Ragha Sudhir Kanaparthi

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SUMMARY

Experienced Project Manager in **Clinical Data Management & SAS Programmer** with over 7.5 years of expertise managing global Phase I–IV clinical and non-interventional trials from start-up to closeout. **PMP-certified** professional with proven ability to **lead cross-functional teams**, vendors, and global stakeholders through complex clinical data workflows, ensuring timely database locks and regulatory compliance (GCP, FDA, EMA, ICH-GCP). Highly skilled in **Medidata Rave, OC-RDC, InForm, Medrio, Claris File Maker, Veeva Vault, and SAS (SDTM, ADaM, TLF)**, with strong command of **Pinnacle 21, SQL, Spotfire and Power BI** for advanced data analysis and visualization. Demonstrated proficiency in eCRF design, database specifications, edit checks, data validation, and discrepancy management. Adept at handling multiple therapeutic areas and experienced in **CDISC/CDASH standards, MedDRA, and WHO Drug coding**. Known for driving process improvement, automation, and risk-based monitoring initiatives in high-stakes clinical environments.

SKILL SET

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- Medidata Rave
- Inform
- OC-RDC
- Medrio
- Claris File Maker
- Veeva Vault
- SAS (SDTM, ADaM, TLF), Pinnacle 21
- SQL
- Excel, Smartsheet, Power-BI, Spotfire, Jira, Confluence, MS Project

THERAPEUTIC AREAS

- Oncology
- Cardiology
- Endocrinology / Metabolic Disorders
- Infectious Diseases
- Immunology / Autoimmune Diseases
- Rare / Orphan Diseases
- Hematology
- Ophthalmology

PROFESSIONAL EXPERIENCE

Parexel, UK.

Data Management Lead- I **Oct 2022 – Aug 2024**

- Led end-to-end clinical data management (CDM) activities for global Phase I - III trials, ensuring timely, high-quality, and regulatory-compliant data deliverables.
- Overseen EDC database design, CRF development, and validation programming in Medidata Rave, Veeva Vault, Oracle InForm & File-Maker.
- Managed and implement CDISC standards (SDTM, ADaM) to ensure regulatory compliance with FDA, EMA, and ICH-GCP guidelines.
- Served as the primary data management lead for cross-functional teams, collaborating with Clinical Operations, Biostatistics, Regulatory, and Medical Affairs to drive data-driven decision-making.
- Led risk-based data monitoring (RBDM) and data visualization initiatives, utilizing SAS, Pinnacle 21, or BI tools to enhance data insights and efficiency.
- Driven automation and process improvement, reducing data discrepancies and optimizing clinical trial data workflows.
- Overseen and managed external CROs, vendors, and EDC providers, ensuring compliance with timelines, quality standards, and contractual obligations.
- Developed and implemented data management plans (DMPs), edit check specifications, query resolution strategies, and reconciliation processes.
- Ensured timely database locks by leading data cleaning, reconciliation, and QC processes across multiple trials.
- Provided input into protocol development for optimal data collection strategies.
- Overseen the design and development of electronic case report forms (eCRFs) in collaboration with clinical teams.
- Reviewed and approved database specifications, edit check specifications, and data validation plans (DVPs).
- Overseen external vendor deliverables such as database builds, edit checks, data transfers, and reconciliation.
- Established clear KPIs, and metrics for vendor performance.
- Provided technical and strategic leadership in data cleaning, query management, and reconciliation to ensure timely and accurate database locks.
- Managed and reviewed clinical trial data, for compliance with GCP, CDISC (SDTM), and FDA/EMA regulatory requirements.
- Served as the primary point of contact for CROs and external vendors, ensuring adherence to quality, timelines, and budgets.
- Led risk-based data review and data visualization initiatives to enhance data-driven decision-making.
- Driven process improvements and automation initiatives within clinical data management to improve operational efficiencies.
- Provided strategic guidance and mentorship to junior and mid-level data managers, cultivating a high-performing team culture.

