

New Value *Creation*

EP-Link CORPORATE PROFILE



New Value *Creation*

EP-Link continues to create new values and never stops its progress, valuing “link” that connects the past to the present and into future.

EP-Link Co., Ltd. was founded in 1999 and has grown as a Site Management Organization (SMO) for clinical trials. Through numerous collaborations and integrations up to the present, various corporate cultures have fused together to shape our company as it is today.

In the midst of the ever-changing environment surrounding pharmaceutical development, including recent issues such as drug lag and drug loss, EP-Link is committed to its mission of "getting new drugs to patients who desperately need them as quickly as possible". EP-Link strives to contribute to solving these social issues through the combined expertise of its specialized staff, primarily its Clinical Research Coordinators (CRCs).

The company name "Link" originates from connecting all stakeholders involved in clinical trials, such as patients, medical institutions, and pharmaceutical companies.

EP-Link will continue to evolve every day to remain a solution provider that you need in the future. I look forward to your continued partnership and support as we strive to achieve our mission together.

April 2025



Representative Director
Hironao Nakajima





[SMO]

EP-Link leverages its overwhelming experience and track record to support the implementation of high-quality clinical trials



[Digital Transformation & Solutions]

EP-Link provides convenient systems and schemes to revolutionize clinical trial operations

EP-Link makes a valuable contribution to the future of drug discovery through the trust it has cultivated and new technologies.

Clinical Research Coordinator (CRC)

- Communication and coordination with relevant functions within the hospital
- Preparation and documentation before the start of clinical trials
- Subject support and adverse event handling
- Communication with clinical research associates (CRAs) and audit support
- Case report preparation

Site Data Manager (SDM)

- Data-related tasks (preparation and review of source documents, data entry, responding to queries, etc.)

Site Management Associate (SMA, clinical trial secretariat)

- Document management and audit support
- IRB/Central IRB operation support
- Clinical trial implementation system, procedure manual preparation, and procedural materials preparation
- Support for the operation of the affiliated Certified Regenerative Medicine Committee (Type 3), preparation for meetings, and preparation of minutes
- Regenerative medicine-related (Type 3) consulting services

Rater Service

- Administration of rating scales for CNS (dispatch of assessments psychologists)
- Rater trainings

Study Introduction & Feasibility

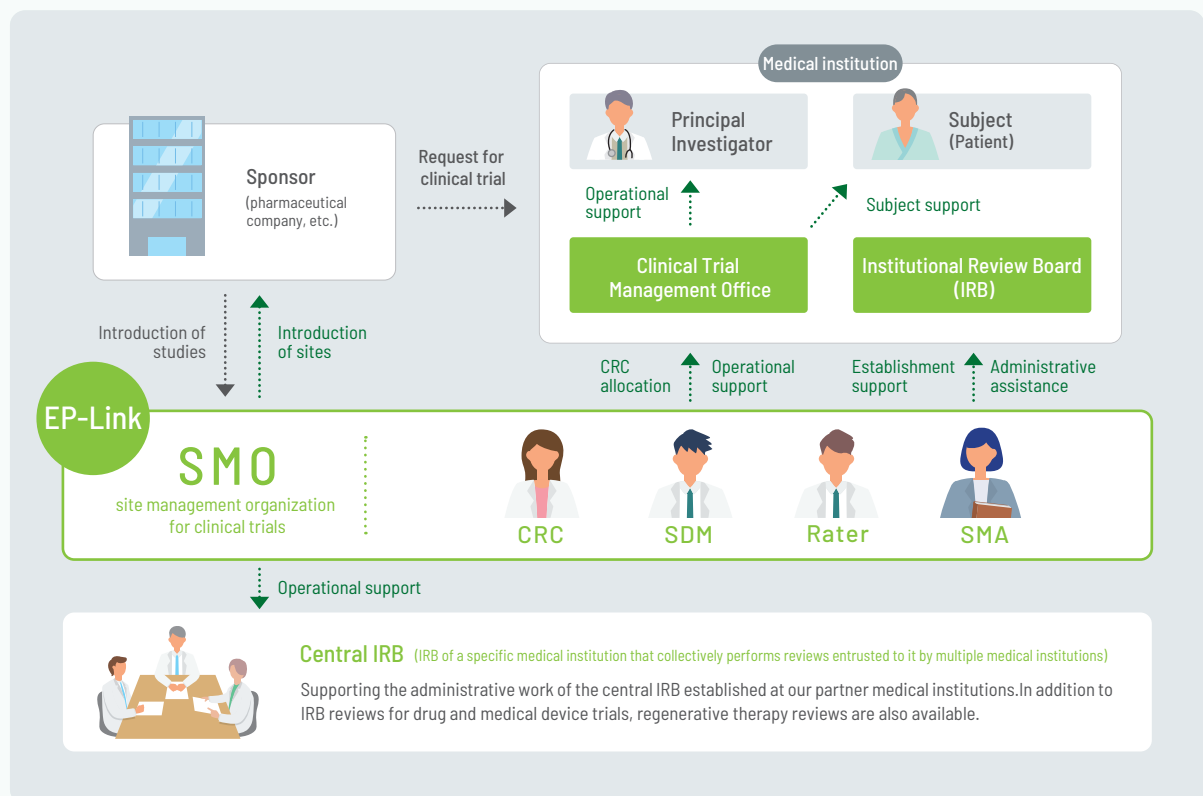
- Introduction of new studies
- Clinical trial feasibility studies
- Establishment of a clinical trial implementation system

