SUDHANYA DAS

Clinical Data Manager

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EXPERIENCE

Remote Internship
06/2025 - 12/2025

CRA School — Montréal, Canada

- Prepare and maintain a site activation plan, ensuring selected sites and countries optimize opportunities for successful study delivery
- Completed informed consent procedures and maintained ongoing patient communication, ensuring patient retention rate throughout the study.
- Strong knowledge of ICH GCP, FDA, and HC Division 5 guidelines.
- Ensured exchange of information and documentation with investigational sites, off -site facilities and vendors throughout study startup phase.
- Maintained project-specific tracking systems and electronic Trial Master File (eTMF) throughout study startup phase.
- Assisted with site documents collection for IRB/IEC submission and/or IP-RED process.
- Identified investigators, led patient recruitment initiatives, performed site initiatives visits (SIV), and conducted pre-study activities for oncology clinical research trials.
- Verify data on CRFs; monitor schedules; file and collate trial documentation and reports; archive study documentation and correspondence; preparing final reports
- Define strategies for patient recruitment, build strategic partnerships with healthcare organizations, and develop new recruitment channels, resulting in an increase in patient retention .

Project Data Manager
02/2021 - 04/2024

Cognizant Technology Services — India

- Leveraged **RAVE, Veeva Vault, Inform,** and **Spotfire** to align project outcomes with client expectations, achieving a 25% reduction in time to database lock Phase II and III studies.
- Accurately and efficiently validate ***electronically captured data***. Write clear queries on missing data and data points failing pre-defined range checks and/or logical checks.
- Lead efforts in building a standard **query library** for common database modules, as well as for therapeutic/drug area specific modules.
- Perform **QC** procedures on assigned database during the trial and additional database closure checks at the end of the study.
- Train and supervise Data Entry personnel and junior data management personnel on study procedures, study specific handling, and management of trial data.
- Strong and comprehensive **CDM** skills spanning from study **start-up**, **study conduct, close out**, **Medical Coding** activities, **CRF design, Edit checks creation, data cleaning and query process.**
- As a part of Study Metrics management, generated **Subject Status Metrics, eCRF** and **Query Tracking Report, Outstanding Query Metrics, Query Aging Report, Local Lab Ranges status**, and **SAE Reconciliation Status**.
- Assist in resolving data coding discrepancies resulting from the coding of medical events, treatment procedures, and medications.
- Prepared Database Modification Request form for any Postproduction changes with respect to **Electronic Edit Checks** or Database Updates.
- Reviewed database edit check specifications for assigned studies and also Device data related to Electronic Patient-Reported Outcome (**ePRO**, as well as clinician-reported outcomes (**ClinROs**), observer-reported outcomes (**ObsROs**), and performance outcomes (**PerfOs**).
- Act as primary contact with **IWRS/IRT** and diary team.
- Generated various reports like **Data Listing Report, Query Report, User Report, Page Status Report,** and **Audit Trail Report** for **Manual review**.
- Expert in various data management tools such as **Jarvis**, **Tesla**, **SAM**, Pinnacle-21, and **SOAR** providing real-time customizable reports.
- Good working knowledge about user management & data source configurations for the **TIBCO Spotfire platform.**
- Monitored project metrics via **Spotfire** and **Edit Check Engine** to ensure precise client requirement fulfillment.
- Experienced in creating a **Risk Management Plan** clearly identifying the risks and mitigation plan and base line the same with all stake holders.

SUMMARY

PROFESSIONAL SUMMARY *Clinical Research Professional with 7+ years of experience, specializing in Clinical Data Management and clinical trials. Reliable, well-organized, resourceful, and diligent CDM leader offering acumen in Phase II and Phase III studies in different aspects of data management from study start up to database lock (DBL). Proficient in Electronic Data Capture (EDC) platforms such as Inform, Medidata RAVE, Veeva Vault.* Plan, manage, and perform data processing and data management activities for assigned projects to ensure tasks are performed in a timely manner and in compliance with trial Sponsors' requirements. *Expertise in developing Data Management Plan (DMP), UAT testing, preparing CRF Completion Guidelines and Data Validation plan.* Certified in TCPS2, GCP, and SAS.
LinkedIn link: https://www.linkedin.com/in/sudhanya-das-a1162977/

TECHNICAL SKILLS

Group Title

SAS Certified, TCPS2, Tableau, Power BI,

KEY ACHIEVEMENTS

Your Achievement

Received **Client Excellence Award** for DB lock of Neuroscience study with 1,200 participants.
Recognized as **Best SME (AbbVie client)** for Project Management.

