

# Breaking Borders: Mastering the Art of Global Business Expansion to Japan

## EPS Corporation

### Katsura Kasahara

Executive Professional, Global  
Business Development



Japan has unique characteristics, such as its pharmaceutical regulations, medical systems, and cultural nuances, that can be challenging for outsiders to navigate. This guide is your essential resource for understanding these complexities and managing global clinical trials, including those in Japan.

**Mastering Drug  
Development in Japan**

**Unpacking Hidden Challenges  
in Drug Development:  
Japan as a Case Study**

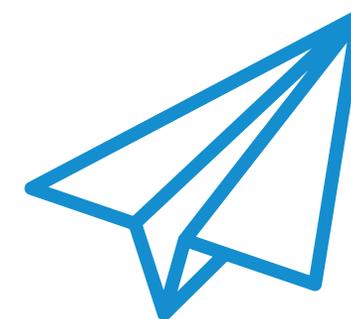
**Boosting Success  
in Drug Development:  
Key Solutions**

# Before We Dive In...



Global pharma growth extends beyond the U.S. and Europe, with Japan presenting opportunities for growth.

Companies that navigate Japan's regulatory landscape can unlock its untapped potential and improve global patient access.



# What You Need to Know



Japan's medical field holds immense growth potential, offering untapped business opportunities.

For development projects, leveraging Global and Local CROs ensures tailored strategies, especially with local CROs providing invaluable regional expertise.



# Potential Business Expansion to Japan

# Do You Know Japan?

## About Japan

Capital	Tokyo
Population	125 million (3x the size of California)
Area	146,000 sq mi (~California)



# Attractive Japan Pharmaceutical Market

**3rd Largest Pharmaceutical Market in the World**

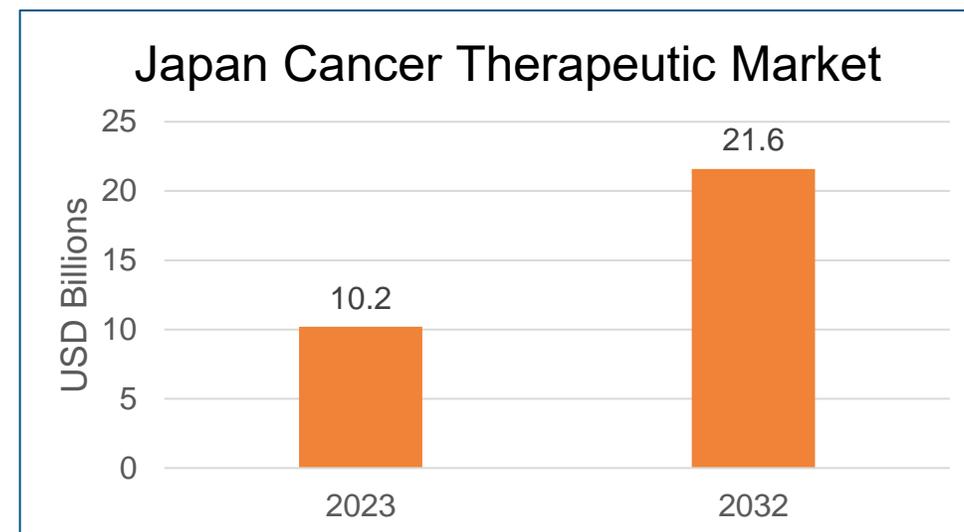
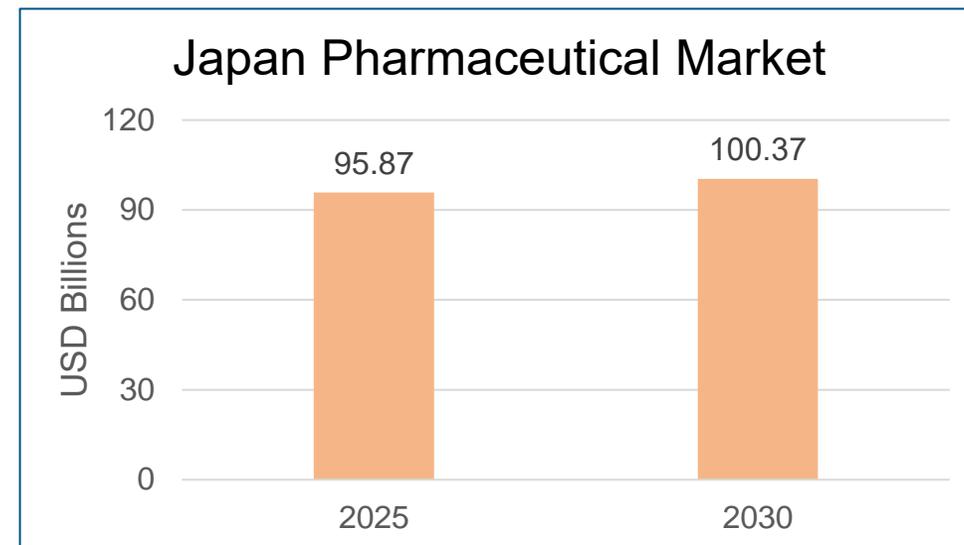
**5-year CAGR of patented products market is 12.3% (2018-2023)**

- Will Remain No. 2 in the World for the Next 5 to 10 Years

**Cancer Therapeutic Market:  
CAGR of 8.7% (2023-2032)**

**Universal Public Health Insurance**

- Accessible to new drugs
- Free to choose any medical institution



Source: <https://www.mordorintelligence.com/industry-reports/japan-pharmaceutical-market>



## The PMDA office in Tokyo

- Scientific judgment application
- NDA review and evaluation
- Clinical trial planning consultation
- Adverse drug reaction info

## The PMDA office in Washington, D.C.

- Enhanced Collaboration
- Regulatory Support
- Easier Communication
- Global Innovation
- Localized Access

