EPS

EPS Corporation

Company Brochure

Ever
Progressing
System

Large Pharmaceutical Market for R&D Driven Companies

Top 3
Market Size in the World

CAGR: 5.0% +
Patented products (excl. NAS)

CAGR: 10.0% +
Patented products (incl. NAS)

NAS: New Active Substances

Japan Clinical Trials and EPS Performance

	MRCT % of Total Trade	Oncology Study	Regenerative Medicine	Rare Disease
EPS Performance	**65%**	**1000 + Protocols**	**60 + Protocols**	**200 + Protocols**
Japan	**60 % Approx.**	—	—	—

One Stop Platform Ecosystem

EPS Dynamically Responds to and Solves Biotech Companies' Needs

EPS Established an ecosystem to support foreign biotech companies entering the Japanese market

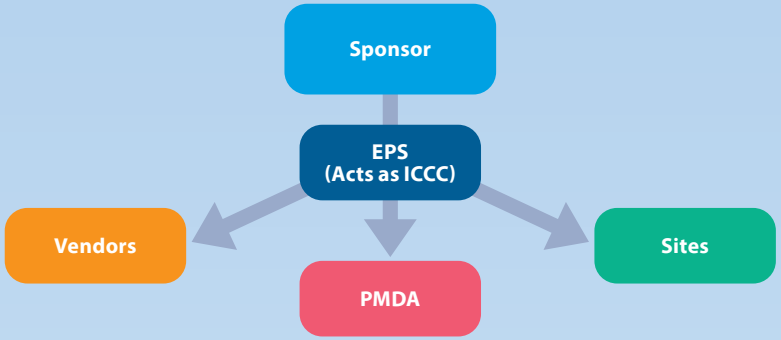
Global Research Business

EPS Corporation serves as a clinical research **"Gateway"** to Japan

We provide a **One Stop Solution** for all your outsourcing needs!

Our "One Stop Solution" brings together the individual services needed by you, our customers. Seamless communication helps you understand the status of each service and leads your project to the optimal quality completion goal.

ICCC (In Country Clinical Caretaker)



Sponsor outside Japan

ICCC inside Japan(EPS)

PMDA	IMP/NIMP	Sites	Document Archive
● CTN submission. ● Safety reporting including ICSR/DSUR.	● Confirm importation process. ● Compliance with GCP and other J-Regulations.	● Contracts. ● IRB documents. ● Safety reporting. ● IMP & Lab kit delivery.	● Store essential documents in accordance with J-GCP.

EPS Group companies cover all your service needs, from first-in-man through to marketed product with our ***One Stop Solution.***

