PARANGUSAN KS

SR. PROJECT MANAGER,
CLINICAL DATA MANAGEMENT

CONTACT

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Bengaluru

EDUCATION

2006 - 2008

DG VAISHNAV COLLEGE (MADRAS UNIVERSITY)

- Master of Biochemistry

2003 - 2006

RKM VIVEKANANDA COLLEGE (MADRAS UNIVERSITY)

- Bachelor of Biochemistry

SKILLS

- Project Oversight Management Experience on Varied Therapeutic Areas.
- First Line Management experience.
- Client Relationship
- Escalation Management
- Experience in Audits and Inspections
- Data Governance Management & Oversight (KPI, KQI, KRI)
- Data Quality & Data Stewardship
- Stakeholder Management
- Team Management
- Operational Finance Management
- Bid Defense (RFP, RFI)
- Medidata Rave, Oracle Clinical RDC
- Microsoft Projects, Power BI. Visio, Excel, Word and PowerPoints

PROFILE

Accomplished **Senior Project Manager** specializing in **Clinical Data Management**, with over 15 years of comprehensive experience. Recognized for adeptly steering projects through all phases of development within the clinical research realm, including oversight of governance indicators such as Key Performance Indicators (KPIs), Key Quality Indicators (KQIs), and Key Risk Indicators (KRIs). Demonstrated expertise in orchestrating data collection, analysis, and reporting while meticulously adhering to regulatory requirements. Proficient in leadership, stakeholder engagement, and fostering cohesive teamwork. Experienced in first-line management, adept at guiding and empowering teams to achieve project success. Dedicated to nurturing strong client relationships and ensuring customer satisfaction through proactive communication and tailored project delivery. Committed to achieving excellence in project outcomes while ensuring adherence to timelines and budgetary constraints.

WORK EXPERIENCE

Thermo Fisher Scientific Ltd.
2023 - PRESENT

(Prev. PPD Pharmaceutical Ltd.)

Sr. CDMPM

Thermo Fisher Scientific Ltd.
2020 - 2023

(Prev. PPD Pharmaceutical Ltd.)

CDMPM

- Oversaw the development and implementation of project plans, including resource allocation, **Risk management** & **Stakeholder communication**.
- Adhered to governance indicators such as Key Performance Indicators (**KPIs**), Key Data Quality Indicators (**KQIs**), and Key Risk Indicators (**KRIs**) to monitor project progress and mitigate risks using Risk Indicators and duly updated Risk Registers and ensured **Data Stewardship**.
- Led multiple projects on the end-to-end management of Clinical Data Management projects each valued **$1.5M-$5M**, ensuring adherence to timelines, budget, **Contract modifications**, and quality standards.
- Developed project budgets and tracked expenditures to ensure cost-effective project delivery.
- Involved in **Bid Defense** presentations, responding to Requests for Proposals (**RFPs**) and Requests for Information (**RFIs**) to secure new business opportunities and maintain client relationships and provided Subject Expertise in Clinical Data Management Solutions.
- Experience since Project initiation till Electronic Trial Master File (**eTMF**) Archival of both **Early phase** studies and **Late Phase** IV studies.
- Managed cross-functional teams to achieve project milestones and deliverables, fostering a collaborative work environment.
- Collaborated with clients to understand project requirements and deliver customized solutions.
- Served as the primary point of contact for **Escalation Management**, effectively addressing client concerns and ensuring high levels of customer satisfaction.
- Proficient in **Medidata Rave**, **Oracle Clinical RDC**, and **Microsoft Project**, with minimal experience in Oracle Inform.
- Utilized **Advanced MS Excel, Power BI and MS PowerPoint** to analyze data, create visualizations, and deliver presentations.
- Experience in handling audits and inspections from various regulatory authorities, with a basic understanding of **CDISC, CDASH, SDTM, and ADaM standards** and **data flows**.
- Provided leadership and guidance to project teams, fostering a culture of accountability and continuous improvement.
- Implemented process improvements using **MS Visio** to streamline workflows and enhance efficiency in data management processes.

INTERESTS

- Photography
- Cycling
- Philately
- Numismatics
- Reading

CLIFFTON STRENGTHS

- Strategic
- Analytical
- Contextual
- Restorative
- Positivity

PERSONAL INFORMATION

DOB : 29 June 1985
Gender : Male
Pronoun : He, His, Him
Marital status : Married
Nationality : Indian
Languages : English, Hindi, Tamil

Accenture Services India Pvt Ltd. 2018 - 2020
(Business Advisory Specialist / Asst Operations Manager

Chiltern Clinical Research Pvt Ltd. 2017 - 2018
Project Data Manager (First Line Manager)

Quintiles Research India Pvt Ltd. 2015 - 2017
Assistant Clinical Data Manager

Icon Clinical Research India Pvt Ltd. 2015 - 2015
Clinical Data Coordinator II

Cognizant Technology Solutions Pvt Ltd. 2014 - 2015
Data Analyst

Icon Clinical Research India Pvt Ltd.
Clinical Data Coordinator I 2010 - 2014

Accenture Services India Pvt Ltd. 2009 - 2010
Sr Process Associate

- **Past Experience include:**
  - **Quality Processes and Compliance**
    - Successfully implemented consistent and efficient quality processes to meet project timelines and deliverables.
    - Regularly reviewed and addressed queries, ensuring the database was accurately updated.
    - Participated in knowledge-sharing sessions and ensured timely submission of timesheets and functional tracking spreadsheets.
    - Achieved turnaround times for tasks impacting milestone delivery.
  - **Documentation and Manuals**
    - Developed eCRF Review Manual and Instructions for both EDC and paper studies.
    - Created and maintained CRF data standards and data entry instructions.
    - Developed mock CRFs, unique CRF casebooks, and annotated CRFs.
    - System Configuration and Validation
    - Reviewed EDC Core Configuration against study requirements and made necessary amendments.
    - Conducted User Acceptance Testing (UAT) according to the Validation Plan for Data Management systems.
    - Maintained operational data flows related to Data Management.
  - **Data Management and Reporting**
    - Reviewed and took action on reports as defined in the DMP and eCRF Review Manual.
    - Provided and reviewed listings for study teams, addressing discrepancies as necessary.
    - Performed consistency checks, reviewed protocol deviations, and managed data listings throughout the study.
  - **Post-Database Lock Activities**
    - Executed updates post database lock when required.
    - Conducted SAE Reconciliation between Safety and Clinical study databases, issuing queries for discrepancies.
    - Produced safety data listings for surveillance and other relevant listings.
  - **Communication and Team Collaboration**
    - Maintained excellent communication with the team and clients, ensuring clear and consistent information flow.
    - Regularly updated team members and clients on project progress, challenges, and resolutions through detailed reports and meetings.
    - Facilitated collaboration and problem-solving by effectively conveying project requirements and feedback.
    - Established strong working relationships with team members and clients to enhance cooperation and project outcomes.