Associate Director/Director, Clinical Data Management

Reports to: Senior Director of Biometrics

Classification: Exempt

Summary:
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 execution of standard CDM processes with internal study resources and/ or vendors.

Essential Functions and Job Responsibilities:

- Provide leadership and mentorship to internal data management staff and contributes to the development of clinical data management within the company
- Formulate short-term and long-term strategies to improve data management 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
- Provide leadership and direction for outsourced activities
- Accountable for hands-on management for trails 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 data management practices, FDA regulations, and CDISC and FDA submission standards
- Educate clinical team members as needed regarding data management processes, workflow, and data standards that may have direct impact on their work
- Implement standardization of data management to complete project deliverables on schedule and according to quality standards and requirements of the study
- Review and provide feedback on study documents such as protocols, Statistical Analysis Plans, CSRs and other documents as required
- Lead vendor and technology evaluation, qualification and selection
- Ensure complete and consistent medical term coding using appropriate standard dictionaries
- Manage reconciliations between clinical and safety databases
- Ensure consistency of serious adverse event data between clinical and drug safety databases
- Ensure smooth and successful timely locking of database
- Ensure timely completion of data management archiving
- Ensure data management 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 data management services from study start-up through study close-out and final reporting

- Responsible for managing and tracking work orders associated with clinical data management activities to ensure that the operating costs for the data management department are achieved within budget
- Complete other responsibilities as assigned and agreed upon

Minimum Qualifications:

- Bachelor's or Master's degree with minimum of 10+ years of clinical data management experience in pharmaceutical and/ or CRO's
- In-depth knowledge of FDA regulations, GCP, GCDMP, CDISC, and ICH guidelines
- In-depth knowledge of clinical trial process, EDC systems (i.e. Medidata Rave, InForm, etc.), database programming, clinical operations, quality management, and systems applications to support operations
- Successful management of and good working relationship with outside vendors
- Complex and international trails experience desired
- Proficiency in the data management processes
- Excellent written and oral communication skills with the ability to communicate clearly to all organizational levels
- Must be able to work productively in a fast-paced collaborative environment
- Work well in a collaborative team environment, and have good organizational, communication and interpersonal skills