Title: AD, Clinical Data Management

Department: Development Operations

Position Summary
This position is responsible for the clinical data management (CDM) operations and oversight of CDM activities for all clinical trials including acting as interdepartmental subject matter expert for the clinical data management functional area and ensuring overall data quality and integrity of the clinical trial data. Key activities include establishing and building relationships with vendors for future delivery of CDM services including ensuring accurate and timely completion of deliverables to clinical data management and clinical project team. Reports to the VP, Development Operations.

Responsibilities
- Leads CDM functions in coordination with the Development Operations team including the execution of department directives and objectives
- Represents CDM and participates in cross-functional (internal and external) project team meetings
- CDM subject matter expert when interacting with cross-functional project teams and external vendors to successfully execute and accomplish project goals including participation in vendor qualification audits
- Develop CDM SOPs as needed
- Ensures compliance with protocols, SOPs and overall clinical objectives
- Coordinates the request for proposal (RFP) process with vendors including: establishing initial contact with vendor’s business development person, generation and execution of a confidentiality disclosure agreement (CDA) with the vendor and reviewing details of the proposal including comparing and contrasting deliverable line items and associate costs with potential to negotiate costs where appropriate
- Evaluate and select the CRO vendors in conjunction with project and clinical team members
- Supervises the CRO/Vendor CDM activities from study start-up, study conduct and study close-out ensuring high quality and on-time deliverables
- Generates data listings or other data review tools for reporting of study metrics
- Assists in identifying, locating, evaluating and validating CDM documents and databases required for report generation or regulatory submission
- Develops knowledge and understanding of industry trends regarding use of CDM databases, EDC systems, data cleaning techniques and database lock efficiencies

Minimum Qualifications
- Bachelor’s degree, a combination of relevant education and applicable job experience may be considered.
- Minimum 5 years of supervisory and management experience
- Minimum 10 years of clinical data management experience
- Strong understanding of the clinical data management process including CDASH and SDTM data formats, and familiarity with physiology, pharmacology, clinical study objectives and methodologies.
- Strong verbal and written communications skills, as well as problem-solving skills
- Able to identify issues, problem solve and propose solutions towards project success including escalation of issues to upper management
- Excellent understanding of the clinical trial database life cycle including CRF design, database development and testing, discrepancy management, data quality review and database close and lock procedures
- Must have strong organizational and decision making skills
- Ability to travel domestically and internationally up to 10%
Preferred Qualifications

- Master's degree
- Experience managing contract and/or permanent CDM staff members
- Project management experience in a team setting within the biotech industry
- Experience as the project management lead and in interacting with multi-project teams and vendors
- Thorough understanding of Good Clinical Data Management Practices (GCDMP)
- Thorough understanding of the clinical research development processes, as well as Good Clinical Practices (GCP) and ICH guidelines
- Excellent computer skills and understanding of SAS and PL/SQL
- Superior skills in MS Excel and relational databases
- Demonstrated experience preparing and managing project budgets and timelines
- Experienced in a senior clinical data management role within a CRO
- Certified Clinical Data Manager (CCDM)

The content of this position description provides a summary of the general nature of the job and may include other duties as assumed or assigned. The Company reserves the right to change this description at any time and require the employee to perform other tasks as required due to business needs.