JOB DESCRIPTION

Position Title: Associate Director / Director, Clinical Data Management (CDM)

Job Summary

The Associate Director / Director is responsible for managing, leading, and overseeing all Clinical Data Management (CDM) planning and operational activities to meet corporate goals, budgets, and timelines. This includes but is not limited to vendor qualification and selection, budget planning and contract negotiations, development of corporate data standards, and training and oversight for all CDM services from study start-up through study close-out, final reporting, and archiving. Additionally, the Associate Director / Director will supervise, manage, and lead the design, implementation and ongoing practices of clinical DM processes with internal study resources and/or vendors.

Responsibilities

- Provides leadership and mentorship to internal data staff and contributes to the development of clinical data management and biostatistics within the company
- Formulate short-term and long-term strategies to improve DM efficiencies
- Cultivate effective and productive working relationships with colleagues, subordinates, vendors, and management as well as solve problems and escalate issues with proposed solutions to Senior Management as needed
- Provides leadership and direction for outsourced activities
- Accountable for hands-on management of trials and resources while maintaining a high level of data quality by adhering to corporate, industry and regulatory agency standards
- Ensure projects are conducted in compliance with operating procedures, GCP, ICH, Good Clinical DM Practices, FDA regulations, and CDISC and FDA submission standards
- Educate clinical team members as needed regarding DM processes, workflow, and data standards that may have a direct impact on their work
- Implement standardization of DM processes and process improvement and efficiency, notably for NDA submission
- Manage the activities of DM team members to complete project deliverables on schedule and according to quality standards and requirements of the study
- Review and provide feedback on draft protocols, Statistical Analysis Plans, CSRs and other documents as required
- Lead vendor and technology evaluation, qualification and selection
- Ensures consistency of protocol, project and clinical database, notably for NDA submission
- Ensures complete and consistent medical term coding using appropriate standard dictionaries
- Manage reconciliations between clinical and safety databases
- Ensures consistency of serious adverse event data across clinical and drug safety databases.
- Ensures smooth and successful timely locking of quality database
- Ensures timely completion of data management archiving
- Ensure DM project documentation is in an audit-ready state
- Lead the development and maintenance of Standard Operating Procedures (SOPs) and Work Instructions related to data management activities

- Budget assessment and contract negotiations, training and oversight for all DM services from study start-up through study close-out and final reporting
- Responsible for managing and tracking work orders associated with clinical DM activities to ensure that the operating costs for the DM department are achieved within budget

Required Skills and Abilities

- In-depth knowledge of FDA regulations, GCP, GCDMP, CDISC, and ICH guidelines
- In-depth knowledge of the clinical trial process, EDC systems (i.e. Medidata Rave, etc.), database programming, clinical operations, statistics, quality management, and systems applications to support operations
- Successful management of and good working relationship with outside contractors a must
- Complex and international trials experience desired
- Demonstrated proficiency in the data management processes
- Possesses excellent interpersonal communication skills (written and verbal)
- Strong attention to detail
- Possesses a positive attitude and works well with others

Education and Experience

- Bachelor's or Master's degree with minimum 10+ years clinical data management experience in pharmaceutical and/or CROs
- Extensive experience in all core DM activities and experience managing DM function and personnel