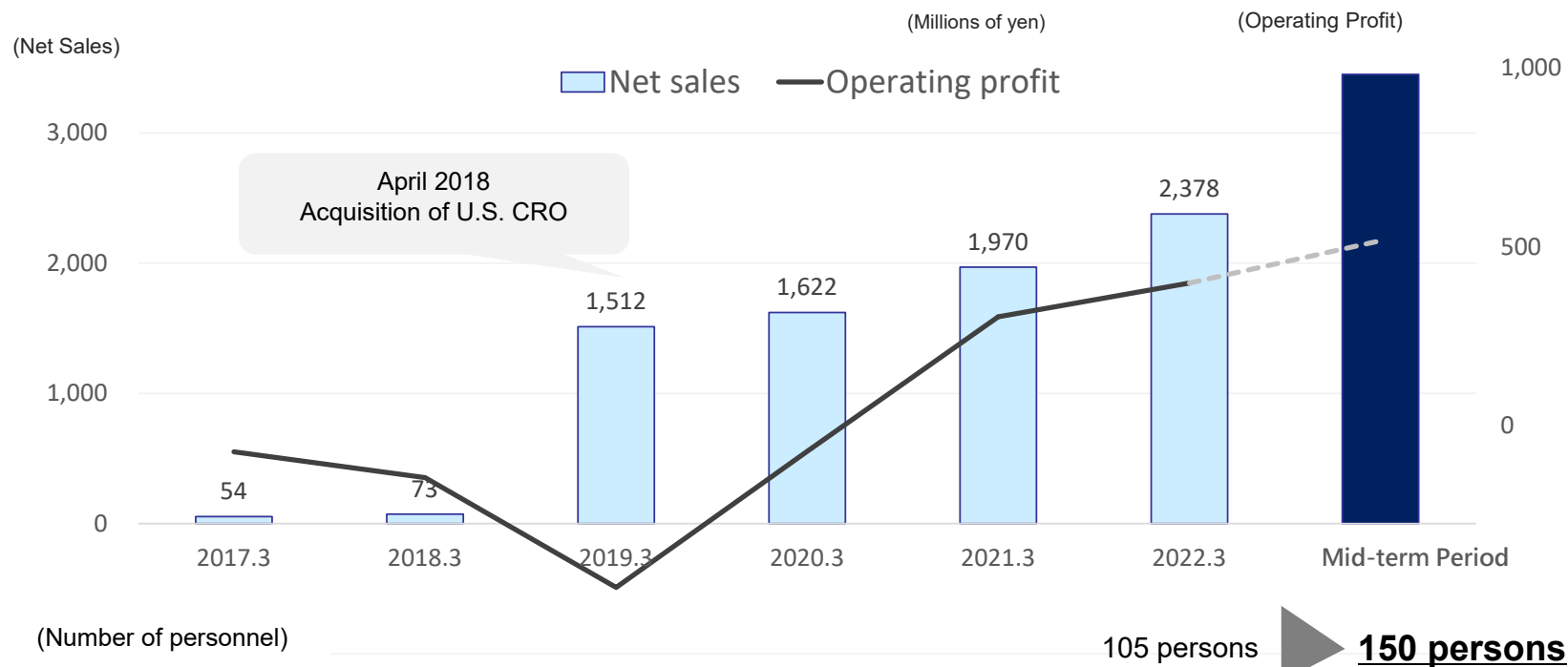
We are strengthening our European business foundations towards the achievement of our medium to long-term goal of 400 employees and sales of 30 million euros in Europe overall.

As of October 2022



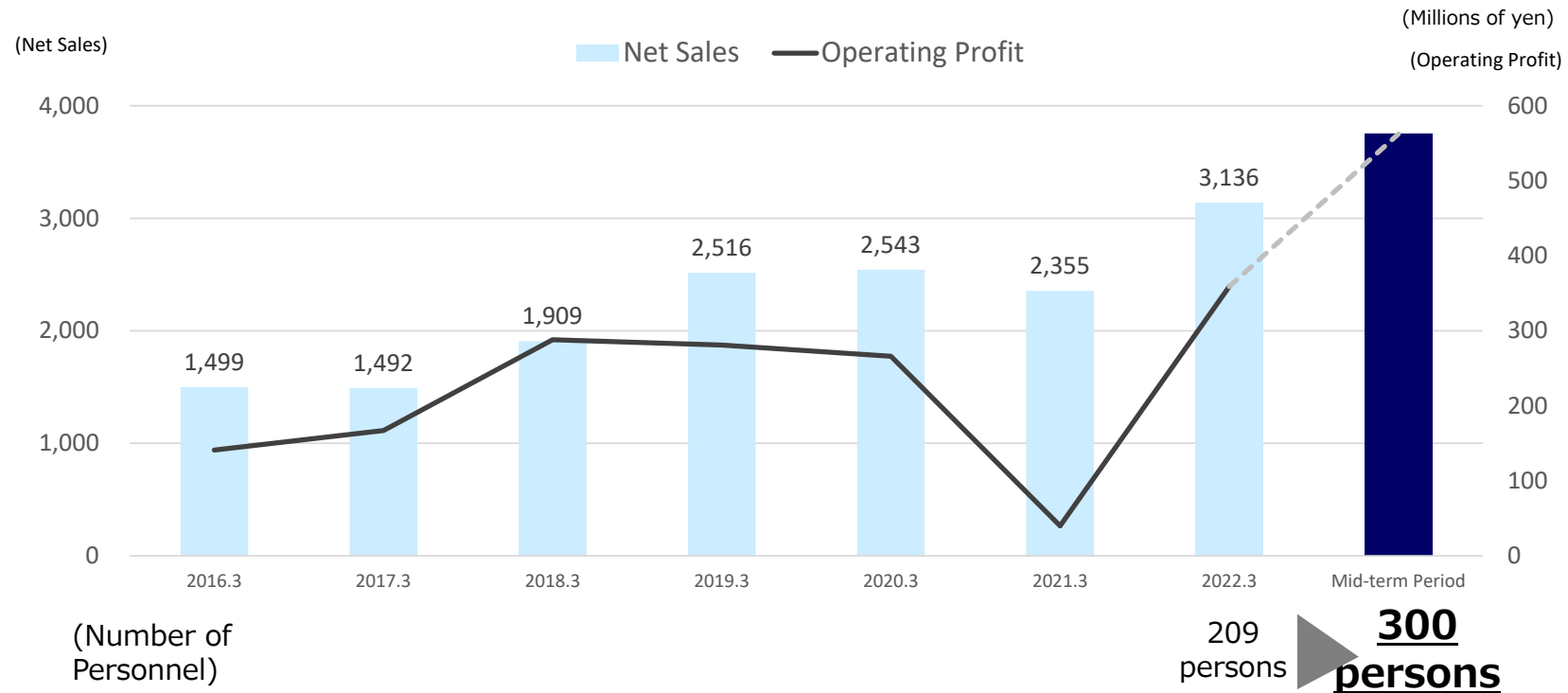
* Linical Americas is the trade name of Linical Accelovance America, Inc.

