Advantages of Conducting Clinical Trials in Japan

Did you know that Japan has...

A Good Market

A Good Environment

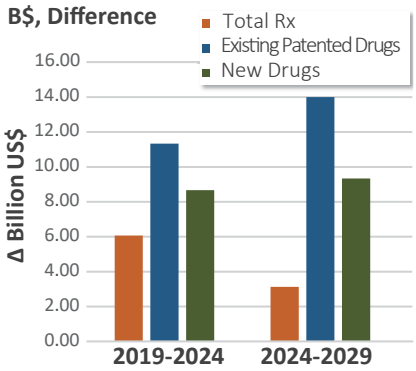
A Good Performance for Clinical Trials?

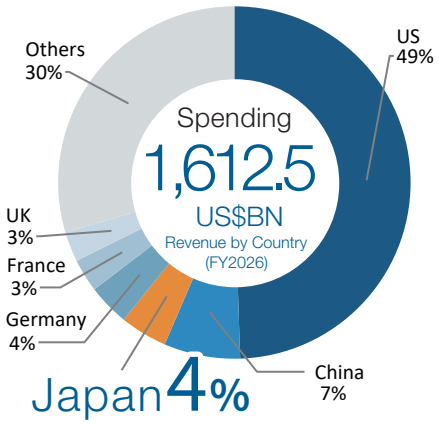
Looking to run Clinical Trials in Japan?
Please leave it to EPS Group,
A One-Stop Solution Provider



Japan is one of the Most Attractive Markets in the World

Japan is the **4th-largest prescription drug market globally**, and it continues to show stable growth. Overall prescription sales grow steadily, with a **5-year CAGR of approx. 2%**. However, as shown in the graph, existing patented products and new drug launches, are growing faster than the total market.





Once Approved, most products will be covered by Japan's National Health Insurance

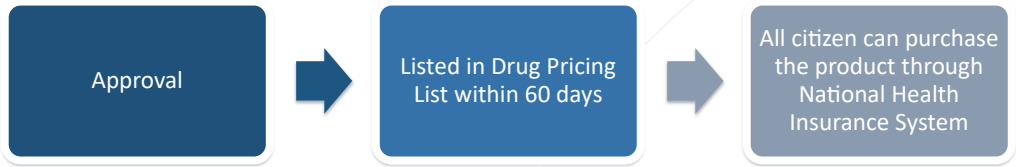
What is Drug Price Listing?

Once the drug is approved, most products will be covered by National Health Insurance System. In addition, the drug price is **listed within 60 days and no later than 90 days after approval.**

About National Health Insurance System in Japan

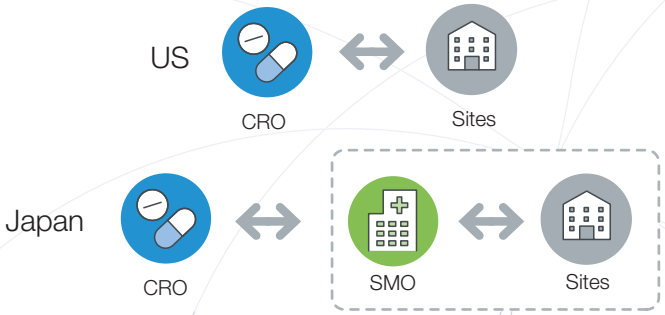
In Japan, all citizens can receive medical care at public healthcare facilities nationwide through public insurance.

→ with the approval and listing of drug prices, it is evident that a **stable income can be anticipated**



In Japan, organization for clinical trials is specialized

Sometimes, it is perceived that conducting clinical trials in Japan is more complicated compared to the US. However, with SMO (Site Management Organization), pharmaceutical companies can conduct clinical trials in Japan similarly to how they are conducted in US.



EPS group has strong Site Network with

7,700 (Approx. 70%)

and KOLs in Japan

In Japan:

- 11,000+ sites for clinical trials
- SMO manages sites to conduct clinical trials

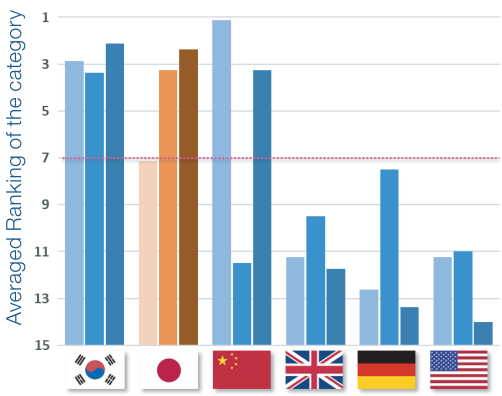
Speed

Shorter and Faster than Ever

The graph shows total speed indicators, the major factor of overall performance, using the three categories of speed, “Patient Enrollment Rate”, “Screen Failure Rate” and “Site Non-Enrollment Rate”. East Asia ranks highly overall, with Japan positioned among the top performers.

