INNOVADERM RESEARCH INC.

Job Description

Project Assistant / Clinical Research Associate Trainee

The Project Assistant / CRA Trainee position is a hybrid role that involves both assisting with the project management of clinical research studies and also monitoring of clinical research sites:

Assisting with project management

- Schedule project meetings and produce meeting minutes
- Distribute documents for internal project-specific training and coordinate training documentation
- Communicate with clinical sites for study feasibility and start-up
- Collect, review and file site essential documents
- Assist sites with local ethics submission
- Initiate and maintain study files
- Assemble and ship the Investigator's Study File
- Prepare shipments of study supplies to clinical sites
- Coordinate new service provider qualification
- Assist with preparation and conduct of Investigator Meeting
- Distribute study correspondence to sites
- Serve as in-house contact to support other CRAs when they are traveling
- Assist with preparing investigator payments
- Assist with project financial tracking
- Prepare study status reports
- Perform other duties as required to accomplish the goals of the project management department

Monitoring

- Conduct site selection, initiation, monitoring, and close-out visits for research sites according to the monitoring plan, Innovaderm/sponsor SOPs and ICH CGP guidelines
- Build productive relationships with investigators and site staff to achieve study objectives, including patient recruitment targets
- Perform source data verification, study drug accountability, data collection, and regulatory document collection
- Maintain ongoing site correspondence and site files
- Complete site visit reports and maintain study-related tracking

Requirements:

- B.Sc. or M.Sc. in a discipline pertinent to clinical research
- Experience in clinical research and in the pharmaceutical industry
- Good knowledge of ICH GCP standards and applicable regulations
- Bilingual French/English (oral and written)
- Ability to prioritize different assignments and work under pressure while maintaining attention to detail and meeting timelines
- Excellent communication, organizational, interpersonal, and team skills
- Strong problem-solving and multi-tasking skills
- Able to travel to clinical research sites
- Proficient in Microsoft® Office (i.e. Word, Excel, PowerPoint)