Job Description

We are looking for a Clinical Study Nurse to work under the guidance and supervision of the Principal Investigator (PI) and sub investigators and conduct high quality phase II and III clinical trials on investigational drugs in systemic autoimmune diseases. This position is responsible for accurate completion of all procedures related to the clinical trials, ensuring also compliance with the relevant protocols and the regulatory requirements as well as health, safety, protection and welfare of research participants.

Responsibilities

- Preparatory paperwork for clinical trials initiation (e.g. ethical approval, contracts etc)
- Initiation and activation of the clinical research site for each clinical trial
- Ensuring compliance with each study protocol by providing thorough review and documentation at each subject study visit.
- Participation in eligibility, recruitment and selection of study participants.
- Collection, storage and shipping of biologic samples related to the protocols of the clinical studies.
- Preparation, storage and administration of the experimental drug.
- Patients' medical education and information.
- Data collection entry and update on patients' status into the electronic case report forms (eCRF) and/or hard copies according to the protocols of the clinical study.
- Compliance with research protocols by reviewing all regulatory requirements to confirm implementation of appropriate methods, practices, and procedures for all research activities.
- Accurate source materials and compliance from site staff
- Appropriate credentialing and training of the entire clinical study team
- Communication and collaboration of specific study requirements to the research team, including internal and external parties, sponsor, monitors, PI, and study participants.
- Compliance with research protocols, by providing ongoing quality control audits, including maintaining ongoing investigational drug accountability.

Qualifications

- Diploma from accredited nursing school
- Valid license
- Clinical nursing experience preferred (not mandatory)
- Clinical trials research experience (not mandatory)
- Proficiency or willingness to learn in Microsoft Office Word and Excel, electronic health systems and databases used in research environment
- Detail oriented and meticulous in all aspects of work
- Ability to work well independently as well as in team environment
- Strong interpersonal and communication skills

Full-time position – 40 hour with a 3 month preceding training period.

Tel: 210 7462513