Your Trusted Partner in Clinical Development
Pioneering CRO, SMO, and CSO Excellence in Japan

EPS

Advantages of Conducting Clinical Trials in Japan

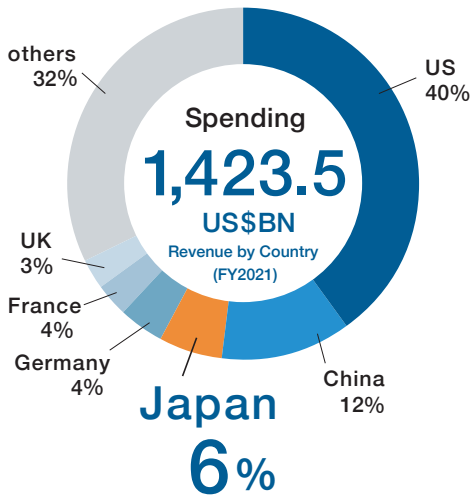
Did you know that Japan has…

A Good Market,
A Good Environment,
A Good Performance for Clinical Trials?

Japan is the 3rd Largest Pharmaceutical Market in the World

Forecast for 2027

Approved new drugs and patented products together constitute
51.0 billion USD (67% of the total revenue), making the Japanese market attractive



Approved New Drugs

- Estimated Market size in FY2027: Approx. 7.6 to 8.3 billion USD

Patented Products/Prescriptions (excepting New drugs)

- Estimated Market size in FY2027: Approx. 42.8 to 43.4 billion USD
- Compound Annual Growth Rate (CAGR) from 2022 to 2027: +6.5% to +7.5%

Japan is a good market for new drugs and patented products since high revenue is ensured as soon as its in the market

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

ⓘ About National Health Insurance System in Japan

In Japan, **all citizens can receive medical care** at public healthcare facilities nationwide through national insurance.
Citizen should pay 10-30% of total medical costs and remaining's are **covered by the national budget.**

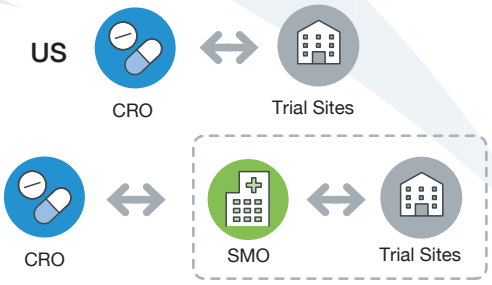
ⓘ What is Drug Price Listing?

Most of approved products will be **priced by the National Health Insurance System** (reimbursement price).

→ with the approval and listing of drug prices, high revenue is ensured during patent period (6-10 years)

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 Site Management Organization (SMO), pharmaceutical companies can conduct clinical trials in Japan similarly to how they are conducted in US.



EPS group has strong connection with

7,200+ (Approx.65%)

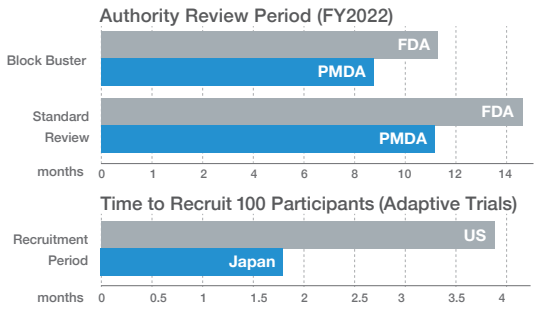
sites and KOLs in Japan

In Japan ▸ 11,000+clinical trials site / SMO coordinates the trial activities at sites

Shorter and Faster than Ever

Speed

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



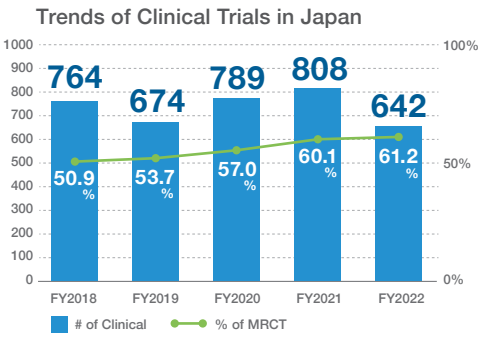
High Quality and Low Dropout Rates

Quality

60%+ of Japan Studies are part of Multi Regional Clinical Trials (MRCT)

➡ Sites&Staff are familiar with ICH Standards

- Nearly 100% GCP inspection compliance
- Low dropout rates
- High reputation of POC (Proof of Concept) studies in Japan
- World's Highest Standard



Noted for improvement

Cost

- Since the fundamental of cost recognition for clinical trials are entirely different, it is complicated to directly compare between US and Japan (e.g. Site cost calculation, basic treatment fee, etc.)
- Costs are on an improving trend, including IRB expenses, etc.

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
- General guidance for practical regulatory application
- Overview of PMDA services and support for selecting consultation categories

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

Looking to run Clinical Trials in Japan?

Please leave it to EPS Group,

A One-Stop Solution Provider.

Contact Us

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.

CRO
Contract Research Organization

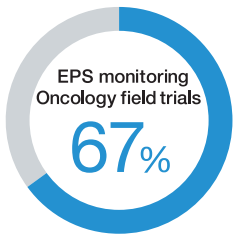
In response to requests from pharmaceutical, medical device and regenerative medicine companies, medical institutions, governmental agencies, and others, we provide One-Stop Solutions to support the development of pharmaceuticals, medical devices, foods, and cosmetics.

SMO
Site Management Organization

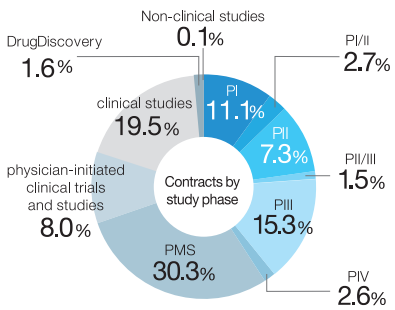
We enhance clinical trials by collaboration with medical institutions across Japan, leveraging digital technology to improve efficiency, including the promotion of Decentralized Clinical Trials (DCTs) and the development of remote systems for clinical trial document management.

CSO
Contract Sales Organization

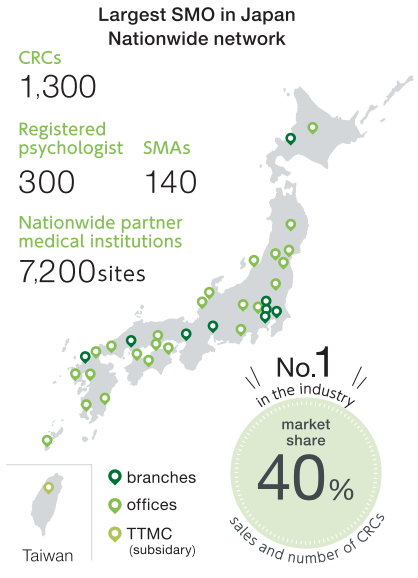
We provide targeted support to pharmaceutical and medical device manufacturers after product approval encompassing contact center operations, and a range of services from pre-approval to post-marketing stages, employing a skilled workforce to effectively fulfill customer needs.



As of Oct. 2024



Oct. 2020 to Jul. 2024



As of Sep. 2024

53 out of 70 member companies of
Japan Pharmaceutical Manufacturers Association
（JPMA）

As of Oct. 2024

Contact

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