



Position: Clinical Research Associate

Job Description:

The Clinical Research Associate performs clinical site monitoring and collects/manages clinical research documents, including Protocol, clinical case report forms, Patient Informed Consent Form (ICF), Investigator Brochure and Clinical Trial Related Documents.

Responsibilities:

- Develop a broad knowledge of drug/device development trends.
- Set up and archive Trial Master File (TMF);
- Review protocol and Investigator's Brochure;
- Check protocol against CRFs and ICF;
- Translate clinical trial related documents, such as protocol, ICFs, etc. when needed
- Prepare study guide and study logs;
- Assist in preparation of protocol training program for investigators and study personnel;
- Communicate with Investigators and Institute Review Board (IRB) or Ethical Committee;
- Obtain the approval letter(s) from IRB or Ethical Committee for clinical trial(s);
- Deliver clinical supplies to clinical research centers;
- Visit clinical research centers;
- Monitor clinical Trials;
- Write monitoring visit report after each visit;
- Assist in organizing and facilitating Investigators' Meeting
- Assist in handling and report of serious adverse events (SAEs);
- Assist in processing annual safety report for ongoing clinical trials;
- Identify and solve problems in clinical trials;

Education and Experience

- Medical degree or BS in healthcare-related science. MS or above welcome.
- 2 years clinical practice in Internal Medicine, especially in Cardiovascular, Oncology, and Infectious Disease.
- Minimum 2 years of CRA experience or worked as a study coordinator at study sites.
- Demonstrated English language skills and communication ability.
- Demonstrated computer skills including MS Office, Outlook and Internet usage.

Reporting Requirements

The Clinical Research Associate reports to the Clinical Research Manager.