Strategies by Region: US



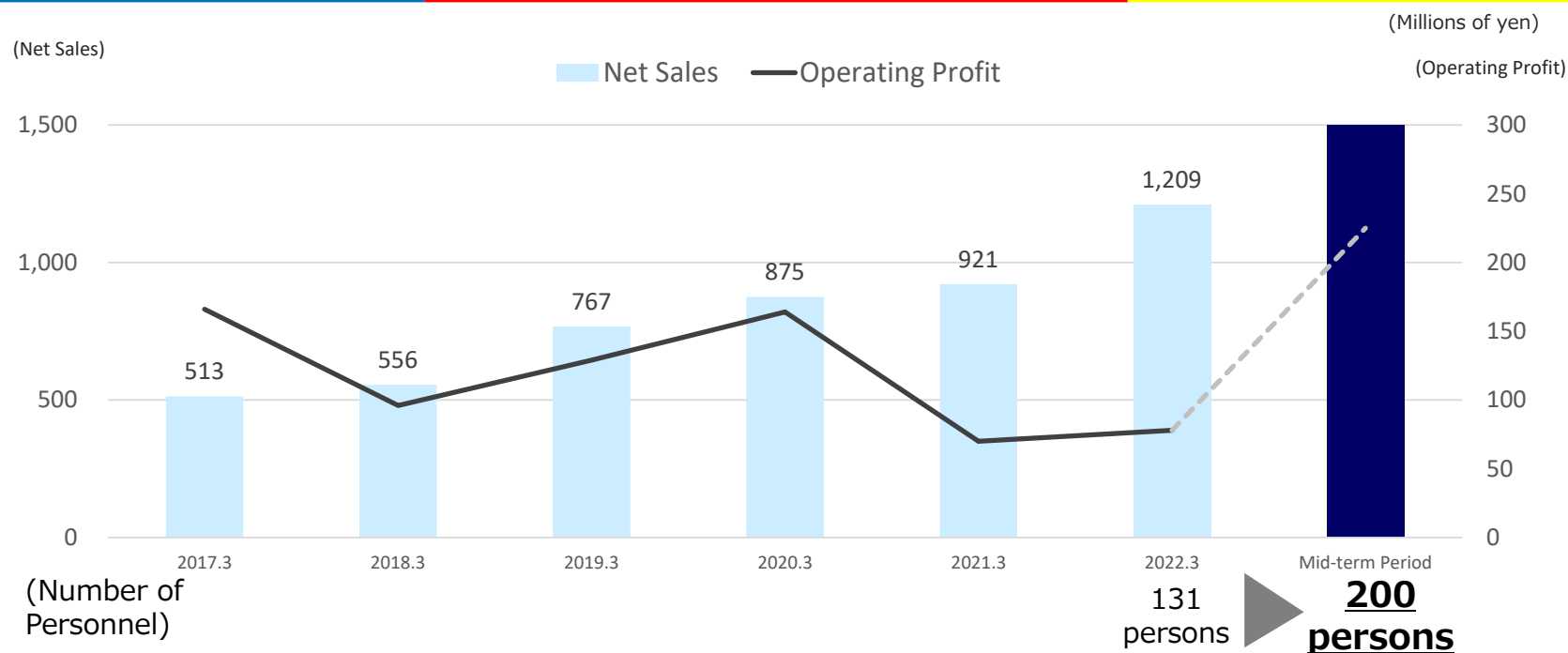
- We acquired Accelovance (USA) in April 2018, returned to profitability the following fiscal year and grew steadily even during the COVID-19 pandemic.
- Results targets: Sales USD 30 million, operating profit margin 15%
- Personnel strategy: **We will aim for a 400-person framework in the long term.** We will consider the use of M&A
- Customer strategy: We are aiming at emerging biopharma companies (EBP) that have appeared overseas.

Strategies by Region: Europe



- Orders increased in the fiscal year ended March 2022 as a result of strengthening sales division, and we achieved significant increases in both sales and profit by improving operating rates.
- Results targets: Sales EUR 30 million, operating profit margin 15%
- Personnel strategy: We will consider internal development or use of M&A for a **400-person framework in the long term**.
- Expansion strategy: We are planning to expand in the UK and establish a base in Italy.

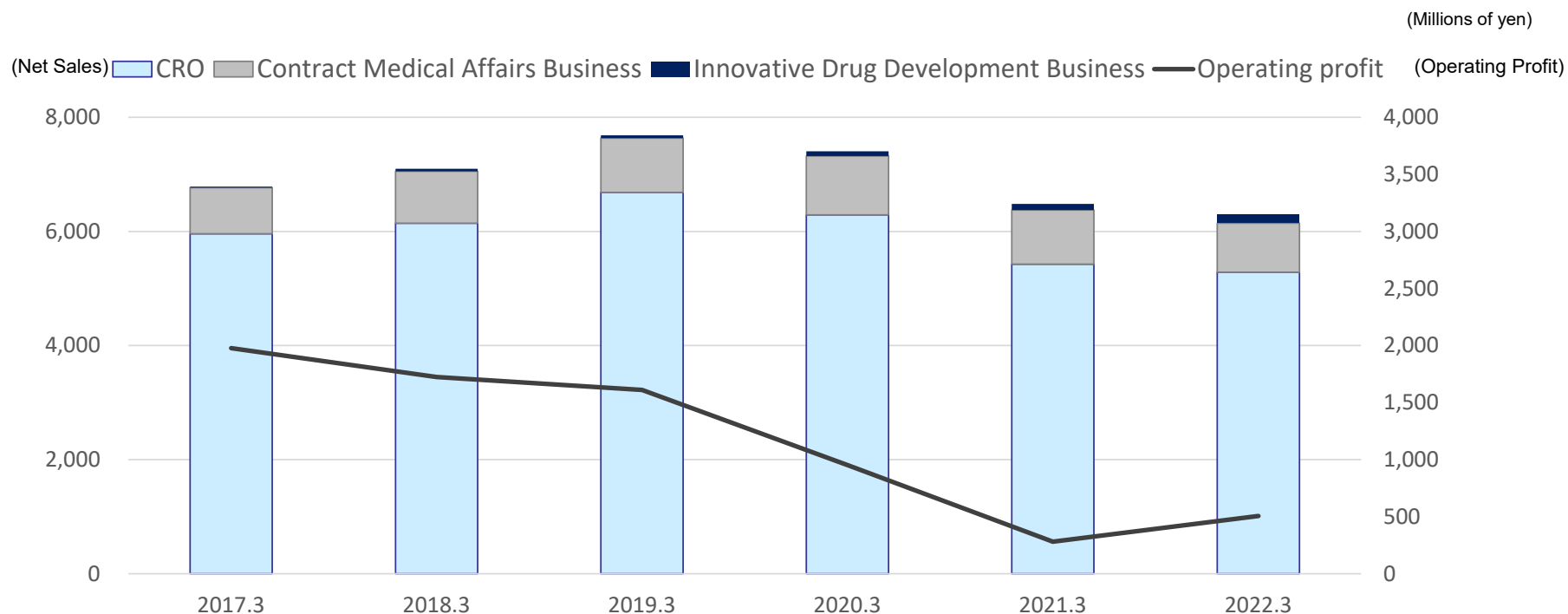
Strategies by Region: Asia



- Both sales and profit increased in South Korea and the region recorded its highest ever sales and operating profit in the fiscal year ended March 2022. Sales also increased in China, but operating income decreased due to advance investments in human resources, etc.
- Results targets: Sales 1.5 billion yen, operating profit margin 15%
- Personnel strategy: We will consider expansion through internal development for a **400-person framework** in the long term.
- Expansion strategy: We will advance development of the Chinese market.

*Operating income from the FY ended March 2017 to the FY ended March 2019 is the amount before amortization of goodwill borne by the Korean business. Goodwill arising from the acquisition of a subsidiary in Korea was fully amortized in fiscal 2019.3.