**Newly Opened  
November 2024**

US Office Address:  
1730 Rhode Island Avenue, NW, Suite 403, Washington, D.C. 20036, USA

# Flexible and Predictable Japan Environment

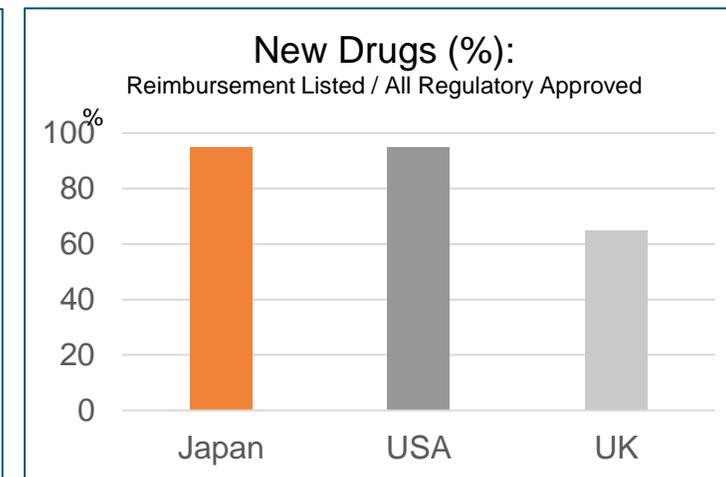
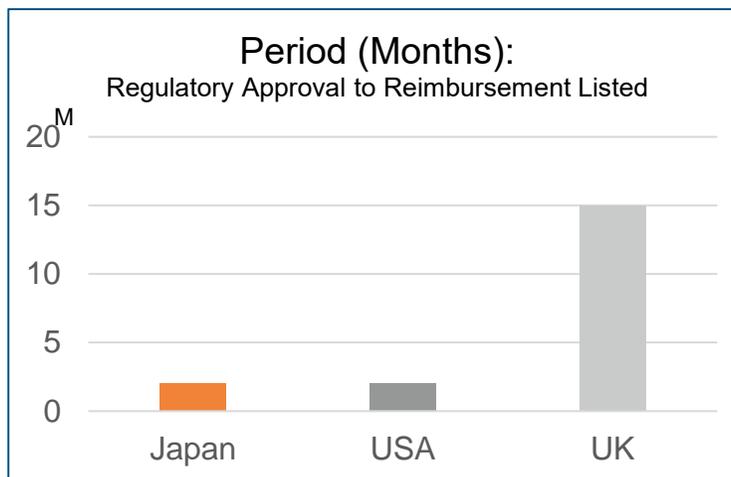
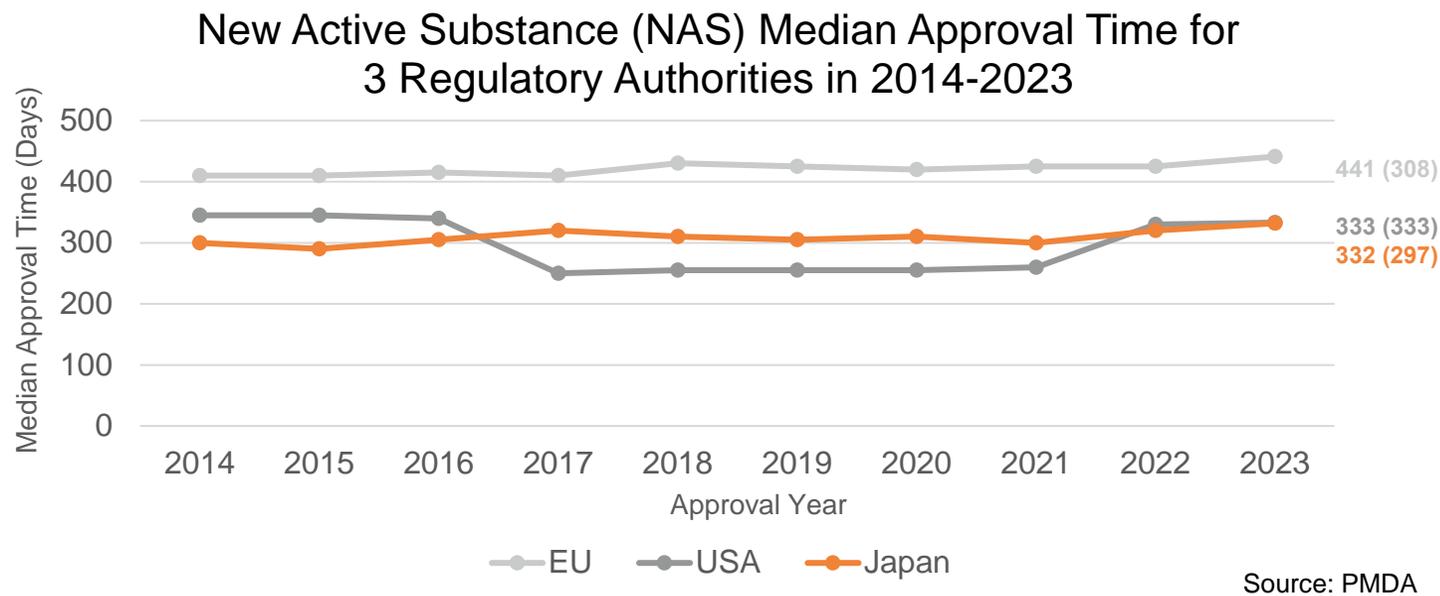


Full International Harmonization  
Regulation based on ICH standard

Comparable NDA Review time

NHI Drug Price:  
Rapid and extensive reimbursement

**NHI: National Health Insurance**



Source: PhRMA analysis of IQVIA analytics Link, US FDA, EMA, Japan PMDA, Health Canada, Australia Therapeutics Good Administration and government insurance coverage data on new active substances approved from 2011 to Q3 2019

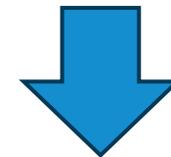
# Well-developed Clinical Trial Environment