Patient Enrolment Rate | Screen Failure Rate | Site Non-Enrollment Rate

- Rapid FPI
- Shorter CTN – CSR period
- Reduction of Clinical Trial implementation period
- High Patient Retention rate
- Efficient & Fast



Clinical trial industry in Japan – Japan CRO Association

Quality

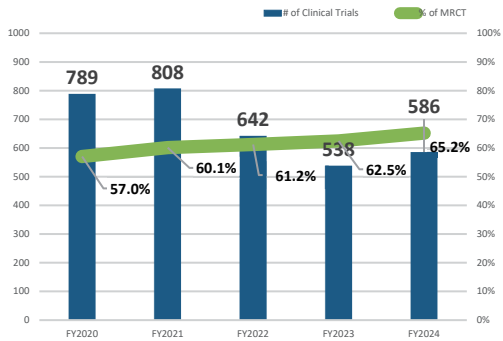
High Quality and Low Dropout Rates

60%+

Multi Regional Clinical Trials (MRCT)

➞ Familiar with ICH Standards

- Nearly 100% GCP inspection compliance
- Low dropout rates
- High reputation of POC studies in Japan
- World’s Highest Standard



Trends of Clinical Trials in Japan

Cost

Cost

- Since the system for clinical trials are entirely different, it is challenging to directly compare between US and Japan
- Costs are on an improving trend, including IRB expenses, etc.
- Noted for improvement

PMDA Launched US Office in November 2024

Free English General Consultation for Development in Japan

PMDA US Office provides

- Information on regulations or procedures under the Act on Securing Quality, Efficacy and Safety of Products
- A general explanation for practical regulatory application
- An explanation of PMDA's services, and support in selecting consultation categories

Contact PMDA US Office or EPS for more information regarding Clinical Trials in Japan

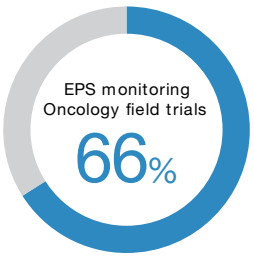
About EPS Group

EPS has evolved since its establishment as a CRO (Contract Research Organization) in 1991, expanding its offerings to include SMO (Site Management Organization) and CSO (Contract Sales Organization) services, thereby becoming a comprehensive provider of various support services for the healthcare industry.

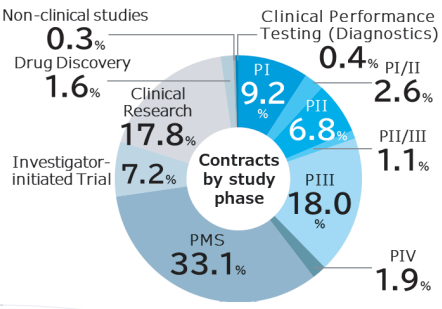
EPNexts

CRO
Contract Research Organization

We provide one-stop solutions to support clinical development and post-marketing activities for pharmaceutical, medical device, and regenerative medicine companies across the entire product lifecycle, including clinical trials, regulatory submission, safety management, and clinical research.



As of Nov. 2025



Oct. 2022 to Nov. 2025

SMO
Site Management Organization

We enhance clinical trials by collaboration with medical institutions across Japan, leveraging digital technology to improve efficiency, including the promotion of Decentralized Clinical Trials (DCTs) and the development of remote systems for clinical trial document management.

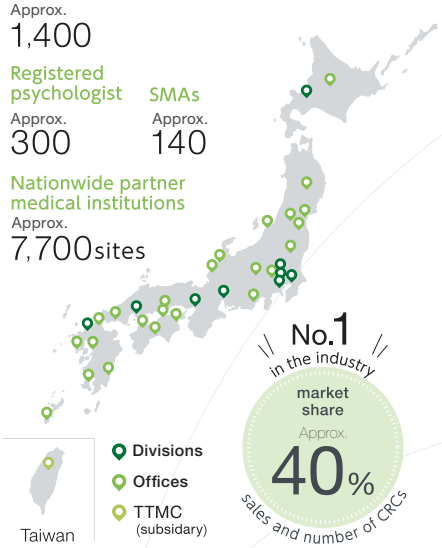
Largest SMO in Japan
Nationwide network

CRCs
Approx.
1,400

Registered psychologist
Approx.
300

SMAs
Approx.
140

Nationwide partner medical institutions
Approx.
7,700sites



No.1 in the industry
market share
Approx.
40%
sales and number of CRCs

As of Sep. 2025

CSO
Contract Sales Organization

We provide targeted support to pharmaceutical and medical device manufacturers after product approval encompassing contact center operations, and a range of services from pre-approval to post-marketing stages, employing a skilled workforce to effectively fulfill customer needs.