Strategies by Region: Japan



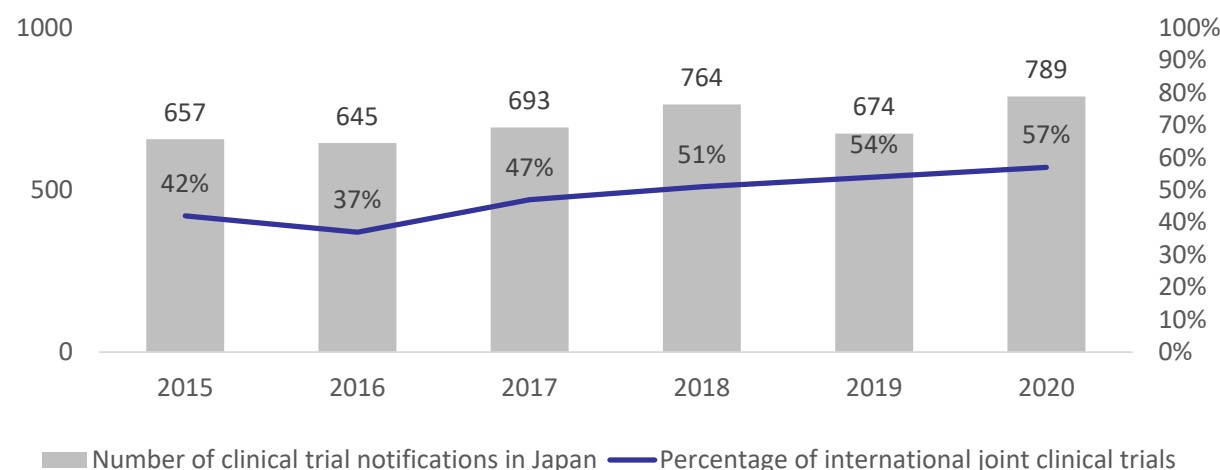
- Although sales decreased from the fiscal year ended March 2020 under the impact of the spread of COVID-19 infections, profit increased in the fiscal year ended March 2022 as a result of controlling costs and conducting lean operations.
- Sales are expected to decrease and profits to increase in the fiscal year ending March 2023 as well.

Strategies by Region: Japan

■ Market environment in Japan

- The number of clinical trials remained flat.
- The proportion of international clinical trials increased.

Trend in the number of clinical trials in Japan



■ Priority items

- Acquisition of Japanese trials in international clinical trials based on expansion of our global CRO business foundations.
- Innovative Drug Development Business : Making it our third pillar
- CRO business: Expansion of target customers, disease areas and services
- Contract Medical Affairs business: Grasp environmental changes and position on growth trajectory again

Source: PMDA "Trend in the number of pharmaceutical clinical trial protocol notifications"

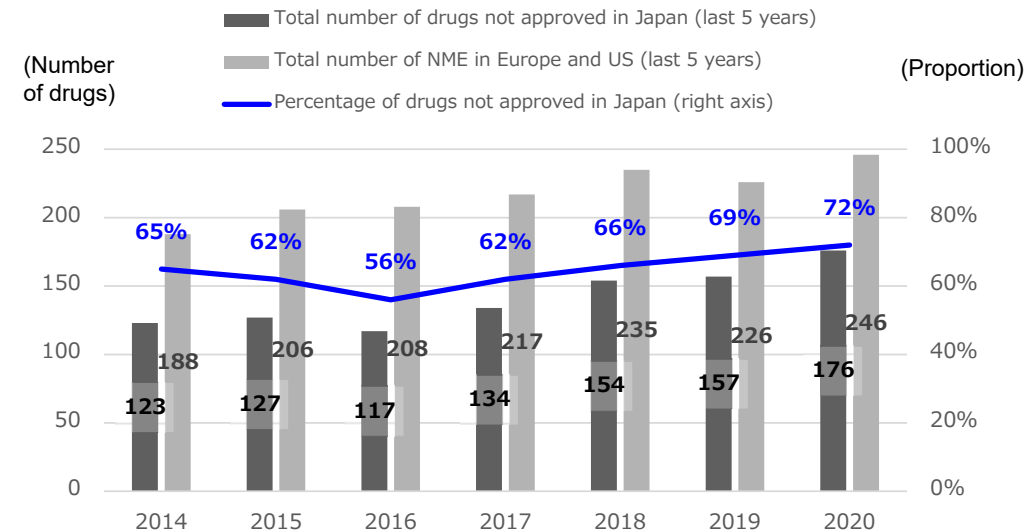
From Drug Lag to Drug Loss

■ What is “drug lag”?

Drug lag is a problem where **it takes a long time** for a drug that has already been approved overseas **to receive pharmaceutical approval in Japan**. It is thought to have two aspects.

1. The problem of "lag" (delay) whereby the time required for approval of drugs marketed in Japan is longer than in other countries => **tending to decrease**
2. The problem of “**drugs not approved in Japan**” that are sold in other countries, but not in Japan => **tending to increase**

Annual trend in the number and proportion of unapproved drugs in Japan (past 5 years)



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

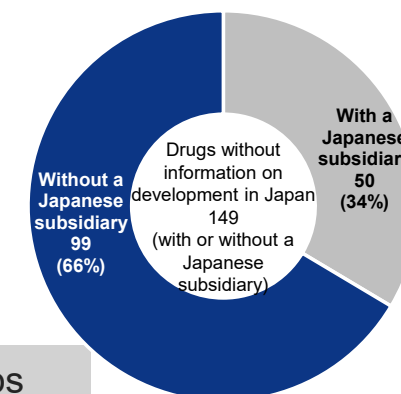
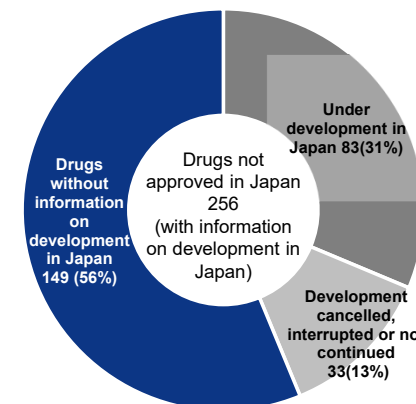
The number and proportion of unapproved drugs in Japan are tending to increase. There are also concerns about “drug loss,” whereby new drugs from overseas do not enter Japan.

State of Drugs Not Approved in Japan

- From survey results of the Office of Pharmaceutical Industry Research
Subjects: Drugs containing new molecular entities (NMEs) approved in Japan, the United States, and Europe from 2010 to 2020
- As of the end of 2020, **72%** of the number of NMEs approved in the United States and Europe over the last five years were **drugs not approved in Japan**.
- Clinical development is being carried out in Japan for 44% of the drugs not approved in the country.

There is no information on development in Japan for the remaining 56%, and it is possible that development is not being implemented.

- Of the drugs for which no information on development in Japan is available, **66%** were developed in Europe and the United States by overseas companies without a Japanese subsidiary (37% of drugs not approved in Japan).



The number of drugs approved in Europe and the United States developed by overseas start-ups without an office in Japan is increasing, and it is possible they may bypass the Japanese market.
How will emerging biopharma companies in Europe and the United States be attracted to development in Japan?

Various Background Issues Have Been Pointed Out

■ 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.

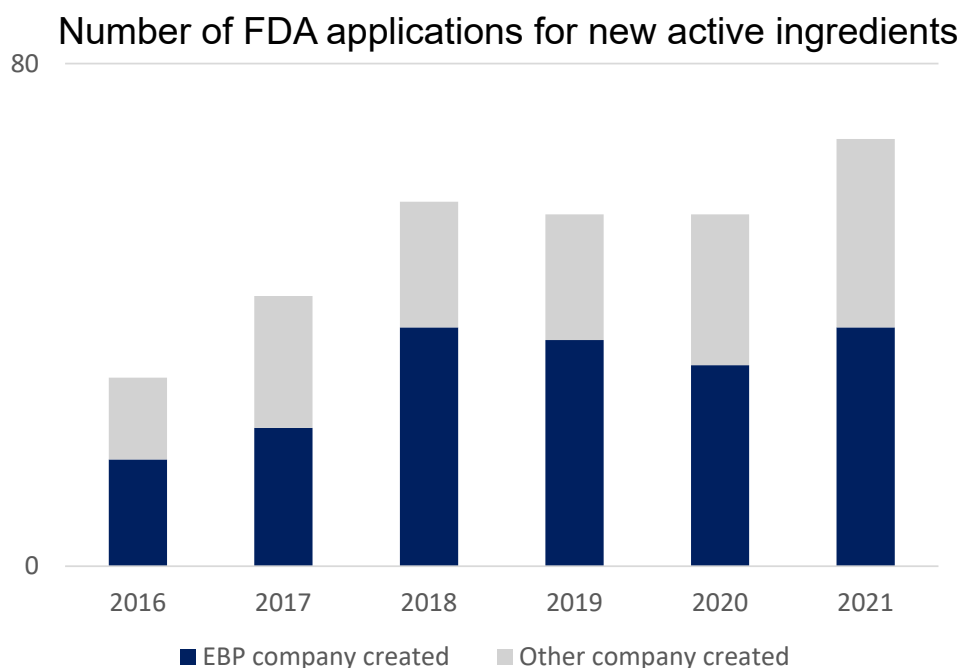
■ The special pharmaceutical affairs and clinical trial environment

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.

and various other issues

The Appearance of EBP Companies Overseas

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



65%

The percentage of the global pipeline of new drug development (phase 1 (P1) clinical trials to approval applications) in 2021 by EBP companies.

