JOB POSTING

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

ABOUT SERNOVA

Listed on the Toronto Stock Exchange, Sernova is a well-funded London, ON based clinical stage emerging biotechnology company focused on innovative science and technologies in the field of regenerative medicine and poised to make a global impact. We are developing novel cell therapy platforms and technologies, consisting of an implantable medical device and immune protected therapeutic cells for the treatment of chronic diseases, including diabetes, hemophilia and thyroid disease, with the potential to significantly improve the quality of life of millions of people worldwide.

Sernova is passionately focused on breaking through the current disease management paradigm, i.e. treating the symptoms vs. addressing the cause, by developing a 'functional cure' for diabetes. Our ongoing U.S. Phase 1/2 clinical study for the treatment of type 1 diabetes has produced encouraging interim results, including establishing insulin independence - a 'functional cure" - for multiple study patients.

We are accelerating our growth plans and looking to complement and build out our team with experienced, skilled and inspired people that want to make an impact within a company that embraces diversity and fosters inclusion. We would love to hear from you about joining our team if you are up to the rewarding challenge to help us develop and introduce our innovative and breakthrough technologies to the world.

For more information about us and our technologies, please visit www.sernova.com.

OPPORTUNITY DESCRIPTION

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.

RESPONSIBILITIES

Clinical Projects

- 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.

- 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.
- 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.
- Review and approval of clinical trial site monitoring reports.
- Assist with the review and analysis of clinical data for clinical trial report generation.
- Review 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.

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.

EDUCATION/KNOWLEDGE and EXPERIENCE

- A minimum of a Bachelor's Degree or diploma in an applicable field.

- Minimum 2 years experience in a clinical research environment.
- CRA and/or trial coordinator experience including initiation, execution and close out of drug and/or medical device clinical trials subject to federal 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.
- 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.

SKILLS AND CORE COMPETENCIES

- Ability to see the "big picture" in a complex & dynamic environment
- Adaptive & proactive in a changing, fast-paced team environment
- A detail-oriented team player who exemplifies the following:
  - Accountability: demonstrates a high level of ownership and commitment to achieving results
  - Communication: listens, speaks and writes clearly and concisely
  - Critical Thinking and Problem Solving: able to systematically break down a problem to determine the cause-and-effect relationships that underly the issue
  - Planning and Initiative: uses an effective system to determine priorities, set goals, create a plan, and take action and measure results; demonstrates the ability to think ahead and act on future needs and opportunities
  - Self-Development: knows own capabilities, seeks out feedback and responds positively to improve performance
  - Evidence-based: uses data, facts and available resources to identify the root cause of a problem and develop hypotheses towards resolving the issue
- Excellent organizational, communication (written, verbal, presentation) and document management skills
- Proficient at collaborating with senior management, cross-functional teams & external partners
- Entrepreneurial, strategic thinker with exceptional work ethic

COMPENSATION

- Salary and other compensation elements commensurate with experience and abilities
- Eligible for the Company's incentive Stock Option Plan and bonus program
- Comprehensive benefits package

ROLE LOCATION: LONDON, ONTARIO

INTERESTED IN THIS OPPORTUNITY and MAKING AN IMPACT? ….. NEXT STEPS

If your skills, abilities, and experience align with the above, tell us how in a cover letter and submit along with your resume to human.resources@sernova.com

Please note, only those candidates moving to the next stage of our recruitment process will be contacted and follow-up emails are discouraged. We wish you the best in your opportunity search and career endeavours.