JOB POSTING

Title:	**Clinical Project Associate (In-House)**
Department:	**Clinical Development & Regulatory Affairs**
Reports to:	**Clinical Research Manager**

Sernova is a clinical stage company with headquarters in London, Ontario, developing regenerative medicine therapeutic technologies including its Cell Pouch medical device, therapeutic cells and immune protection technologies to sustain and enhance the lives of people living with chronic metabolic diseases. Our goal is to improve the treatment and quality of life of people living with diseases such as insulin-dependent diabetes, blood disorders such as hemophilia, and other diseases through the replacement of proteins or hormones that are missing or in short supply within the body.

We are a rapidly growing, publicly traded company that embraces diversity and fosters inclusion throughout our organization. For more information about us and our technologies, please visit www.sernova.com.

I: General Functions and Scope

We are looking for an enthusiastic, experienced, and highly motivated clinical research professional to coordinate clinical development activities and support clinical operations. They will work closely with and support Sernova's Clinical Operations and Project Management Team to ensure the smooth and timely initiation and execution of clinical trials in accordance with clinical trial protocols, GCP/ICH guidelines, regulatory requirements, and corporate objectives. This person must thrive in a fast-paced environment, be nimble to work on multiple activities simultaneously, and be motivated by the opportunity to contribute to the development of new technologies and their potential medical applications. This is an office-based position working at the office located in London, Ontario.

II: Specific Responsibilities

Corporate:

- Support Clinical Trial Management in the timely and compliant execution of clinical studies (Phases I to III).
- Ensure clinical trial document management in compliance with GCP/ICH and federal regulatory requirements.
- Develop and maintain relationships with vendors and research partners, as required for project needs.
- Support internal and external communication activities through updates and reports for Internal team members and clinical research partners.

Project Responsibilities:

- Assist Clinical Trial Management effort to develop, review, track, and archive study documents, including, ICFs, Case Report Forms (CRFs) and CRF Completion Guidelines, Project Specific Plans, Standard Operating Procedures (SOPs) and Investigator Brochure.
- Assist in ensuring the Local Department Files, Clinical Trial Master System (CTMS) and Trial Master File (TMF) are maintained in an inspection-ready state. Review for completion, compliance and address findings as needed.
- Track site and study status as assigned.
- Review adequacy of potential clinical investigators and clinical trial sites. Includes evaluation of facilities, personnel, patient referral base, and adherence to GCP/ ICH.
- Train clinical investigators and their personnel regarding clinical trial protocol and regulatory requirements as applicable.
- Collect and review site essential documents and study logs as needed.
- Act as a primary contact with vendors, select clinical trial site personnel and CRO project team.
- Monitor compliance with the clinical trial protocol, CFR, GCP/ICH guidelines, and overall protocol objectives.
- Assist with management and accountability of clinical trial supplies, including Investigational Product, research specimen samples and study instrumentation.
- Assist with management of clinical trial safety and efficacy issues, including, but not limited to review and follow-up of Serious Adverse Event reports.
- Assist in the preparation for Data Safety Monitoring Board (DSMB) Meetings, perform reviews on presentations, tables, listings, and figures.
- Assist in the preparation, conduct and follow-up of in-house and clinical site quality audits.
- Coordinate clinical team meetings, including agenda preparation, minutes, and action item tracking as assigned.
- Assist in the review and approval of clinical trial site monitoring reports.
- Assist with the review and analysis of clinical data for clinical trial report generation.
- Assist with review, approval, and reconciliation of clinical trial related invoices.
- Coordinate meetings with internal team, CRO, site(s) and clinical trial supply vendors, including agenda preparation, minutes, and action item follow-up.
- Coordinate planning and execution of Investigator meetings, Project Kick-Off meetings and Data Safety Reviews.
- Lead document management support for clinical research team.
- Actively contribute to process improvements.
- May conduct clinical trial site co-monitoring and independent monitoring visits including: Pre-study, Initiation, Interim Monitoring, and Close-out visits. Follow all outstanding site issues to resolution and/or document attempts to resolve issues upon closure of clinical trial sites.

III: Education/Knowledge and Experience

- A minimum of a Bachelor's Degree or equivalent is required, preferably in medical/scientific field.
- Minimum 2 years experience in a clinical research environment.
- CRA experience including initiation, execution and close out of drug and/or medical device clinical trials subject to federal and international regulations. Experience in cell therapies and/or combination product trials is an asset.
- An understanding of drug and/or medical device product development.
- Recent training and certification in GCP.
- Solution driven, highly collaborative and good communicator.
- Demonstrated ability to effectively collaborate within a functionally and geographically diverse team.
- Effective written communication skills with an ability to articulate clear and concise reports.
- Highly organized.

IV: Skills and Core Competencies

- Excellent written and verbal communication skills.
- Experienced and hands-on team player with excellent interpersonal skills.
- Problem solving ability, creative and lateral thinking capability.
- Ability to work independently and within diverse teams.
- Ability to work under pressure, within time/resource considerations to accomplish objectives.
- Pragmatic with a positive and supportive attitude.

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of Sernova Corp.

Candidates interested in this opportunity should submit a cover letter and resume outlining their qualifications to human.resources@sernova.com no later than June 29th, 2022.

We would like to thank everyone for their interest, but only qualified candidates selected for an interview will be contacted.