Description	
Job Title	Clinical Research Associate
General Accountability	Primary contact with the investigative site study nurse. Responsible for data collection from investigative study sites, assuring adherence to Good Clinical Practice (GCP) guidelines and compliance to study protocol and procedures. Ensure quality of data submitted from study sites and assure timely submission of data, including appropriate reporting and follow-up for all safety events by site personnel.
Duties and Responsibilities	1. Establish relationship with study site personnel. 2. Establish the Trial Master File at each site including essential and non-essential documents. Ensure current copies of lab certificates, regulatory approvals, clinician's credentials, etc., are updated in a timely manner and are in compliance. 3. Ensure the conduct of the study is in compliance with the currently approved protocol/amendment(s), with current GCP guidelines and with applicable regulatory requirements. 4. Ensure reported data are accurate, complete, and verifiable from source documents. Resolve any discrepancies using Query Process. 5. Verify that Adverse Event reporting is accurate and follows GCP guidelines and applicable regulatory requirements. Escalate any reported Serious Adverse Event in timely manner. 6. Document clinical trial progress to ensure completeness of documentation and data collection in adherence with the project timelines. 7. Ensure collected clinical data is entered in the database in a timely manner, and extract data as required for reporting purposes. 8. Keep track of Investigational Product Accountability. 9. Provide support to Senior Clinical Management Team. 10. Conduct training for colleagues or study team as requested. 11. Fulfill other duties as required.

Competencies	
Education	Bachelor's Degree in health or medical sciences such as nursing, pharmacy or basic sciences Minimum experience of 2 years as a Clinical Research Associate
Certifications	
Key Attributes (experience, skills and technical knowledge)	• Excellent oral and written communication skills • Excellent planning and organizational skills with effective time management • Excellent interpersonal skills • Meticulous, independent and capable of working with minimal supervision • Ability to chair meetings • Initiative and problem solving skills

	• Thorough understanding of clinical research principles and processes. Ability to input into process initiatives, procedures related to Good Clinical Practices (GCP). • Good understanding of FDA and /or EU Directive regulations, ICH Guidelines and Health Canada regulatory requirements • Proficient knowledge of Microsoft Office, Clinical Database Management