**Highest # of hospitals (8,000) and beds (13.1 per 1,000 people) in the world**

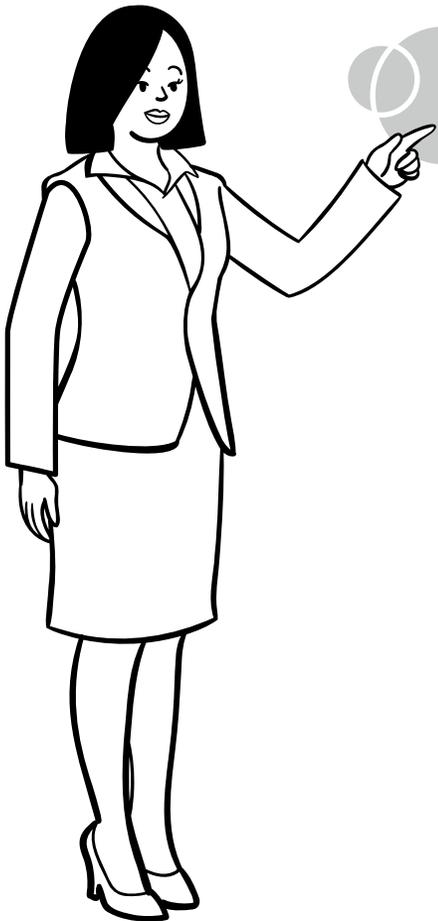
**Key Medical Institutions: 14 core clinical research hospitals and 80+ university hospitals**

**No government certification needed at study sites**



**Ideal for clinical studies!**

# Challenges and Solutions for Business Expansion to Other Countries



## **Culture and Language ???**

(Cultural and genetic diversity, National Character, Language, Disclosure...)



## **Authorities and Regulations ???**

(Safety and ethical standards, Drug price...)

## **Medical System and Patients ???**

(Health insurance, Clinical study institutions and investigators, Patients...)



## Distinguishing between Regional / Local CROs and Global CROs

Global CRO	Regional / Local CRO
<ul style="list-style-type: none"><li>• Large-scale clinical trials in multiple countries</li><li>• Clinical trials where standardization and consistency are keys</li></ul>	<ul style="list-style-type: none"><li>• Clinical trials in one country or a small number of countries</li><li>• Clinical trials that require flexibility and address region-specific issues</li></ul>

# Comparison: Regional / Local CROs vs Global CROs

Aspect	Global CRO	Regional / Local CRO
<b>Scope</b>	Globally committed with multi-country operations.	Regionally focused.
<b>Expertise</b>	Standardized processes with unified data.	Expert in local regulations and culture.
<b>Responsiveness</b>	Less flexibility from standardization.	Quick and locally tailored responses.
<b>Cost</b>	Higher costs from study size and management fees.	Lower costs with fewer change orders.
<b>Client Base</b>	Global pharmaceutical firms.	Smaller firms, startups, and local firms.
<b>Advantages</b>	Extensive resources and global reach.	Strong local ties and KOL collaboration.

# Relative Effectiveness: Regional / Local CROs vs Global CROs

Aspect	Global CRO	Regional / Local CRO
<b>Scope</b>	Smooth management of multi-country trials.	Targeted strategies for regional challenges.
<b>Quality</b>	Consistent multi-country quality.	Patient focused, locally adaptable solutions.
<b>Efficiency</b>	Cost-efficient for large-scale trials.	Cost-efficient for smaller regions / studies.
<b>Team Management</b>	Unified global team collaboration.	Strong local partners (KOLs, vendors, etc.)
<b>Execution</b>	Reliable standardization for global studies.	Quick and flexible execution.

# What Types of Projects Would a Local CRO Be Effective at?

Local CROs work effectively particularly in with knowledge of the features and advantages in the country or region

## Rare Disease

**KSF: Capturing information on patients**

- Patients' Associations, Patient Registries
- Medical specialists, KOLs
- Research groups, research teams
- PMDA/MHLW: Minimum data package for NDA
- MHLW: Orphan drug designation

## Biologics/ Cell therapy/ Gene therapy

**KSF : Supply and quality**

- CDMOs, distributors
- PMDA consultation
- Investigator selection

## Oncology Area

**KSF: Feasibility and investigators selection**

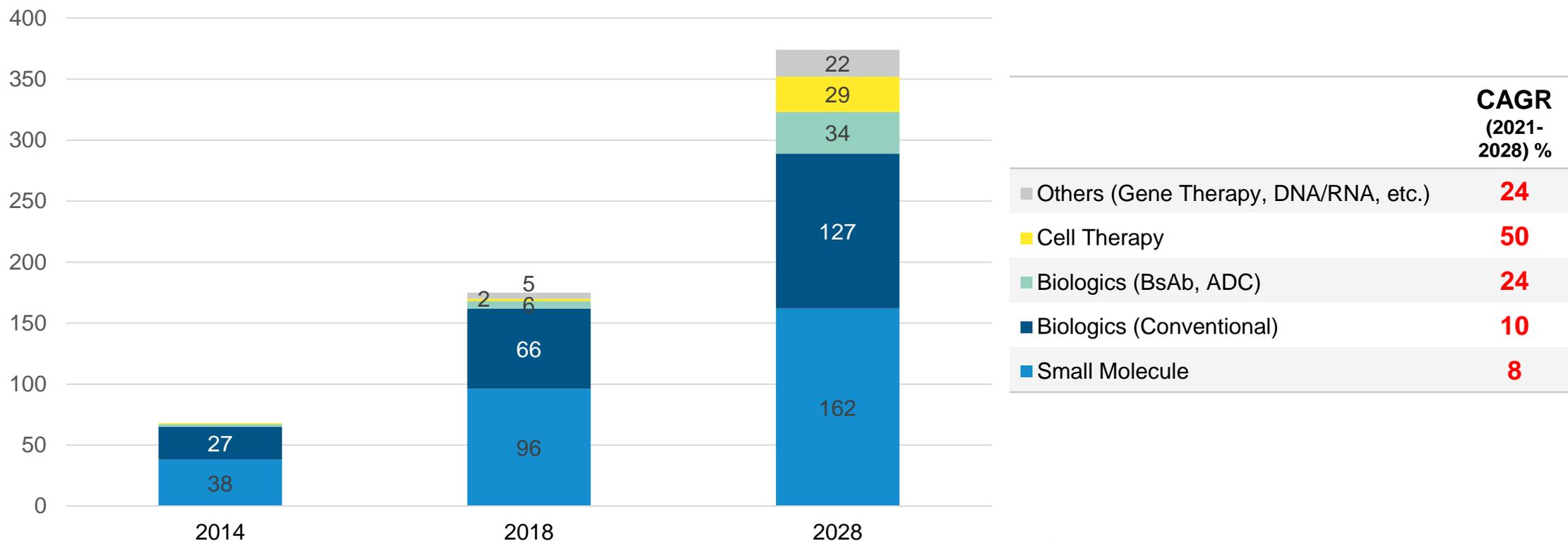
- Competing studies
- Minimum drop-out cases