It is tending to increase year by year.

Drug approvals for foreign start-ups and other companies that do not have offices in Japan are increasing.

There are also concerns over the possibility that the Japanese market will be bypassed.

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

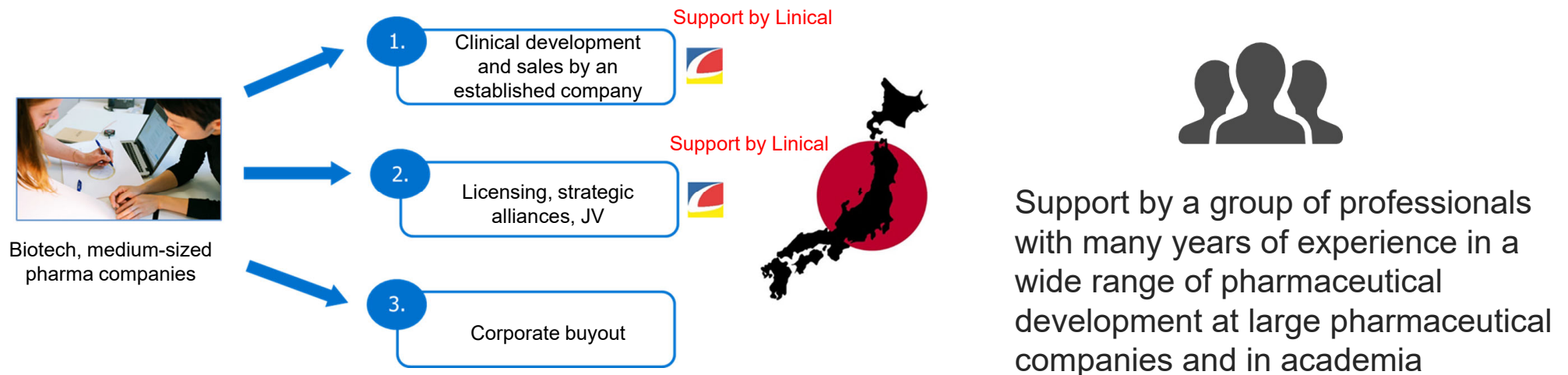
Innovative Drug Development Business as an Entry Point to the Japanese Market

■ Needs for Innovative Drug Development Business

Japanese and overseas biotech ventures, medium-sized pharma companies

Who 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



Mission as a Global CRO Originating in Japan

- In addition to supporting the launch in Japan of overseas start-ups through Innovative Drug Development Business, we also support the integration of Japan into the global trials of European and American companies and the development of new treatment methods such as apps so that Japanese patients can receive cutting-edge treatment.

Although it is difficult for a single company to solve all problems, Linical will work continuously as a global CRO originating in Japan to prevent drug loss in Japan.

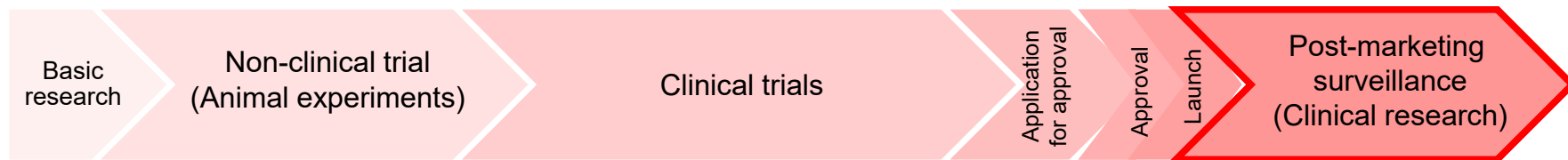
Expansion of Target Customers, Disease Areas and Services

	Customer	Disease area	Services
Initial stage	Large pharmaceutical companies in Japan	Oncology	Monitoring
		Neurology	
		Immunology	
Currently	Large pharmaceutical companies in Japan	Oncology	Monitoring
	Large pharmaceutical companies overseas	Neurology	Project management
	Bio-ventures in Japan and overseas	Immunology	Quality Control/Auditing
		Ophthalmology	Data management
		Dermatology	Medical writing
		Regenerative medicine	Pharmacovigilance, etc.

In the aging society of the future, we will lead work in areas where expansion can be expected, such as **ophthalmology and dermatology, which are directly linked to QOL, regenerative medicine with new modalities, and therapeutic applications.**

Changes in the Clinical Trial Market

■ What are the studies carried out after the manufacture and sale of drugs?



Studies are implemented to survey and research the safety and efficacy of drugs while **they are actually being administered to patients**.

They use **real-world data (RWD)** collected in everyday clinical environments, unlike clinical trials conducted in a controlled environment.

Various types of everyday patient data

- Electronic medical records
- Medical expense statements (medical payment information)
- Medical examinations
- Wearable devices, etc.

The use of real world data in drug development is becoming more active.

The Merits of Using Real World Data

■ The Merits of Using Real World Data



Greater efficiency of the drug development process



Reduction of the burden on healthcare facilities



Promotion of the development of areas where the implementation of randomized controlled trials (placebos) for rare and intractable diseases, etc., is difficult

■ Issues for use

In addition to restrictions on access to medical data, the standardization of data, consolidation of data, etc.,

ensuring the quality of data for use in approval applications

Increased need for outsourcing to CROs is expected in association with changes in post-marketing studies.

State of Use of Real World Data

■ Regulatory movements in Japan, the United States and Europe

Europe (EMA)	United States (FDA)	Japan (PMDA)
<ul style="list-style-type: none"> 40% of initial manufacturing and marketing approvals for products on the market include RWE. Activities aimed at using RWE and establishing its value in regulatory decision-making on drug development, approval and supervision in Europe by 2025 are progressing. 	<ul style="list-style-type: none"> The 21st Century Cures Act was passed in 2016. The focus is on using RWD and RWE to support regulatory decision-making on additional drug indications. Various guidance on use has been prepared. 	<ul style="list-style-type: none"> The RWD WG was established in 2021. The basic thinking on the use of RWD and on securing its reliability are currently under consideration. A system for use in applications for drug approval and reexamination of registry data, etc., is being built (face-to-face advice on registry databases, etc.). An application for an additional indication was recently approved with specific TS-1 clinical research data.

