



Make your trial FAST & COST EFFECTIVE with a fully qualified Site Management Organization

Read more

# **EP-SOGO**

**No.1 Site Management Organization in Japan and Taiwan** 

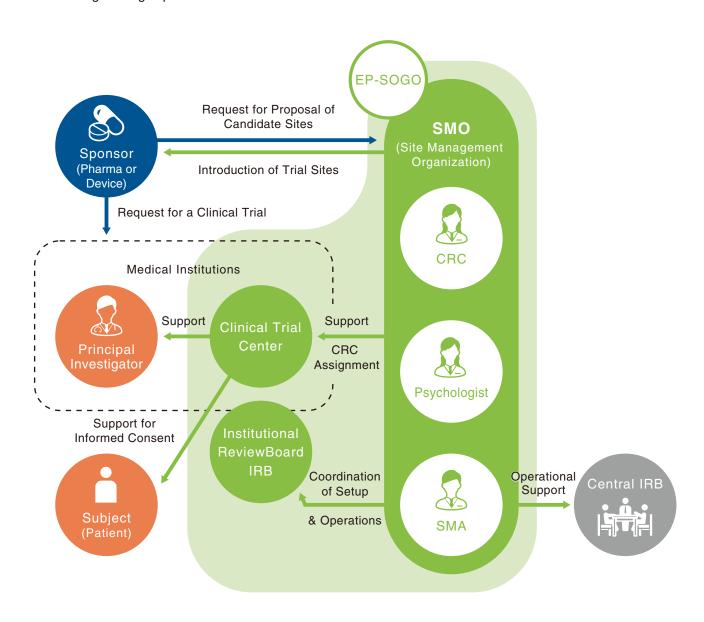
Site Management	P2	
Clinical Site Network		
Clinical Research Coordinators	P5	
IRB & Central IRB	P7	
Rater Service	Р8	
Corporate Information	P9	



# Make your trial FAST & COST EFFECTIVE with a fully qualified Site Management Organization

As the No.1 site management organization (SMO) in Japan and Taiwan, EP-SOGO provides professional and centrally controlled site management services such as:

- Providing accurate site information
- Ensuring fastest document preparation
- Finding the right patients in time



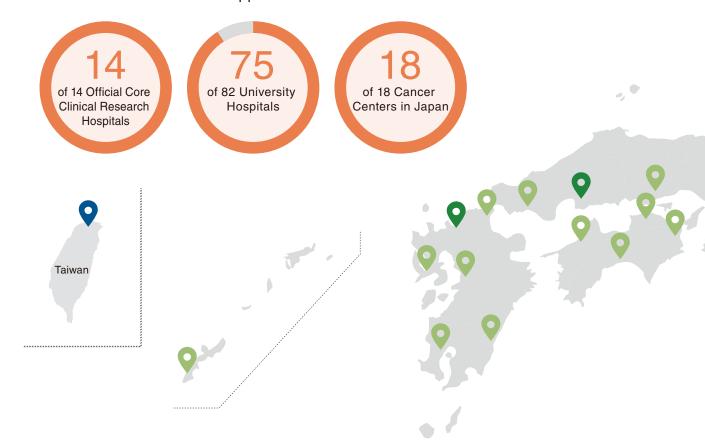
# EP-SOGO's network of 6,900 clinical sites accommodates your needs for any trials

EP-SOGO releases you from stressful site management. For a successful study, it is strongly recommended that you entrust your studies to the site management organization (SMO) with the greatest coverage of sites and CRCs. EP-SOGO, with the greatest network of 6,900 contracted clinical sites in Japan and Taiwan, enables you to have the biggest chance of enrolling the most patients at the best sites into your trial. EP-SOGO also provides state-of-art digitalized tools including "SYNOV-R" for secure remote SDVs, "DDworks NX/Trial Site" for document management, and "TOMA-s" for progress management to maximize the efficiency of clinical trial. Several mega-pharma companies have already assigned EP-SOGO as their preferred SMO. Like these companies, you will be free from stressful site management by utilization of systematically controlled site management by EP-SOGO, the largest SMO in Japan and Taiwan that can propose the best clinical sites for you.