**KSF: Key Success Factor**

# Diversification and Transition of Modalities in Japan

- Per capita legal drug use in Japan and Western Europe is double that of other regions
- Biologics/ Immunology products lag behind other countries and are expected to grow in the future

Diversification and Transition from Small Molecules to New Modalities



Source: <https://www.bcg.com/ja-jp/publications/2024/challenges-in-clinical-development>

## KSF: Feasibility and Investigator Selection

### Prevalence Ranking (2020)

	1st	2nd	3rd	4th	5th
Total	Colon	Lung	Stomach	Breast	Prostate
Male	Prostate	Colon	Lung	Stomach	Liver
Female	Breast	Colon	Lung	Stomach	Uterus

### Number of Deaths (2022)

	1st	2nd	3rd	4th	5th
Total	Lung	Colon	Stomach	Pancreas	Liver
Male	Lung	Colon	Stomach	Pancreas	Liver
Female	Colon	Lung	Pancreas	Breast	Stomach



**461 Hospitals  
for Cancer Treatment**

**KSF: Key Success Factor**

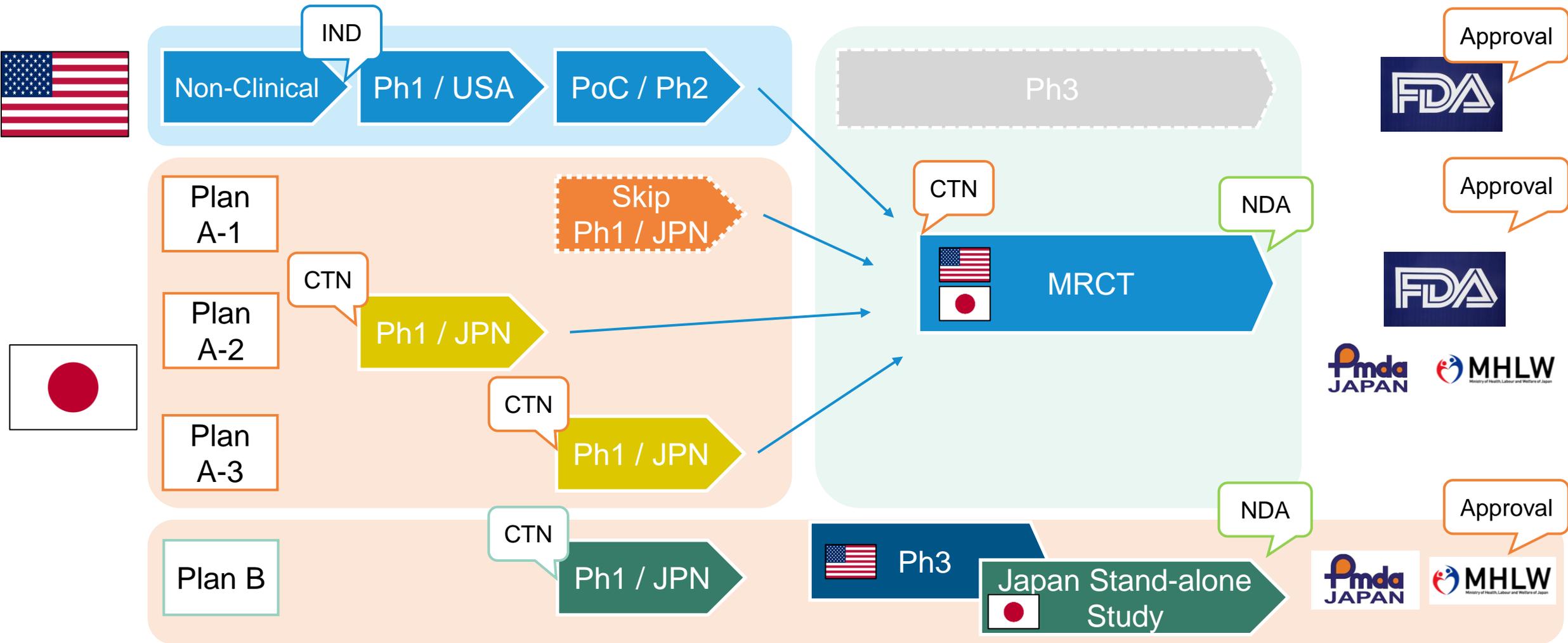
Source: [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/kenkou/gan/gan\\_byoin.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kenkou/gan/gan_byoin.html)

