JOB TITLE: Clinical Data Manager
DEPARTMENT: Data Management

Working under the direction of a Director of Data Management, the Clinical Data Manager is responsible for the clinical data management function of Trial Runners. This includes development of CRF/eCRF design, generation of the data clean-up specifications, overseeing database design and testing, review of clinical data, and the creation and maintenance of study documentation. Responsible for planning and implementing policies, procedures, practices and strategy for the data management function and managing the direction, planning, and execution of the data management activities, including vendor relationships, budgets and timelines, in order to meet corporate goals and objectives.

RESPONSIBILITIES:

- Interact with Clinical Operations, Safety Team, SAS Programmers, and Statistics to define the necessary listings needed for the support of data clean-up and database finalization.
- Manage review of listings within Clinical Data Management (CDM) for quality, content, format and output
- Allocate resources to the study team in support of the quality review of final summary tables and listings used in the preparation of the Clinical Study Report (CSR), Interim Reports of sponsor defined analysis
- Manage interaction with sponsors to ensure compliance to standards, timelines, relevant guidelines and expectations of clinical data management activities
- Identify and defines priorities and timeline issues
- Oversee data management function SOP review and development, employee training, and associated requirements
- Procure and oversee outside vendors and consultants as required
- Oversee data management activities with regard to protocol review, study activation, data review, maintenance and quality for multi-institutional sites
- Oversee development and use of department performance metrics to monitor the data collection process and identify process improvement opportunities
- Coordinate data entry, database design, verification and validation activities within data management group and among various sources of clinical data

REQUIREMENTS:

- Demonstrated ability to effectively manage and prioritize multiple programs
- Understanding of clinical data management applications and systems
- Experience in developing data management procedures and processes
- Excellent written and oral communication skills
- Proficient knowledge of medical terminology and expertise with ICH/GCP and regulatory compliance guidelines for clinical trials
- Solid understanding of clinical drug development process
- Good computer skills (MS Office products, word processing, spreadsheets)
- High attention to detail and accuracy and ability to manage multiple project teams
- Excellent prioritization and organizational skills and demonstrated ability to delegate appropriately
- Ability to work on extremely complex problems where analysis requires evaluating various factors
- Ability to exercise independent judgment in developing methods, techniques and evaluation criteria for obtaining results
- Advanced people management skills and positive flexible outlook
- Excellent interpersonal communication skills and works effectively on cross-functional teams

EDUCATION REQUIREMENTS:

- Bachelors Degree in Life Sciences/Computer Sciences or related field, or significant relevant work experience required
- Minimum 5 years experience in Clinical Data Management in a biopharmaceutical setting (industry and/or CRO)
- Minimum 1 year experience leading a data management team with direct reports

NOTE: This job description is not intended to be all inclusive. Employee may perform other related duties as delegated to meet the ongoing needs delegated of the company.