



Senior Clinical Research Associate

We are looking to expand our Clinical Operations Team. With two drugs in Phase 2 and an extensive preclinical pipeline, we are looking for individuals interested in making a major contribution to the success of the company and our programs. We are looking for individuals who are seeking a challenging position and an opportunity to grow with a dynamic team. Only a strong team can bring these drugs to the people who so desperately need them.

Requirements

The right candidate will have significant experience in Infectious Disease and/or Cardiovascular Acute Care.

- Participate in study development ,startup process including reviewing protocols a
- Anticipates moderately complex obstacles and client difficulties and implements solutions to achieve project goals
- Review and approve all Informed Consents
- Track and report patient recruitment and retention metrics.
- Designing/reviewing CRFs
- Review and validate all incoming Case Report Forms from a clinical perspective to assure consistency and quality of data.
- Participate in the identification and selection of potential investigators in conjunction with the CRO/third party vendor to ensure that the sites have adequate experience & time to fulfill their obligations to the study
- Assist in the preparation of, or support global CRO team involved in regulatory and ethics committee/IRB submissions by reviewing country & site specific ICFs & study dossier for on-time ethics submission
- Manage effective and timely co-ordination of the supply (and subsequent disposal) of clinical materials to the study sites or specific country depots to ensure that the sites can start to actively recruit patients as soon as ethics approval has been granted.
- Conducts appropriate and timely review of study plans, regulatory documents, enrollment status reports and site monitoring reports received from vendors/CROs for accuracy and completeness
- Develop study documents as needed
- Field daily phone calls from vendor & vendor partners and address issues in a timely manner
- Per clinical SOPs, maintain clinical files including; training records, project files, vendor files, and sponsor directives
- Participate in periodic review of clinical SOPs
- Participate & present at Investigator meetings as required
- Participate in clinical training programs & maintain awareness of developments in the field of clinical research as needed.

Bachelors/RN preferred +5years clinical research experience with at least 2 years monitoring experience Infectious Disease or Cardiovascular

Strong working knowledge regulatory guidelines both FDA and international Agencies

Working knowledge of data management practices and electronic data capture systems

Strong attention to detail and good organizational skills

Solid oral and written communication skills with ability to communicate effectively and professionally with various clinical trial and site personnel

In-house position with travel estimated at approximately 25%. Must have flexibility with schedule to accommodate interactions with team members and sites globally