Partner Clinical Sites in Japan and Taiwan

Approx. **6,900** Sites

EP-SOGO's Support Track Record

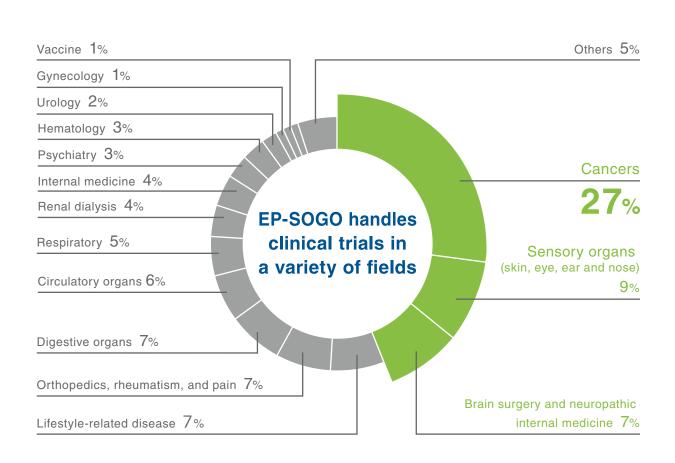




# Access all the sites you need, find the right patients, and implement your trial in the right way with professional CRCs

EP-SOGO has the greatest number of qualified Clinical Research Coordinators (CRCs) of any SMO in Japan. They support clinical trials in our network of 6,600 clinical sites, enabling fast implementation of your trials, even for large-scale trials enrolling a huge number of patients. Our CRCs' expertise covers any therapeutic areas including oncology, which requires specific extensive knowledge for complex oncology clinical trials. EP-SOGO CRCs are systematically trained, and ready to provide support in all challenging therapeutic areas.

## Experience with Therapeutic Areas



A Clinical Research Coordinator (CRC) provides onsite support for clinical trials working with investigators. EP-SOGO has numerous CRCs available even for the therapeutic areas requiring advanced expertise, including cancers and circulatory diseases, to handle every type of clinical trial. Additionally, through human resource development focusing on communication, EP-SOGO trains CRCs to provide subjects with emotional support and to assist in the execution of safe and smooth clinical trials from various aspects.

### CRC's Main Tasks

01 — FLOW



## Before starting a clinical trial

- ▶ Preparation of the informed consent form
- Preparation of the clinical trial materials
- ▶ Training needed for executing the clinical trial
- Participation in the start up meeting
- ▶ Coordination and communication with the trial site



02 —



### During the clinical trial

- Support to check the eligibility of the subject
- ▶ Support for the informed consent
- ▶ Schedule management of the clinical trial
- ▶ Support to create the case report form (EDC entry)
- Support for AE / SAE reporting
- ► Attendance to monitoring / direct access (including the coordination of off-site monitoring and remote SDV)
- Support for shipping investigational products and study materials to the patient's home



03 — FLOW

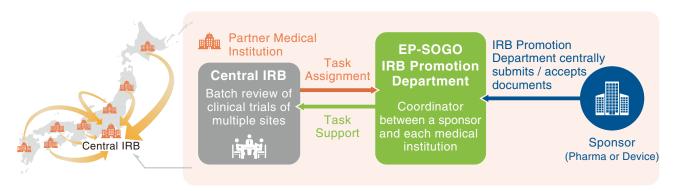


## When the trial is complete

- Arrangement or return of the clinical trial materials
- Support to create the end-of-study report
- Arrangement of stored documents
- ▶ Attendance to audit and regulatory inspection

# EP-SOGO's IRB and Central IRB support enables quick start-up of your clinical trials

EP-SOGO coordinates establishment and supports administration of in-house IRBs (Institutional Review Board). In addition, EP-SOGO supports management of central IRBs (single IRBs) established in our partner sites. We have also established remote IRB meetings via video conference with standardized procedures. This strategy is rapidly becoming a popular style. Since 2017, EP-SOGO has also supported Certified Committees for Regenerative Medicine.



# **Site Management Associates**

EP-SOGO supports you comprehensively to create an environment required for clinical trials with our qualified site management associates (SMAs). This includes, but not limited to coordination of establishing clinical trial centers and IRBs, preparation of the documents stipulated in GCP and training for the site staff on the general concept and details of GCP. EP-SOGO has a wide range of achievements for supporting any size of clinical sites. Depending on a variety of needs, EP-SOGO supports you totally or for a single task.

