SENIOR DATA MANAGER/MANAGER, DATA MANAGEMENT

POSITION SUMMARY

The Senior Data Manager/Manager, Data Management will lead and coordinate data management activities for multiple assigned projects within Denovo. This position has oversight of activities leading to the final delivery of clean, QC'd clinical data for the purpose of clinical study reports and publications, including submission to regulatory agencies. This position provides technical and operational expertise to the Denovo project teams under the guidance of the Senior Director, Data Management and will work together to define end to end processes and procedures for the set-up, collection, and management of clinical data.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

These may include, but are not limited to:

- Lead data management activities for Denovo studies, to include database setup, CRF design and validation, edit checks, ongoing data review, SAE reconciliation, Medical Coding, Protocol Deviations and critical data review towards final database lock
- Review and approve data management plans (DMP) and review statistical analysis plans (SAPs) and shells for tables, listings, figures
- Manage and oversee contract research organizations (CROs) handling clinical trial data
- Take a lead role in the review, issue and resolution of Sponsor queries for CRF cross-functional data cleaning (based on edit checks, manual review and from the Denovo Biopharma Data Review Plan)
- Work with study team members by preparing and distributing study related reports, resolving questions, and providing DM guidance
- Work with data management, biostatistician, and SAS programmers to harmonize data collection, compile and maintain SAS data standards, including CDASH CRF collection, CRF specification guidelines and edit check documents
- Support the review of the critical data-populated tables, figures, and listings as part of the database clean-up and prior to database lock
- Provide technical assistance supporting (and creating new) standards within the DM department, driving standards to be utilized across all Denovo Biopharma sponsored studies
- Support Denovo Biopharma's business development efforts as needed
- Maintain all the necessary documentation to support accuracy and integrity of clinical databases
- Co-author and maintain appropriate data management SOPs

- Review statements of work, work orders and bids from vendor contracts
- Assure regulatory compliance of vendors and investigational sites with company SOPs, FDA and ICH guidelines, and other applicable regulations and guidelines

JOB QUALIFICATIONS

Education, Certifications, Experience

- Bachelor's degree in life sciences with a minimum of 5+ years (8+ years for Manager, Data Management) experience working in a CRO, pharmaceutical or biotech environment (an equivalent combination of education and experience may be considered)
- Degree in math, computer science or related field is a plus

Knowledge, Skills and Abilities

- Working knowledge of data management software (EDC, IXRS, ePRO, and other remote capture systems used in the industry), database design and programming is a plus
- Excellent verbal and written communication skills
- Effective time, cost and resource management skills
- Knowledge of SAS, Understanding of CDISC standards (CDASH, SDTM, etc) is highly desired
- Equipment: PC, scanners, facsimile machine, voice mail and e-mail systems, and common office machines, or ability to be trained. Knowledge of other equipment required: N/A
- Software Knowledge: MS Office (Outlook, Word, Excel, Power Point), Microsoft Project, SAS. Knowledge of other software required: EDC

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.