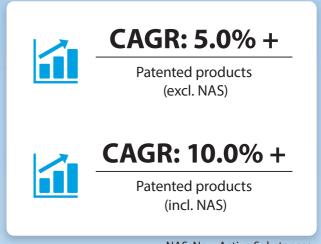


# Large Pharmaceutical Market for R&D Driven Companies





NAS: New Active Substances

#### **Japan Clinical Trials and EPS Performance**

<i>i</i>	MRCT % of Total Trade	Oncology Study	Regenerative Medicine	Rare Disease
EPS Performance	<u>65%</u>	1000 + Protocols	60 + Protocols	200 + Protocols
Japan	<b>60 %</b> 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

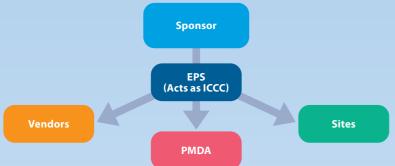


We provide a One Stop Solution for all your outsourcing needs!



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

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



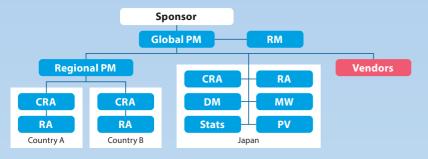
# **Global Research Business**

#### 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 Project management structure**





#### **EPS Also Provides a Functional Service Provider (FSP) Model**

Flexible and compliant with regulatory requirements

Clinical Operation

Project Management Data Science Pharmacovigilance

Regulatory Consulting

#### **Regulatory Affairs Capability**

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

#### **Operations staff coverage**

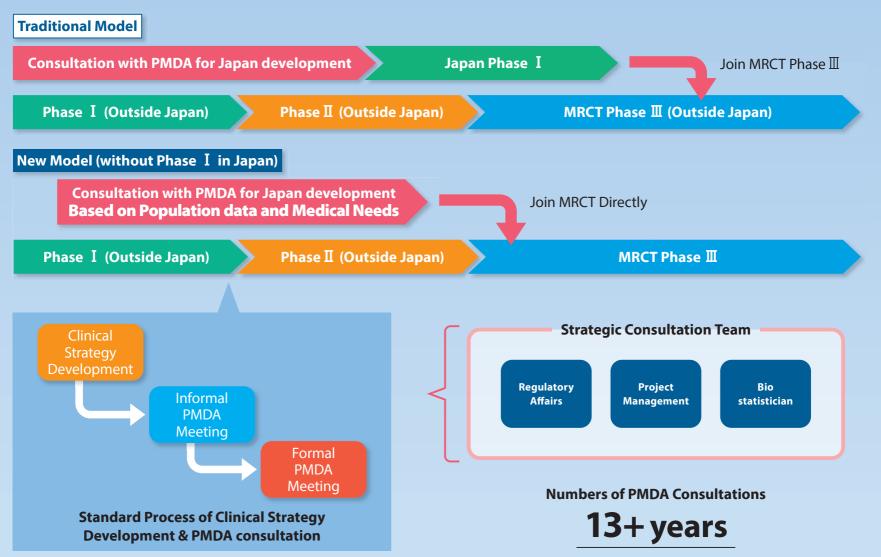
	Location	PM	со	DM	SA	RA	PV	QM	Scientific Leadership	Central Analysis & DSMB
EPS	Japan	✓	✓	✓	✓	✓	✓	✓	✓	✓
	South Korea	✓	✓	*	*	✓	*	*	*	*
	Taiwan	✓	✓	*	*	✓	*	*	✓	*
	China	✓	✓	✓	✓	✓	✓	✓	✓	*
Partners	United States	✓	✓	✓	*	✓	✓	✓	<b>√</b>	<b>√</b>
	United Kingdom	✓	✓	*	*	✓	*	*	/	*
	Netherlands	✓	✓	*	*	*	✓	*	1	*
	Singapore	✓	✓	*	*	✓	✓	*	/	*
	Hong Kong	✓	✓	*	*	✓	*	*	1	*
	Malaysia	✓	✓	*	*	✓	*	✓	/	*
	Philippines	✓	✓	*	*	*	*	*	✓	*
	Australia	✓	✓	✓	*	✓	✓	✓	1	✓
	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.



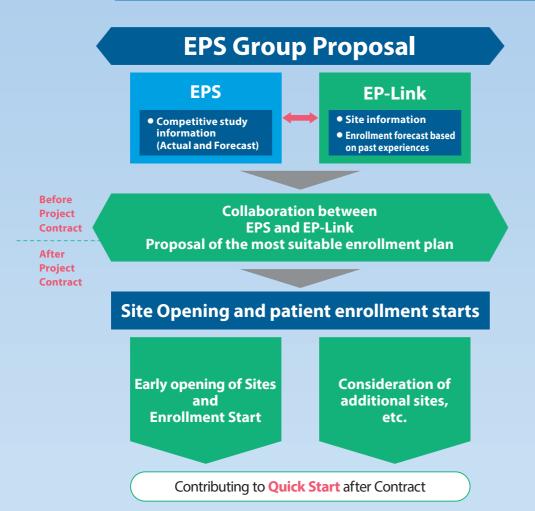
# **Quick Study Start Up**

**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)



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.