# Case Study

# Typical Cases of Clinical Development Plans in US



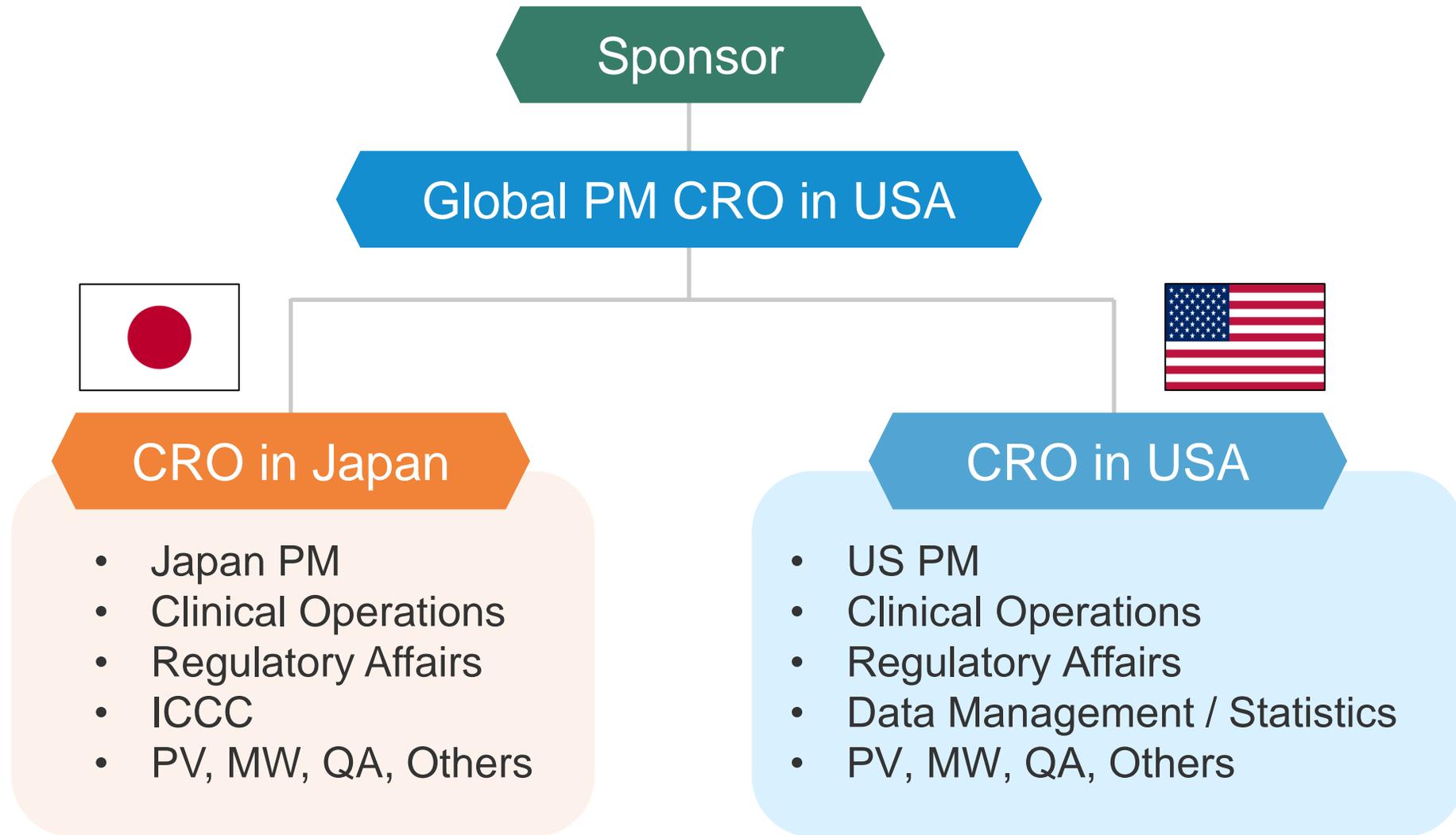
# Typical Cases of Clinical Development Plans in US / Japan



MRCT: Multi-Regional Clinical Trials

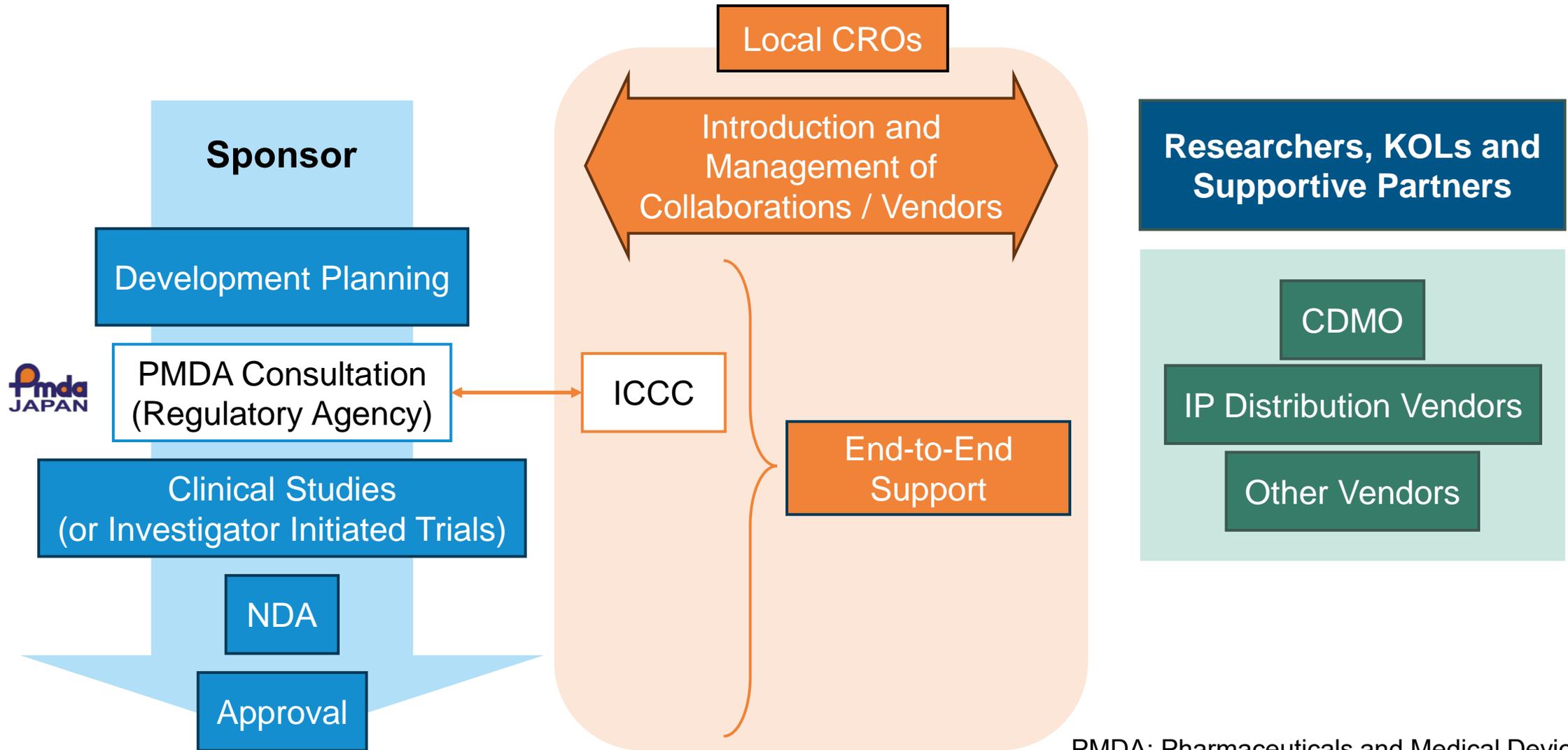
Plan A: Join MRCT    Plan B: Japan Stand-alone