Services & Solutions

- Site Start-up Specialist "SSS"
- Remote SDV System "SYNOV-R"
- Cloud system for clinical trial documents "DDTS"
- Patient referral scheme "Patient LINK"
- Decentralized clinical trials "DCT"
- Creation of clinical trial materials "CCTM"
- Clinical trial education system "CTES"
- Patient & public involvement "PPI"

Full support for clinical trial sites aiming for high quality and efficient clinical trials

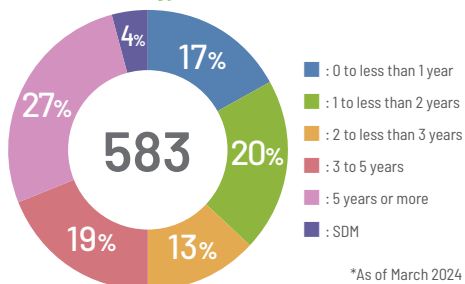
Since its founding, EP-Link has expanded its Site Management Organization (SMO) business, supporting the implementation of clinical trials at medical institutions. EP-Link acts as a bridge between pharmaceutical companies that sponsor clinical trials and medical institutions, and provides optimal solutions that meet customer needs. EP-Link contributes to reducing the burden and improving quality and speed in the clinical trial environment, providing strong support to people involved in clinical trials.



EP-Link's strength in the oncology

EP-Link has many CRCs who are able to work in oncology studies, which require extensive expertise. EP-Link has a long history of supporting cancer centers and cancer treatment coordinating hospitals throughout Japan.

Number of CRCs with experience in oncology trials as the main CRC



Partner medical institutions



A leading SMO company

EP-Link's Strengths



Number of Protocols

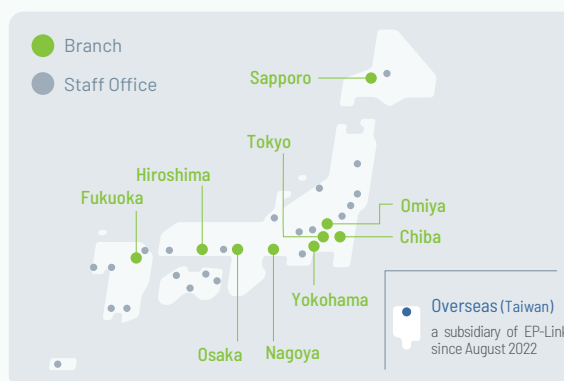
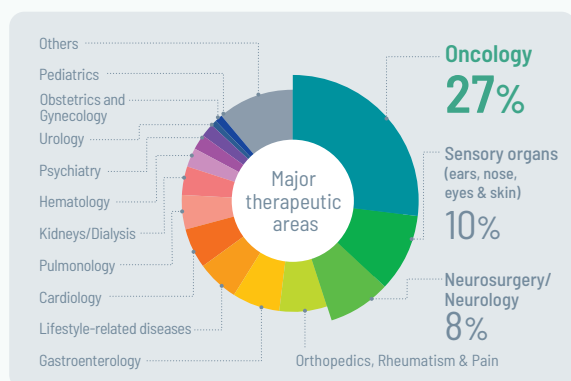
Over 6,600

*Number of protocols entrusted between October 2011 and September 2024



Number of partner medical institutions

Approximately 7,200



EP-Link has overwhelming strengths in oncology, one of the most difficult therapeutic area, and supports major medical institutions and academia throughout Japan. EP-Link has accumulated experience and know-how in many therapeutic areas, including rare diseases, dermatology, orthopedics, and lifestyle-related diseases.

