Resume Example: Clinical Data Manager

SUMMARY OF EXPERIENCE

- Therapeutic Area experience including - Sleep, CNS, Oncology, Women's Health, Schizophrenia, Health – Medical Devices and Dermatology Therapeutic Areas
- Expertise in end-to-end Data management activities in both Paper and EDC systems (Medidata RAVE, Oracle InForm, Oracle clinical RDC)
- Experience in representing DM function in core teams which includes early development (phase 1s), development core teams (phase 2, 3 and 4) and submission teams
- Experience in working with IT team to implement clinical systems - CTMS, ARGUS, and Wind chill PLM
- Knowledge of regulatory guidelines, GCDMP, 21 CFR 11, CDISC standards and their application to Data Management practice
- Expertise working with cross-functional teams (Clinical operations, Biostatistics and Statistical programming, Clinical team, Medical Monitor, Safety, Early development, Drug supply)
- Participation in Internal audit and FDA audit
- Expertise working/managing vendors and CRO and Functional service provider (FSP) and vendor selection process for CRO, EDC vendor, IRT Vendor, ePRO Vendor
- Experience in implementing Clinical Data Factory (analytics)
- Experience in managing people both in house FTEs and remote group of consultants (line management), Managing Molecule level projects (DM project management)
- Expertise in DM project management, resourcing and budgets

EDUCATION

Master's Degree in Microbiology
Bachelor's Degree in Microbiology

EXPERIENCE

Pharmaceutical Company City, State Timeframe
Associate Director, Clinical Data Management

- Provide oversight for the data management staff for Phase 1 through 4 clinical trials for molecules in both Sleep and Oncology TA
- Develop and implement methods to demonstrate oversight of CROs and other vendors
- Provide technical expertise for the development of data management and other clinical trial documents (Data Management Plans and associated documents, Protocols, Centralized Monitoring Plans, etc.)
- Responsible for and manage data management activities of studies assigned to me as well as the Clinical Data Managers assigned to studies under the molecules I'm responsible for
- Ensure that the Data Management component of the TMF and other documentation required to support regulatory submissions and inspections are maintained to the standard required
- Coordinate closely with Clinical Operations, Clinical Development, Biostatistics, Statistical Programming, Drug Safety, Project Management and Regulatory to ensure operational excellence
- Contribute to strategic planning to ensure optimized use of data management resources
- Participate in and/or lead the development and implementation of standards and processes related to both clinical data and risk-based trial management

Principal Clinical Data Manager Timeframe

- Was responsible for providing oversight and management of multiple studies in a molecule level
- Led one phase 3 study and provided oversight for other lead DMs for another phase 3 study and multiple phase 1 studies in the sleep therapeutic area
- Completed hands on data management tasks as well as oversaw end to end data management activities from a study start up to study close out

- Was responsible for project budgeting, resourcing and creating timelines for the DM activities
- Worked closely with finance and accounting to create/review and approve the SOWs (scope of work), WOs (work orders), COs (change orders) and CNFs (change notifications)
- Was a part of the inspection readiness team as a DM SME and went through a mock inspection conducted by the company
- Was a part of the submission core team who worked on submission packages as well as responding to FDA questions
- Responsible for people management of my direct reports and project management for the lead DMs worked for other studies within the molecule

Senior Clinical Data Manager Timeframe

- Lead Data Manager for two phase 3 studies and phase 1 studies in sleep therapeutic area
- Responsible for completion of all data management activities
- Responsible for the review of new protocols/protocol amendments and worked closely with CROs and internal team (Clinical operations, Biostats, Stat programmers, Medical Monitor and safety) for designing eCRFs, Edit checks, CRF completion guidelines and other DM documents
- Worked closely with CROs to monitor the progress of data management activities with CROs as well as other vendors (IVRS, ePRO, labs, ECG, PSG, and PK) on assigned studies
- Worked closely with CRO DM to create various data management documents which includes DMP, eCRF completion GL, Edit checks, Data transfer agreements, UAT plan, Vendor oversight plan, Data review plan, programmed listings etc.
- Worked with the internal study team to review all the clinical study plans like Monitoring plan, project management plan, SAE reconciliation plan, coding plan, protocol deviation plan, communication plan, Statistical analysis plan etc. and provided CDM input
- Worked with director CDM infrastructure for the development of data management SOPs, Work Instructions, and process documents

Research Company City, State Timeframe
Senior Clinical Data Manager

- Lead Data Manager for hemorrhagic stroke studies (CNS therapeutic area)
- Responsible for startup, conduct and closeout activities of all studies in the hemorrhagic franchise (3-5 studies), which were in different clinical phases (1-4) and worked closely with EDC vendors (Medidata RAVE, InForm) for database build activities and Database closeout activities
- Worked/managed CROs, central labs and local labs, ensuring timely deliverables
- Performed coding for Adverse Events, Medical History and Concomitant Medications using, MedDRA, WHO Drug Dictionaries and perform consistency review of coded terms
- Collaborated with Medical Sciences for coding review and approval
- Participated in tasks related to a new/existing department process and significantly participated in development of a new process/revision of an existing data management process, SOPs and WIs.
- Participated/trained Investigators and Coordinators at Investigator Meeting in the CRF, the EDC system, and the completion guidelines

Pharmaceutical Company City, State Timeframe
Senior Clinical Data Analyst

- Responsible for all start up, conduct and close out activities for medical devices and derma studies
- Supported Clinical Trial teams to effectively manage information flow, data collection, review and clarification activities according to appropriate regulatory and company and departmental guidelines
- Worked closely with Clinical and Biostatistics team for data management activities
- Defined Data Management timelines and metrics
- Created data management plans for the design, and implementation of clinical data collection, review, clarification and reporting systems for clinical studies
- Created documentation for testing, implementation, validation and utilization of systems used in Clinical Data Management activities, mostly EDC and IRT
- Worked closely on data reconciliation, coding, review and clarification activities
- Coordinated internal data management activities and the resources supporting them