CRO — Clinical Research Services for Pharmaceutical and Medical Device Clients

SMO — Site Management and Support Services for Clinical Sites

CSO — Contract Medical Representative and PMS Services

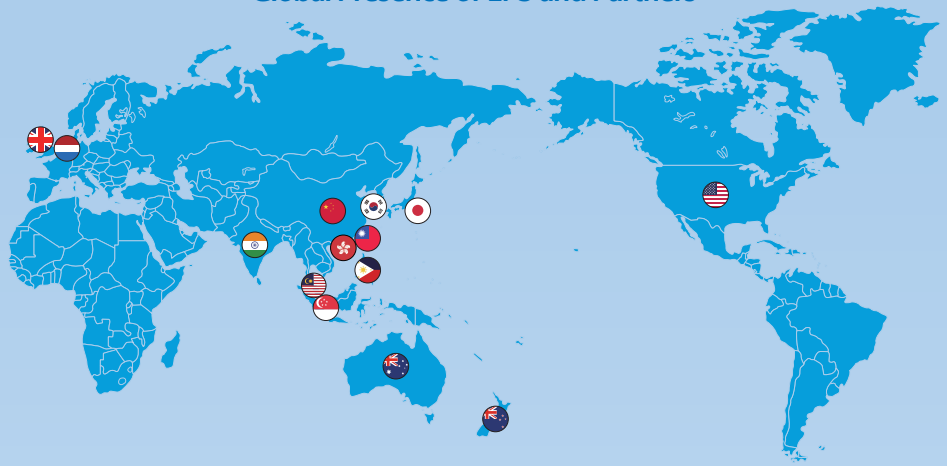
Global Research Business

Japan to Overseas & Overseas to Japan

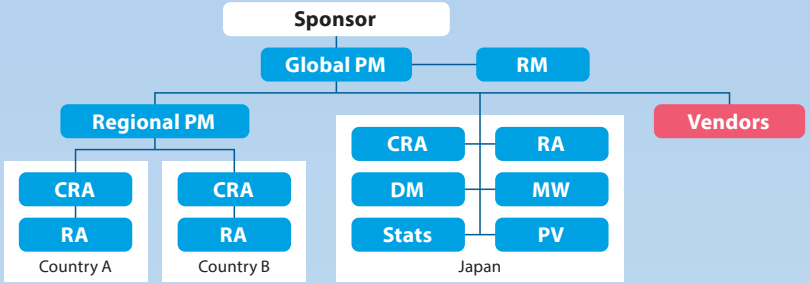
EPS supports cross-borders clinical development

By collaborating with strategic partners, EPS utilizes country specific expertise to seamlessly provide support for overseas expansion, from consulting to acting as a Gateway for clinical development, as well as regulatory compliance.

Global Presence of EPS and Partners



Global Project management structure



EPS Also Provides a Functional Service Provider (FSP) Model

Flexible and compliant with regulatory requirements

- Clinical Operation
- Project Management
- Data Science
- Pharmaco-vigilance
- Regulatory Consulting

Regulatory Affairs Capability

	Country	Drug	Medical Device
EPS	Japan	✓	✓
	South Korea	✓	✓
	Taiwan	✓	✓
	China	✓	✓
Partners	United States	✓	✓
	Canada	✓	✓
	Europe	✓	✓
	Singapore	✓	✓
	Hong Kong	✓	✓
	Malaysia	✓	✓
	Philippines	✓	✓
	Australia	✓	✓
	New Zealand	✓	✓
	India	✓	✓

Operations staff coverage

	Location	PM	CO	DM	SA	RA	PV	QM	Scientific Leadership	Central Analysis & DSMB
EPS	Japan	✓	✓	✓	✓	✓	✓	✓	✓	✓
	South Korea	✓	✓	*	*	✓	*	*	*	*
	Taiwan	✓	✓	*	*	✓	*	*	✓	*
	China	✓	✓	✓	✓	✓	✓	✓	✓	*
Partners	United States	✓	✓	✓	*	✓	✓	✓	✓	✓
	United Kingdom	✓	✓	*	*	✓	*	*	✓	*
	Netherlands	✓	✓	*	*	*	✓	*	✓	*
	Singapore	✓	✓	*	*	✓	✓	*	✓	*
	Hong Kong	✓	✓	*	*	✓	*	*	✓	*
	Malaysia	✓	✓	*	*	✓	*	✓	✓	*
	Philippines	✓	✓	*	*	*	*	*	✓	*
	Australia	✓	✓	✓	*	✓	✓	✓	✓	✓
	New Zealand	✓	✓	*	*	*	*	*	*	*
	India	✓	✓	✓	✓	✓	✓	✓	✓	✓

✓: Local staff ＊: Central Service

Optimal Clinical Development Strategy Package

To reduce complexity,
EPS proposes the most effective Clinical Development Strategy based on our experiences, knowledge, and opinions of KOLs.

Traditional Model

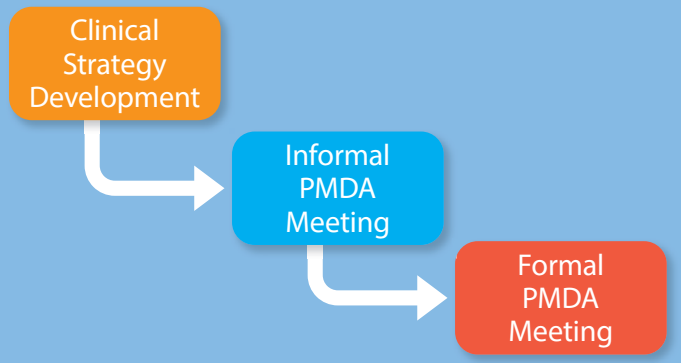
Consultation with PMDA for Japan development → Japan Phase Ⅰ → Join MRCT Phase Ⅲ