EP-Link has branches and staff offices in 31 locations across Japan and has the largest number of partner medical institutions in the industry. Its partner medical institutions include clinical research core hospitals and university hospitals. This allows EP-Link to provide optimal matching to meet the various needs for clinical trials.



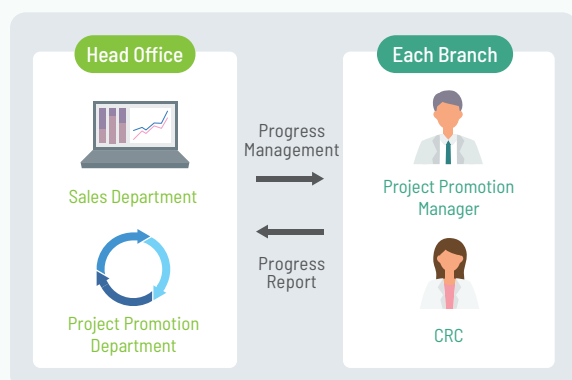
Progress Management System

Strategic Enrollment & Progress

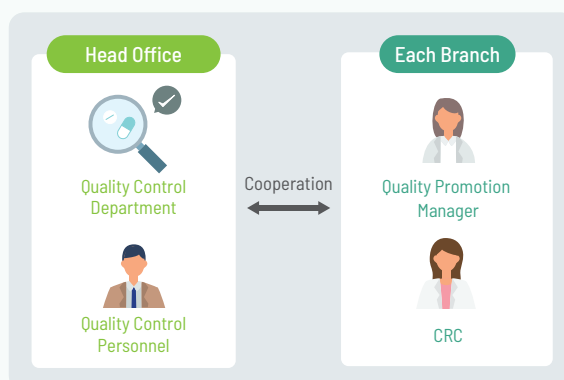


Quality Management System

Cross-functional Management



Each branch has dedicated staff to manage and promote enrollment and progress. They work closely with the relevant departments at head office and have a thorough project management system in place that covers everything from preliminary preparations through the enrollment period, post-start, and study close-out.



The quality control department at the head office and the Quality Promotion Manager at each branch work closely. EP-Link strives to improve and standardize the quality of its operations through the promotion of risk-based process management, rapid response to accidents, and regular training.

Highly specialized and skilled personnel support clinical studies in every aspect

Human Resources

Clinical Research Coordinator (CRC)

EP-Link has numerous experienced CRCs to support clinical trials, ensuring smooth and safe clinical trials

CRCs support the progress of clinical trials under the direction of the principal investigator. EP-Link has a large number of CRCs who can play an active role in therapeutic areas, including those requiring a high level of expertise, such as oncology and cardiology, and can handle all types of clinical trials. In terms of human resource development, EP-Link also place emphasis on communication skills. EP-Link trains CRCs to empathize with patients and support the smooth and safe conduct of clinical trials from multiple perspectives.

EP-Link has more than 1,300 CRCs throughout Japan



CRCs are located in 9 branches and 22 staff offices throughout Japan. EP-Link is able to handle clinical trials in a wide range of therapeutic areas in various regions.

Development of professional CRCs



EP-Link has established a unique educational system that fosters a wide range of knowledge, including specialized medical and pharmaceutical knowledge.

Focus on development of CRCs specialized in oncology



Regular in-house training by oncology specialists is held to develop professional CRCs.

English translation support team for global clinical trials



EP-Link has an in-house English translation support team and also hold English training for CRCs, enabling strong operations of global studies.

Human Resources

Site Data Manager (SDM)

Working closely with CRCs to contribute to streamlining clinical trial operations and improving data quality

SDMs are specialists who have experience as a Clinical Research Associate (CRA), etc., and are responsible for data-related tasks in collaboration with CRCs. SDMs reduce the burden and increase the efficiency of clinical trial sites, and improve the quality of contracted trials.

Tasks to be done by CRCs at medical institutions

Subject support

Arrangement of source documents

Data entry

Query resolution support

Tasks supported by SDMs

Site Management Associate (SMA, clinical trial secretariat staff)

Total support for creating the environment necessary for clinical trials

SMA's provide comprehensive support for creating the environment necessary for clinical trials, including assistance with setting up a clinical trial office. EP-Link's SMA's have an average of over 5 years of work experience. 70% hold professional qualifications related to SMA. Utilizing that experience and knowledge, EP-Link provides flexible support, from full-scale support to pinpointing specific needs.

