JOB DESCRIPTION

Position Title: Clinical Research Associate

Job Summary

The In-House CRA will work closely with the Clinical Operations Team in assisting with protocol feasibility, country assessment(s), site identification, patient recruitment, study monitoring, case report form development and study management. This position will interface with site coordinators, field clinical staff, Clinical Research Organizations (CRO), and other company representatives.

Responsibilities will include, but are not limited to, the following

- Participate in feasibility assessments, Investigator selection and site start-up activities
- Participate in preparation of site and monitoring related trial documentation (e.g., consent forms, study manuals/forms, training materials, monitoring plans) as needed
- Perform monitoring visits both independently and as a co-monitor to oversee the contracted CRA including site qualification, site initiation, routine monitoring and close-out visits in accordance with monitoring plans
- Ensure site compliance with study protocols, GCP/ICH, applicable regulations prior to, during and following visits.
- Work with site personnel and study team to resolve issues
- Document monitoring activities in monitoring reports and follow-up letters. Communicates serious issues identified during on-site monitoring visits to the team in a timely manner
- Review monitoring visit reports and escalates any issues identified to the Clinical Trial Manager

Skills/Knowledge Required

- Working knowledge of GCP, ICH and relevant CFRs is required
- Ability to work independently and manage multiple projects with minimal supervision
- Strong communication skills, both written and oral
- Demonstrated problem solving skills, a strong sense of urgency, keen attention to detail, and the ability to plan, organize and successfully execute in an environment under time and resource pressures
- Domestic and International travel as necessary (generally 30%, maybe greater depending on study needs)
- Enjoy working in a fast-paced, small-company environment.
- High level of organization, attention to detail, and accuracy

Qualifications

- Minimum of BS/BA degree in science with at least 4-7 years of relevant experience.
- Two years of full time monitoring experience at clinical sites