# CRO Collaboration Between US and Japan for MRCT



PM: Project Manager  
PV: Pharmacovigilance  
MW: Medical Writing  
QA: Quality Assurance  
ICCC: In-Country Clinical Caretaker

# Operational Scheme by Local CROs



PMDA: Pharmaceuticals and Medical Devices Agency  
ICCC: In-Country Clinical Caretaker

## Project Overview

- **Company:** US based Biotech company, first time in Japan (unfamiliar with Japan)
- **Indication:** Rare disease
- **Scope of Work:** PM, Monitoring, Regulatory Affairs
- **Expectations:** Skipping Ph1 with the Japanese and participating in MRCT in time
- **Challenges:**
  - Less familiarity with Japanese regulations / requirements
  - No prior relationships with KOLs
  - Need to conduct multiple studies simultaneously

MRCT: Multi-Regional Clinical Trials



## How did we lead to success?

# Example of Success: Sponsor X

## Sponsor X

- Rare disease
- The Expectations
- Less familiarity with Japan
- No prior relationships with KOLs
- Multiple studies simultaneously



- Provide sufficient information
- Early-stage Consultation
- Preliminary input to PMDA
- Collaboration with patient advocacy / KOLs
- Bridging Sponsor X & investigators

**Successful  
regulatory approval**

**Skipped Ph1 in Japan**

# Conclusion

# What You've Learned Today



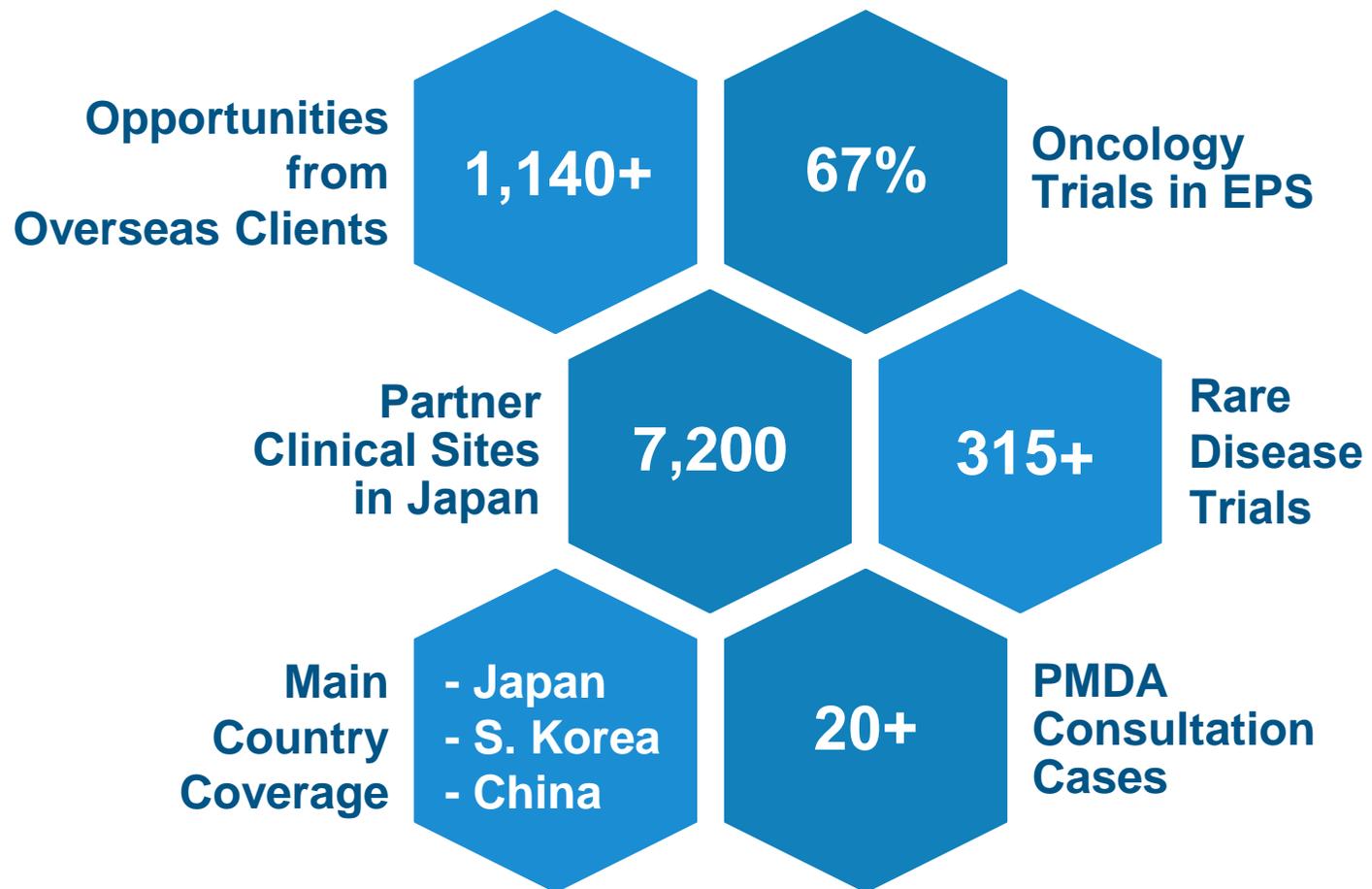
Japan's medical field holds immense growth potential, offering untapped business opportunities.

