**Swaroop Nadgowd**

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Professional Summary

* Over 3.8 years of data management experience in various therapeutic areas (Autoimmune Disorder, Rare Diseases and Solid Tumor) Involves with database setup, conduct, and lock.
* Experience in various databases which include Medidata RAVE, Clintrial, BioClinica Express, Phase Forward InForm, 4D Client, and Oracle Clinical.
* Collaborate with colleagues and vendors to achieve business goals by assuring the correct and timely gathering of a variety of clinical data through efficient CRF/eCRF design, edit specifications, and query resolution processes.
* Experience in clinical data management from early phase development to late phase clinical development and post-marketing.
* Extensive knowledge of Data cleaning, query process, and reconciliation of all clinical data.
* Work with the CRO and coordinate activities for the medical review of coding data and approval of adverse events, medical history, concomitant, and protocol-related medications.
* Primary point of contact (POC) for internal and external stakeholders in all DM related activities for   
  assigned projects.
* Collaborate with Clinical Operations to ensure the Clinical Trial Master File (TMF) is maintained   
  appropriately throughout the trial.
* Successfully managed & maintained a satisfactory relationship with vendors with a Strategic, Tactical, or Functional Outsourcing of Data Management activities.
* Lead project implementation including successful setup of multiple studies and lock with   
  challenging requirements and stringent timelines and budgets.
* Communicated and coordinated with different global teams in various studies.
* Excellent analytical and planning capabilities with a commitment to achieve clinical data management objectives in a timely manner.
* Worked on the reporting tools like J Review.
* Working experience with SAS teams and applicable knowledge on SAS
* Self-motivated and able to handle multiple tasks.
* Good Written, verbal communication skills, and interpersonal skills.
* Plans appropriately with Manager to ensure adherence to timelines, identifies and proposes solutions to address resource and timeline issues and sets priorities within the group

Skills

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| * Environment: Medidata Rave (Classic and iMedidata), Oracle Inform, Oracle Clinical (RDC), Clintrial, Veeva Vault. * Domain Skills: DMP, Edit Check Specifications, SAE Reconciliation, Lab Reconciliation, UAT, Data Lock Activities, eCRFs design, J-Review, Business Objects, Discrepancy Management, 21 CFR part 11, ICH-GCP guidelines, CDISC-CDASH, Paper and EDC trials | * Technical Skills: SQL, SAS, SDTM & ADaM review, TLF review, MS project, Smart sheets, Tableau, Micro Soft-Office Suite (Word, PowerPoint, Micro Soft Excel, Micro Soft Access, Outlook). J-Review |

Work History

ICON, New Jersey, Remote, Contract May 2019- Current

Lead Clinical Data manager

* 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.
* Ensuring that all CRF Specifications and Data Specifications meet ICON Data Collection Standards, proactively making certain that expected high quality data is in compliance with applicable pharma industry regulations and standards required by regulatory agencies. (e.g., CDISC, SDTM for FDA submissions)
* 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 and Provide support to Health Authority inspections and audits
* Contributed towards developing guidelines/checklist that aids in streamlining of activities for Data Management (DM) during study close-out
* Provides strong quality and project oversight over third party vendor responsible for data management deliverables
* Coordinate and perform successful conduct of user acceptance testing with participation of Clinical and Biostatistics team and Data Quality Review meetings with cross functional study team members to ensure on-going review of trial data currency, quality, and completeness
* Reviewed DM related study plans including Data Quality Management Plan, Data Validation Plans, Data Review Plan, eCRF Completion Guidelines and other study documents to ensure quality and standardization
* Contributed to clinical system development activities to ensure system support for the study's data review needs, focusing on critical data and processes, and identifying risks.
* Ensured that CDM review requirements are implemented in accordance with the study's protocol risk evaluation and integrated data review plan (IDRP), and that ongoing data review activities are compliant with study plan requirements.
* Development and maintenance of study plan documents specifying data review strategy and applicable procedures on assigned protocols/projects, including but not limited to DMP
* Worked to centrally review clinical data at the aggregate level, using analytic reporting tool(s) to support risk identification and data patterns/trends, and assisted in risk mitigation by using signal detectors and quality indicators.
* Communicated and triaged issues to the relevant roles for follow-up and action to address the root cause
* Maintains and tracks meeting minutes, issues and decisions logs, and escalations.
* Independently negotiates the timelines and makes study level decisions.

