Job Description

Department: Clinical Data Management
Job Title: Principal Clinical Data Manager, Clinical Data Management
Reports to: Associate Director/Director, Clinical Data Management

Primary Objective of Position

The Principal Clinical Data Manager, Clinical Data Management, is responsible for leading study data management activities including, but not limited to, coordination of CRF design, development, review and sign off; Reviews and approves CRO generated Data Management documents, coordinates database live and close out activities with the CRO, provides guidance to CRO to manage query flow and implements quality control plan. The individual may participate in reviewing vendor audit plan and statistical analysis plan as needed; may participate in vendor qualification and selection as appropriate, and participates in monitoring vendor performance

Major Duties/Responsibilities

- Reviews listings to identify data discrepancies and tracks resolutions
- Works with Study team to design mock CRFs based on the protocol
- Leads database design, implementation and testing activities
- Supervises all Data Management deliverables and associated timelines with the CRO to ensure a quality database lock
- Co-ordinates with Clinical Operations, Biostatistics, Statistical Programming, Safety and other departments, as needed, to resolve data issues

Skills & Abilities

- Excellent organizational skills and ability to prioritize tasks
- Must be able to work under tight timelines
- Possess excellent communication skills
- Anticipates change and reacts quickly and intelligently to accommodate business needs.

Physical Demands

The physical demands described are representative of those that must be met by an employee to successfully perform the primary functions of this position.

The physical demands of the office are normally associated with extended amounts of time in front of a computer. While performing the duties of this job, the employee is frequently required to stand, walk, and sit.

May involve travel up to 10%

Education & Professional Experience

Required:

- Bachelor's Degree in a biological sciences or other medically related areas
- Minimum of 7 years of data management experience in the biotechnology/pharmaceutical industry

- Familiarity with data management software (e.g. Medidata, Oracle Clinical)
- Working knowledge of coding dictionaries – MeDDRA and WHODRUG

Preferred:

- Knowledge of Oncology clinical trials
- Nursing background
- Vendor management experience
- Familiarity with SAS

Approvals

Employee

Signature_____ Title_____ Date_____

Supervisor

Signature_____ Title_____ Date_____