CERTIFICATION

Certificate Name

TCPS2 (Tri-Council Policy Statement, Canada)

ICH-GCP & **Canadian GCP**

Base SAS Certified

EXPERIENCE

Clinical Data Manager
09/2019 - 01/2021

Syneos Health — India

- Managed Vendor reconciliation i.e. **IRT, Central LAB**, Pharmacokinetic Reconciliation enhancing clinical trial efficiency & data integrity.
- Developed and maintained the **Data Management Plan (DMP)**, **Data Quality Review Plan (DQRP)**.
- Defined and monitored clinical trial dataflow and quality control (QC) processes in accordance with corporate Standard Operating Procedures (SOPs), Good Working Practices, and unit guidelines.
- Monitored clinical trial data flow and **QC** processes in accordance with corporate Standard Operating Procedures, Good Working Practices, and departmental guidelines.
- Ensured project team maintains and prepares final archival of data management documentation relevant to study and assist the corporate archivist in assembling and archiving such documentation.

Data Manager/Medical Surveillance Specialist
07/2017 - 08/2019

IQVIA — India

- Achieved optimized study outcomes by ensuring patient safety, by analyzing {100+} daily lab & ECG data.
- Performed the validation of data fields captured in the database against the CRF when appropriate.(Validate data entry screens and edit check programs.)
- Validated the completeness, accuracy and consistency of the clinical trial database on an ongoing basis through the use of ad hoc queries.
- Ensured the **User Acceptance Testing (UAT)** is carried out and documented, validated data entry screens and edit check programs.(Created dummy data for testing data entry screens and edit checks).
- Collaborated with external laboratories and clinical study personnel to ensure that adequate laboratory evaluations are obtained in accordance with protocol requirements.
- Worked as Primary contact for **eCOA Library** to Unify implementation teams and managed the **eCOA Library** repository, relevant documents and maintained audit and inspection readiness.

Clinical Research Coordinator
10/2016 - 06/2017

HealthCare Global — India

- Streamlined with **ICH/GCP, HIPAA**, and trial regulations to align with trial integrity.
- Screened and took consent of all participants to ensure eligibility in trial studies.
- Used Interactive Voice Response Systems **(IVRS)** or Interactive Web Response Systems (**IWRS**) to enter patient information, randomize patients, and keep drug supplies organized for the trial.
- Supported clinical safety monitoring teams by performing quality control (QC) review of document deliverables including clinical study reports (CSR), clinical study protocols, Informed Consent forms, patient safety narratives, safety management plans, scientific publications, and other documents intended for regulatory.
- Along with onsite **Principal Investigator (PI)**, radiologists worked on digital imaging, annotations and metadata pertaining to study Mets in brain from systematic Cancers to understand accurate information on number, size, location of metastatic lesions.
- Prepared research ethics proposals and amendments of reports on milestones, achievements, took responsibility for day-to-day running of research protocol.
- Performed lab duties such as specimen handling and processing for studies in accordance with necessary protocols.
- Planed and prepared for external audits in collaboration with other members of the Clinical Trial Team.
- Took basic **vital signs** – blood pressure, weight, height, ECG, administered study drugs through oral, IV infusion and Subcutaneous injection interventions, study drug accountability and reconciliation.

SKILLS

Medidata Rave · Inform · Veeva Vault · Jarvis · Spotfire · TESLA · SAE Reconciliation · eCOA · ePRO · ClinRO · IVRS · IWRS · Data Validation and Data Cleaning · User Acceptance Testing · Electronic Data Capture · Informed Consent · ICH/GCP · Pinnacle-21 · SAS listing · Data Management Plan (DMP) · ECG reading · Biometrics · Database Lock · Project Leadership · Study start up & Conduct · Data Quality Review Plan (DQRP) · SAM · Constructive problem-solving attitude with deadline focused on time lines. · Google spreadsheet · Microsoft Excels · Oncology RACIST criteria

EDUCATION (WES-VERIFIED)

PG-Diploma
CRA School of Montreal

06/2025 - Present — Montréal, Canada

Master of Clinical Research
University of Mysore

09/2014 - 10/2016 — India

Master of Human Genetics
West Bengal University of Health Sciences

09/2011 - 10/2013 — India

Bachelors in Genetics
Bangalore University

08/2008 - 06/2011 — India