#### STEP2 STEP3 STEP1 ► Coordination of establishment Preparation of clinical trial Preparation for site qualification and operation of clinical trial documents including progress visit by the sponsor secretariat and IRB reports and end of trial report. Preparation of CVs of investigators Support to create SOP (Standard) Correspondence for the sponsor and the list of clinical trial staff. Operating Procedures) of the Preparation of IRB submission ▶ Preparation of IRB submission clinical site and IRB package package for continuing review ▶ Education of the site staff and ▶ Site contract amendment Preparation of site contract IRB members documents

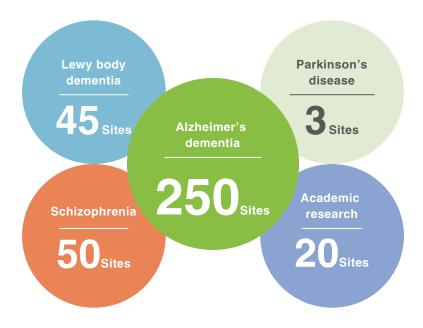
# 330 high-quality raters are available for your CNS trials

EP-SOGO dispatches raters to clinical sites for administering rating scales in CNS and Psychiatric trials. EP-SOGO's raters have advanced expertise and skills and are familiar with the industry and workings related to clinical trials. You can utilize our raters to make the operation of your study more efficient and solve various issues related to efficiency, speed, cost, and data quality during execution of clinical trials.



## Experience with Diseases

EP-SOGO has provided raters for many studies including Alzheimer's disease and Lewy body dementia.





Kenichi Yamamoto

Representative Director

EP-SOGO CO.,Ltd

# **New Value Creation**

**Beyond Innovation** 

EP-SOGO continues to create new values and never stops its progress

As the frontrunner in the Japanese SMO sector, EP-SOGO provides support for clinical trials and post-marketing trials conducted by medical institutions.

The clinical and post marketing trials business climate is undergoing major changes. The use of digital transformation is accelerating rapidly, as seen in the growing need for remote viewing of medical records due to the increased adaptation of Decentralized Clinical Trials (DCT) and impacts of the pandemic.

To adapt to these environmental changes, EP-SOGO have been creating solutions such as "SYNOV-R", which is a next-generation remote SDV system. We are also advocating to relevant regulatory authorities and associations to enable further decentralization in clinical trials.

Since our founding in 1999, we have committed ourselves to delivering new drugs as quickly as possible to patients who are waiting for new drugs. Based on this unwavering belief, EP-SOGO will continue to move forward with a strong desire to improve and invigorate the environment for clinical trials in Japan and other Asian countries.

# **Company Profile**

Corporate Name	EP-SOGO Co., Ltd.
Address	Kagurazaka AK Bldg., 1-8 Tsukudocho, Shinjuku-ku, Tokyo 162-0821, Japan
Establishment	December 1999
Employees	1,670 (As of October 1, 2022)
Web Site	https://www.epsogo.co.jp/en/
e-mail	info@eps.co.jp
Parent Company	EPNextS, Inc.
Subsidiary	Total Trial Management Consulting Co. Ltd. (Taiwan)

# **Corporate Philosophy**

### **Our Mission**

We will contribute to the advancement of the healthcare industry by providing high-value-added solutions to our clients.

### **Our Vision**

If we improve each day, we can progress ourselves daily, and will continue to do so. Ever Progressing System

## **Our Values**

For our Clients	We always place the highest priority on meeting clients' needs and providing high-value-added services.	
For our Business	We will contribute to the advancement of society through sustained development of our businesses.	
For our People	We will grow through our service to clients, and improve the quality of life (QOL) of all our stakeholders.	



### **Meaning of Our Logo**

Our logo reflects the corporate philosophy of EPS GROUP.

The three circles represent our EPS Group policy (for the clients, for the business, and for the people), of our commitment to progress to the future.

**EP-SOGO Co., Ltd.** 

https://www.epsogo.co.jp/en/ info@eps.co.jp