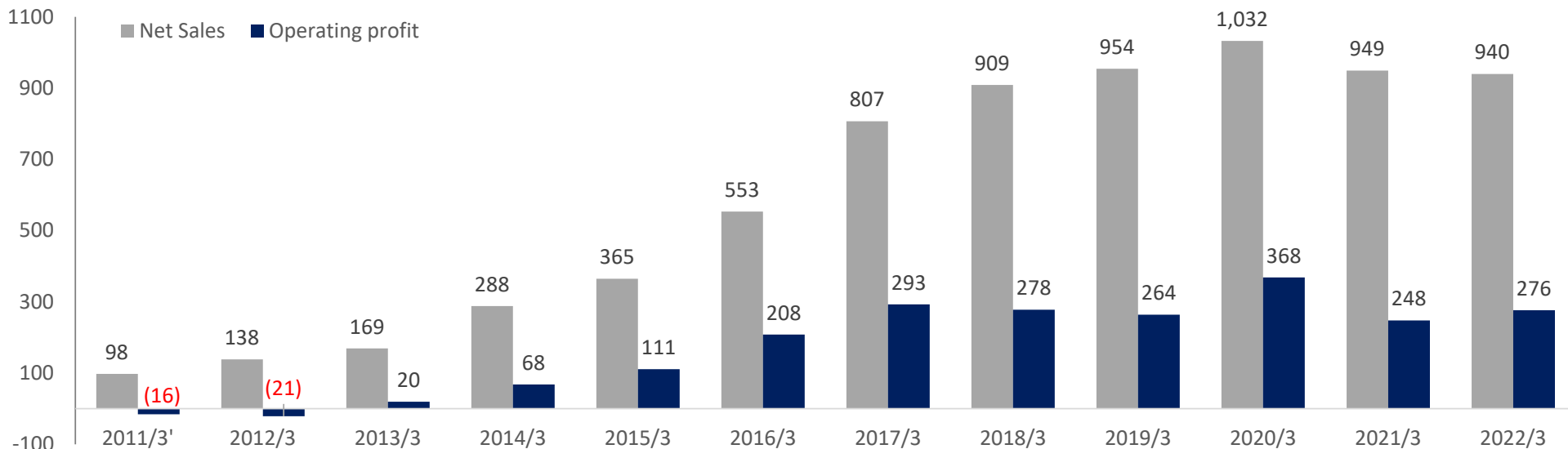
Use of real-world data is currently progressing globally.

Linical's Contract Medical Affairs Business Is a Pioneer of Clinical Research Support.



- Linical started supporting large-scale clinical research as a pioneer of clinical research support in 2011.
- We have accumulated results in various forms of research, including [large-scale interventional clinical research](#) (later specified clinical research) at more than 250 institutions and [global clinical research in Japan, Taiwan and Korea](#).
- Collaboration with global organizations also enables implementation in a framework matched to global needs.

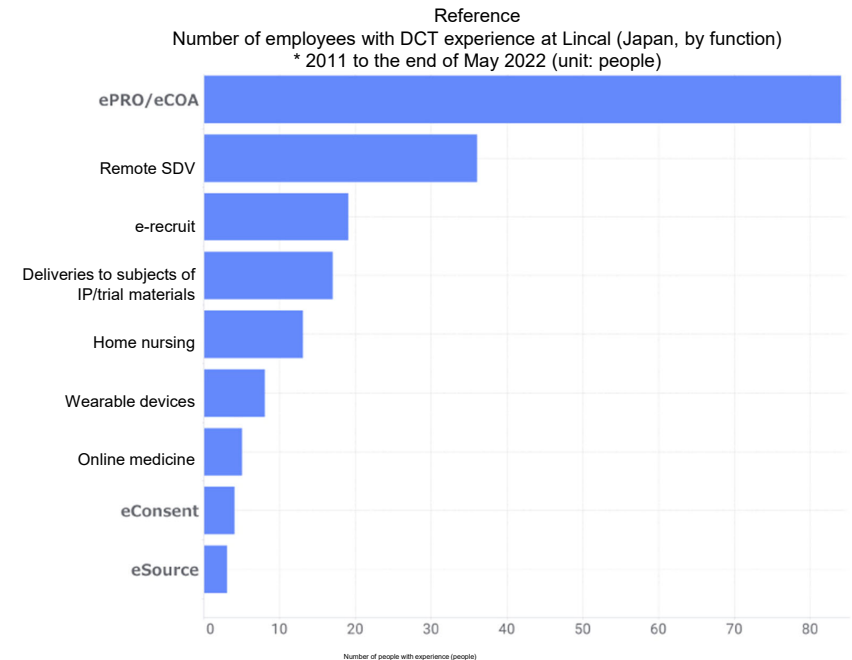
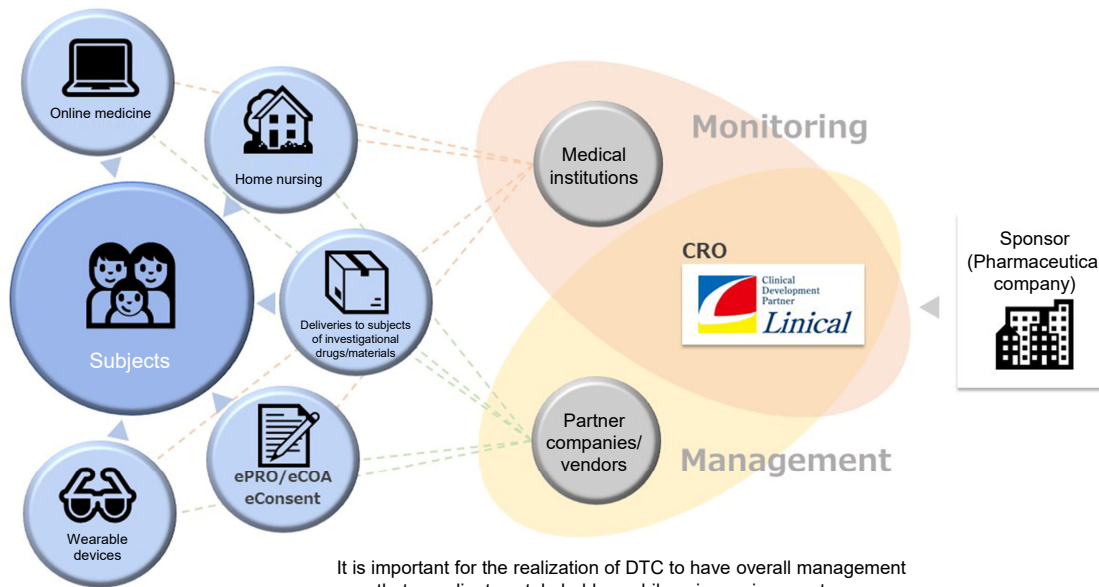
(Millions of yen)



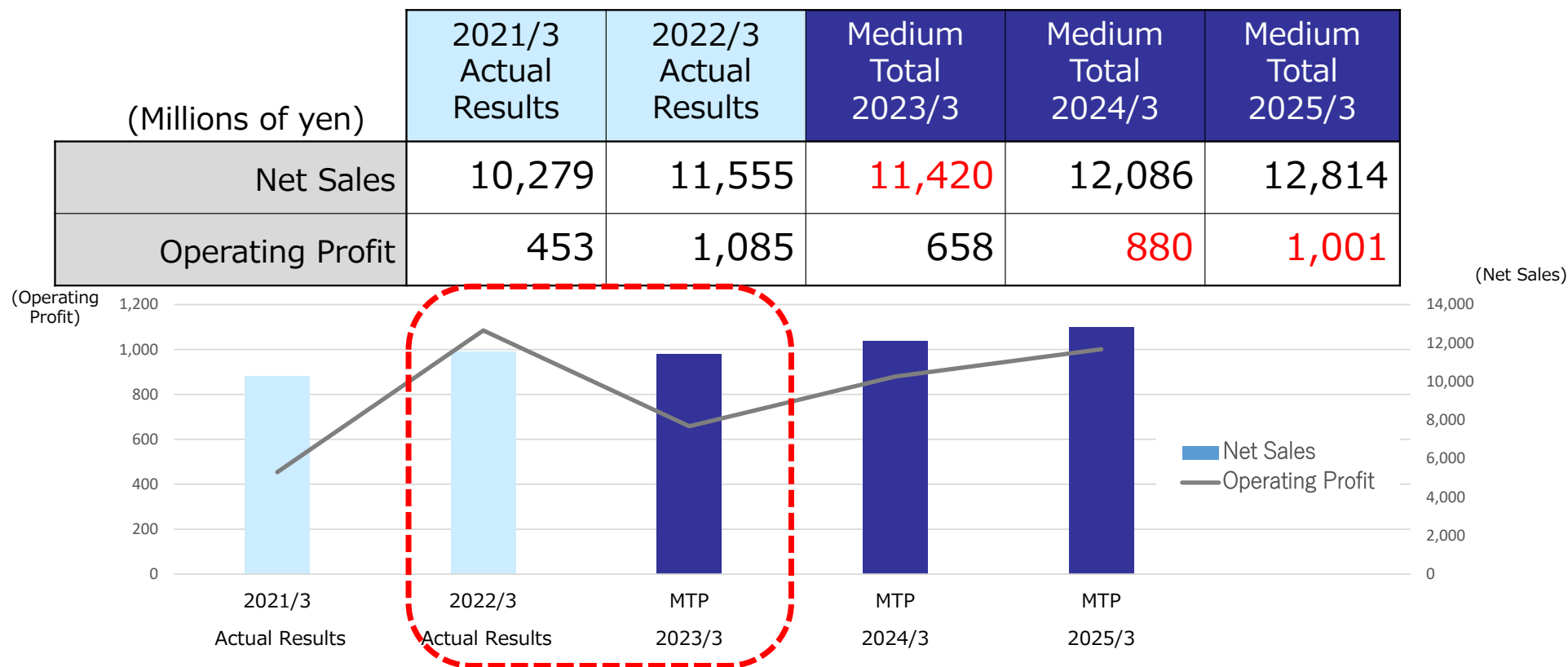
We will take changes in the market environment as a business opportunity and return to a growth path again

