



Position Title: Clinical Data Manager

Reports to: Sr. Director, Bioinformatics

Department: Clinical Operations

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General Summary:

The Clinical Data Manager is responsible for all data management tasks for multiple clinical studies from set up in electronic data management system (EDC) to database lock. Other responsibilities include:

Principal Duties and Responsibilities:

- Review data and generate queries according to the data validation plan (DVP)
- Maintain documentation relating to clinical data management including maintaining the data management portion of the Trial Master File
- Write and maintain DVP
- Interface with site personnel, monitors and clinical operations staff to provide support related to data management (including EDC system issue resolution)
- Assist in streamlining clinical data management procedures to create effective practices
- Set up studies in EDC system
- Train monitors and site personnel on EDC system
- Write edit checks in XML and data listings in SQL or R or other languages (on the job training provided)
- Contribute to development of reports and plans (ie: clinical study reports/statistical analysis plans)
- Coordinate with pharmacovigilance to review and generate queries related to serious adverse events
- Correspond with and oversee data management vendors
- Perform tasks according to company standard operating procedures (SOPs)

Qualifications:

Education

- Bachelor's degree or equivalent experience

Experience/Skills

- Minimum of three years of direct clinical data management experience in the biotechnology or pharmaceutical industry
- Working knowledge of Good Clinical Practices and ICH guidelines related to CDM
- Exceptional organizational skills, highly adaptive in the face of changing priorities and practices
- Effective written communication skills

Position Requirements:

- May require limited travel for training purposes

NOTE: This description is not intended to be all inclusive or a limitation of the duties of the position. It is intended to describe the general nature of the job which may include other duties as assumed or assigned.