56 out of 69 member companies of Japan Pharmaceutical Manufactures Association (JPMA)
As of Dec. 2025



As of Apr. 2026

CRO Company List

Japan
- EPS Corporation
- EP Mediate Co., Ltd.
- EP Yamanashi Co., Ltd.
- Micren Healthcare Co., Ltd

Global
- EPS AMERICAS CORP.
- EPS International Korea Ltd. (South Korea).

SMO Company List

Japan
- EP-Link Co., Ltd.

Global
- Total Trial Management Consulting Co., Ltd. (Taiwan)

CSO Company List

Japan
- EP-PharmaLine Co., Ltd.

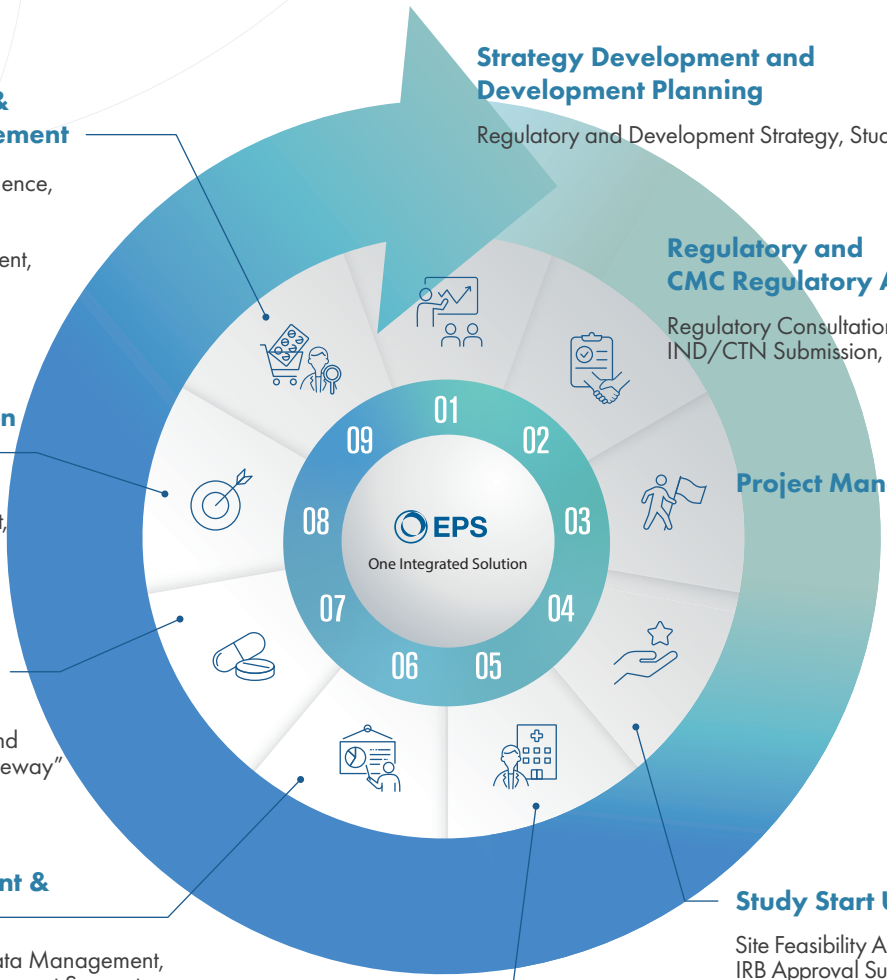
EPS Group Value Proposition

One Partner. Full Support. Across the Entire Development Journey

EPS Group provides integrated solutions across the entire drug development and commercialization lifecycle in Japan.

Integrated CRO x SMO x CSO Solutions

All functions. One partner. Seamless execution.



Strategy Development and Development Planning

Regulatory and Development Strategy, Study Protocol Development

Regulatory and CMC Regulatory Affairs

Regulatory Consultation Support, IND/CTN Submission, Medical Writing, ICCC*

Project Management and Lead

Study Start Up

Site Feasibility Assessment and Selection, IRB Approval Support and Site Contracts

Clinical Operation

Patient Recruitment & Retention, Study Monitoring, Safety Report, Clinical Supply Management, Vendor Management

Data management & Biostatistics

EDC Development, Data Management, Study Protocol Development Support, Statistical Analysis, Programming

NDA submission

Medical writing, eCTD Development and e-Application via "Gateway"

Commercialization Solutions

Market Access, Strategic Pricing Support, Launch Support

Post-Marketing & Lifecycle management

PMS, Real World Evidence, Pharmacovigilance, Protocol Development and Study Management, Publication Support

*ICCC : In-Country Clinical Caretaker

Contact

EPS Group
Address: TSUKUDO TERRACE, 2-1 Tsukudohachimancho, Shinjuku-ku, Tokyo, Japan
Email Contact: eps-gr-contact@eps.co.jp

EPS


EPS