Handling of DCTs

- We are also promoting initiatives for decentralized clinical trials (DCTs) using e-sources such as wearable devices.
- We are currently expanding our DCT partners in Japan and overseas.



Med-Term Business Plan and Current Performance



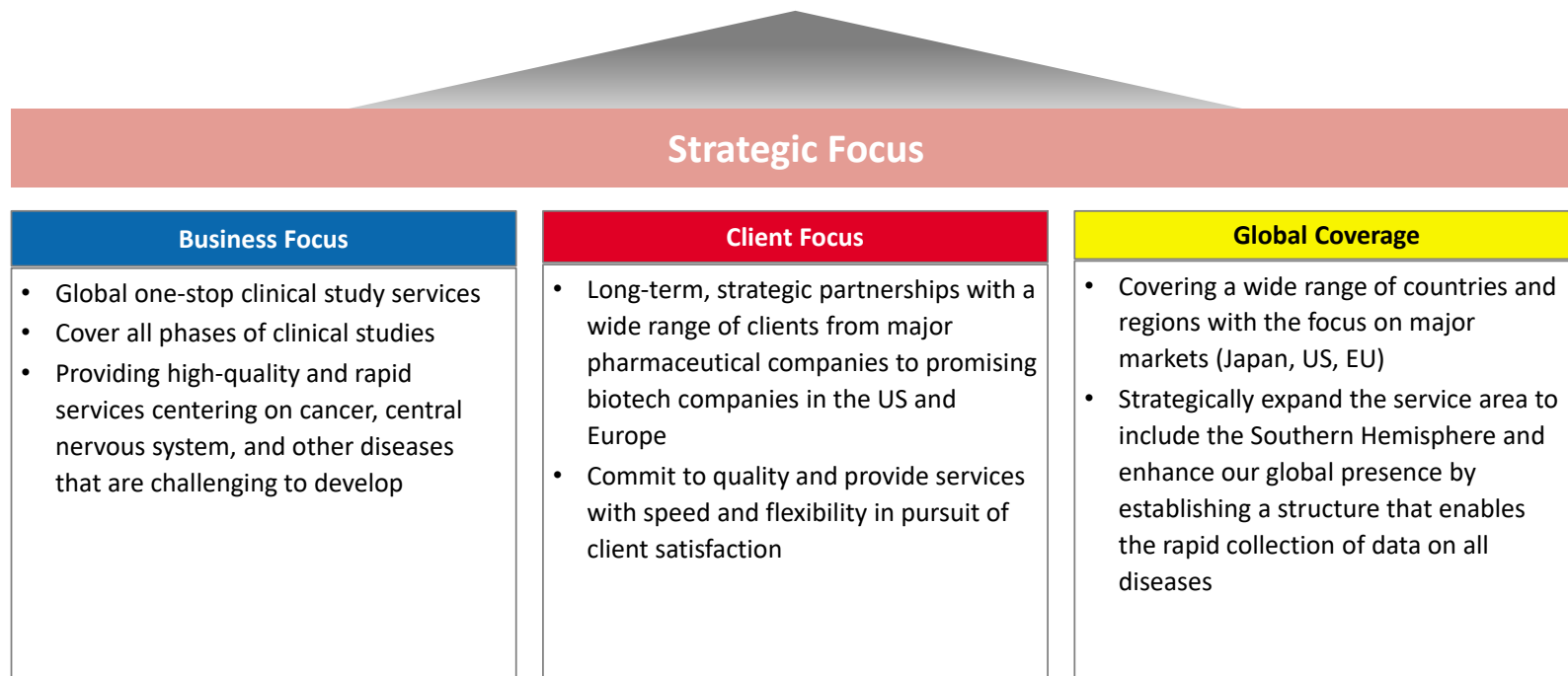
We achieved the medium-term management plan targets for sales for the fiscal year ending March 2023 and operating profit for the fiscal year ending March 2025 ahead of schedule in the fiscal year ended March 2022. We will review the plan and aim for improvements in corporate value over the medium to long-term based on sustainable growth and the improvement of profitability

Med-Term Management Vision/Goals for Complying with Listing Criteria

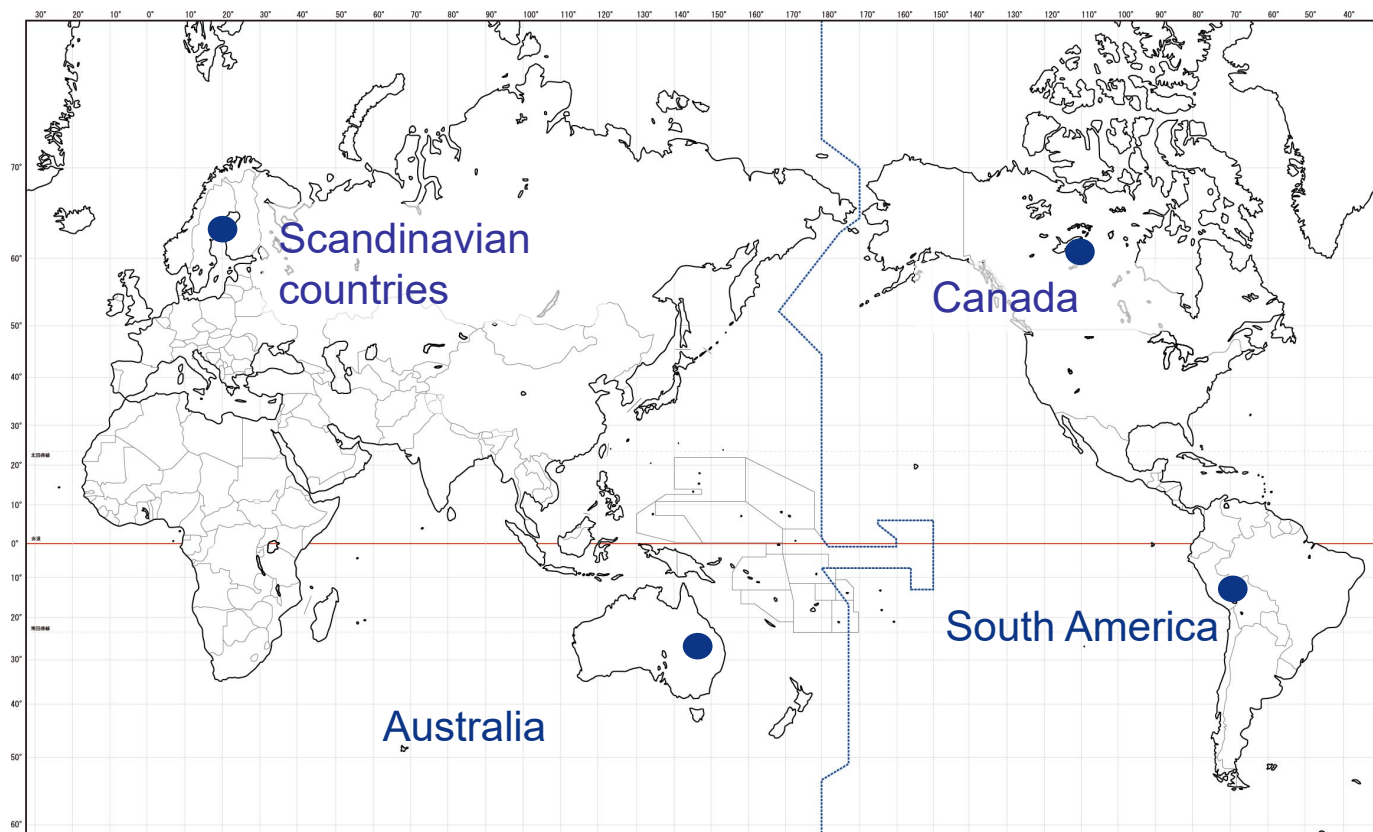


To be the global-leading CRO originating in Japan & a strategic partner for our global clients

Become Japan's first strategic partner as a global CRO



Potential Areas for Further Expansion



We will consider expanding the areas we cover in Japan, the United States and Europe while taking time differences into account.