For development projects, leveraging Global and Local CROs ensures tailored strategies, especially with local CROs providing invaluable regional expertise.



## Visit EPS booth #75

to see how our CRO expertise can support your clinical development and foster innovative collaborations!





**EPS Corporation**

**Thank You**

# References

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[Japan Pharmaceutical Market - Size, Companies & Growth \(mordorintelligence.com\)](#)

Updateされている (2025年と2030年)

[日本のがん治療薬市場は2032年までに216億米ドルに達する見込](#)

[IQVIA 国内医療用薬の特許品市場 23年度までの5年平均成長率は+12.3% 市場全体は+1.9% | ニュース | ミクスOnline](#)

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[000271827.pdf](#)

JPLA例会 (2024年9月) KO大中村教授

PhRMA analysis of IQVIA analytics Link, US FDA, EMA, Japan PMDA, Health Canada, Australia Therapeutics Good Administration and government insurance coverage data on new active substances approved from 2011 to Q3 2019

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[000906892.pdf](#)

[【2024年7月時点】日本の病院数はいくつ？医療施設動態調査から読み解く課題とは | ニッポンの介護学 | みんなの介護求人](#)

- Page 17

[iqvia-institute-global-use-of-medicines-2024-forweb.pdf](#)

BCG: 製薬企業の臨床開発と顧客エンゲージメントにおける課題と今後の論点、2024年7月(EPSによる英訳)

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[がん診療連携拠点病院等 | 厚生労働省](#)

[最新がん統計：\[国立がん研究センター がん統計\]](#)

# Top Regenerative Medicine Solution Provider in APAC 2024

**MEDTECH**  
OUTLOOK TOP 10  
**REGENERATIVE**  
**MEDICINE**  
SOLUTIONS PROVIDERS IN APAC - 2024

## EPS Corporation

### Offering Comprehensive Lifecycle Management of Medical Innovations

As a leading clinical research organization (CRO) in Japan, EPS Corporation prides itself on an expansive portfolio that spans the entire gamut of product development and clinical research, from initial planning to post-marketing endeavors. The organization's strength lies in its robust team of approximately 3,300 staff members equipped with extensive expertise and a wealth of experience. This enables EPS to address unmet medical needs and proactively tackle challenges across multiple therapeutic domains, with a primary focus on oncology and CNS fields.

EPS offers comprehensive support for regenerative medicine, an area where its prowess is widely acknowledged. Its involvement covers an extensive spectrum, encompassing services that range from early-stage planning and regulatory consultations to complete outsourcing of clinical trials, assistance with drug approval applications, and ongoing Post Marketing Surveillance (PMS) support.

"We stand among a select few CROs in Japan capable of offering holistic support throughout the lifecycle of regenerative medicine products," says Takehisa Yamada, president and representative director at EPS Corporation.

Navigating the landscape of regenerative medicine poses distinct challenges, especially concerning evolving regulatory frameworks and the dynamic nature of the field. EPS Corporation is adept at addressing these challenges, particularly those related to unique Japanese regulations. The company's extensive experience in dealing with the Pharmaceuticals and Medical Devices Agency (PMDA) enables it to guide clients effectively through the intricacies of compliance and regulatory adherence. EPS excels in handling operational issues specific to regenerative medicine, such as product logistics and negotiations with investigational sites.

EPS takes a methodical step-by-step approach to understand the PMDA's perspectives. This involves close collaboration with clients to devise development strategies that align with both regulatory requirements and clients' risk tolerance levels. The high satisfaction

levels expressed by clients' post-project completion, leading to repeat orders and expansion into new therapeutic areas, serve as a testament to EPS' effectiveness.

Regulatory compliance is pivotal in global drug development, and EPS shines in this arena. With Japan hosting some of the strictest regulations for regenerative medicine, its expertise in meeting these standards essentially paves the way for compliance with regulations in other regions, significantly facilitating the global expansion of drug development initiatives.

EPS' success stories are best exemplified through the transformational impact of regenerative medicine products in enhancing patients' lives. These groundbreaking products have been instrumental in areas where conventional treatments fell short, such as cardiovascular, skin, nerve, and cartilage regeneration, alongside treatments for malignant tumors. By aiding in the development of therapies that restore damaged tissues and organ functions, EPS has played a pivotal role in improving the quality of life for patients across various therapeutic domains. While numerous CROs have surfaced, EPS remains distinguished due to its extensive track record, specialized expertise, and its capability to prepare Common Technical Documents (CTDs) for regenerative medical products, particularly in the critical Chemistry, Manufacturing, and Controls (CMC) aspect.