Phase Ⅰ (Outside Japan) → Phase Ⅱ (Outside Japan) → MRCT Phase Ⅲ (Outside Japan)

New Model (without Phase Ⅰ in Japan)

Consultation with PMDA for Japan development
Based on Population data and Medical Needs → Join MRCT Directly

Phase Ⅰ (Outside Japan) → Phase Ⅱ (Outside Japan) → MRCT Phase Ⅲ



Standard Process of Clinical Strategy Development & PMDA consultation

Strategic Consultation Team

- Regulatory Affairs
- Project Management
- Bio statistician

Numbers of PMDA Consultations

13+ years

Quick Study Start Up

Site Start Up → Enrollment & Treatment

To shorten Study Start Up period, EPS can provide the most effective Study Start Up process by collaboration with EP-Link (EPS Group SMO company)

EPS Group Proposal

EPS
- Competitive study information (Actual and Forecast)

EP-Link
- Site information
- Enrollment forecast based on past experiences

Before Project Contract / After Project Contract

Collaboration between EPS and EP-Link
Proposal of the most suitable enrollment plan

Site Opening and patient enrollment starts

- Early opening of Sites and Enrollment Start
- Consideration of additional sites, etc.

Contributing to **Quick Start** after Contract

Data Driven Site Selection & Recruitment

500+

Relationships with high performing sites

80% +

Met required timeline and patient recruitment goals.

Since its founding in 1991, EPS Group has grown as a Japanese pharmaceutical contract research organization (CRO) pioneer and a leading company meeting our customers' needs with their drug development. We have made constant efforts to expand and grow our services to provide One-Stop service which covers Drug Development to Post-Marketing Pharmacovigilance under EPSHD's group management. Additionally promoting our Decentralized Clinical Trial (DCT) platform and creation of new solutions utilizing Real World Data have been implemented to enhance our business. We will contribute to the development of the healthcare industry by creating high added value solutions such as new service models and using digital technologies, and the strength of Japan's largest domestic site management organization (SMO)EP-Link an EPS company. Moreover, we will fulfill our mission: contribution to society, optimizing and promoting clinical trials in Japan which helps solve the drug loss issue in Japan.

EPS will create "the new normal of CROs".

What provides our major “professional service” are human resources. We have improved our service capabilities through expertise, solid teamwork, and taking care of and growing our employees in the medium- and long-term time frame. Also, our business has been expanded by thinking highly of connections with people.

As a trusted partner to our customers, we will focus on “enhancement of expertise and quality of service”,“improvement of productivity and creation of a sustainable growth model”, organizational management, work style reform, and “establishing an energetic and positive organization”.

Consequently, we will build the ideal model as “the new normal of CROs”. We are dedicated to continuous improvement so as to create a future where people live a healthy and fulfilling life, and deliver medicine to patients promptly.

Experience

EPS has an overwhelming number of contracts in the field of oncology and clients think “EPS when it comes to oncology”. Also, EPS has an abundant track record in highly challenging fields such as Central Nervous System, Cardiovascular, and Designated Intractable Diseases. EPS is also known as a front-runner in the field of Regenerative Medicine. In Clinical Trials and Post-Marketing surveillance, we have established a system that allows us to quickly and comprehensively handle everything from planning to completion. We have earned the trust of our clients for our expertise and responsiveness.

Knowledge Management

Our strengths lie in our ability to provide a full range of services from Drug Development to Post-Marketing Pharmacovigilance, and our know-how which covers a wide range of disease areas. At EPS, professionals in various fields are fully prepared to comply with the regulations such as ICH E6(R3) GCP Principles. The EPS team is also contributing to the improvement of the industry as a whole by synergistically utilizing and sharing its knowledge and expertise with other related organizations.

Medical Quest

Through the development of pharmaceuticals, we have supported medical care and the pharmaceutical industry which is an important part of the social infrastructure. We will continue to contribute to the development of medical care by making full use of new technologies and Information and Communication Technology (ICT). In Decentralized Clinical Trials (DCT), which is expected to become widespread soon, we have already established a front-runner position and have been implementing a DCT platform. We intend to focus on the patient engagement and utilization of healthcare data and further develop our business in the areas of community medicine and health promotion. We will continue to be deeply involved in creating a fulfilling living environment for people by taking a more encompassing perspective view of medicine.

