## CLINICAL DATA MANAGER/ANALYST

* Performed the review of clinical data using SAS programming. Coordinate and participate in the data lock process.
* Responsible for ensuring data management documents are inspection ready.
* Track and address issues associated with data management metrics such as clinical report form and query backlogs.
* Assist in the design and development of clinical trial documents such as case report forms, case report form instructions, field edit descriptions, paper flow, and data validation plan.
* Provide a clean, locked, quality database on time and within budget.
* Participate in database audits, peer reviews, and database quality reviews.
* Create, run, and review data reports to ensure database consistency and quality.
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## CLINICAL DATA MANAGER - ABC CORPORATION

* Assisted in electronic data capture training and clinical trial start-up meeting.
* Responsible for ensuring data management documents are inspection ready.
* Track and address issues associated with data management metrics such as clinical report form and query backlogs.
* Assist in the design and development of clinical trial documents such as clinical report forms, clinical report form instructions, field edit descriptions, paper flow, and data validation plan.
* Provide a clean, locked, quality database on time and within budget.
* Participate in database audits, peer reviews, and database quality reviews.
* Create, run, and review data reports to ensure database consistency and quality.

**Clinical Data Manager**

* Responsible for imaging systems and data for osteoporosis and bone safety clinical trials.
* Coordinate and set up all sites at the study start-up.
* Create and validate protocol-specific databases and data transfers.
* Write study specific Data Management Plan and Data Transfer Specifications.
* Write Report Specifications, and validate all reporting modules.
* Contact study sites for query issues and/or resolutions as well as all other data issues.
* Perform data transfers and overall database management.
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**Clinical Data Manager**

* Key Accountabilities Play the role of Trial Data Manager (TDM) and liaise with Contract Research Organizations (CRO) to ensure deliverables are duly met.
* Plan, perform, co-ordinate, supervise DM activities for clinical trials.
* Perform holistic data review using J-Review reports - to identify data trends/issues like fraudulent data entry, duplicate data entry, out of range lab values etc.
* Extensive QC of activities performed by CROs to ensure high quality deliverables and identify
* any training gaps.
* Discuss Study status and challenges with Clinical Trial Head (CTH) and other members of Clinical trial team.
* User Acceptance Testing (UAT) of eCRFs and associated checks.
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**Clinical Data Manager**

* Developed SOPs and Data Management Plans (DMP) for clinical studies.
* Ensured that all clinical data management activities are compliant with DMP, SOPs, CFR 21 Part 11, and ICH GCP.
* Represented Clinical Data Management (CDM) in core meetings.
* Collaborated with CROs, statisticians, Study Project Manager, Medical Officers, and DBAs to determine data management deliverables and timelines.
* Oversaw all data management activities, including discrepancy management, SAE reconciliation, data cleaning, and data coding.
* Projected led in data freeze and database lock.
* Responsible for delegated responsibilities to subordinates.
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**Clinical Data Manager**

* Created annotated CRF's in compliance with CDASH standards. Performed clinical trial data management activities for Phases I to IV.
* Created a Data validation plan including edit checks and Manual listings.
* Generated the project-specific timelines, deliverables, and attained with at most quality.
* Developed Data Management plan, Data transfer agreements, CRF Completion guidelines, and other DM specific documents.
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* Provided a clean, locked, quality database on time and within budget.
* Participated in database audits, peer reviews, and database quality reviews.
* Created, ran, and reviewed data reports to ensure database consistency and quality.
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**Clinical Data Manager**

* Designed and validated clinical databases including designing or testing logic checks.
* Generated data queries based on validation checks or errors and omissions identified during data entry to resolve identified problems.
* Developed project-specific data management plans that address area such as data coding, reporting, or transfer, database locks, and workflow processes.
* Designed forms for receiving, processing, or tracking data.
* Processed clinical data including receipt, entry, verification, or filing of information.
* Developed technical specifications for data management programming and communicate needs to information technology staff.
* Prepared data analysis listings and activity, performance, or progress reports.
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**Clinical Data Manager**

* Identified discrepancies, queried sites, and followed to resolution.
* Interacted with external project team members to help with data collection and clean-up efforts.
* Provided support to research assistants and other research personnel at the sites pertaining to data collection.
* Assisted in the development of progress reports for studies. Assisted in the development and writing of departmental SOPs.
* Performed data-management training for the research staff, including preparing training materials.
* Maintained Protocol-Specific Binders; extensive knowledge of protocol-specific CRF and Completion Instructions.
* Participated in team meetings, Local and Lead Node, and data-management conference calls.
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## Sr. Clinical Data Manager Resume

* Well versed in the execution of data management architectures, policies, practices, and procedures in order to manage the information lifecycle.
* Performed all Data Management activities from CRF design to database lock.
* Participated in vendor selection, site management/training, and quality assurance activities.
* Reviewed CRF completion guidelines, monitoring plans, and clinical.
* Monitored reports for accuracy and completeness.
* Managed study timelines, budgets, metrics, and data review plans. Responsible for the integrity of all Investigator data.
* Produced, validated, and compiled all Clinical Trial safety report tables across multiple protocols.
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* **Clinical Data Manager**
* Reviewed, prepared for entry, query processing, discrepancy management, Adhoc reporting, listing generation.
* Developed study-specific database requirements and edit check requirements.
* Worked closely with clinical database programmers to provide specifications at the time of study database development.
* Created and maintained data management plans, Data Review guidelines, and other study-specific work instructions or guidelines for multiple projects.
* Responsible for the design and development of Case Report Forms (CRF) in collaboration with CRAs or Clinical Project/Program Managers.
* Performed Remote Data Capture study user acceptance testing and database QC.
* Generated CRF completion guidelines, process flowcharts, Standard operating procedures (SOP), assist in work instructions and training guidelines, etc.