Takehisa Yamada,  
President and Representative Director

**“**We stand among a select few CROs in Japan capable of offering holistic support throughout the lifecycle of regenerative medicine products

With a focus on new modalities and a flexible approach to regulatory requirements, EPS continues to spearhead advancements in the dynamic landscape of pharmaceuticals, medical devices, and regenerative medicine products. The ultimate goal is to ensure a brighter future for patient care and treatment innovation. **”**

## VENDOR VIEWPOINT



### EPS CORPORATION/EPNEXTS: A CRO THAT CREATES NEW OPPORTUNITIES TO BRIDGE THE WORLD WITH JAPAN

By Noryuki Takai, Executive Corporate Officer, EPS Corporation



Getting borderless in Japan is ranked among the top three countries in the world in the pharmaceutical market and is working on several measures to further lead the world as a leading pharmaceutical country. In December 2023, new guidelines were issued and now many considerations are being made by the Japan Ministry of Health and Welfare. One of these guidelines states that, depending on certain caveats, a Phase I trial in Japan before joining a Multi-Regional Clinical Trial (MRCT) is not necessary (as had previously been the case). Other guidelines include reviewing the orphan drug designation system and promoting the development of pediatric drugs. We strongly believe that these are great breakthroughs and now it is the perfect time to enter the Japanese market.

**A**dvance your journey to Japan with EPS. Starting a new business in a foreign country is a completely new challenge for anyone and any company. Each country has a long history and a lifestyle and culture

that is rooted in that history. When considering expanding pharmaceutical business to a different country, there are differences not only in pharmaceutical regulations and medical systems, but also in customs, culture, and language. In addition, each country has many unique characteristics that are difficult to understand by foreigners. Although efforts have been made to harmonize and standardize pharmaceutical development, marketing, and sales on global basis, the uniqueness of each country that has been cultivated over many years remains. For Japan to continue to be one of the leading countries in the world for pharmaceutical business, Japan is currently promoting regulatory reforms to make entering the Japanese pharmaceutical market easier for non-Japanese companies. Now it is the perfect time to think about expanding your business into Japan. Why not bring your valuable pipeline to Japan?

For the past 30 years, EPS have been providing CRO services specializing in clinical development support and

## EPS Corporation



The annual listing of 10 companies in APAC that are at the forefront of providing Regenerative Medicine solutions and impacting the marketplace

have been widely recognized and highly praised by various stakeholders in Japan. We have experience conducting over 1,000 clinical study protocols in oncology, over sixty clinical study protocols in the regenerative medicine field, and over two hundred clinical study protocols in rare diseases. Additionally, we have conducted many multi-national joint clinical studies both domestically and internationally. We are also actively pursuing new initiatives such as DCT (Decentralized Clinical Trial), promotion of patient participation in clinical studies which is a topic of ICH E6R Annex2 as well as RWD utilization. Utilizing this strength to provide one-stop support for the development and commercialization of innovative new drugs and new modalities in Japan, as well as post-approval processes, EPS will become an opportunity creator for start-ups to help deliver innovation to Japanese patients.

EPS, which knows everything about Japan, will take on the challenge of this reform and create opportunities in Japan for excellent overseas pharmaceuticals. We would like to review Japan from an overseas perspective and create the best solutions from the perspective of Japanese medical institutions and patients.

Thus, EPS is implementing a number of measures to encourage entry into the attractive Japanese pharmaceutical market.

EPS has begun collaboration with Frontage Laboratories, Inc. (USA) to promote implementation of Phase I studies including Japanese healthy volunteers in the United States.

Creating new solutions

Companies around the world are working to utilize big data and build evidence in the healthcare field. EPS has started a collaboration with NTT Data, one of Japan's largest companies in this field, and EPS is also collaborating with multiple companies for contributing to evidence building and leveraging EPS's 30-plus years of experience. We believe that by leveraging each company's areas of expertise, we will accelerate the

development of new solutions. Would you like to collaborate with EPS, become a member of the drug development ecosystem, and create new solutions?

In addition, although SMO services have developed independently in Japan, we are promoting innovation by further improving efficiency, increasing speed, reducing costs, and ensuring data integrity by integrating a part of the functions of CRO and SMO. EP-LINK, which provides SMO services within the EPNEXTS group, is Japan's largest SMO company, and we believe that this initiative will bring about major changes in drug development in Japan.

Our mission

**“**We understand the unique challenges of entering the Japanese market and can help you navigate the process smoothly," states Noryuki Takai, Executive Corporate Officer, EPS Corporation

At the EPNEXTS group of companies (comprised of EPS' CRO, SMO, and CSD businesses), we aim to shorten drug development by as much as possible, deliver groundbreaking treatments to patients as quickly as possible, and accumulate a wide range of treatment evidence after launch to spread safe and effective treatments. To achieve this, we will continue to evolve with the following four "3S" keywords.

- Service: Develop a high-quality service supply system by building on the experience and expertise we have cultivated over the years.
- System: Build a system that allows new initiatives.
- Solution: Create innovative business solutions in the healthcare field.
- Stage: Move into the next stage as a new business entity that combines the three core businesses of CRO, SMO and CSD. **”**

### About MedTech Outlook

The medical technology is always evolving and is a major component of healthcare system. The MedTech evolution and its manifestation have been effective in prevention, diagnosis, treatment and management of ailments and rehabilitation from illnesses. MedTech has pervaded not only every anatomical categorization but also the healthcare facility ecosystem. The rapid innovation has along with the numerous benefits throws a different set of challenges across design, validation and regulation.

MedTech Outlook will serve to be a platform that bridges the spectrum between MedTech Technology providers and the Healthcare facilities/ Medical institutes. We strive to monitor and inform about the MedTech trends, challenges and solutions. MedTech Outlook wants to assist purchasers/producers, decision makers and leads of operations/healthcare managers from peer vetted authoritative contributions.

The magazine will be following a unique learn-from-peer approach where the decision makers and experts will be sharing their invaluable views about medical technologies which have had an impact in providing the healthcare.