Innovative Clinical Research, India

Senior Clinical Data Analyst **Sep 2016 - Oct 2019**

- Performed database set up activities for studies on Inform platform including but not limited to attending meetings to track the progress of study start-up activities.
- Ensured Data Management CROs delivered quality data and documentation on time, within budget and according to quality standards and SOPs.
- Identified and designed CRFs.
- Designed annotated CRFs based on protocol specifications and CDASH requirements.
- Manual reviewed CRF data and data dumpling listings.
- Prepared data management study documents such as Validation plan (VAP), CRF Completion Guidelines (CCGs), Data handling plans, and Data Transfer Agreements (DTAs).
- Created edit checks documents for a given protocol.
- Developed validation specifications and User Acceptance Tests (UAT).
- Reviewed and reconciled Serious Adverse Events (SAE).
- Skilled in Medidata rave and has experience in J Review.
- Reviewed and revised all documents for the Trial Master File.
- Led a team of Clinical Data members.
- Utilized SAS programming skills within the protocol team and performed all programming needed for clinical trial analysis and reporting.
- Performed QC for the discrepancies and supported the defect trackers.
- Provided input to vendor data transfer specification document.
- Maintained study-related documents in a central repository.
- Been Responsible for developing reports for safety and efficacy as per study requirements.
- Worked on different clinical trials like Demographics, Medical History, Vital signs, Adverse Events (AE) and physical examination.
- Enabled the quality review of patient data supported in regulatory filings and uploaded it into eTMF.
- Worked closely with Statistics & Programming to ensure high-quality data output including data cleaning and validation.

Innovative Clinical Research, India

Clinical Data Analyst **Jun 2014 - Aug 2016**

- Assisted in the design, review, and testing of electronic Case Report Forms (eCRFs) and edit checks within EDC systems (e.g., Medidata RAVE, InForm)
- Performed data entry review, discrepancy management, and basic query generation/resolution to ensure data accuracy and completeness
- Collaborated with cross-functional teams including clinical operations, biostatistics, and medical coding to ensure clean and consistent study data
- Participated in user acceptance testing (UAT) of clinical databases and documented findings and resolutions
- Supported data cleaning activities by reviewing data listings and resolving data inconsistencies according to the Data Management Plan (DMP)
- Assisted with Serious Adverse Event (SAE) reconciliation and lab data reconciliation with external vendors

- Maintained data management documentation including CRF Completion Guidelines, edit check specifications, and data review tracking logs
- Monitored clinical data flow from sites, vendors, and EDC to ensure timely data entry and resolution of outstanding queries
- Familiar with CDISC/CDASH standards and medical coding using MedDRA and WHO Drug dictionaries
- Contributed to interim data review meetings and database freeze/lock activities under supervision
- Ensured timely delivery of high-quality data by supporting milestone tracking and issue escalation
- Gained exposure to data migration and transfer activities between systems or sponsors
- Demonstrated ability to prioritize tasks and handle multiple studies in a fast-paced environment

EDUCATION

- International Operations & Supply Chain Management (Master of Science), Jan 2020- Nov 2021
  College/University: Glasgow Caledonian University, United Kingdom

- Bachelor of Technology in Mechanical Engineering, Aug 2009- Apr 2013
  College/University: Jawaharlal Nehru Technological University, India

CERTIFICATIONS

- Project Management Professional (PMP), Issued July 2025
  Institution: Project Management Institute (PMI)

- Data Landscape of GenAI for Project Managers, Issued June 2025
  Institution: Project Management Institute (PMI)

- Atlassian Agile Project Management Professional, Issued March 2025
  Institution: Atlassian

- Artificial Intelligence & Machine Learning Program, Issued March 2025
  Institution: Indian council for technical research & development

- Lean Six Sigma Yellow Belt (CIPS), Issued November 2021
  Institution: Chartered Institute of procurement & supply