

MEHREEN SEHER

CLINICAL PROJECT COORDINATOR - Data & Resource Management, Execution and Monitoring

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SKILLS

- **Programming & Data Tools:** R, SQL, Tableau, Excel, REDCap, OpenClinica, Medidata Rave, Castor EDC.
- **Clinical System:** Oracle Clinical, PostgreSQL, Oracle Siebel CTMS, Medidata CTMS, Trial Interactive.
- **Documentation:** IRB submissions, eTMF management, ICH-GCP, HIPAA, FDA regulations, protocol writing.
- **Research Operations:** CTMS tracking, clinical monitoring, data capture workflows, grant/report writing.

WORK EXPERIENCE

Project Consultant – Operations

April 2023 – January 2024

Freelance

Remote

- Piloted deployment of 7+ digital health systems by driving requirement mapping, API integration, cloud migration, and data encryption protocols, accelerating implementation timelines while ensuring GDPR-compliance.
- Facilitated SCRUM ceremonies, backlog grooming, sprint planning, and retrospective sessions with cross-functional engineering teams, boosting velocity by 22% and achieving 100% on-time delivery using JIRA and Confluence.
- Architected data interoperability solutions utilizing HL7 and FHIR standards, enabling seamless integration between disparate clinical platforms and enhancing client system communication throughput and scalability.

Clinical Research Fellow

August 2022 – April 2023

Clinical Research Facility of Galway, Health Research Board

Ireland

- Coordinated 9+ NIH-funded Phase II–III clinical trials by managing IRB submissions, protocol adherence, EDC system configuration, monitoring, and GCP compliance, improving data quality and regulatory compliance.
- Streamlined adverse event reporting, CTMS deliverables, and data validation processes by leveraging Veeva Vault and Tableau dashboards, reducing deviation resolution time by 31% and enhancing audit readiness.
- Implemented data capture strategies using REDCap and Oracle Clinical, optimizing CRF design, database validation, audit trails, and improving patient data accuracy while reducing manual data entry errors.

Research Associate

December 2021 – June 2022

Advarra

India

- Reviewed 300+ clinical research submissions weekly under GCP frameworks, utilizing risk assessment matrices, SOP alignment, and compliance audits to achieve 98.7% regulatory compliance and maintain quality standards.
- Developed tracking dashboards using Microsoft Power BI, Excel macros, and VBA scripting to monitor submission statuses, automate follow-ups, and reduce manual intervention, cutting follow-up time by 25%.
- Directed quality assurance and discrepancy management sessions, employing root cause analysis, CAPA plans, and Six Sigma methodologies to mitigate issues by 22%, ensuring audit-ready documentation and SOP updates.

Project Assistant – Medical Writing

January 2021 – December 2021

Confidential (Remote)

India

- Supervised delivery of 40+ clinical study reports (CSRs) and investigator brochures (IBs) by managing version control, QC checklists, manuscript formatting, and author-reviewer workflows using EndNote and Track Changes.
- Designed risk mitigation plans for protocol deviations by applying root cause analysis, deviation tracking logs, corrective/preventive action (CAPA) frameworks, and statistical process control (SPC), reducing rework by 28%.
- Collaborated with SMEs to clarify clinical data by utilizing metadata, controlled vocabularies, data dictionaries, ontology mapping, and semantic interoperability, enhancing the precision and clarity of medical narratives.

Project Assistant – Operations

August 2019 – December 2020

HumLife360

Remote

- Executed deliverables across 12+ tech-healthcare pilots by updating operational trackers, refining SOPs, coordinating logistics, and utilizing Google Workspace, Slack, and Asana to reduce support escalations by 24%.
- Enhanced user onboarding and training programs by developing interactive e-learning modules, incorporating LMS analytics, user feedback loops, and gamification techniques, increasing satisfaction scores by 19%.
- Coordinated cross-team communication and issue resolution by leveraging ticketing systems, escalating blockers, facilitating daily stand-ups, utilizing JIRA, and monitoring KPIs, accelerating pilot completion timelines.

PROJECT EXPERIENCE

Cardiac Imaging in Breast Cancer

12 Months — J Clin Med, Vol. 12(19),

Primary Author and Researcher

6295 (2023)

- Directed a systematic review on multimodality imaging for cardiotoxicity detection in cancer patients.

EDUCATION

MS in Clinical Research – Project Management and Policy Making

August 2022 – July 2023

National University of Ireland, Ireland

BS in Biotechnology

June 2018 – May 2021

Bangalore University, India