Senior Clinical Study Manager

Houston, Texas
October 15, 2010

SUMMARY:
Manage all aspects of clinical studies to ensure studies are completed, on time, within budget and in compliance with SOPs, FDA regulations and ICH/GCP guidelines.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Accountable for the functional management of the CRAs, Clinical Trial Assistant(s) and the Administrative Assistants working within the clinical program.
- Plan and manage clinical trial(s) including: participating in the selection of investigators and study sites
- Serve as a primary contact for the sites, responding to issues and recommending corrective actions, as well as discussing recruitment issues
- Monitor and track clinical trial progress and provide status update reports
- Manage all clinical trial vendors (eg, IVRS, central labs, IRB, and central ECG)
- Oversee the Field Monitors (eg, review of all trip reports) and provide guidance on site issues
- Assist in the development of case report forms and participate in the EDC and IVRS specification process
- Participate in the planning of investigator meetings and making presentations as required
- Participate in the preparation of study-specific training materials, study reference binders, and subject diaries
- Participate in the review of clinical data at the CRF, data listing, and report table levels
- Participate in the preparation of project and study related documents including: informed consent forms, clinical trial outlines, monitoring plans, synopses, protocols and amendments, IND Annual Updates, NDAs, and other documents as required
- Identify training needs and mentor direct reports within the program; accountable for effective and efficient use of internal and external resources to achieve deliverables

- Oversee clinical trial strategies, monitoring, and implementation activities
- Represent Clinical Operations at the Project Team level for individual studies
- Conduct performance reviews, professional development plans and vacation management of direct reports; facilitate conflict resolution
- Partner with other research and development groups to achieve deliverables
- Travel as required to carry out responsibilities
- Manage project timelines and vendor performance to meet departmental and corporate goals
- Provide leadership in the role of managing projects and as the Clinical Operations representative on study Project Team(s)
- Manage activities through subordinates and delegate activities appropriately
- Build clinical teams and interact in a positive, professional manner
- Assist in the hiring and training of Field Monitors
- Manage budget and payment process for all clinical trial vendors including sites
- Performs other duties as assigned

SUPERVISORY RESPONSIBILITIES:

- Manages one or more exempt or non exempt direct reports
- Acts as advisor to subordinates to assist them with study related problems or difficult issues and to assist with meeting timelines

EDUCATION / EXPERIENCE / QUALIFICATIONS:

- BA/BS/MS in scientific discipline; an advanced life sciences degree and/or certification (eg, PMP, RN, or RAC) is highly preferred, but not required
- 8 years experience in the pharmaceutical/clinical research environment with at least 3 years of CRA experience and 4 years of study management experience
- Working knowledge of drug development process
- Understand line management function
- Able to prioritize and handle multiple tasks simultaneously
- Prior management/supervisory experience
- Must have demonstrated expertise in relevant clinical operations activities
- Ability to work on problems of diverse scope and extremely complex in nature which may cross many functional areas
- Ability to exercise independent judgment within generally defined practices and policies that lead to methods or processes for obtaining results
- In-depth knowledge of ICH/GCP guidelines and FDA regulations

PHYSICAL DEMANDS:

On a continuous basis, sit at desk for prolonged period of time at company facility to intermittently answer telephone, file/fax/or copy documents, and write or use a

keyboard to communicate through written means. Walking and lifting up to 20 pounds may be required. The noise level in the work environment is usually low to moderate. The physical demands described above are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

For more information please send a resume to info@metronomxgroup.com.