The Montreal Health Innovations Coordinating Center (MHICC) is a full service contract research organization targeted on multicenter and multinational clinical trials. We provide services to the academic community and to the pharmaceutical, biotechnology and medical device industries. Our main goal is to establish a partnership with our customers to ensure a successful implementation of their project while respecting the scope of work, budget, timelines and highest standards of quality.

**RESPONSIBILITIES**

- Review the protocol, Case Report Form (CRF), Investigator Brochure and all study related documents
- Ensure the scope of work is respected by the study team
- Generate the study management plan, monitoring plan, recruitment plan and communication plan in collaboration with MHICC management and sponsor
- Organize study start up activities, including investigator recruitment and selection, collection of regulatory documents, IRB/EC submissions and participation in Investigator meeting planning and execution
- Collect and retain all study essential documents in compliance with ICH/GCP/local law on clinical trial documentation and record retention guidelines
- Develop study-specific and project management tools in order to assure consistency and quality data
- Provide training to internal and external study personnel on protocol, CRF completion, adverse event reporting, laboratory sample handling/shipping and all study requirements before the beginning of the study and on an ongoing basis
- Create and present a monthly progress report, including achievements and potential challenges and/or risks for MHICC upper management
- Ensure that study drug, central laboratories supplies and all other essential study supplies are distributed as required
- Assure correspondence and information management between sponsor, sites, Clinical Research Associates (CRAs), subcontractors, suppliers, vendors and MHICC is adequate and timely
- Review and approve clinical monitoring reports
- Ensure review of the clinical trial master file for completeness
- Provide work instructions/guidelines to their assigned Clinical Trial Assistant and CRAs
- Proactively identify and resolve issues that could jeopardize the timely completion of the trial
- Assist sites in preparation of sponsor, regulatory agencies or MHICC audits
- Participate in MHICC and/or sponsor required training programs
- Facilitate and assist payments to investigator/site and study related invoices
- Ensure that sponsor requirements, timelines and deliverables are met

**REQUIREMENTS**

- Master’s or Bachelor’s degree in life sciences or related discipline and 4 years of experience in clinical research and project management in the pharmaceutical industry, biotechnology, or in a contract research organization
- Strong leadership, project management and interpersonal skills.
- Must have strong analytical and problem-solving skills.
- Prioritize effectively
- Selected candidates must demonstrate excellent organization, communication and management skills and leadership skills
- Bilinguisme (French/English)
- Computer literacy and proficient in Microsoft Office including Excel
WORK CONDITIONS

- 35 hours weekly base
- Pre-approved overtime paid
- Flexible work schedule for work-family balance
- Hybrid model (working from home and office)
- 4 weeks' vacation after one year
- 13 statutory holidays
- Defined retirement benefits
- Group insurance
- 9.6 day off sick days

TO SUBMIT YOUR APPLICATION

- Final date to apply: January 15, 2024
- Email: rh@mhicc.org
- Please indicate the job title for which you are submitting your application


We offer equal employment opportunities to all.

Only candidates that have been selected for an interview will receive a written answer.