Establishment of a clinical trial implementation system

- Support for setting up and running clinical trial secretariat and Institutional Review Board (IRB)
- Support for creating SOPs (Standard Operating Procedures) for medical institutions and IRBs
- Educating site staff and IRB committee members

Before the start of the clinical trial

- Support for sponsor's site qualification
- Support for preparation of CVs for the principal investigator and clinical subinvestigators, as well as a list of study collaborator
- Support for Institutional Review Board (IRB) submission
- Support for clinical trial contract procedures

Clinical trial start to end

- Support for preparation of various documents such as clinical trial status reports and the end of clinical trial report
- Handling inquiries from the sponsor to the clinical trial office
- Support for Institutional Review Board (IRB)'s subsequent review submission
- Support for requests to change the clinical trial contract

Assessment Psychologists

EP-Link provides assessment psychologists to medical institutions for clinical studies and trials

Neuropsychological assessment using rating scales is essential in clinical studies and trials in the fields of psychiatry and central nervous system. EP-Link has a large number of assessment psychologists with advanced expertise and skills. They are also well versed in operations and industry knowledge related to clinical trials, and contributes to solving issues related to the efficiency, speed, cost, and data quality of industry-sponsored clinical trials.

Standardized administration of rating scales



To minimize inter-rater variability, EP-Link regularly provide rater training.

Unbiased evaluation of efficacy



EP-Link's assessment psychologists visit medical institutions on the contracted dates and only administer the rating scale of the clinical trial. The rating scales are administered under unbiased conditions.

Reducing the workload of site's medical professionals, including doctors



With EP-Link's support, rating scores are administered without taking up the time of site staff.

Full support system



EP-Link has a comprehensive support system, including follow-up on obtaining rater certification and handling inquiries after the start of the study.

EP-Link is the only company in the industry with a CRC team of over 1,300 people.
In addition to CRCs, EP-Link also has many other experts working on clinical trials.



CRCs
1,321



SDMs
50



SMA's
141



Assessment Psychologists
300

*As of September 2024

スペシャリストによる試験立ち上げ支援

NEW

Service

Specialist Support for Study Initiation

SSS (Site Start-up Specialist)

Achieving "Efficiency" and "Lead Time Reduction" in Study Initiation



SSS is a specialist in initiating studies at medical institutions, with extensive experience as a Clinical Research Associate (CRA) in launching numerous studies and familiarity with medical institution procedures. By utilizing SSS, it becomes possible to commence necessary procedures for study initiation early, without waiting for CRA assignment. SSS, with its wealth of experience and expertise, provides efficient and effective support for study initiation.



Reduce the burden of increasingly complicated clinical trial work with EP-Link's unique solutions

System

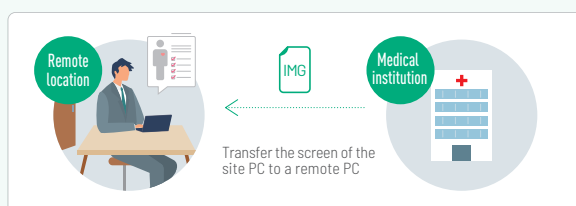
Remote SDV system

SYNOV-R

A next-generation system that enables safe access to source documents such as electronic medical records from remote locations



SYNOV-R is a remote SDV system that uses unique network technology to enable secure access to source documents such as electronic medical records from remote locations. In addition to this **STRONG SECURITY**, it also enables users to **CONTROL & MANAGE VIEWING**.



System

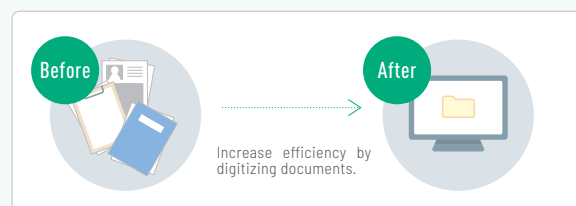
Clinical Trial Document Cloud System

DDworks NX/Trial Site (DDTS)

A cloud-based system for electronic management of clinical trial documents that improves operational efficiency and quality



DDTS is a solution that digitizes various clinical trial documents and enables their exchange and management on the cloud. By using electronic data as the original, it contributes to business efficiency and paperless operations. Furthermore, computerizing clinical trial process management helps reduce costs and improve security.



