Lead Clinical Data Manager

**Summary:**

Around 9+ years Experienced Senior Clinical Data Manager with a demonstrated history of working in leading CROs & Pharma&Biotech. Skilled in Clinical Data Management, Quality Management, and Team Building.  Skilled in Electronic Data Capture (EDC), Clinical Data Management, RAVE and Oracle inform with good exposure in all phases I, II and III studies. Have worked in therapeutic areas like Oncology, Metabolic disorders (Type 2 Diabetes), Pediatric vaccination trials etc.

**Professional skills:**

* Solid ability to adeptly juggle multiple tasks
* Strong communication skills Self-motivated and result oriented.
* Ability to work independently and within the team to achieve short- and long-term goals.
* Knowledge of Word, Windows and Excel based operating systems

**Responsibilities:**

* As a study lead, accountable for all DM deliverables per the established timeline and providing instruction to DM study team(s) and review of their study team’s output to ensure the highest delivery quality.
* Responsible for all DM activities across all assigned clinical trial which includes preparation of study documents, set-up, initiation, conduct, database lock.
* Ensure that all allocated projects are carried out in strict accordance with the relevant protocols, SOPs, and the specified standards of **GCPs.**
* Work with the Project Manager(s) to build timelines to meet contracted milestones by communicating with leads in different disciplines and the full project team as necessary.
* Anticipates and identifies operational challenges; including mitigation plans and risk management plans and reviews them with the Project Manager and sponsor
* Track scope changes and work with the Project Manager to ensure that Sponsor approval is received, and the scope change processed.
* Involved in writing and review data management plans and data validation plans. Ensures study specific Documents & Agreements are put in place
* Demonstrates and performs any other related duties as assigned by management. Ensures all activities in the Data Management Plan are completed.
* Worked on data cleaning, quality control procedures for assigned study data in **Medidata RAVE** and other **EDC** databases.
* Develop Data Transfer Agreement (**DTA**) between external data vendors.
* Coordinate with database programming, medical coding, and statistical programming teams to ensure study progression.
* Oversee the data review activities on assigned studies.
* Good knowledge on clinical data system design / development / validation.
* Contributed towards developing guidelines/checklist that aids in streamlining of activities for Data Management (**DM**) during study close-out
* Design and review **eCRFs** and ensure eCRFs meet the data collection requirements of the study through review of protocol and other supporting documentation to ensure consistency

**Responsibilities:**

* Mostly involved in the study conduct and study closeout phases
* Ensures accuracy, completeness and consistency of clinical data and data structure.
* Worked on data review in support of data cleaning, quality control for operational study data in Medidata RAVE.
* Utilized reports to track study progress and ensured timelines and quality expectations were met.
* Identified and resolved data entry errors and generated Data Clarification Forms (**DCF’s**) as required.
* Reviewed and tested **eCRFs** screen design and written data management plans for **EDC** for different studies.
* Planned and executed all data activities in accordance with client requests.
* Perform UAT for edit checks and database screen.
* Generated weekly data summaries and reports.
* Liaised with the sponsor and other functional group as required and communicated with management regarding all data management activities, issues/trends within study.
* Develop Data Transfer Agreement (**DTA**) between external data vendors.
* Coordinated with the lead data manager to develop Lab and **SAE** Reconciliation Plan.
* Addressed and resolved queries generated by sponsors, third party monitors and billing department.
* Rectified and identified discrepancies and acted as a primary contact for issues resolution.
* Monitors the quality and coordinates all data management **QC** activities for projects.

**Responsibilities:**

* Performed a variety of independent activities including query management, SAE Reconciliation, External lab, **PK** reconciliation.
* Responsible for creating ad-hoc report using Excel and automated reports using MS **SQL**
* Planned and executed all data activities in accordance with client request.
* Ensured the studies are conducted as per the **SOPs** and protocol requirements.
* Oversee data management lifecycle of large clinical trials composing and verifying results and reports
* Designated tasks appropriately within the team ensuring all work conducted is completed to the acceptable quality in accordance with Global Standard Operating Procedures (**SOP**s)and the Data Validation Manual to ensure study progression.
* Review Case Report Forms to confirm capture of data according to protocol and amendments.
* Responsible for providing clean data to teams to verify Accuracy.
* Track, set and manage project developed case report forms.
* Involved in creating Edit check specification and performing User Acceptance testing (**UAT**).
* Resolved data discrepancies and errors and omissions with thoroughness.
* Ensured timely submission of data clarifications/queries. perform quality control, assist with reconciliation driving case closure.
* Perform/review **SAE reconciliation.**
* Implemented and maintained standard operating procedures and policies.

**Responsibilities:**

* Reviewed clinical research study protocols and documenting the protocol requirements.
* Ensured **FDA** regulatory standards compliance **(particularly 21 CFR parts 11),** performing quality assurance on electronic data capture tools.
* Perform industry specific analysis for strategic decision making
* Responsible for analysis and interpretation of the data for reviews and creating reports
* Interaction with the cross functional teams for understanding and gathering requirements
* Worked on **CRF’s** designing.
* Participated in database finalization, validation of data and closeout activities
* Responsible for extraction of large datasets using SQL to perform statistical analysis
* Responsible for documenting deliverables, and communication plan
* Data cleaning and Expertise in building tables, writing SQL statements/queries, data reporting
* Provided advanced analytical support for clinical and business operations.
* Responsible for documenting out of scope activities
* Worked in the therapeutic area of **Gastroenterology (Acute Pancreatitis)**

**Educational Qualifications:**

* Bachelor’s in Economics from Utkal University, Bhubaneswar, India 1996
* Master’s in economics with specialization in Mathematical Economics from Ravenshaw University, Cuttack, India. 1998
* Diploma in Management from IGNOU, India.2000