By having a base in the southern hemisphere, we would be able to implement clinical trials on seasonal diseases throughout the year.

Aiming for the Strongest CRO

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.

(Appendix) About Linical

Corporate Profile

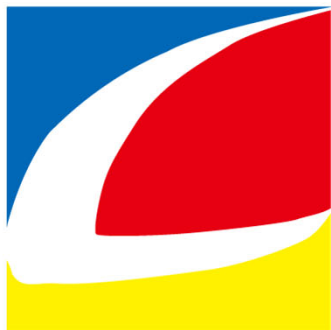


■ Company name	Linical Co.,Ltd. (TSE Prime 2183)
■ Head Office	1 -6 -1 Miyahara, Yodogawa-ku, Osaka
■ Establishment	June 7, 2005
■ Representative	Kazuhiro Hatano, President and CEO
■ Capital Stock	214 million yen
■ Business Description	Clinical Research & Development (CRO) business and Contract Medical Affairs Business
■ Number of Employees	843 (417 in Japan and 426 overseas) * As of March 31, 2022
■ Number of Consolidated Subsidiaries	19 companies (all overseas)

Linical aims to be a **global CRO originating in Japan** and contributes to new drug development as a drug development professional

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.

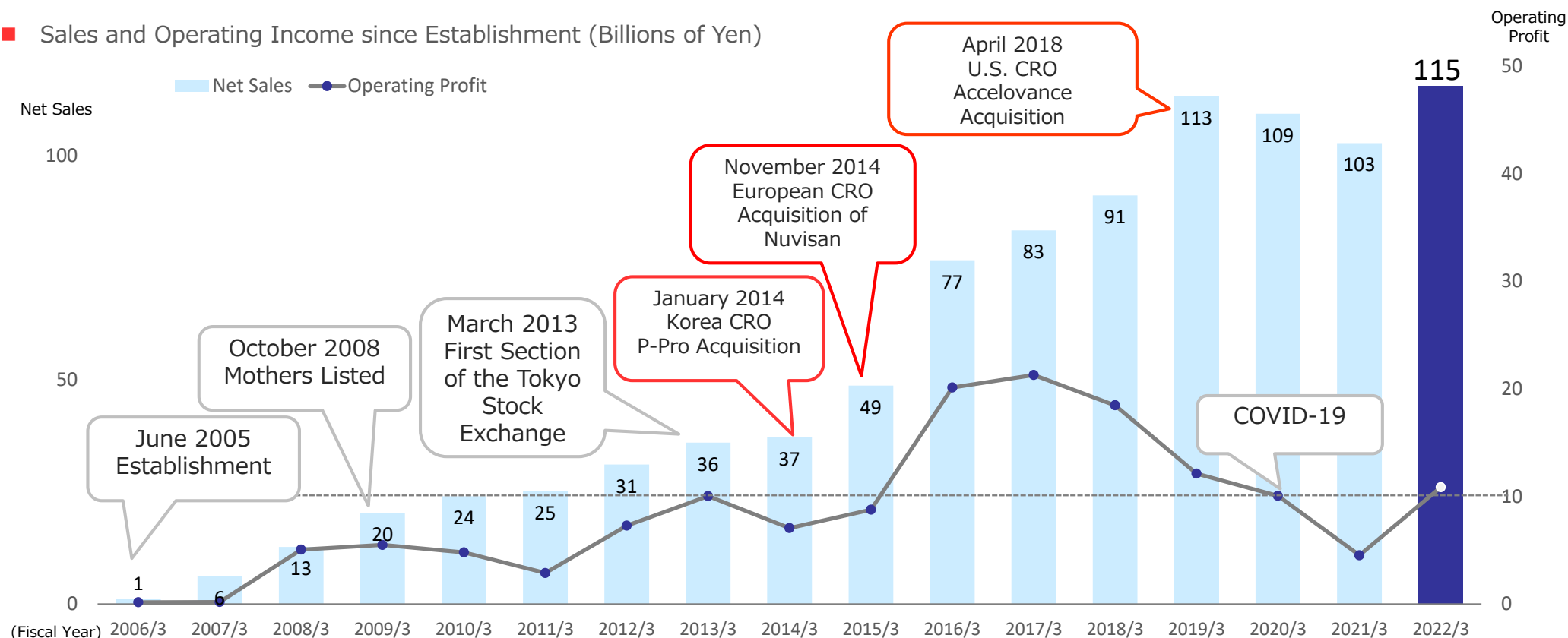
Targeted Disease Areas



Since our establishment, we have focused on the areas of oncology, neurology and immunology, **which have a high degree of difficulty and many unmet medical needs.**

Trends in Sales and Operating Income since Establishment

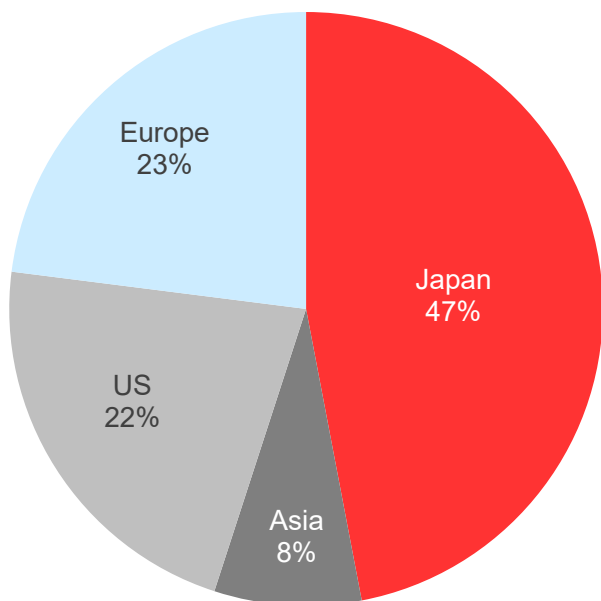
■ Sales and Operating Income since Establishment (Billions of Yen)



We achieved our highest ever sales while the impacts of COVID-19 remained in each region
Operating profit has also recovered to pre-COVID-19 levels

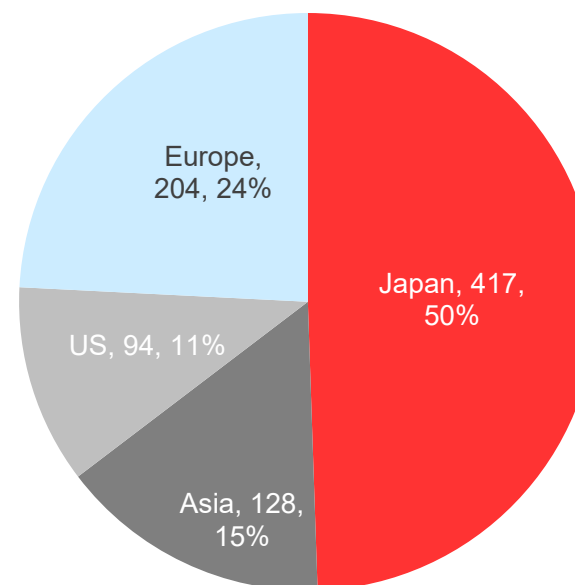
Sales and Number of Employees by Region

■ Sales 11,555 million yen
(Fiscal year ended March 2022)