Global Development

Simultaneous global drug development programs with global trials crossing national and regional boundaries are increasing in number. We work towards optimizing clinical trials in Japan and to enhance our business approach to pharmaceutical companies and startup biotechnology companies with the goal of enabling more clinical trials to be held in Japan. Also, we are continuing to grow as a global CRO by organizing systems which holistically support pharmaceutical development.

Creation of Valuable Solutions

EPS contributes to the development of the healthcare industry to shape a future teeming with health and fulfillment.

Takehisa Yamada

Representative Director,
EPS Corporation

EPS' Targeting Position

An indispensable partner in resolving challenging issues

We support your new initiatives with our collective knowledge and experience. We will propose and implement the most appropriate solutions.
If you have any such needs or concerns with challenging issues, please contact us first.

Trial GATE

An indispensable partner in problem-solving that can work with you from the start of your project to the finish line.

Virtual GO

DCT platform

Clinical Trials

Clinical Research

Post Marketing Surveillance

Safety Information

The DCT platform promoted by EPS

EPS is working on building a structure that will support implement,and operate Decentralized Clinical Trials (DCT) as a centralized service center between not only sponsors and institutions but also service providers and patients. We offer a one-stop service throughout the clinical trial life cycle that covers consulting for preparing a DCT during the study planning phase to reviewing and proposing improvement plans at the end of clinical trials.

※Examples of support contents

Patient Engagement Support Solution

Voicebook

Patient Engagement in pharmaceutical development.

We believe that once “patients-centric clinical trials” get implemented a trustworthy relationship between our customers and patients would be built and the domestic clinical trials would be promoted improving the public image.

Voicebook

EPS Patient Engagement

- Patient Survey Service
- Patient Interview Service
- PLS*Creation Service
- Patient Involvement coordinator Material Review Service

Patient Involvement coordinator
(EP-Link Co., Ltd.)

＊Plain Language Summaries (PLS):A brief description of the clinical trial results in everyday language that is understandable to trial patients and their families who do not have a medical or scientific background

EPG Groups' Three Unique Strengths

01

“Patient Involvement coordinator”, a specialized profession in patient engagement.

As patient involvement coordinators, our highly expert CRCs act as a bridge connecting patients who cooperate with the pharmaceutical development and our clients.

02

Patient engagement support.

As a neutral observer, we unbiasedly draw out patients’ true opinions with a no direct conflict of interest.

03

Total support fused by CRO's and SMO's strengths.

The expert diverse teams comprising members from EPS Group gives full support from planning to preparing reports.

Clinical Development Services

CMC Regulatory Affairs

In the field of CMC, our expert staff apply highly specialized skills to perform the tasks described below. They deliver regulatory affairs services with impeccable quality in support of customers inside and outside Japan across a broad range of activities. Our CMC services range from support for drug substance filings and drug product approvals to advice on GMP and consistency check.

Data Management

With one of the largest teams of data human resources in Japan, we derive data accurately and quickly, regardless of the domain or study phase.

