

# Monitoring

## Realizing High Quality and Speedy Monitoring

Our monitoring specialists, trained by our company's special education for monitors and possessing a high level of expert knowledge, perform monitoring in compliance with GCP, SOPs, protocol and requests of the client. Various documents generated and collected in the study undergo strict quality checks by the quality control department and are filed and archived properly.

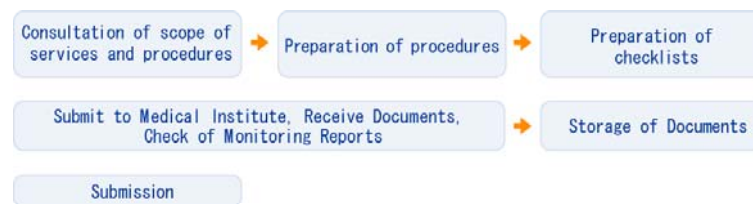


### Major Services

- Review of Medical Institutions and Investigators on GCP Compliance
- Explanation of Protocol to Investigators on GCP compliance
- Support Clinical Trial Plan Notification, Change Notification and Premature Termination/Completion Notification
- Recruit Investigators and Medical Institutions for Clinical Trials and Process Site Contracts
- Response to IRB Review Results
- Contracts Finalization
- Arranging Startup Meetings
- Supply and Collection of Investigational Products
- Visits to Medical Institutions and investigators, and Dissemination of Information

## Improving Monitoring Quality through Meticulous and Appropriate Checks

To check whether a clinical trial is being conducted in compliance with related laws and regulations, using quality control approaches as part of quality assurance, and performing timely, meticulous and appropriate checks from an objective viewpoint, we strive to maintain and improve the quality of monitoring.



## Cultivate Monitors with Professional Skills

We have an 'Educational Training Committee' to cultivate professional monitors and improve expertise knowledge and working ability. We provide initiation training of monitors, role-playing and OJT (office/field work). After monitors finish attending all lectures and pass the examination, the chairman of Educational Training Committee issues certificates of initiation training. After these training, monitors will take more advanced practical training prior to involvement in monitoring.

### ADVANTAGE of EPS

- Our experience in supporting studies in various therapeutic areas and diseases enable us to provide not only monitoring but also developing appropriate clinical trial plan proposals.
- We have a great deal of accomplishments in study areas requiring a high degree of professionalism, such as cancer, central nervous system and metabolism.
- We have allocated QC specialized staff to check on quality at all times, for improvement.
- We support Data and Safety Monitoring Board (DSMB) to operate properly in a neutral position independent from sponsors or investigators.