

Pharmacovigilance

Experienced Experts Provide Prompt and Accurate Support

Our experienced experts support collection, evaluation and analysis of safety information for clinical trials, post-marketing clinical studies, post-marketing surveillance (specified drug use investigations, drug use investigations), academic literature investigations and reports development to the Pharmaceuticals and Medical Devices Agency.

We also transcribe overseas adverse drug reaction/infection case reports into appropriate format for submission to Regulatory Authorities.

Major Services

- Primary Assessment of Overseas Information in CIOMS and MedWatch Forms and Translation into Japanese
- Primary Assessment of Clinical Trial/Post-Marketing Safety Information in Japan and Translation into English
- English Translation (CIOMS/MedWatch Preparation) Services
- Support for Instructions to Monitors and MRs
- Preparation of Research Reports and Adverse Drug Reaction/Infection Case Reports (drafts) from Academic Literature and Submission to the PMDA
- Preparation of Adverse Drug Reaction/Infection Case Reports, Research Reports, Measure Reports and Defect Reports (drafts) and Submission to the PMDA and Listed into SGML
- Preparation of Adverse Drug Reaction Reports (Draft) for Overseas Offices and Regulatory Authorities in Various Countries and Translation into English
- Provision of Consultation for General Pharmacovigilance Activities and Other Related Activities
- Consultation by Contract Specialist Physicians for Adverse Events
- Preparation of Various Reports (Preparation of Documents (Drafts) for Company Safety Evaluation Committees, Preparation of Documents (Drafts) for HQ and Overseas Affiliates)

ADVANTAGE of EPS

- Our staff, having worked in the safety information management departments of pharmaceutical companies and fluent in English, is able to provide you full support for all your individual or total pharmacovigilance needs.
- Through contracting with physicians who are knowledgeable in safety information and MedDRA, we are able to provide MedDRA coding consultation.
- Through our contract specialist physicians, we are able to provide consultation for adverse events which are difficult to assess.

Clinical Trials Management System and ASP Services

Clinical IT Solutions for Improving the Speed and Quality of Clinical Trials

Our company has developed numerous computer systems for patient enrollment, drug allocation to satisfy client's needs. Utilizing the robust system development experience and accomplishments, we provide you with a clinical trial IT solution in compliance with GCP, GPSP and related laws and regulations to improve the speed and quality of a clinical trial.

Major Services

- Development and Operation of an Internal System Specialized in Contract Study (Services)
- Development, Marketing and Operation of Clinical Development Full Support Systems and Individual Activity Support Systems
- Provision of Personnel Support for Clinical Trials, including Related Systems Involved

EPS's IT Solutions

- E-DMS (local) / E-DMS Online (ASP-Version)
- Nursing Plan Support System
- Monitoring System
- Electronic Medical Chart System

E-DMS Online

EPS Online Data Management System for Clinical Trial
— Support Package EDC —

Full Service Support Package for Clinical Development from Patient Registration/Enrollement to Statistical Analysis

Service Provided by
e-Trial Co.,Ltd



ADVANTAGE of EPS

- Utilizing rich experience and know-how in CRO services, we develop appropriate and high-level systems to meet industry needs. Accumulated know-how is incorporated into system development as appropriate.
- We are able to develop a large-scale system.
- We propose a system that matches the needs of the industry in Japan.