Medical Writing

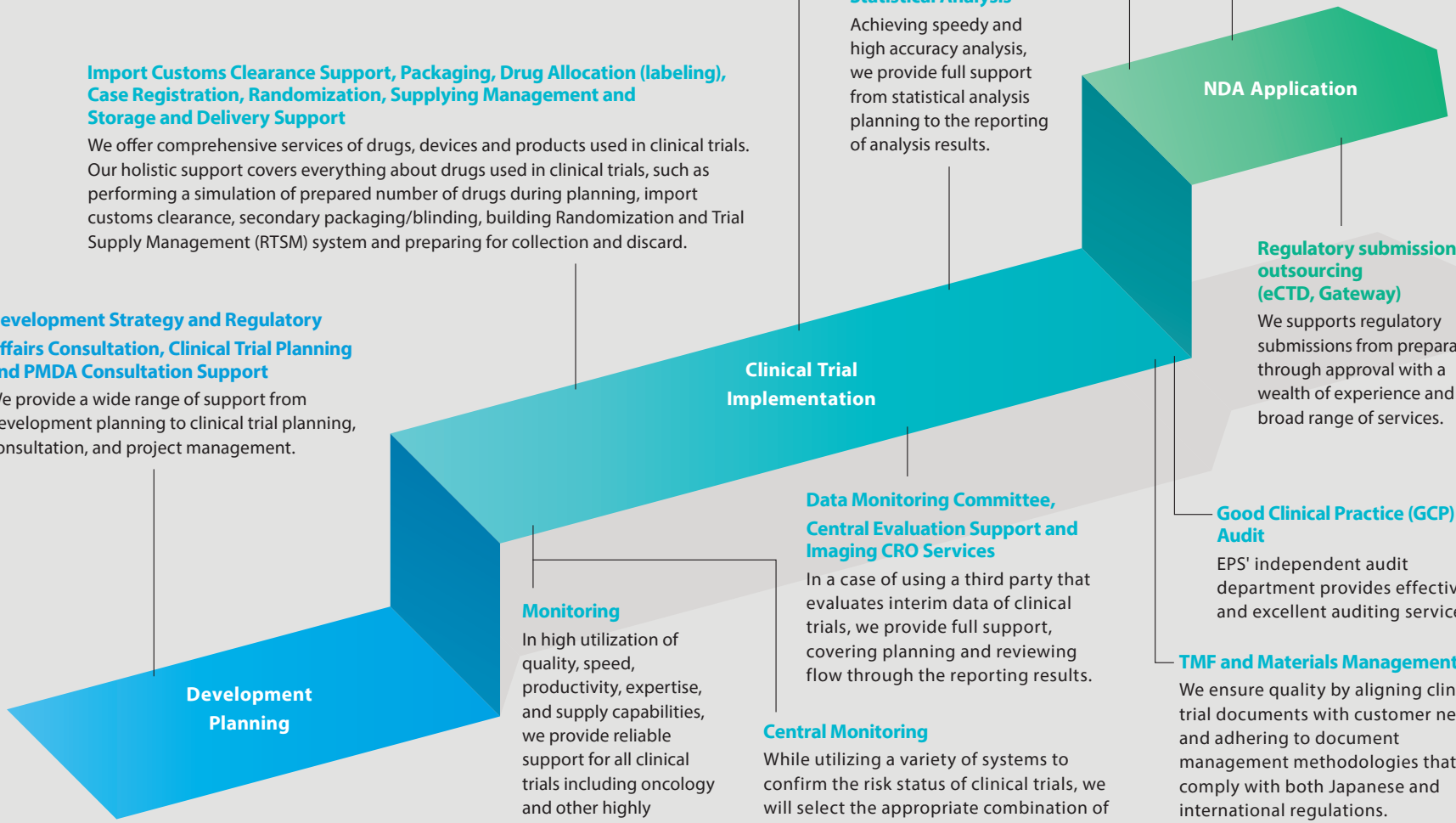
In high utilization of quality, speed, productivity, expertise, and supply capabilities, we provide reliable support for all clinical trials including oncology and other highly challenging clinical trials.

Statistical Analysis

Achieving speedy and high accuracy analysis, we provide full support from statistical analysis planning to the reporting of analysis results.

Import Customs Clearance Support, Packaging, Drug Allocation (labeling), Case Registration, Randomization, Supplying Management and Storage and Delivery Support

We offer comprehensive services of drugs, devices and products used in clinical trials. Our holistic support covers everything about drugs used in clinical trials, such as performing a simulation of prepared number of drugs during planning, import customs clearance, secondary packaging/blinding, building Randomization and Trial Supply Management (RTSM) system and preparing for collection and discard.



Development Strategy and Regulatory Affairs Consultation, Clinical Trial Planning and PMDA Consultation Support

We provide a wide range of support from development planning to clinical trial planning, consultation, and project management.

Regulatory submission outsourcing (eCTD, Gateway)

We supports regulatory submissions from preparation through approval with a wealth of experience and a broad range of services.

Data Monitoring Committee, Central Evaluation Support and Imaging CRO Services

In a case of using a third party that evaluates interim data of clinical trials, we provide full support, covering planning and reviewing flow through the reporting results.

Good Clinical Practice (GCP) Audit

EPS' independent audit department provides effective and excellent auditing services.

Monitoring

In high utilization of quality, speed, productivity, expertise, and supply capabilities, we provide reliable support for all clinical trials including oncology and other highly challenging clinical trials.

