

Patient Registration/Enrollment Center Services

Patient Registration/Enrollment

Speedy Eligibility Assessment in Compliance with Protocol

We obtain highly reliable data that can sustain analysis by entering subject cases into a central enrollment system using telephone, web, or facsimile in accordance with our strict quality control criteria. We enroll subjects and check the eligibility of subjects by crosschecking subjects against the inclusion and exclusion criteria to attain speedy eligibility assessment in accordance with protocol.

■ Major Services

- Enrollment of Subjects by Telephone / Fax / Web (Database Controlled Centrally)
- Computer-aided Contracting with Medical Institutions and Registration Physicians
- Balancing of Group Based on Prognosis Factors (Dynamic Assignment)
- Assignment of Investigational Products for Use
- Report of Entry Omissions and Discrepancies
- Eligibility Assessment in Accordance with Protocol
- Management of the Status of Enrollment

Project Management

Appropriate Management of the Clinical Trial (Including Investigation) Monitoring the Progress Status in Real Time

We manage the trial progress status with a focus on the notification of laboratory test dates, sending of case report forms, management of collection status, and notification to the client of the trial by fax or e-mail. We are able to provide real time progress status checking via the web.

■ Major Services

- Notification of Visit Points/Scheduled Laboratory Testing Items by Subject
- Preparation of a Clinical Trial (Including Research)
- Management of the Subject Enrollment Status
- Management of the Clinical Trial (Including Investigation) Progress Status
- Notification of Visit Schedules
- Receipt of the Termination Status from Physicians
- Management of the Sending and Collection of Various Notifications, CRFs and QOL

Drug Allocation

Opening of the Emergency Key in an Emergency Emergency Reception is Available 24 hours

In a double blind trial, we prepare a key code, assign drugs based on the key code, prepare emergency keys and store the key code until completion of the trial to maintain blindness. We are also able to open the emergency key in an emergency and to perform 24-hour emergency reception services.

■ Major Services

- Preparation and Storage of Key Code
- Checks for Indistinguishability
- Preparation of Emergency Keys
- Assignment of Investigational Products
- Opening of the Emergency Key
- 24-hour Emergency Reception Services

ADVANTAGE of EPS

- We provide education and training in line with quality control process and prepare patient registration/enrollment procedure in accordance with the GCP.
- We are able to provide dynamic allocation via WEB as well.
- We perform management of dispatch / collection of CRF and QOL.
- We are able to provide patient registration/enrollment status by graphs.
- By preparing an operating procedure for assignment, we propose an accurate work process, even for a large amount of drug allocations.
- We prepare records and check for indistinguishability.