EP-Link offers a variety of clinical trial schemes and services to meet the needs of today's clinical trial environment.

NEW Scheme Patient referral scheme **Patient LINK**

EP-Link's patient referral service solves challenges in enrollment



Patient LINK is a service where EP-Link intermediates in referring patients who are subjects of clinical trial medical institutions (trial sites) from EP-Link's other partner medical institutions (partner sites). It helps to resolve the issue of subject recruitment and contribute to shortening the clinical trial period.



Smooth enrollment and transfers lead to efficient clinical trials.



Scheme Decentralized clinical trial **DCT**

EP-Link supports clinical trials that are not dependent on visits to clinical sites



By promoting the concept of patient-centricity and utilizing digital technology, EP-Link provides opportunities for patients who have previously found it difficult to participate in clinical trials due to geographical factors, etc.



Remote clinical trial participation

Utilizing EP-Link's site network throughout Japan to support the introduction of partner sites

NEW Service Creation of clinical trial materials **"CCTM"**

EP-Link's experienced team of experts prepares a batch of clinical trial materials

Staff with CRC experience use their expertise to create case files, worksheets, and other clinical trial materials. In addition to improving work efficiency, it also improves issues such as cost and quality.

NEW Service Clinical trial education system **"CTES"**

EP-Link provides training that condenses practical know-how in clinical trial work to meet the needs of medical institutions and sponsors.

EP-Link provides medical institutions and clinical trial sponsors with the various knowledge it has accumulated over many years that is necessary for carrying out clinical trial operations.

NEW Service Patient and public involvement **"PPI"**

EP-Link supports drug development with the voices of patients

EP-Link utilizes our network of approximately 7,000 partner medical institutions to collect information on the needs of patients, their families, and medical institutions. EP-Link delivers them to pharmaceutical companies and contribute to the development of high-value pharmaceuticals.



ものづくり日本大賞
優秀賞

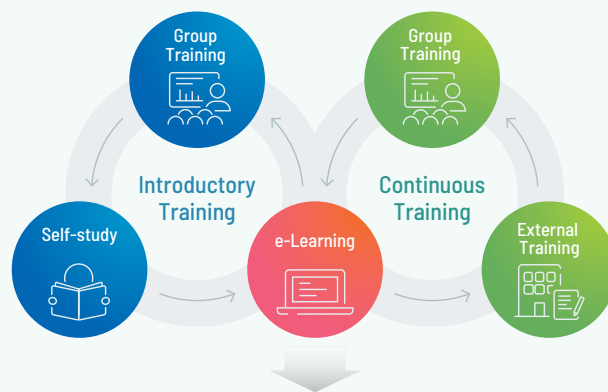
SYNOV-R Development Group Receives Excellence Award at the "9th Monodzukuri Nippon Grand Award"

The development group of EP-Link has been awarded the Excellence Award in the "9th Monodzukuri Nippon Grand Award," hosted by four ministries in Japan: the Ministry of Economy, Trade and Industry; the Ministry of Land, Infrastructure, Transport and Tourism; the Ministry of Health, Labour and Welfare; and the Ministry of Education, Culture, Sports, Science and Technology. This recognition was given for their efforts in improving the efficiency of pharmaceutical clinical trial processes, including the development of "SYNOV-R," an innovative tool that significantly reduces clinical development timelines.

The entire company is focused on improving service quality and developing professional human resources

Human Resource Development

A site management organization (SMO) needs a wide range of specialized knowledge, including medical, pharmacological, and GCP-related legal knowledge. In addition, a variety of qualities are required to act as a "bridge" between pharmaceutical companies and medical institutions, such as coordination and negotiation skills, communication skills, and a strong sense of ethics. To develop employees with this wide range of knowledge and skills, EP-Link have established a unique educational system that focuses on continuity and practicality, fostering human resources with a wealth of expertise.



EP-Link is working to improve the skills of each employee as a business person

Human Resource Development System

		Joining / Training Period	Growth Period / Establishing Career Path	Management Period / High Performance Period
General Education	By Position	New Employee Training		New Manager Training
		Follow-Up Training		Secondary Manager Development Training (Selective Type)
	By Purpose	Compliance / Information Security / Harassment Prevention / Safe Driving / English		
		Training Of On-The-Job Trainers		Evaluator Training
Specialized Education	By Job Type	Training & Study Sessions for Each Department		
	CRC SMA BD	CRC/SMA Introduction Training	Obtaining Certification (JASMO, etc.)	
		On-The-Job Training (Practical Training)	Oncology CRC Specialized Training (Basic/Continuous Training)	
		Disease-Specific Training / Quality Control / GCP / SOP / Infection Prevention		
		Participation In Various Academic Conferences		
Others	Elective, Voluntary Training			
	e-Learning			

ISMS Certification

EP-Link has been certified with JIS Q 27001:2014 (ISO/IEC 27001:2013), the applicable standard for information security management systems (ISMS).