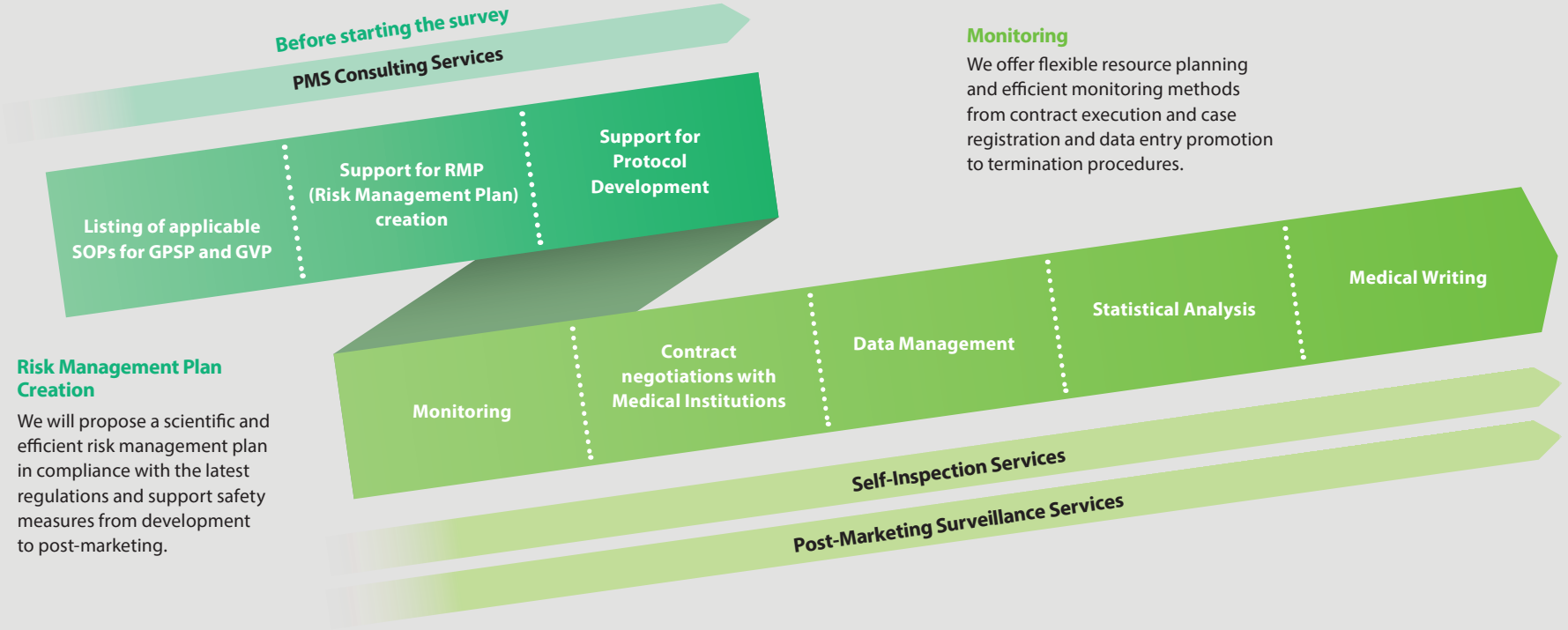
Central Monitoring

While utilizing a variety of systems to confirm the risk status of clinical trials, we will select the appropriate combination of central and on-site monitoring process.

TMF and Materials Management

We ensure quality by aligning clinical trial documents with customer needs and adhering to document management methodologies that comply with both Japanese and international regulations.

Post-Marketing Surveillance Services



Risk Management Plan Creation

We will propose a scientific and efficient risk management plan in compliance with the latest regulations and support safety measures from development to post-marketing.

Monitoring

We offer flexible resource planning and efficient monitoring methods from contract execution and case registration and data entry promotion to termination procedures.

Data Management

We have one of the best systems in Japan that can participate in all stages of the investigation process and contribute to improving the overall quality and speed of the investigation by foreseeing risks.

Statistical Analysis

Full-Support from statistical analysis planning to analysis results report.

