Vipul Karkar

Principal Clinical Data Scientist, Novartis

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EXPERIENCE

Principal Clinical Data Manager, CDM 05/2022 - Present

Novartis | Hyderabad, Telangana, India

Working on highest priority Oncology global trial of Novartis involving Collaboration with various stakeholders like Biostatistician, Programmers, Medical Monitors, Project Managers, Quality Control, Safety Managers, Vendor Program Managers, etc. to meet the Project timelines. Documentation and Inspection of all Clinical Trials Documents to match regulatory and industry standards.

Key Accomplishments:

- Successfully cleaned and achieved a stringent timeline for interim database lock with no quality issue
- Actively working on streamlining the Clean Patient Tracker
- Received 7 different awards for communication, innovation, client relationship, consistent data quality, and mentoring/training more than 60 team members

Associate Manager, CDM 03/2018 - 05/2022

IQVIA Biotech | Thane, Maharashtra, India

Managed multiple Oncology trials from a study start-up to study closeout. Worked on overall 23 global trials in the Oncology, Dermatology, Endocrinology, and Cardiovascular Therapeutic area, including Devices trials. Led 7 trials as Lead Data Manager. Functioned as a Single Point of Contact on multiple clinical trials involving Client Communications and Collaboration with various stakeholders like Biostatistician, Programmers, Medical Monitors, Project Managers, Quality Control, Safety Managers, Third-Party Vendors, etc. to meet the Project timelines. Documentation and Inspection of all Clinical Trials Documents to match regulatory and industry standards.

Key Accomplishments:

- Streamlined the data management activities for study start-up reducing the database go-live time frame
- Revamped the Data Quality Control process by constructing VBA automation, reducing the manual interventions, and increasing the consistency of the data
- Successfully locked 4 global phase-III trials with no quality issue
- Developed productivity tracker to track all the metrics in a single system (MS Access), reducing the overall time utilization by more than 70%
- Received 7 different awards for communication, innovation, client relationship, consistent data quality, and mentoring/training more than 60 team members

Sr. Clinical Data Coordinator 10/2016 - 02/2018

Karmic Lifesciences LLP | Ahmedabad, Gujarat, India

Supported 6 paper studies and 8 EDC studies, including 4 different EDC systems. Helped Manager in restructuring Data Management SOPs. Worked on Listing reviews, reconciliations, and query management activities. Study start-up and close-out were a major part of the profile. Prepared various trial set up documents which include eCRF Specifications, Data Management Plan (DMP), Project Management Tracker, Data Extraction Specifications, Data Validation Rules (DVR), eCRF Completion Guidelines (eCCG), Data Transfer Agreement/Specification (DTA/DTS), Data Coding Specification, Data Entry Specification, UAT Plan, UAT Report, Edit Check Specifications (ECS), Major Protocol Deviation Document, Quality Control Plan, DVR Test Scripts.

Key Accomplishments:

- Optimized Paper eCRF tracking, DCF Generations, and Data Entry Tracking System
- Successfully locked 9 projects with 1 minor finding.
- Developed a tool to auto-generate edit checks and CRF completion guidelines based on trial design document which reduced a lot of time to initiate these processes
- Received employee of the quarter award for the contribution to multiple projects as lead, implementing, and restructuring the data management processes.

Clinical Data Analyst 09/2013 - 10/2016

Cognizant Technology Solutions | Mumbai, Maharashtra, India

Worked on Data Entry, Query Management, Reconciliation, and Listing Review for 3 Oncology and 2 Post Marketing Surveillance studies. Had successfully written more than 4700 emails to teams across the globe to intimate and complete the missing pieces of information for the projects as a part of the Clinical Trial Management System. Faced Audits and Inspections from Sponsor, Third Party, and Regulatory

Key Accomplishments:

- Optimized reconciliation process for the PK, PD, and lab data with VBA automation
- Achieved 100% data quality for all the assignments throughout employment in the organization
- Helped Manager to develop the Data Entry Dashboard.
- Received 6 different awards for quality, communication, continuous improvements, and innovations

EDUCATION

Gujarat Technological University, Gandhinagar | Masters of Pharmacy (Pharmacology) 2013

Rajiv Gandhi University of Health Sciences, Bangalore | Bachelors of Pharmacy 2010

SKILLS

Technology: VBA, MS Office, Rave, Inform, SAS PheedIt, Acceliant, Octalsoft, DSG-eCaselink, jReview, Business Object, SQL, Cognos, Impact

Soft Skills: Project Management, Clinical Data Management, Collaboration, and Innovation, Mentoring, Leadership, Stakeholder Management, Interpersonal Communication, Quality Management, Risk Management, Lean Six Sigma, Agile Methodology, Programming

Hard Skills: Study Setup/Startup, Study Closeout, Clinical Trial Methodologies, Data Cleaning Methods, Specs writing, Report Creations, CDASH, CDISC, Medical Terminology/Coding, TMF management, Lab/Vendor/Third Party Reconciliation, Quey Management, Data Quality, Inspection/Audit, Drug Development

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