



## **Position: Clinical Data Manager**

### **Job Description:**

The Clinical Data Manager coordinates all data management tasks for a given clinical study or studies involving investigational or non-investigational drugs, biologics and devices and acts as the primary point of contact for all data management activities for a given clinical study or studies.

### **Responsibilities:**

- Reviews and understands study protocol and assures consistency internal to the protocol and the goals of the study/program
- Designs Case Report Forms (CRF) and coordinates review by project team
- Communicates with client regarding CRF design issues
- Coordinates the printing and shipping of CRFs
- Develops Data Management Plan (Edit Check Specifications, CRF Completion Guidelines, and Self Evident Correction Guidelines, etc) for each assigned clinical study
- Coordinates the review of clinical trial data, Identifies erroneous, missing, incomplete, or implausible data and writes queries
- Coordinates with IT Applications to ensure proper clinical database design and incorporation of central or core lab data. Ensures that all external data is imported into the database
- Oversees coding of adverse events and medications
- Assigns tasks to data reviewers
- Coordinates with Project Coordinator to assure timely submission of CRFs and queries from sites
- Represents Data Management at project team meetings and provides updates to project team on status of CDM tasks
- Communicates with Project Manager and Project Coordinator regarding project team and/or client issues
- Ensure that all preparatory steps to lock a clinical database are accomplished and database is locked successfully and within the timelines
- Ensures adherence to all timelines associated with data management
- Assures that the data management needs of project(s) are met, reporting all areas of concern to the Manager of CDM Department to assure timely and appropriate resolution of clinical team and/or client issues
- Assures that all aspects of data management are performed in accordance with client requirements and applicable corporate SOPs/WPDs, Federal Law, Guidelines and ICH standards, as appropriate
- Supervises, coaches, and develops staff
- Ensures that required training for directly supervised staff members is identified, provided in within a reasonable timeframe, and is current

### **Education and Experience:**

The Data Manager must have previous data management experience within a pharmaceutical company or CRO environment and managerial experience.



- Bachelor's degree in medical or healthcare-related science. MS or above welcomed.
- An advanced scientific degree (M.S., PhD.) or clinical certification (R.N., M.D.) is desirable.
- At least three years of clinical data management experience in a pharmaceutical company or CRO or equivalent education and experience
- Supervisory experience preferred
- Demonstrates strong skills in the management and resolution of data-related issues
- Familiar with Windows Environment and its applications (Word, Excel and PowerPoint)
- Experience with relational database systems and SQL query language preferred
- Fluent in English listening, speaking and writing
- Demonstrates strong communication and analytical skills
- As this position requires interaction with internal and external customers, good interpersonal skills are required
- Demonstrates team-building skills and demonstrate the ability to work successfully in a team environment
- Demonstrates well organizational skill and able to prioritize multiple tasks
- Has the ability to manage multiple projects, as necessary
- Knowledgeable about the Federal regulations and requirements governing the conduct of drug, biologic and device studies including, but not limited to, GCP and ICH requirements
- Experienced in developing and leading effective presentations in public settings

## **Reporting Requirements**

The Data Manager reports to the Manager of Clinical Data Management.



## Approvals

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**Manager of Human Resources**

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**Date**

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**General Manager**

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**Date**