SUN PHARMA, California, Remote, Contract May 2017 – Mar 2019

Senior Clinical Data Manager

* Serving as the project manager for Data Management activities throughout one or more trials and maintaining a close collaboration with key internal stakeholders, such as DM External Data Leads, Clinical Trial Managers, Medical Directors, Clinical Research Scientists, Programmers, and Biostatisticians
* Accountable for all parts of the CDM process for Electronic Data Capture (EDC) trials, from study initiation to database lock.
* Query generation, resolution, and reconciliation activities to support and deliver the clinical data according to quality and integrity specialization and project timelines and productivity targets
* Participated in developing project documents like DMP, Data Validation Documents, CRF Completion Guidelines, and Data Transfer Agreements (DTA).
* Performed Data review, SAE reconciliation, lab data reconciliation and IRT reconciliation.
* Ensuring that Data Management Vendor deliverables adhere to the protocol, ICH-GCP, and SOPs.
* Global library of annotated CRFs created in accordance with CASH standards.
* Involved in developing a data validation strategy that included edit checks and manual listings.
* Interacted with PIs, sites, and CRA to resolve discrepancies.
* Planning and oversight of trial data cleaning activities, including leading the data review, cleaning strategy, and the creation of the Data Review & Cleaning Plan in collaboration with the Clinical Study Team
* Working cross-functionally with Clinical Study Team, including Clinical Operations, Biostatistics, Statistical Programming, Pharmacovigilance, CROs and external vendors to develop timelines and ensure appropriate design, documentation, testing, and implementation of data deliverables according to internal and regulatory standards
* Oversees third-party vendors such as CROs and CDM technology solutions by contributing to budgetary items, vendor selection and management, risk management, and communication management.
* Planning and oversight of database lock activities to ensure high-quality data deliverables are achieved within timelines, including the creation of the Data Release Plan
* Continuously identifying and mitigating trial-related risks
* Reviewing Data Management vendor work orders and ensuring budget for Data Management related activities
* Performing quality control of Data Management documentation and e-trial master file oversight
* Ensured all the CDM activities are in compliance with FDA regulatory standards (21 CFR part 11)

GSK, Texas, Remote, Contract May 2015 – Jan 2017 Clinical Data Manager

* Responsible for supporting the planning, oversight, and implementation of DM activities in the study lifecycle of Autoimmune and solid tumor studies.
* Created Annotated CRF’s in accordance with CDASH standards
* Supervised end-to-end execution of data management services for assigned projects/studies, partnering with CROs and other suppliers to ensure high-quality outputs are on time and within budget to support drug development processes and global submissions
* Participate in DMM activities, including data review and query management, ensure quality database design such as documentation, testing, validation, and implementation of clinical data collection tools, CRF and non-CRF, using an EDC system and other data collection systems.
* Contributing to the Data Quality Management Plan (DQMP) defining and documenting the data quality review strategy for each clinical trial in collaboration with various BMS stakeholders (e.g. statistics, medical, safety, development, GCO, etc.), enabling the quality review of patient data supporting regulatory filings, publications and other high-profile business activities.
* On a monthly basis, conducted and participated in manual evaluations of clinical trial data for EDC discrepancy control and Contributing to the development of edit check requirements and case report forms (CRF).
* Participate in the development and maintenance of Standard Operating Procedures (SOPs) and Work Instructions related to data management activities.
* Ensure required study specific DMM documents in the Trial Master File are of high quality and filed contemporaneously to support downstream inspection and submission readiness activities.
* Query review and management, report delivery to study teams, study timeline and database snapshot coordination for analysis, including Safety Review Team, Interim Analysis, etc., and review clinical data continuously to ensure data accuracy.
* Reviewed Data Management process control papers such as the Data Management Plan, Data Quality Checks Specification, User Acceptance Testing, and Data Transfer Agreements/Specifications, as well as reconciliation and data review and quality plans.
* Perform and review SAE reconciliation as well as external/vendor Lab data reconciliation for several clinical studies and performed Query Management, which entails issuing and processing site questions.
* Assured that clinical trial data was handled correctly and consistently in accordance with GCP, GEP, and FDA guidelines.
* Designee, generate, and review research metric reports to the study team's satisfaction.

ACCENTURE, India, Full Time Jan 2013 – Apr 2015

Clinical Data Coordinator

* Maintained data management project documentation files; performed independent reviews of data management deliverables following documented CDM guidelines.
* Monitored study metrics and runs project-specific status reports for management.
* Primary Liaison from CDM team with the clinical team, Biostatisticians, both internal and external team
* Worked with SAS and Oracle programmers to develop and revise edit checks to ensure data precision
* Served in the role of backup for the data team lead in managing the day today CDM operations.
* Ensured that studies are conducted per protocol requirements, SOP's, ICH GCP guidelines
* Developed annotated CRF's based on the protocol specifics and CDASH requirements
* Created edit check document for a given protocol and Reviewed data through listings and auto queries.
* Performed discrepancy management (both automatic and manual) Perform/review SAE reconciliation.
* Freeze and/or lock eCRFs (as appropriate) within the Electronic Data Capture System
* Perform User Acceptance Testing and collaboratively work with CDMS personnel to see issues found through re-testing and resolution
* Review CRF and eCRF data for completeness, accuracy, and consistency via computerize edits and manual data checks
* Conduct quality control review of clinical trial data.
* Conduct data review of CRFs, eCRFs, reports, or data listings, as applicable
* Maintained study metrics and provided management with project-specific status reports.
* Followed documented guidelines to review data management deliverables for assigned projects

Publications

**S.M. Biradar1 , K. Maurya2 , A. Naikal3 , S. Sarnadgowd4 , Rajesh M. Honnutagi5 , Ravi Kattimani6 , Sivakumar B.7 , V.T. Kallyanappagol8** Study on -[To Study the Prescribing Pattern of Drugs in Dengue Patients of a Tertiary Care Hospital:](https://www.isroset.org/pdf_paper_view.php?paper_id=2196&19-ISROSET-IJSRBS-02912.pdf) International Journal of Scientific Research in Biological Sciences**.**

Academic Qualifications

* **Masters in Health informatics, Governors State University, Chicago, IL**
* **Bachelors in PharmD (Doctor of Pharmacy), India.**