ATHIRA SURESH CCRP

CLINICAL DATA MANAGER - EDC Validation, UAT, & Data Cleaning

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SKILLS

- **Data Management**: Study start-up, EDC validation, edit checks, CRF review, DMP, DVS, and query cleaning
- **Systems Tools**: Medidata Rave, Inform, REDCap, Veeva Vault, CTMS, eCOA, Excel trackers, and Power BI
- **Therapy Areas**: Oncology, Hematology, Cell Therapy, Gene Therapy, Metabolic Medicine, General Medicine
- **Documentation Compliance**: DVS scripts, validation, TMF maintenance, SOP adherence, protocol guidelines
- **Regulatory Standards**: ICH-GCP, FDA 21 CFR Part 11, sponsor requirements, and inspection preparation

WORK EXPERIENCE

Clinical Validation Analyst I **3 Years**
ICON PLC *India*

- Spearheaded DM study setup activities, including review of protocols, annotated CRFs, and Data Validation Specifications (DVS/LVS) prior to database build and UAT.
- Served as validation point of contact for 6+ simultaneous studies, coordinating activities and timelines across Data Management, Programming, Clinical Operations, and QA.
- Executed User Acceptance Testing for eCOA and EDC databases for 60+ studies, performing edit check validation, data entry testing, and system rule verification as per regulatory requirements.
- Tested 100+ edit checks per study, documenting defects in tracking systems and coordinating re-testing cycles to ensure resolution within quality timelines.
- Achieved 100% on-time delivery of validation cycles across assigned studies, passing test results to the programming team with zero critical or high-severity failures per protocol.
- Conducted thorough data review and SDV checks across study databases, generating queries and verifying corrections to maintain data accuracy and traceability as per the protocol.
- Performed database updates and data cleaning for 30+ clinical studies, verifying corrections and maintaining audit trails to ensure compliance with data integrity requirements.
- Coordinated SAS programming requests and reviewed output listings for assigned studies in pre-database lock, verifying data completeness and quality per specifications.
- Liaised weekly validation status updates to DM leads and sponsors, escalating risks and resolving issues to maintain validation timelines for 30+ studies.
- Mentored 3+ junior team members during onboarding periods, providing training on validation procedures and quality standards to improve process consistency across the team.

Clinical Data Coordinator Intern **7 Months**
Cytespace *India*

- Facilitated PI in screening 100+ patients, managing consent and enrollment per protocol, ensuring accurate scheduling and compliance with study requirements.
- Executed site-level data collection, CRF completion, and source document verification, ensuring 100% GCP compliance and reducing data discrepancies by 15%.
- Collaborated with CROs and sponsors to resolve 200+ data queries, achieving 95% query resolution within timelines and improving data integrity across studies.
- Maintained regulatory binders and essential documents, supporting 4+ monitoring visits and audits, ensuring zero findings during compliance inspections.
- Updated CTMS with subject and visit data for 50+ participants, improving tracking accuracy by 20% and supporting real-time reporting for study teams.
- Facilitated REB submissions and approvals, expediting review cycles by 25% and ensuring timely readiness for monitoring visits and audit preparation.

EDUCATION

Advanced Diploma in Food Science and Technology January 2022 – April 2023
Centennial College, Scarborough, ON

Bachelor of Technology in Biotechnology Engineering August 2014 – May 2018
University of Calicut, India

CERTIFICATIONS

- **Certified Clinical Research Professional (CCRP®), SOCRA** July 2025
- **Good Clinical Practice (GCP), NIDA Clinical Trials Network** May 2025
- **SOP Writing Training, eHACCP.org** June 2023
- **Verified International Academic Qualifications, WES** September 2023
- **Certified Food Safety HACCP Manager** September 2023