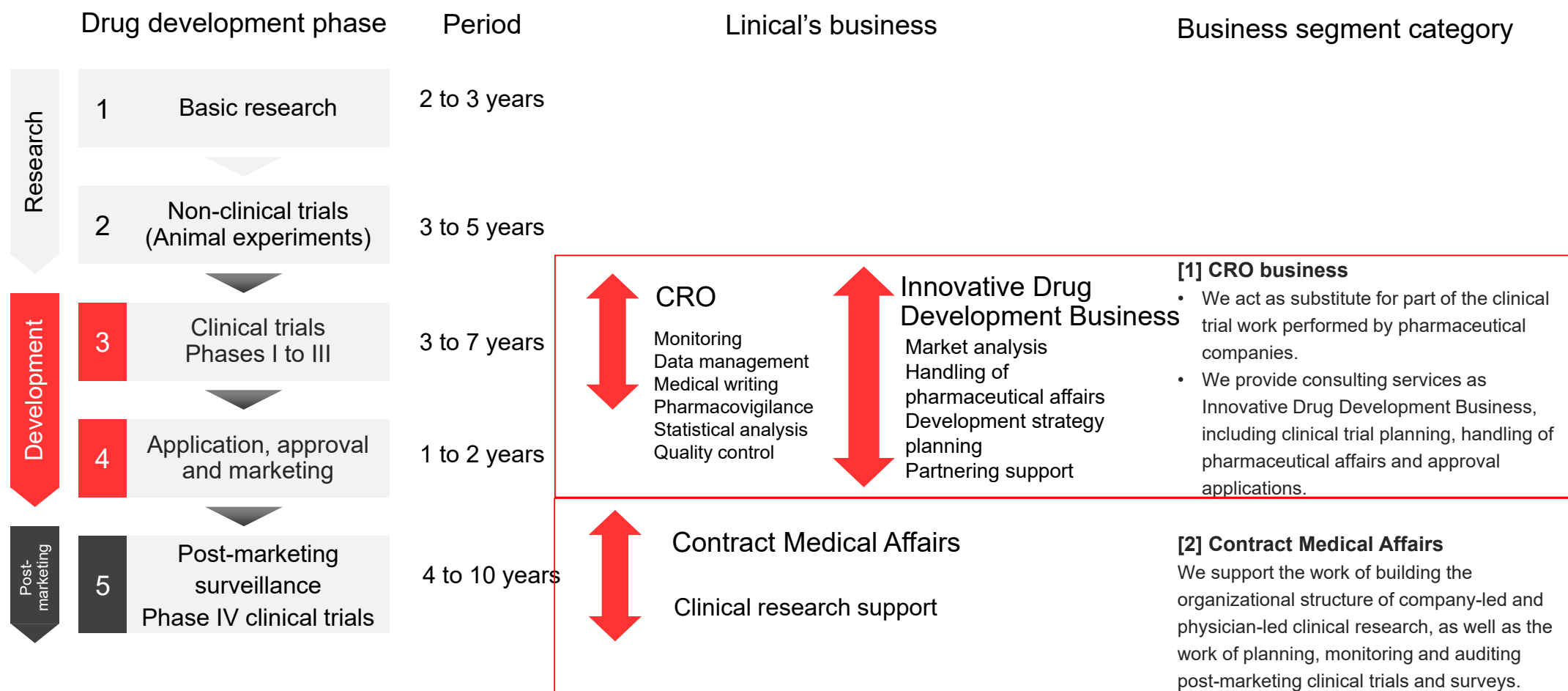
Overseas ratio 53%

■ Number of employees 843 people
(As of the end of March 2022)

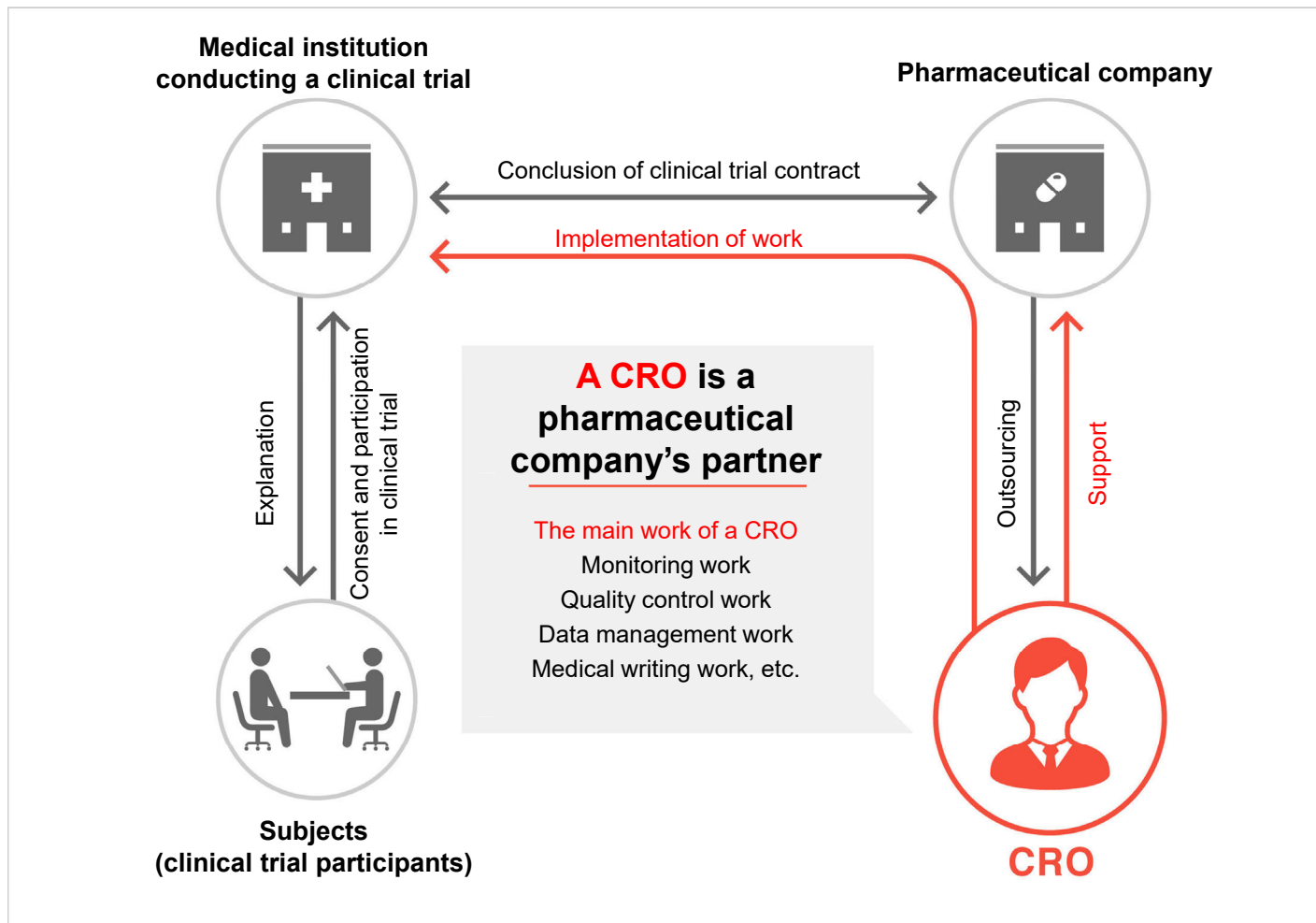


Overseas ratio 50%

Business Overview



The CRO Business Model



What is CRO Business?