Medical Writing

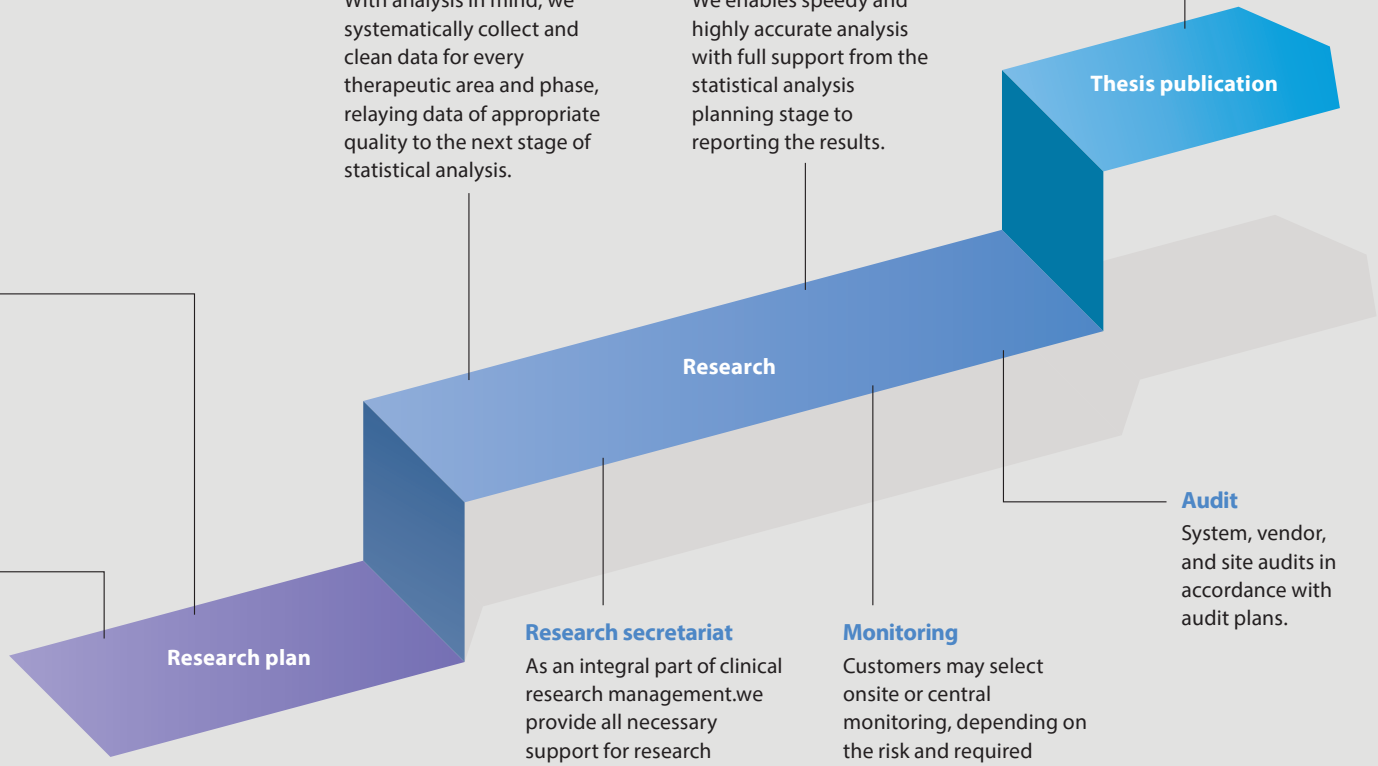
Responding flexibly to clients' requests for consultation on research plans to efficiently producing high-quality documents.

Clinical Research Services

Medical Writing
We comply with all regulations and guidelines and deliver high quality documents to meet customer needs.

Data Management
With analysis in mind, we systematically collect and clean data for every therapeutic area and phase, relaying data of appropriate quality to the next stage of statistical analysis.

Statistical Analysis
We enables speedy and highly accurate analysis with full support from the statistical analysis planning stage to reporting the results.



Research systems and structures
Project managers with specialization in clinical research build optimal systems and structures for each research project.

Research planning and Consulting
We provides broad support, from planning and research planning through consultation and project management.

Research secretariat
As an integral part of clinical research management.we provide all necessary support for research operations.

Monitoring
Customers may select onsite or central monitoring, depending on the risk and required quality of the research.

Audit
System, vendor, and site audits in accordance with audit plans.

EPS

https://www.epsi-global.com

Contact us

2024.03