Registered departments: Business Planning Promotion Department, Comprehensive Planning Office, Sales Promotion Department, Information Systems Department and Quality Control
Scope of registration: clinical trial site management services

People-oriented Work Environment

EP-Link provides an environment where all employees can work positively, including promoting the active participation of female employees and supporting employees raising children, and have been certified by the Ministry of Health, Labor and Welfare.



EPS Group: Supporting the Present and Future of the Health Industry

EPS Group was established in 1991 as a systems company specializing in medical statistics as its core business. Since then, EPS Group has progressed by focusing on services that support new drug development trials, and has now evolved into a group of companies that supports a wide range of researchers and the health industry. "Ever Progressing System" - We aspire to be constantly evolving. This is the sentiment behind our company name, EPS. The EPS Group, in collaboration with our partners, works to fulfill the aspirations for health of individuals and society, one step at a time. We want to be the ones supporting the health of the future - that is the wish of the EPS Group.

EPS Holdings, Inc.

EPS Holdings, Inc. is the holding company of EPS Group leading the development of the healthcare industry.

EPS Holdings aims to be a group that grows sustainably together with society to realize a prosperous and bright future where everyone can live healthy and shine.

Corporate Name : EPS Holdings, Inc.

Representative Director : Hao YAN

Locations : TSUKUDO TERRACE,2-1
Tsukudohachimanchō,
Shinjuku-ku, Tokyo, Japan

Establishment : May 1991

Capital : 100 Million yen

EPNextS, Inc.

EPNextS is a subsidiary of EPS Holdings, Inc. and oversees the CRO, SMO, and CSO businesses that form the foundation of the group. It is also the parent company of EPLink.

EPNextS creates new solutions with the synergies that only it can offer, creating the next society together with our partners.

Corporate Name : EPNextS, Inc.

Representative Director : Tatsuma Nagaoka

Locations : TSUKUDO TERRACE,2-1
Tsukudohachimanchō,
Shinjuku-ku, Tokyo, Japan

Establishment : Oct 2022

Capital : 100 Million yen

[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.

EP-Link's 25 Years of History

- 1999 ○ EP-Link Co., Ltd. (current company) was established in Koraku, Bunkyo-ku, Tokyo in December.
- 2005 ○ EP-Mint Co., Ltd. was established through the merger of EP-Link Co., Ltd. and Mint Co., Ltd. in July.
- 2011 ○ EP-Mint Co., Ltd. was listed on JASDAQ in September.
- 2012 ○ EP-Mint Co., Ltd. acquired S-Medical Service, Inc. in April.
- 2013 ○ EP-Mint Co., Ltd. signed business cooperation agreement with Sogo Rinsho Science Co., Ltd. in March.
- 2015 ○ EP-Mint became a subsidiary of EPS Holdings Co., Ltd. in January.
- 2016 ○ EPS Holdings, Inc. merged with Sogo Rinsho Holdings Co., Ltd., and conducted business integration in January.
EP-Mint Co., Ltd. and Sogo Rinsho Science Co., Ltd. merged to become EP-SOGO Co., Ltd. becoming the largest SMO in Japan in May.
EP-SOGO Co., Ltd. acquired Sogo Rimsha Holdings Co., Ltd. and makes Sogo Rinsho Medefi Co., Ltd. a subsidiary in October.
- 2018 ○ EP-SOGO Co., Ltd. acquired SMO MEDHISHISU Co., Ltd. in January, and EXAM Co., Ltd. in July.
- 2022 ○ Total Trial Management Consulting Co. Ltd. (Taiwan) became a subsidiary of EP-SOGO Co., Ltd. in August.
EP-SOGO Co., Ltd. became a subsidiary of EPNextS Co., Ltd. (established in October 2022), an intermediate holding company that oversees the core businesses of the EPS Group in October.
- 2024 ○ The company name was changed to EP-Link Co., Ltd. in April.
25th anniversary in December.

EP-Link Co., Ltd.

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Corporate website