Noriyuki Takai
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

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.







health claims



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





**Clinical Research** 

**Safety Information** 

Surveillance



# The DCT platform promoted by EPS

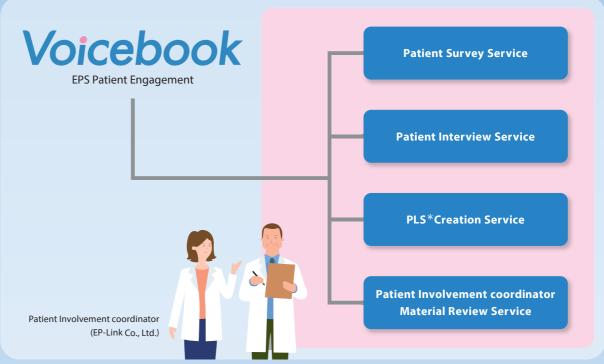
EPS is working on building a structure that will support implement, and operate Decentralized Clinical Trials (DCT) as a centralized service center between not only sponsors and institutions but also service providers and patients. We offer a one-stop service throughout the clinical trial life cycle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



# 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.



\* 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.

#### 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.

#### **Statistical Analysis**

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

#### **NDA Application**

#### **Regulatory submission** outsourcing (eCTD, Gateway)

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

#### **Clinical Trial Implementation**

#### **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.

#### **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.

EPS' independent audit

**Good Clinical Practice (GCP)** 

**Audit** 

department provides effective and excellent auditing services.

#### **Development Planning**

#### **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.

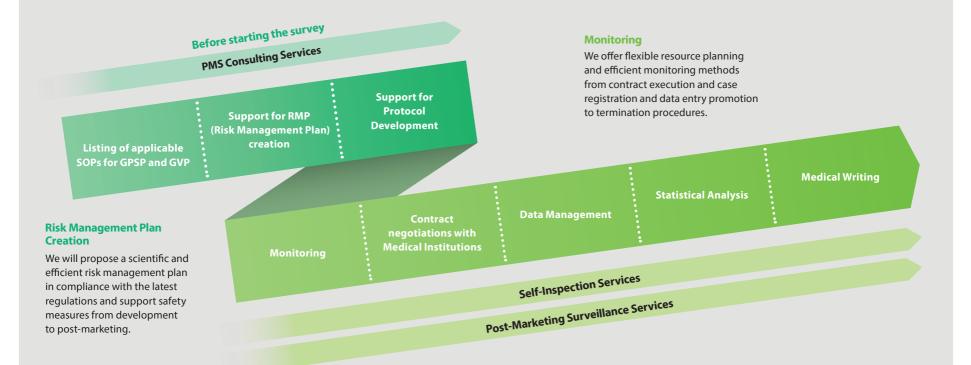
#### **Central Monitoring**

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



#### **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.

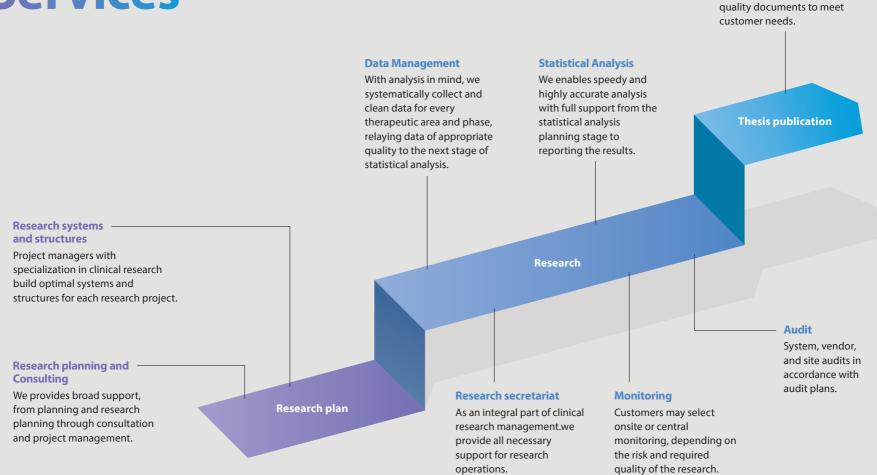
#### **Statistical Analysis**

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



https://www.epsi-global.com

Contact u



