

Title: Clinical Trial Manager

Job Summary:

This is a critical role in the Clinical Development group at Concert. The Clinical Trial Manager will work closely with team members and be responsible for the planning and execution of assigned clinical studies.

Responsibilities:

- Responsible for overseeing the conduct of one or more concurrent Phase 1/Phase 2 clinical studies
- Contribute to the development of the protocol, if required
- Work directly with CROs, vendors, investigators, monitors, and other external partners as needed
- Contribute to CRO/vendor selection
- Coordinate tasks related to budgets and contracts
- Contribute to the development and review of all study related documentation (Investigator's Brochure, Lab and Pharmacy manuals, Informed Consent, Patient Diaries, Clinical Study Reports, etc.)
- Contribute to the development and review of data management related activities
- Case report forms, User Acceptance Training, IVRS, Edit Check Plan, Data Management Plan, Monitoring Plan, Statistical Analysis Plan
- Work with Pharmaceutical Development on the study drug quantity, packaging and label requirements
- Create Trial Master Files for clinical trials, as needed
- Contribute to the planning and execution of Investigator Meetings, Study Initiation Visits
- Review and contribute to development of department standard operating procedures
- Review and present clinical trial data at internal meetings
- Coordinate/lead team calls as needed, write and distribute minutes

Qualifications:

- Science background, BS/MS degree
- Minimum 3 years clinical operations experience in industry
- Strong knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials (Phases 1-3)
- Strong communication, leadership, interpersonal, organizational and multi-tasking skills
- Independently motivated
- Excellent attention to detail and problem solving skills
- Ability to get project/task to the next step in an efficient manner
- Capable of changing direction quickly if needed
- Ability to work effectively/congenially in a team setting
- Aptitude for keeping project on time and within budget
- Travel as needed

If you would like to be considered for a job on the Concert team, send your resume in the body text of an e-mail (no attachments please) to: careers@concertpharma.com.

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